LIBERAL MEDICINE

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Abstract

I argue that citizens have rights of self-medication, and that prohibitive pharmaceutical regulations are therefore unjust. Pharmaceuticals are among the most important consumer goods we will ever purchase. Yet despite, or perhaps because of their importance, pharmaceuticals are heavily regulated in ways that other consumer goods are not: through premarket approval requirements and prescription drug systems.

I begin with a historical overview of pharmaceutical regulation (Ch. 1). I then show that prohibitive pharmaceutical polices cause death and suffering by discouraging innovation and by preventing patients from accessing beneficial and lifesaving drugs (Ch. 2). Indeed, adopting less prohibitive pharmaceutical policies is one way that a liberal society might promote public health. (Ch. 3) I then argue that liberal principles are often incompatible with pharmaceutical paternalism (Ch. 4). Further, seriously ill patients have rights of medical self-defense that entail rights to use unapproved drugs (Ch. 5). People also have rights to use drugs to end their lives even if they are not sick or disabled. (Ch. 6) Together, these arguments justify conditional rights of self-medication and call for extensive reforms to the current system of regulation. I then argue that the same principles of anti-paternalism that are used to justify the doctrine of informed consent also justify unconditional rights of self-medication (Ch. 7).

Governments that enforce prohibitive pharmaceutical regulations are morally culpable for the harms and wrongful deaths that are caused thereby (Ch. 8). Even though citizens overwhelmingly support prohibitive policies, prohibitions themselves do not serve the public interest (Ch. 9). To close, I propose several institutional reforms including the legalization of almost all pharmaceuticals and changes to medical practice
(Ch. 10). I also discuss some circumstances where limits on self-medication are justified (Ch. 11).

More generally, this is an argument for more extensive rights against paternalistic interference in medicine, and a call to end deadly and ineffective pharmaceutical regulations. All governments are unjust insofar as they restrict patients’ access to therapeutic medicine. Institutional protections for rights of self-medication aim to remedy this everyday injustice, and in so doing, save lives and empower patients.
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Introduction

Many of us take some kind of therapeutic medication every day, or at least whenever we get headaches, heartburn, tennis elbow, or poison ivy. Therapeutic medicine might have saved your life if you’ve ever taken an antibiotic to treat a childhood infection, gotten a vaccine, or had surgery that required anesthesia. If they haven’t yet, pharmaceuticals almost certainly will save or extend your life in the future. Most people die either from heart disease or cancer, but innovations in pharmaceuticals including chemotherapy, personalized medicine, and statins, are reducing mortality and extending life expectancy for patients with these common but deadly conditions.

Pharmaceuticals are important—access to therapeutic medicines is a matter of life or death for thousands of patients every day. Pharmaceuticals are also pervasive—many of us use pharmaceuticals daily. Perhaps because of their importance and pervasiveness, perhaps despite it, pharmaceuticals are not treated like other consumer goods. While most products are permitted in an open market, pharmaceuticals are regulated and prohibited. All pharmaceuticals must be pre-approved by regulatory agencies before they are sold. Most pharmaceuticals require physicians’ notice and are not sold over the counter to any willing consumer. All developed countries regulate access to medical treatment in these ways. In America, for example, patients cannot legally use drugs or devices that have not been approved for safety and efficacy by the Food and Drug Administration (FDA). Once a drug has been approved, patients are not permitted to weigh the risks and benefits of drugs for themselves. Instead, they must obtain prescriptions from licensed physicians. Some dangerous or deadly treatments are prohibited altogether.
The justification for these prohibitive policies is paternalistic. Patients’ access to medical treatment is limited because if patients could legally access any treatment without approval or prescription requirements, patients might harm themselves. Liberal theorists have long discussed the permissibility of paternalism, and while some liberals believe that paternalism is presumptively impermissible, most liberals concede that there are some instances where paternalism may be warranted. My argument is that citizens have rights of self-medication and that pharmaceutical prohibitions cause needless pain and suffering; so liberal theorists ought to reject these paternalistic policies.

1. Why Self-Medication?

At this point, you might be wondering why the right of self-medication warrants such a lengthy investigation. Liberals who have long focused on worthy topics such as multiculturalism, speech, privacy, the right to an education or political participation, might wonder if self-medication really rises to the level of these other pressing issues. I contend that self-medication is relevantly similar to these other rights, and in some ways even more significant, but for now I will simply point to some reasons to think that self-medication is an important and surprisingly neglected topic.

First, permitting or denying the right to self-medication has life and death consequences. Political philosophy is concerned with how government has an impact on our lives. I cannot think of a more significant impact then the thousands of lives that are saved and deaths that are allowed as a result of access to medicine. Further, medical choices are often the most intimate and strongly felt choices we make. Some kinds of choices (e.g. intimate choices that relate to bodily autonomy and choices that are closely linked to our sense of self,) are the kinds of choices that we want to be able to make for
ourselves even if our ability to make those choices ultimately undermines our capacities or well being. Medical choices have this character, and so I will argue, call for special protection.

The question of self-medication also sheds light on political morality more generally. Regulatory policy, including the regulation of medical treatment, is one of the primary ways that the state shapes our choices and influences our behavior and welfare on a daily basis. While we rarely vote or write our congressmen, and few of us will ever serve in public office, issue a judicial opinion, or negotiate global economic policy, we all interact with the coercive power of the state when whenever we get sick. For every citizen, self-medication calls the justifications for state power into question at some point.

Though the pharmaceutical industry and the agencies that regulate it have a pervasive impact on our lives, we can barely influence these actors or contest decisions that pervasively influence our health. This feature casts drug regulators as potential despots who often wield unchecked control over our lives and deaths. At their best, they use this power benevolently, but I will suggest in most cases their influence is more harmful than helpful. There is also a strong liberty interest at stake when states prohibit citizens from accessing the means to save or improve their lives. Further, pharmaceutical choices are often as intimate and important as other kinds of choices that merit strong protection from state interference, such as matters of sexual privacy, control over one’s body, and procreative choices.

Last, this argument has broader implications. Once we see that we have a right of self-medication and that the prohibitive polices that are in place in most liberal societies are actually unjust, other practices and prohibitive policies may be cast in a new light. In
developing a rationale for the right of self-medication, I will also reconstruct a plausible justification for paternalism, which will shed light on whether other paternalistic prohibitions are justifiable as well. Further, I will discuss the doctrine of informed consent and the role of physicians in medical decision-making, and my argument for a right of self-medication will shed new light on the principle of do no harm. Through the lens of pharmaceutical regulation I will also shed light on the ethics of regulatory agencies more generally. Further, regulators who limit access to lifesaving goods are as morally responsible for any resulting deaths or injuries, just as they would be for those deaths that would result from permitting people to access dangerous goods. Officials currently seek to minimize the deaths caused by dangerous drugs while the human cost of limited access often outweighs the potential costs of permissive policies. This asymmetry that is built into the current regime is indefensible.

For all these reasons, the right of self-medication deserves our attention. People live or die because of pharmaceutical policy. These policy choices ought to be informed by principles of justice. I show that the status quo regulatory framework is harmful and radically unjust and that justice requires that states protect and institutionalize a right of self-medication. Though the right to self-medication is not absolute, all developed nations currently exceed their authority to limit citizens’ rights of self-medication.

2. Methodology

At this point a word about my methodology is in order. I will not begin from first principles to argue for my view. Rather, I will draw on principles that I find in contemporary liberal societies, current practices, and a range of perspectives. Because I am not working from a single comprehensive viewpoint, my arguments will at time seem
inconsistent. For example, I will argue that patients often have a right to use dangerous and deadly medication, but I also argue that even these choices are not basic rights, they still ought to be protected. My goal is to show that there are many paths that support a right of self-medication.

In taking this approach, I am guided by the methodological approach of Jeff McMahan, Alan Buchanan, and other applied ethicists.1 Buchanan writes,

I wish my arguments to have some practical effect, and I believe that this goal can best be achieved if they are directed against paternalist justifications which are actually employed by the practitioners of medical paternalism…the arguments I advance require a minimum of theoretical baggage…. It would be unfortunate if successful attacks on medical paternalism had to await the development and defense of a full-blown theory of moral rights. By articulating the inadequacy of the justifications that the paternalist himself advances, however, one need rely only upon those moral views to which the paternalist himself subscribes. My goal, then, is to present effective criticisms of medical paternalist practices that rely upon a minimal base of moral agreement between the paternalist and his critic.2

Like Buchanan, I will not try to develop a full-scale argument against all paternalism, nor will I rely on a general theory of rights and personal autonomy, as many Kantian and libertarian ethicists have, to argue against paternalism in medicine.3 Instead I show that

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even if some paternalism is permissible, the practices of paternalism that characterize medicine today are not. This is not to say that I reject the general Kantian line against paternalism. I do not. Neo-Kantian and libertarian anti-paternalists will accept that my conclusion is delivered straightforwardly from their moral framework, but the truth of neo-Kantianism or libertarianism is not the only reasons to support the conclusion that paternalist restrictions on self-medication are unjust.

My argument is thus built on a pluralist foundation. Consequences matter, but so do rights. Self-medication is one of the rare topics in political philosophy where both consequentialist and deontic arguments condemn the current system, yet popular opinion is blind to this injustice. Most people no longer expect or demand the right to self-medicate. I suspect that this is because selective media attention to drug disasters ensures that they are remembered for generations while the deadly consequences of regulation are often overlooked. Yet policy should not be driven by dramatic accounts of adverse drug effects, and more systematic studies of the effects of pharmaceutical regulation show that the current systems of regulation have terrible consequences overall.

Throughout this dissertation I will use many empirical examples, historical analysis, and social scientific evidence that is relevant to the question of self-medication. While I am convinced that the evidence against prohibitive policies is decisive, the normative argument is not hostage to the empirics. Even if an institutionalized right of self-medication would at times have bad consequences, it is still required by justice. My arguments therefore unfold with increasing strength and decreasing qualifications, the strongest and least contingent arguments are the rights-based ones, but consequentialist

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4 As I will argue in Chapter 1, public opinion in America once favored self-medication and it was considered a basic right.
arguments also tell in favor of less prohibitive drug policies. That said, no rights are absolute and empirical considerations do matter more for some of the views that I discuss than for others. If institutionalizing a right of self-medication had truly catastrophic consequences, if self-medication consisted in citizens harming others or themselves, then limits would be defensible. Where consequences are relevant in this way I will note the limits of self-medication.

3. Overview

To orient the reader, it might be helpful to preview the arguments that I will make on behalf of self-medication. The argument unfolds in four parts. First, I describe how the right of self-medication fits into the history of pharmaceutical regulation, liberal theory, and current institutions. Next, I present several arguments in favor of a right of self-medication. Then, I discuss objections to self-medication. Last, I advance some tentative claims about how a right of self-medication might inform public policy.

I describe the history of pharmaceutical regulation in Chapter 1. There I focus on the evolution of the United States Food and Drug Administration. I show that the justification for pharmaceutical regulation has historically been driven by powerful economic interests and public cries for regulation in the wake of tragic drug disasters. Nineteenth century America was a unique historical moment because there was relatively less drug regulation than earlier and subsequent eras, which was consistent with the more general laissez-faire polices of that time. I will describe life during this era to show that rights of self-medication were once considered basic, and that access to pharmaceuticals both benefited and endangered citizens and the public health.

\footnote{I discuss these limits, such as antibiotic use, in Chapter 11.}
Chapter 2 presents a more comprehensive account of the consequences of pharmaceutical regulation. Through a comparative analysis of regulatory frameworks, I suggest that pharmaceutical regulation costs more lives than it saves. I focus on four negative effects of pharmaceutical regulation: drug loss, approval lag, limited patient access and substantial economic costs to patients and the public. I will discuss specific historical examples of drug disasters in more detail. Additionally, I will show that the practice of prescribing approved drugs ‘off label’ for unapproved conditions, and the unrestricted markets in developing countries can give us further insight into the effects of a less prohibitive system. On the basis of this evidence I argue that the benefits of pharmaceutical regulation are greatly overstated while the costs are often overlooked.

In Chapter 3, I situate self-medication within a broader liberal framework. In some ways, liberal arguments in favor of a right to health care also support a limited right of self-medication. While some have argued that the provision of health care is in tension with self-medication, I will suggest that a right of self-medication is actually a mechanism for indirectly providing health care to all citizens and improving public health. In any case, it is not incompatible with this aim. I conclude that liberal and libertarian theorists should mostly agree about self-medication, even though they might disagree about the public provision of health care.

In Chapter 4, I begin to develop the case for self-medication, within a liberal framework. Many liberal theorists believe that some paternalistic prohibitions are permissible as long prohibitive policies promote citizens’ autonomous capacities overall. I call this view *liberal paternalism*. Liberal paternalists believe that is permissible for liberal states to paternalistically prohibit prostitution, recreational drug use, or guns, but
that certain religious practices or forms of expression ought to be protected from paternalistic legal limits because such a constellation of liberties and prohibitions best promote citizens’ capacities to autonomously participate in a fair society. I reconstruct two prominent versions of liberal paternalism to show that even if one accepts many forms of paternalism in public life, paternalist prohibitions on pharmaceuticals are not justified. Instead, liberal paternalists should at least endorse rights to safe medication and no more than those forms of paternalism that promote good decision making through non-prohibitive means without limiting patients’ choices.

In Chapter 5 I address patients with terminal illnesses, severe medical conditions, or degenerative illnesses. I argue that this class of patients is especially entitled to rights of self-medication, particularly the right to use unapproved drugs. In these cases, the right of self-medication is a species of the more general right to preserve one’s own life. Any person whose life is endangered, or who lives below a minimum level of capacity or well being, should not be prohibited from accessing therapeutic medicines, even if the drugs are especially risky.

Deadly drugs also merit special consideration. Unlike most drugs, the drugs that are used in physician assisted suicide and euthanasia are a crucial precondition for people to exercise the right to choose the time and manner of one’s own death. In Chapter 6 I argue that patients have unconditional rights to access deadly drugs. I propose that deadly drugs ought to be regulated like handguns or other consumer goods that have deadly potential, but that patients ought to be permitted to use deadly drugs to end their lives, even if they are not terminally ill or severely disabled. I argue further that unconditional rights to die are required by a principle of non-discrimination. In that chapter I also
discuss the special case of consumers with depressive reasons for suicide, and I argue that even clinically depressed patients ought to be permitted to use deadly drugs to commit suicide in most cases.

Chapters 3-6 therefore develop conditional defenses of self-medication for particular cases. Drugs that would enhance patients’ autonomous capacities, drugs for the severely sick and terminally ill, and deadly drugs should all be permitted. In Chapter 7, I advance an unconditional defense of self-medication. There I argue that the same considerations that entitled patients to withhold medical consent, even against medical advice, also entitle patients to access medicines. For this reason, anyone who is competent such that she has rights of informed consent also has rights of self-medication. My argument in this chapter is both consequentialist and rights-based, but the rights-based argument takes priority over consequentialist considerations. For this reason, even if self-medication had bad consequences (and I suggest it would not) patients are entitled to make self-harming treatment decisions with drugs just as patients have rights to refuse medical treatment even when refusal would have bad consequences.

I then address two common objections to the right of self-medication. First, in Chapter 8 I address the prevention argument for pharmaceutical regulation, which states that regulatory agencies let some patients die of their diseases in order to prevent deadly medicines from killing other patients. Since letting die is generally less morally serious than killing, regulators might then act permissibly even if they prevent dangerous drugs from killing patients, even if regulations allow more suffering and death on balance because patients die of their diseases. In this chapter, I show that this objection to self-medication is flawed. Rather, pharmaceutical regulators cause wrongful death and
suffering by preventing them from accessing therapeutic drugs, but manufacturers don’t necessarily. Drug manufactures are no more responsible for consumers’ poor decisions than auto manufacturers and car dealers. Of course manufacturers and retailers are responsible for disclosing the known risks and properties of the cars or the drugs they sell, and testing is useful to that end, but ultimately responsibility lies with the informed consumer.⁶

Then, in Chapter 9 I will discuss the idea that pharmaceutical regulation is a public good, despite the fact that it might harm specific individuals. Dan Carpenter’s comprehensive history of the Food and Drug Administration provides convincing evidence that pharmaceutical regulators enjoy widespread popular support. Moreover, citizens seem to know what pharmaceutical regulators do and they seem relatively more aware of the costs and benefits of drug regulation than of other kinds of regulation. One explanation for this support is that citizens realize that they are unable to make medical decisions, for whatever reason, so they collectively self bind to create a regulatory agency that will compensate for this deficit, and they look to regulators to provide medical expertise as a public good. I call this justification the public goods argument. I will show that this argument does not justify the current prohibitive model. In any case, that

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⁶ New cars are also currently regulated for safety, though used cars are not. One implication of my argument, which I accept, is that premarket safety requirements for new cars (e.g. seatbelt requirements) are also impermissible. Though I will not defend this claim explicitly in the following chapters, one reason to reject seatbelt requirements is that they impeded innovation that could have ultimately lead manufacturers to develop even better seatbelts. This is a general problem, when manufacturers are forced to comply with premarket regulations the returns to innovation decrease. In any case, liability reforms, rather than regulatory mandates, were likely sufficient in the auto case to push manufacturers to make safer cars. I will argue that liability reforms are similarly promising for drugs. Peter William Huber, *The Liability Maze: The Impact of Liability Law on Safety and Innovation* (Brookings Institution Press, 1991). Chapter 4, especially Pg. 164.
pharmaceutical regulation risks entrenching the very cognitive biases that regulatory institutions were designed to mitigate. In an appendix I develop this empirical point in a formal model.

Finally, I consider the practical implications of this argument in Chapter 10. I propose specific institutional reforms that would better respect citizens’ rights of self-medication, (which I will preview in more detail in the next section.) These reforms include a move to non-prohibitive testing requirements, behind the counter status for most drugs, legalization of pharmaceuticals, tort reform, and non-prohibitive public health campaigns to promote good medical decision-making. I also discuss the culture of paternalism in medicine more generally.

In Chapter 11 I discuss the limits of self-medication. First, I consider that a right of self-medication might at times have negative externalities, and that others might be harmed by a patient’s treatment decisions. One worry about self-medication is that overuse of antibiotics will lead to a public health disaster. Some argue that prohibitive policies are required for the collection of good medical data. Finally, one might worry that self-medication will cause unacceptable levels of inequality. I will respond to these arguments, some of which justify some limits to self-medication. Second, I consider medical paternalism towards children and the mentally disabled. If these patients are genuinely not competent to make medical decisions, then paternalism is warranted. I propose a test for assessing genuine incompetence, and suggest that there are actually few where mental incompetence justifies paternalistic limits on medical autonomy. In particular, recreational drug users and teenagers are most likely competent to make drug choices, just as they are competent to refuse other forms of medical care.
Despite these caveats, medical paternalism remains radically unjust in almost all its current forms. Patients live or die based on whether they have access to pharmaceuticals, and their access is limited by the state. Political philosophy is principally concerned with those situations where the state holds citizens’ lives in its hands. In the case of pharmaceuticals, citizens should take back this authority and responsibility, reclaim the right of self-medication, and have the courage to hold our lives in our own hands.

4. Policy Implications

How would the world look if patients had rights of self-medication? Here are some policies that follow from the right of self-medication. What follows in this section is only a sketch, which can inform the arguments in the rest of the dissertation by describing how a right of self-medication might be institutionalized.

Foremost, a right of self-medication requires the legalization of most pharmaceuticals. Currently, if a patient buys drugs that are unapproved by regulatory agencies or if she accesses drugs without a prescription she is subject to criminal penalties. Cancer patients who seek potentially lifesaving experimental treatments, uninsured Americans who wish to purchase asthma inhalers and insulin without first paying to see a physician, and those without a medical condition who could nevertheless benefit from using pharmaceuticals are legally prohibited from accessing their drugs of choice.

I propose ending the prohibitions and criminal penalties attached to experimental drugs. Manufacturers can rightly be required to submit their products for government inspection and oversight, but patients who wish to purchase unapproved drugs ought to
be permitted to do so. I also propose an end to the prescription drug system. With the exception of antibiotics, I will argue that all prescription-grade drugs should be available over the counter or behind the counter. Over the counter drugs are sold like other consumer goods. Behind the counter drugs are sold by pharmacists, but anyone who requests the drugs can legally purchase them. This proposal means that patients ought to be permitted to buy prescription-grade drugs either by talking to a doctor or pharmacist about the risks and benefits of treatment, or by waiving their rights against risk and purchasing the drugs without any consultation.

Legal access to pharmaceuticals also requires an end to criminal penalties for using dangerous medicines. Further, rights of self-medication require substantial revisions to medical malpractice law. Currently, pharmaceuticals are not treated like other products. Physicians and manufacturers who provide pharmaceuticals are liable for any adverse interactions or side effects even if patients actively requested the medicine and were informed of the known risks and side effects. Patients are not legally permitted

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7 As Coleman and Mendlow helpfully explain, tort law enables citizens who have been injured to sue for compensatory or punitive damages, in contrast to criminal law, which operates in the public interest. Medical malpractice is currently regulated by tort and criminal law, which means that physicians are vulnerable to lawsuits from patients and the public. Unlike other branches of tort law however, patients cannot waive their rights to sue under tort law. Epstein suggests that this model fails to respect patient’s and physicians rights and has bad consequences, and I agree. I will discuss this further in later chapters. See Jules Coleman and Gabriel Mendlow, “Theories of Tort Law,” in *The Stanford Encyclopedia of Philosophy*, ed. Edward N. Zalta, Fall 2010., 2010, http://plato.stanford.edu/archives/fall2010/entriesort-theories/; Richard A Epstein, “Medical Malpractice: The Case for Contract,” *Law & Social Inquiry* 1, no. 1 (September 6, 2006): 87–150.

8 While most consumer goods are regulated by standards of strict liability, in medicine, providers are often also held to standards of fault liability if adverse medical effects are due to negligence. Strict liability reflects the idea that manufacturers and providers have a general duty to not injure consumers. Strict liability standards are often invoked in consumer protection cases. For example, even if manufacturers of a dangerous medical
to waive their rights to hold providers responsible when they help patients make risky consumer choices. I therefore suggest that providers or public institutions might collectively bear the costs of risky pharmaceutical choices, either through a strict liability system or public health care, while patients could retain their right to sign liability waivers and make risky medical decisions. Alternatively, a private contract model, wherein patients contract with providers and privately agree upon specific standards of liability and negligence might expand access. I endorse either solution—a right of self-medication only requires that legal requirements, including both prohibitions and liability, do not effectively limit patient choice. Drug manufacturers and other providers ought to be held only to the same standards of criminal negligence and fraud as other kinds of service providers and manufacturers.

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treatment took all necessary precautions to ensure that the treatment is safe, if the treatment injures a group of patients then the manufacturers are liable to compensate the injured patients for their injuries. Fault liability is more commonly invoked in medical malpractice cases. For example, if a physician’s negligence causes injury to a patient, then that physician is liable to pay damages to the patient to compensate for the injury, but physicians are not generally held to standards of strict liability. In most cases in the United States, medical malpractice holds physicians responsible for wrongful injuries, not all kinds of injuries. Robert L Rabin, “Three Prespectives on Medical Injury: A Commentary,” DePaul Law Review 54 (2005 2004): 527.


Placing experimental and unsafe drugs on the market, behind the counter would substantially shift responsibility for patients’ health from regulators, manufacturers, physicians, and pharmacists, to the patients themselves. One worry is that patients are not capable of making informed choices, even with the advice and instruction of regulators, manufacturers, physicians, and pharmacists. If so, self-medication could lead to a public health crisis. In response to this worry, I suggest that states and professional organizations should encourage educated patient choices through public health campaigns, online information databases, public education, strict labeling requirements and standards of truth in advertising. I also suspect that some of patients’ seeming inability to make medical choices is a kind of learned helplessness that is enabled by prohibitions. Patients who wish to continue to rely on medical experts should not be prohibited from forming trusting doctor-patient relationships, but reliance on experts ought not be legally required. With time and freedom, patients could learn to become as informed about their medical choices as they are about other important consumer choices.\footnote{For an argument for drug policy reform that exploits this analogy between buying a computer and using a drug see Michael Huemer, “‘The Drug Laws Don’t Work,’,” \textit{The Philosophers’ Magazine}, September 26, 2011.}

5. Against the Culture of Paternalism

More generally, I propose a cultural shift in medicine away from hard paternalism. To clarify, hard paternalism refers to policies that limit choices for a competent citizen’s own benefit whereas soft paternalism refers to policies that limit choices for a citizen’s benefit because she is not capable of making informed choices for
herself. In medicine, hard paternalism describes instances when competent and informed patients are prohibited from independently making medical choices. Soft paternalism describes situations when medical professionals or policymakers make choices on behalf of underage, unconscious, or mentally incompetent patients. Most of my arguments are aimed at hard paternalism, though I discuss soft paternalism in Chapter 11.

Additionally, paternalism can either be strong or weak. Strong paternalist policies limit choice by prohibiting citizens from making certain choices, often through the criminal law. Weak paternalist policies structure citizens’ choices by incentivizing decisions that are in the citizens’ interest. Sometimes, this is also called ‘nudging’ people to make good choices. For example, recreational drug prohibitions are a form of strong paternalism. Such prohibitions criminally prohibit the sale and use of some drugs for the sake of society and users. Cigarette taxes and labeling requirements are a form of weak paternalism, they seek to structure consumer choices in a way that will make citizens healthier, but they don’t formally take away anyone’s option to smoke. I am mainly

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13 Sometimes this distinction is called hard vs. soft paternalism, I am using these terms to avoid confusion
14 Sunstein and Thaler are the most famous proponents of this strategy for crafting public policy. They argue that insofar as the government is entitled to make any public policy, it ought to make public policy in ways that promote people’s welfare. Nudge is a form of paternalism that aims to accord with due respect. So for example, insofar as taxation is permissible, the tax burden may be distributed in ways that encourage good decision-making. Insofar as the government is providing a benefit, like health care, they should encourage people to choose the best health plan for their needs. For more on this see R. H Thaler and C. R Sunstein, “Libertarian Paternalism,” The American Economic Review 93, no. 2 (2003): 175–179; C. R Sunstein and R. H Thaler, “Libertarian Paternalism Is Not an Oxymoron,” U. Chi. L. Rev. 70 (2003): 1159; Richard H. Thaler and Prof. Cass R. Sunstein, Nudge: Improving Decisions About Health, Wealth, and Happiness, 1st ed. (Yale University Press, 2008).
focused on strong forms of paternalism, and most my arguments do not in principle rule out weak forms of paternalism.

There are many examples of prohibitive policies in medicine that rely at least in part on a hard paternalist rationale. The clearest examples can be found in pharmaceutical regulation and approval. Most liberal societies restrict access to drugs and medical devices through some kind of regulatory system and the justification of these policies is explicitly for the sake of potential patients and consumers. My analysis and examples will focus on the United States, where the Food and Drug Administration (FDA) reviews and regulates all drugs. In the US, it is illegal to purchase drugs that have not been reviewed and approved by the FDA. Providing or purchasing prescription drugs without a prescription is a felony offense. These policies are not unique; most other developed nations regulate experimental drugs similarly. 15 Once reviewed, medical treatments may be sold over the counter like other consumer goods or by prescription only. Some drugs are not approved and are therefore prohibited full stop. Regulatory regimes outside the US also allow some drugs to be sold behind the counter, meaning that the drugs require only approval of a pharmacist, not a physician. 16

Physicians and public officials justify these prohibitions in the name of patients’ well being. While health and happiness are surely valuable, they are valuable only insofar as patients value or should value their health and happiness. Medicine ought to aim to treat the whole patient and not just her health or her level of happiness. Some treatment

16 Some groups like the Academy of Managed Care Pharmacies (AMCP) have lobbied the FDA for the introduction of this category in the United States as well.
decisions that patients autonomously make could undermine their health or happiness, but
this doesn’t mean that those treatment choices are poor decisions overall. Just as a
patient might undergo a risky cosmetic surgery procedure to improve her appearance, and
thereby promote her overall well being, a patient might choose to access a dangerous
drugs that will undermine her health overall, but nevertheless improve her life on
balance. For example, a patient with severe arthritis might reasonably judge that the
benefits of pain relief outweigh the cardiac risks of Vioxx. A stockbroker might
recognize the risks associated with using Adderall, but judge that the potential career
gains from using the drug are worth the risks. In both cases, consumers judge that overall
health is not their top priority and their consumer choices trade off health for other
values. However, unlike in the cosmetic surgery case, pharmaceutical consumers are
currently prohibited from making these judgments for themselves.

What is the justification for this asymmetry between medical choices and other
consumer choices? Part of this asymmetry can be explained by the culture of medicine.
Physicians and regulatory officials are charged with improving patients’ and the public
health, and they may worry that unrestricted pharmaceutical use would unacceptably
harm the public health. A second explanation for this asymmetry is that people seem to
think that decisions involving our bodies are different from other consumer choices. This
is reflected in familiar debates in bioethics. Why do we think that selling our kidneys is
more morally fraught than selling our homes or cars? Why do we think that taking drugs

\[17\] This claim is a call for consistency. Other decisions undermine our health, but might be
all things considered in our interest. For example, a consumer might choose to buy
cheaper and more convenient food that is less healthy than expensive food that takes time
to prepare. While she recognizes that choice is worse for her health, it might still be better
for her than the healthy alternative, if she judges her time and money to be more
important than health. I will discuss this at length in Chapter 7.
is different than getting our thrills by playing extreme sports or sailboat racing? Why do we think that it is worse to harm someone’s body than it is to harm his reputation or property, even if the consequence of the bodily harm to the victim himself is less significant than the losses he would suffer from reputational harm? Something about the body is special, and rightly or wrongly, choices regarding our bodies are treated differently from other kinds of consumer choices. These intuitions are entrenched and I do not propose to change them. Rather, I will argue that it is precisely because choices involving our bodies and health are so important to us that we ought to be entrusted to make them for ourselves.

6. Conclusion

What follows is a vision for how medicine could be. My argument builds from limited rights of self-medication to unrestricted markets in most pharmaceuticals. All countries that enforce prohibitive pharmaceutical policies violate important rights. The most serious violations are those that prevent poor citizens from accessing affordable medical care and terminally ill patients from accessing potentially lifesaving drugs. My arguments for these populations therefore have the most urgency. Yet the everyday injustice of drug regulation is morally serious as well, and more just institutions are possible. Though regulatory agencies like the FDA provide a valuable public service by providing information, they also cause needless suffering and death and fail to then respect the public’s entitlement to make informed choices.

Reform is needed. The expansion of patients’ rights to include self-medication would protect citizens who are currently endangered and harmed by policies that make drugs unavailable. More importantly, self-medication would give each patient the ability
to take responsibility for her health, save or end her own life, and live in accordance with her values. Any just society would strive to adopt policies that were informed by these principles of responsibility, value pluralism and freedom. For all these reasons, justice requires self-medication.
I. A History of Self-Medication

Before the twentieth century, citizens in the United States enjoyed rights of self-medication. For example, in 1765 Thomas Jefferson assumed that self-medication was a fundamental right—his argument that liberty of conscience was similarly important and intimate rested on this premise. Yet with the rise of the administrative state in the twentieth century came a host of regulations that limited citizens’ access to therapeutic and recreational drugs. Pharmaceutical regulations were initially aimed at ensuring that drugs were unadulterated and properly labeled, but gradually extended to include prohibitions of experimental drugs and the selective prohibition of prescription-grade drugs.

In this chapter, I will describe the evolution of pharmaceutical paternalism. This historical account shows us that prohibitive policies often did not address the underlying problems that they were intended to solve, and perhaps more importantly, that there are alternatives to pharmaceutical prohibitions. I then suggest that an institutionalized right of self-medication is possible once again.

1. The History of Pharmaceutical Regulation

For most of human history, a mix of law and custom dictated who could provide or use medical services and medication. In ancient Egypt, pharmacists mixed prescription

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1 Jefferson assumes the basic status of self-medication in arguing for freedom of conscience when he wrote, for example, “Reason and free enquiry are the only effectual agents against error. Give a loose to them; they will support the true religion, by bringing every false one to their tribunal… If it be restrained now, the present corruptions will be protected, and new ones encouraged. Was the government to prescribe to us our medicine and diet, our bodies would be in such keeping as our souls are now.” Thomas Jefferson and Frank Shuffelton, Notes on the State of Virginia (Penguin, 1999). Query XVII
powders, pills, and ointments and gave patients detailed instructions for their proper use.²

Ancient Greeks regulated medicine through informal professional codes, such as the Hippocratic oath, which paternalistically forbade physicians from providing harmful, deadly, or abortive drugs to patients, even if patients requested them.³ Early accounts of Jewish law describe a positive duty that physicians provide medicine and faith healing, and a further duty that patients seek medical care; on some interpretations failing to provide medicine and medical care was morally equivalent to directly spilling a patient’s blood.⁴

The earliest accounts of governmental regulations of pharmaceuticals date to Roman law.⁵ According to the ancient historian Livy, in 331 BC hundreds of women were executed for brewing and administering poisons that they believed to be beneficial.⁶

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³ As Robert Veatch points out, not all ancient Greeks affirmed the Hypocratic Oath. For example, Stoics were famously accepting of suicide and self-harm. There is also some speculation that the Roman law governing medical liability is derived from laws in ancient Greece. For a discussion of this controversy see David Ibbetson, “Wrongs and Responsibility in Pre-Roman Law,” *The Journal of Legal History* 25, no. 2 (2004): 99–127. See also, Robert Veatch, *Cross-Cultural Perspectives in Medical Ethics*, 2 Sub. (Jones and Bartlett Publishers, 2000). Pg. 7
⁴ Veatch, *Cross-Cultural Perspectives in Medical Ethics*. Pp. 67-69
⁵ The twelve tables, one of the earliest legal codes, forbids poisoning in Table VI Law XIV. This code dates to 450 BC. Interestingly, earlier accounts of Roman law did not address the conduct of physicians except insofar as their actions compromised the health of slaves, in which case malpractice was considered a form of property damage. Vivian Nutton, *Ancient Medicine* (Psychology Press, 2004).
⁶ Kaufman writes, “The first known instance of the crime of poisoning at Rome was in 331 B.C., when a high mortality, the result, probably, of a pestilence, was attributed to poisoning. Even Livy doubted the validity of the charges, but he gives the whole account as found in his sources. After many leading citizens had died from the same disease, a slave-girl gave information to the curule aediles that the reason for this high mortality was the poisons prepared and administered by the Roman matrons. On investigation they found about twenty matrons, including patrician ladies, in the act of brewing poisons, which they declared were salutary. On being forced to drink their own concoctions to
It is speculated that they were literally given a taste of their own medicine as punishment. Still, throughout the ancient era governments largely overlooked medicine except insofar as poisons were used in crimes. Ancient physicians were trained as craftsmen, and like other craftsmen they were “servants of the art, not of the patient,” meaning that they were expected to repair the body by restoring its natural state, but not to serve any patient request, such as requests for healing natural ailments due to aging, or enhancing capacities. Early Greek and Christian law sometimes forbade providing abortive or deadly drugs, but otherwise did not limit access to medicines. This is not to say that caveat emptor (buyer beware) was the rule in all jurisdictions. Beginning in the ninth century private professional cooperatives called frankpledges recorded acts of deceitful trade and paid fines in cases where their members sold deficient goods, but in general governments did not directly regulate the availability of most consumer goods, including drugs.

Medical regulation began to change when medical training became more intellectualized and prestigious, thus attracting higher-status citizens to its ranks. By the tenth century, the Visigothic and Ostrogothic Kingdoms and Welsh Law empowered legislators and judges to regulate physicians and pharmacists, and governments even prove the charges false, they perished by their own wickedness. Following this, a hundred and seventy more were found guilty of the same offense.” D. B Kaufman, “Poisons and Poisoning Among the Romans,” Classical Philology 27, no. 2 (1932): 156–167. See also Veatch, Cross-Cultural Perspectives in Medical Ethics. and L Cillers and FP Retief, “Poisons, Poisoning, and the Drug Trade in Ancient Rome,” Akroterion 45 (2000): 88–100.


8 Ibid.

subsidized licensed medical providers.  

Throughout the medieval period, pharmaceuticals were regulated by legally certified professional guilds, and by the thirteenth century Parisian apothecaries were subject to inspections from the University and licensing requirements. These regulations quickly spread throughout Europe. By the fourteenth century German apothecaries were not permitted to sell drugs without authorization from a university-trained physician, and Italy adopted similar regulations in the fifteenth century. The justification for these early regulations was that trained physicians were necessary to uphold ethical standards in medicine. However, as with other historical accounts of guild systems, it seems that many of these regulations were motivated by the economic ambitions of high-status physicians who viewed activities like

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11 Vern Bullough’s account of early medicine has very helpfully informed the following narrative. Bullough writes, “The physician argued, somewhat successfully, that all medicine should be under him in order to preserve ethical standards. While he himself might not deign to do surgery or have anything to do with surgery, the physician had to rely on drugs and concoctions to cure his patients. His livelihood depended in part upon the apothecary so, that he was willing to fight hard to keep the apothecary under his control. A logical way of so doing would have been to combine the apothecary and physician in the same person, a development that did occur to some extent in England at a later date. This, however, would lower the status of the physician by changing his occupation from a speculative one to a manual one, i.e., preparing medicines. The apothecary had developed from the herbalist and spicer, merchants or traders, and were already members of the laboratories, although some managed to raise themselves to positions of power in the cities. Rather than weakening his own status by such an alliance, or allowing the apothecaries to extend themselves, the physician appealed to king or pope for control over the apothecaries. In the thirteenth century the apothecaries and herbalists were censured by the medical faculty of Paris for expanding their practice to the point where it infringed on the rights and duties of the physicians. Effective control over the apothecaries was not achieved until the king intervened to grant the medical university in Paris control over the apothecaries, including the right of inspection. The university was quick to prosecute any individual for violating its regulations.” Vern L. Bullough, “Status and Medieval Medicine,” *Journal of Health and Human Behavior* 2, no. 3 (October 1, 1961): 204–210.
12 Ibid. Pg. 209.
bloodletting and surgery as manual labor. Elite doctors therefore delegated the practical treatment of patients to lower class barbers and apothecaries who worked under a physician’s ethical supervision for a fee.\footnote{This medieval practice explains why barbers today place red and white poles outside of their shops. Historically, barbers were primary care providers and the poles were wrapped with bandages which had been used for bloodletting and treating wounds. As physicians became more involved in patient care, barbers kept the poles as a symbol of their profession. \textit{Ibid.} pg. 207-208}

In addition to these legislative regulations, judicial institutions also continued to specifically address pharmaceutical malpractice, misbranding, adulteration, and poisoning, into the modern era.\footnote{For example, in 1729 Samuel Pufendorf addressed the tension between strict and fault liability in self-medication when he argued that women who used deadly love-potions ought to be absolved from liability insofar as they were not aware even of the possibility of harm, but that insofar as the possibility was apparent to a woman, she was legally liable for negligent use. Samuel Pufendorf (Freiherr von) and Samuel Pufendorf, \textit{Of the Law of Nature and Nations: Eight Books} (The Lawbook Exchange, Ltd., 1729). Chapter V, pg. 51.} Pharmaceutical regulation and limits on access coincided with rises in state power. Where governments were strong and medical professionals were high-status, powerful interest groups used public power to limit access to medicines, codify professional training and to legally enforce codes of ethics.\footnote{For example, medical regulation persisted in France throughout the nineteenth century, though unlicensed pharmacology was still practiced but subject to prosecution. England regulated the practice of pharmacy, but did not regulate specific pharmaceuticals (except for a few narcotics) until the end of the nineteenth century, and apothecaries were permitted in some jurisdictions. see Matthew Ramsey, “Medical Power and Popular Medicine: Illegal Healers in Nineteenth-Century France,” \textit{Journal of Social History} 10, no. 4 (July 1, 1977): 560-587 and Bernice Hamilton, “The Medical Professions in the Eighteenth Century,” \textit{The Economic History Review} 4, no. 2 (February 11, 2008): 141-169. and James J. Kerr, “Notes on Pharmacy in Old Dublin,” \textit{Dublin Historical Record} 4, no. 4 (June 1, 1942): 149-159.}

2. Self-Medication in Nineteenth Century America

Set against this narrative, the relatively laissez faire era of the nineteenth century
marks a brief respite from the steady rise of the regulatory state.\textsuperscript{16} Unprecedented economic growth, democratization, and the rise of enlightenment ideals in Europe and North America produced fairly laissez faire policies, particularly in the United States and Australia where states were relatively weak.\textsuperscript{17} In the nineteenth century the federal government did not prohibit the sale or use of drugs, and citizens and policymakers widely affirmed rights of self-medication.\textsuperscript{18} This period in US history shows that an alternative system of self-medication, product liability, and public health regulation was possible.\textsuperscript{19}

First, consider the right of self-medication, which was once considered an

\textsuperscript{16} I characterize this as relatively laissez faire because America did have many regulations on health and health care, including licensing laws and pharmaceutical branding and sales restrictions or price controls at the state and local level. See James Harvey Young, \textit{American Self-dosage Medicines: An Historical Perspective} (Coronado Press, 1974).Chapter 1

\textsuperscript{17} The eighteenth and nineteenth centuries were also relatively laissez faire in Europe, which also enforced few limits on consumer choice. See Terry M. Parssinen, \textit{Secret Passions, Secret Remedies: Narcotic Drugs in British Society, 1820-1930} (Manchester University Press ND, 1983). See also J. L Montrose, “Contract of Sale in Self-Service Stores, The,” \textit{Northern Ireland Legal Quarterly} 10 (1954 1952): 178.


\textsuperscript{19} There are several explanations for this relative lack of overall regulation in the US and Europe, compared to the earlier guild systems that preceded this period and the extensive regulatory state that would follow. First a growing appreciation for consumer choice coincided with the enlightenment, democratization, and new political ideologies that prized individual liberty. This explanation comports with Louis Hartz’s hypothesis that America was freer than Europe because it did not inherit the cultural baggage of feudalism and the aforementioned status hierarchies of the medieval guild system. America was therefore especially well placed to embrace the enlightenment ideals of the eighteenth century, though those ideals obviously took hold in Europe as well. Second, economic growth in the eighteenth and nineteenth century created countless new products and opportunities for consumer choice which were previously unregulated because they were unimaginable. There is some controversy about this hypothesis because it seems as if the same status relationships that carried over in British law from its feudal past also shaped early and antebellum employment law in America. See Louis Hartz, \textit{The Liberal Tradition in America}, Second ed. (Mariner Books, 1991).
important personal liberty that ought to be protected from government limits, even from prohibitions in the name of public health. According to Daniel Carpenter’s detailed history of the FDA,

Votaries of self-medication frequently voiced their support for stronger labeling disclosure requirements for drug manufacturers, in part out of the belief that the intelligent layman needed maximal information to render an informed pharmaceutical purchasing decision. Yet the supporters of auto-therapy usually disdained state and federal regulatory measures. One of the most relevant political implications of their ethic was a time-honored “right of self-medication.” In operation, this included the absolute liberty of the consumer or patient to purchase any and all medications for the amelioration of his or her ailments. Whatever the disease, and whatever the purported cure, the layman should be able to exercise his own scientific judgment in drug purchasing decisions.20

Support for self-medication was also driven by a general mistrust of medical professionals, and a limited supply of quality physicians that could accommodate westward expansion. Self-medication was also tied to a prevalent belief in economic liberties; as Martha Mitchell writes, “any effort to legislate on the subject raised the cry of monopoly and destruction of individual right.”21

Product liability also underwent substantial changes in the nineteenth century. Before the eighteenth century, the title theory of contracts prevailed, meaning that judges and juries were empowered to assess whether an agreement between a vender and a

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20 Carpenter, Reputation and Power. Pg. 79
consumer was fair based on whether the parties were entitled to make the sale or contract (title) and whether transfer was transparent and consensual. If drugs were damaged, adulterated, ineffective, or deficient in some way the manufacturers and vendors could be held liable even if the consumers consented to the exchange. The industrial revolution of the late eighteenth and early nineteenth century brought unprecedented economic growth, global trade, and the rise of government bond markets, which all created an increasingly complex and impersonal national marketplace. These new economic conditions required a new model of product liability so in 1817 the Supreme Court adopted the principle of *caveat emptor* and developed the will theory of contracts, which held all parties to a contract as liable for the effects of their voluntary choices. This understanding of economic exchange, driven by Adam Smith’s influence, revolutionized product liability by emboldening manufacturers to sell risky products to consumers without legal sanction. Manufacturers were protected from liability as long as the consumers were not actively misled about the nature of the product.

The historical overlap between rights of self-medication and *caveat emptor*

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22 Libertarians like Murray Rothbard have notoriously tried to revive the title theory, and Nozick seems to endorse a version of it. See Murray N. Rothbard, *The Ethics of Liberty* (NYU Press, 2003). Chapter 19.

23 See *Laidlaw v. Organ*. In that case Hector Organ purchased over 100,000 lbs of tobacco from Laidlaw & co. on the last day that the war of 1812. Laidlaw asked Organ if he knew of anything that would affect the value of the product, and Organ failed to disclose that he knew that the price of tobacco would increase due to the end of the war. Laidlaw seized Organ’s tobacco upon learning the news subsequent to the contract, and Organ sued for breech of contract. In a unanimous decision Justice John Marshall wrote, “The vendee of merchandise is not bound to communicate to the vendor intelligence of extrinsic circumstances exclusively within the knowledge of the vendee which may affect the price of the same….But at the same time, each party must take care not to say anything tending to impose upon the other. “Laidlaw V. Organ - 15 U.S. 178 (1817),” *Justia US Supreme Court Center*, n.d., http://supreme.justia.com/cases/federal/us/15/178/case.html.
shaped a very weak and decentralized system of public health regulation that starkly contrasts with the policies that came before and after the nineteenth century. The first federal law that regulated pharmaceuticals was passed in 1848 when Congress forbade the importation of adulterated drugs, but even this regulation was rarely enforced.24 Mostly, pharmaceuticals were regulated like other products, through the tort system. Pharmaceutical manufacturers were legally prohibited from making fraudulent claims, and were required to disclose the known risks of some products, but pharmaceuticals were generally subject to little more regulation than food, gunpowder, or livestock. As long as consumers were given accurate information, they were at liberty to purchase almost any drugs and medications.

At this point, it is worth pausing to consider what it was like during the laissez faire drug regime of nineteenth century America, (setting aside the patchwork of prohibitions on recreational intoxicants, which I will soon address.) The germ theory of disease only emerged at the end of the nineteenth century, and so medicine in the nineteenth century was incredibly uncertain, even in Europe. In the US, physicians were poorly trained, expensive, and in short supply.25 At the end of the Colonial period, medical care in America was provided by a range of professionals, including midwives, clergy, untrained laymen and European-trained physicians, (American universities did not offer medical training.)26 In 1860 Oliver Wendell Holmes Sr. wrote, “the medica

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25 While the germ theory of disease developed throughout the nineteenth century applications were not widespread until the twentieth century. Koch’s postulates the first comprehensive test of the theory, were published in 1890. J. Lederberg and others, “Infectious History,” *Science* 288, no. 5464 (2000): 287–293.
26 Hamilton, “The Medical Professions in the Eighteenth Century.” Pg. 156
materia, as now used, could be sunk to the bottom of the sea, it would be all the better for mankind-and all the worse for the fishes,” a sentiment that reflected general American skepticism of traditional (European) medical wisdom.\textsuperscript{27} Academically trained physicians had no more legal or cultural authority than other providers.\textsuperscript{28} All of these providers practiced eclecticism, a mix of pharmacology, homeopathy, and phrenology, faith healing and even Indian mesmerism, and most providers also made their own drugs.\textsuperscript{29}

By the mid-nineteenth century druggists became the first line providers of medical treatment. Druggists provided anything the market would bear, including smallpox vaccinations, bandages, optometry, dentistry, and midwifery.\textsuperscript{30} As the progress of nineteenth century industrialization extended to the pharmaceutical industry patients gained new options for self-medication and druggists played an increasingly important role in examining imported medicines, compounding new drugs, and advising patients about the risk and benefits of new treatments.\textsuperscript{31} Druggists provided more tangible and effective care than traditional methods of folk-healing and cost much less than a

\begin{itemize}
\item \textsuperscript{27} Jeffrey Clayton Foster, “The Rocky Road to a ‘Drug Free Tennessee’: A History of the Early Regulation of Cocaine and the Opiates, 1897-1913,” \textit{Journal of Social History} 29, no. 3 (April 1, 1996): 547–564.
\item \textsuperscript{29} Hugh M. Ayer, “Nineteenth Century Medicine,” \textit{Indiana Magazine of History} 48, no. 3 (1952): 233–254.
\item \textsuperscript{30} The American and Australian experiences with pharmaceuticals were similar, since neither inherited the European guild system and both countries faced problems of medical training and supply as they rapidly expanded. See Judith Raftery, “Keeping Healthy in Nineteenth-Century Australia,” \textit{Health and History} 1, no. 4 (December 1, 1999): 274–297. Pg. 283
\end{itemize}
consultation with a trained physician. Further, trained physicians also acted as druggists, mixing and selling compounds to patients, because the custom at the time (and in some states, the law) forbade physicians from charging fees for service unless medicine was given or a specific invasive procedure was performed.  

Yet when we look beyond federal regulations, the story of pharmaceutical prohibitions in the nineteenth is a bit more complex than caveat emptor and a culture of self-medication. On the state level, public policy protected a right to almost any medication, but not all intoxicants. Pharmacists sold narcotics and opiates, like morphine over the counter, and as recreational use of cocaine and opiates became widespread in the nineteenth century, physicians began publishing calls for more effective restrictions on the sale of narcotics to children under ten, and also described the dangers of using opiates when pregnant. Concerns about addiction grew as well, and indeed opiate and narcotic consumption was widespread.

In response to widespread recreational drug use, alcohol and opium prohibitions were passed, with varying degrees of success, at the state level throughout the nineteenth century. Some states split the difference between prohibitions in permissions. For example, in Fisher v. McGirr (MA, 1854) Justice Shaw acknowledged that the state could prohibit the manufacture and sale of alcohol, but also claimed that privately owned alcohol could not

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35 Some states split the difference between prohibitions in permissions. For example, in Fisher v. McGirr (MA, 1854) Justice Shaw acknowledged that the state could prohibit the manufacture and sale of alcohol, but also claimed that privately owned alcohol could not
public’s moral health and the state’s interest in a well-ordered society, though there is some speculation that early prohibitions also aimed to protect wealthy pharmacy owners from Italian and Chinese immigrants who mainly sold cocaine and opium. Where prohibitions failed, they were struck down on the grounds that all citizens had rights against the moral paternalism of public officials. These debates would set the stage for subsequent prohibitions on pharmaceutical use.

The rhetoric in judicial opinions and prohibitive policies illustrates the conflicting views towards alcohol and intoxicants in the nineteenth century. On one hand, some justices argued that prohibitive policies were no different than other legitimate state policies to ensure public morality and safety. Vermont’s Justice Storrs wrote, “The subjection of private property (including alcohol) in the mode of its enjoyment to the public good… is a principle lying at the foundation of government. It is a condition of the social state, the price of its enjoyment.” On the other hand, Indiana Supreme Court Justice Perkins struck down alcohol prohibitions in Beebe v. State, arguing that any justification for such prohibitions must lie in ideas like “European Jurisprudence” which were “dangerous, indeed utterly blind guides to follow in our free and limited

be seized without warrant. This decision contrasted with the judgment of the New York Appelate court in Wynehamer v. People (NY, 1855) which held that insofar as alcohol was a form of private property, seizure was always illegal even if the state had passed prohibition laws. Willian J. Novak, People’s Welfare: Law and Regulation in Nineteenth-Century America (University of North Carolina Press, 1996). Pg. 149-234.

36 For example, anti-opiate legislation was initially targeted at Chinese businesses and was explicitly aimed to punish Chinese users. Anti-opium legislation explicitly distinguished between whites and non-whites and how early narcotic legislation targeted Chinese opium dens. Also, early anti-drug policies, especially those that addressed cocaine, were aimed at poor Italian immigrant pharmacists in Chicago. See Lawrence Friedman, Crime And Punishment In American History (Basic Books, 1994). Pg. 137, and Joseph Spillane, “The Making of an Underground Market: Drug Selling in Chicago, 1900-1940,” Journal of Social History 32, no. 1 (October 1, 1998): 27-47.

37 Novak, People’s Welfare.Pg. 181
government.”

Perkins further condemned paternalistic policies in no uncertain terms when he wrote:

The people of a [paternalistic] country had no rights except what the government of that country graciously saw fit to confer upon them, and it was its duty like a father towards its children to command whatever it deemed expedient for the public good… [Such governments] could prescribe what the people should eat and drink, what political, moral and religious creeds they should believe, and punish heresy by burning at the stake for all the public good.

Elsewhere, Perkins wrote that prohibition laws offended against man’s natural right to “free-agency” and that laws against alcohol use dictated: “a man shall not use for all enjoyment what his neighbor may abuse.” Perkins further suggested prohibitions would “make eunuchs of all men.”

These debates about prohibition reflected two competing commitments that nineteenth century Americans inherited from their revolutionary past. On one hand, European and puritanical Christian impulses persisted from the colonial era to some extent, especially in New England. The widespread view that public officials could promote public morality justified passing alcohol prohibitions as a kind of moral paternalism. On the other hand, Americans also were staunchly committed to individual rights, especially property rights and self-medication. According to Novak, these competing commitments explain why the earliest expansions of substantive due process

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38 Ibid. Pg. 184
39 Ibid. Pg. 184.
40 Ibid. Pg. 184.
41 Ibid. Pg. 184.
and public prohibitive power came in cases that involved the use of intoxicants, because the question of alcohol prohibition so clearly illustrated the tension between individual freedom and moral paternalism.\textsuperscript{42}

This thesis also explains why courts and legislators drew a line between self-medication and recreational alcohol use. Unlike intoxicants, medical drug use did not lead to licentiousness or instability, and while some public officials at the time recognized a mandate to promote public \textit{morality}, policymakers did not yet seek to promote \textit{public health}.\textsuperscript{43} This thinking changed in the twentieth century when a series of public health tragedies sparked public support for federal pharmaceutical regulation.

\textbf{3. The Beginning of Public Health Regulation}

Today, pharmaceutical regulation is widespread; all developed nations enforce some prohibitions or selective prohibitions of risky drugs and America is no longer exceptionally permissive.\textsuperscript{44} Was the laissez faire approach of nineteenth century a mere anomaly that was overtaken by the same moral paternalism and economic protectionism of the medieval guild system? Or, did the twentieth century bring a novel and unprecedented regulatory framework? To be sure, twentieth century regulations do reflect elements of the moral regulation and protectionism that preceded American lais\`{e}z faire, but the main justification for the current system of pharmaceutical regulation was new. Rather than passing prohibitive laws to ensure public morality, twentieth century

\textsuperscript{42} Ibid. Pg. 188.
\textsuperscript{43} Another possible reason for the asymmetry between rights of self-medication and alcohol use is that pharmacology remained relatively primitive in the nineteenth century, whereas alcohol manufacturing became more centralized and pervasive, and was thus an easier industry to regulate.
\textsuperscript{44} Novak, \textit{People’s Welfare}. And Jeffrey Clayton Foster, “The Rocky Road to a ‘Drug Free Tennessee’.”
regulations aimed to protect the public’s health from their own voluntary health decisions. In short, while earlier regulations aimed to protect the health of our souls, regulation today also aims to protect the health of our bodies.

American pharmaceutical regulation began in 1902 when contaminated smallpox vaccines and diphtheria treatments caused a public outcry about the safety of manufactured and imported medicines. In response, Congress authorized the US Hygienic Laboratory to license drug manufacturers. In 1906 Congress passed the Pure Food and Drug Act, which empowered the USDA’s bureau of Chemistry to penalize companies that sold adulterated or misbranded drugs, in response to similar concerns about contamination. Together, these laws brought pharmaceutical sales under the jurisdiction of federal agencies, and in 1927, Congress moved the Bureau of Chemistry to its own agency, which is now the FDA. This legislation was importantly different from earlier European pharmaceutical regulations in two respects. First, the regulations aimed to control products as well as professions. Unlike the earlier guild systems, which did not directly oversee the quality of therapeutic medicines, these regulations aimed to make better products, not better producers. Second, the twentieth century American legislation explicitly aimed to protect and promote the public’s physical health, as well as morality.

This is not to say that the “moral health” of the public was entirely overlooked in this period. In 1914, Congress passed the Harrison Narcotics Tax Act, which was intended to discourage opiate use for addiction treatment by imposing a tax on drug

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45 Jeffrey Clayton Foster, “The Rocky Road to a ‘Drug Free Tennessee’.”Pg. 76
46 Carpenter, Reputation and Power.76
47 The agency was initially called the Food, Drug and Insecticide Administration
48 For example, the father of the new regulatory authority, Harvey W Wiley once wrote that the national food and drug law was ‘intended to protect the health of the people’ Carpenter, Reputation and Power.pg 76
providers who distributed morphine or cocaine for non-medical uses or to treat addiction. The Harrison Narcotics Tax Act was the first nationwide legislation to introduce a distinction between prescription and over the counter drugs. Drugs were given prescription-only status if their use was considered immoral or if they could potentially harm minors. The Narcotics Tax act was the first piece of national legislation that took on the aforementioned debates between moral paternalists and proponents of “free-agency.” This national debate may have peaked with the passage of the 18th amendment, but it continues to inform drug policy today.

Nevertheless, public health remained the primary justification for policies that regulated the medicinal use of drugs. In 1938 the Elixir Sulfanilamide tragedy sparked public outcry, and calls for still more regulation of pharmaceuticals:

Within a month, it's estimated that more than 100 people, mostly children, had died horrific deaths as their kidneys shut down and they went into convulsions (after using S.E. Massengill Co.’s Elixir Sulfanilamide.) The owner of the company, when pressed to admit some measure of culpability, famously answered, “We have been supplying a legitimate professional demand and not once could have foreseen the unlooked-for results. I do not feel that there was any responsibility on our part.”

Although Elixir Sulfanilamide had undergone premarket testing, initiated by the manufacturer, the company failed to test the diethylen glycol solvent used for the elixir. The company’s chief chemist committed suicide after the tragedy, but there were few

49 Ibid. See also, Donald T. Dickson, “Bureaucracy and Morality: An Organizational Perspective on a Moral Crusade,” Social Problems 16, no. 2 (October 1, 1968): 143–156.
legal consequences for unintentional poisonings. S.E. Massengill Co could only be held liable for misbranding the drug as an elixir (though the drug did not contain alcohol,) and the company paid a small fine.

In response to this incident, Congress passed the Food, Drug, and Cosmetic Act in 1938, which expanded the FDA’s power to enforce responsible labeling standards, and required pharmaceutical manufacturers to submit New Drug Applications (NDA’s) that included reports about safety testing, manufacturing procedures, and quality control. The 1938 Act also required manufacturers to designate their products as behind the counter or over the counter, and manufacturers could be held legally liable if they mislabeled a dangerous drug as over the counter. It is important to note that even at this point, federal drug regulation was largely non-prohibitive once a drug was approved. Instead, regulatory officials sought to limit the conduct of manufacturers and pharmacists to ensure that citizens had access to safe and accurately labeled drugs, but the option still rested with patients, in consultation with their physicians perhaps, to decide which drugs to use.

Though public health concerns clearly motivated the 1938 legislation, it would be overly simplistic to explain American pharmaceutical regulation solely as an effort to ensure the public health in response to drug disasters. This legislation marked the end of the caveat emptor standard for pharmaceutical sales. Legislators were motivated by the worry that consumers would purchase dangerous drugs like Elixir Sulfanilamide, even if the pre-1938 labeling requirements had been followed. “Buyer beware” was no longer

51 Ibid.
52 The act calls a ‘behind the counter’ status a ‘prescription-only’ status, but it was not illegal to sell ‘prescription-only’ drugs without prescriptions, so for clarity and consistency, I’m labeling this status as behind the counter instead.
enough, so the courts were no longer consumers’ sole defense against dangerous medicines. It is then unsurprising that the 1938 legislation was passed one year after \textit{Lochner v. New York} was overturned, marking the end of a more general commitment to \textit{laissez faire} policies.\textsuperscript{53} Like the end of \textit{Lochner}, the 1938 legislation was also driven by support from powerful business interests, in this case the Council on Pharmacy and Chemistry of the American Medical Association supported the expansion of the FDA to legally enforce the safety and efficacy standards that informed their seal of acceptance program.\textsuperscript{54} In these ways, the 1938 legislation can also be understood as a reflection of the broader New Deal shift away from \textit{laissez faire} policies, a shift which was at times motivated by protectionism as well as public health.

\textbf{4. Beyond Safety}

In 1938 Congress was explicit that premarket approval requirements ought not extend to prohibitions of existing and approved medicines, but that manufacturers must show the FDA that new drugs were safe for use. The Act states that it is “not intended to restrict in any way the availability of drugs for self-medication. On the contrary, it is intended to make self-medication safer and more effective.”\textsuperscript{55}

Yet once a drug’s level of safety was tested, inconsistent labeling decisions by manufacturers gave consumers, physicians, and pharmacists no clear guidance about the relative safety of new and existing drugs. Further, as new drugs entered the marketplace, manufacturers, pharmacists, and physicians from competition.


\textsuperscript{54} Carpenter, \textit{Reputation and Power}. Pg. 76, as above, the pharmaceutical regulations of 1938 protected established and wealthy pharmacists and physicians from competition from lower-status businesses such as Chinese and Italian pharmacists.

especially long-term therapies, pharmaceutical experts and public officials became increasingly concerned about consumers’ abilities to assess the safety of drugs and to use drugs safely. Prohibitions on the purchase of especially potent or risky drugs without a prescription were later passed in the 1951 Durham-Humphrey amendments to the 1938 Act.\(^5\) The 1951 amendments granted the FDA the authority to designate which drugs, once approved for safety, could be sold over the counter and to selectively prohibit the sale of prescription-grade drugs.\(^6\) Prescription-grade drugs were defined as:

A drug intended for use by man which –

(A) Because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug;

Or

(B) Is limited by an approved application under section 505 to use under the professional supervision of a practitioner licensed by law to administer such drug.\(^7\)

The FDA has historically interpreted this amendment to mean that any drug that is otherwise safe ought to be sold over the counter.\(^8\)

The FDA’s prohibitive power expanded once again in 1962, when Congress

\(^5\) Carpenter, *Reputation and Power*. Pg. 152.

\(^6\) Ibid. Pg. 152


\(^8\) Food and Drug Administration, *Overview of Issues for the Joint Nonprescription Drugs Advisory Committee and the Pulmonary-Allergy Drugs Advisory Committee* (FDA, May 11, 2001).
passed the Kefauver-Harris Amendments to the 1938 act. Like the 1938 act, the Kefauver-Harris Amendments were passed after a public health crisis, when thousands of children in Europe were born with deformed limbs as a result of mothers’ consumption of the morning sickness treatment Thalidomide. The United States was spared from the Thalidomide crisis when Dr. Francis Kelsey delayed the manufacturer’s application for approval. When the dangers of Thalidomide became clear, Kelsey became a national hero for protecting American families from the dangerous drug and her story buoyed support for an even stronger FDA. Yet as Kelsey later wrote,

The Food, Drug, and Cosmetic Act passed in 1938 was indeed adequate to prevent marketing of thalidomide in this country, but the episode did serve to call attention to the inadequacies of this Act and hastened if not ensured its amendment in October 1962.60

And so, congress passed Kefauver-Harris amendment in 1962, which was mainly designed to provide cheaper drugs by reducing protections for exclusive patents, but the bill also effectively revolutionized drug safety in the US by expanding the agency’s power to require that manufacturers register with the FDA, abide by standards of quality control, submit to periodic inspection and advertising regulations, and establish that drugs are not only safe but effective as well. Finally, the FDA assumed the authority to oversee all required clinical trials.61 These efforts at regulatory expansion were already underway within the agency before Thalidomide was linked to birth defects in Europe, but the Thalidomide crisis further legitimated pharmaceutical regulation in the United States and

61 Ibid.
undermined public support for self-medication.\(^{62}\)

The final major expansion of pharmaceutical regulation came in 1970, when congress passed the Comprehensive Drug Abuse Prevention and Control Act, which enabled the Drug Enforcement Administration (DEA) to enforce prohibitions of prescription drugs.\(^{63}\) The 1970 act also expanded the FDA’s power to also distinguish between legitimate medical uses and illegitimate medical uses for addictive drugs, and empowered the DEA to punish recreational prescription drug abuse.

The period from 1951-1970 witnessed a shift from public health and safety, which was the initial purpose of pharmaceutical regulation, back to the moralistic paternalism of the European guild system. As pharmaceutical markets expanded, and the public witnessed terrifying drug disasters like the Elixir Sulfanilamide crisis and Thalidomide babies, support for self-medication eroded. By the 1960’s policymakers were no longer concerned about citizens rights of self-medication and caveat emptor died with the New Deal. Without the rights tradition of the nineteenth century, regulators went from using public policy to enable public health to using prohibitive policies to ensure the public health, and by 1970, the public morality as well.

5. The Current State of Regulation

Nineteenth century frontier countries like the United States and Australia were exceptional in their embrace of self-medication. Historically, governments and professional guilds regulated pharmaceuticals, but physician shortages and weak central governments combined to allow for a brief era of pharmaceutical freedom. In the latter

\(^{62}\) Ibid.
half of the twentieth century the pendulum of public power swung back in favor of strong central governmental regulation, and the United States today has one of the most restrictive and prohibitive set of pharmaceutical regulations.

Nevertheless, liberalization of pharmaceuticals is regaining political momentum today as new treatment possibilities challenge both premarket and post-market regulations. First, consider recent developments in personalized medicine and diagnostics, which stand to challenge the current system of premarket drug approval. Since 1962, FDA has approved drugs for safety and efficacy by requiring four phases of testing before the can be legally sold and marketed: long term animal tests, phase 1 clinical trials for safety, phase 2 trials for dosing efficacy and phase 3 trials for overall efficacy and side effects.  

For a typical drug, the approval process takes 6-11 years and costs up to $2 billion. Yet new developments in biotechnology may require that regulatory agencies adopt radically different testing procedures in the near future. Specifically, genomic, proteomic, and metabolomic diagnostic testing points to promising new possibilities for personalized medicine- therapies that target not just a given illness, but an individual patient’s particular illness. Some of these developments in personalized medicine are already informing treatment decisions. For example, breast cancer patients

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64 Phase III alone requires testing on 1000-3000 disease-state patients over the course of several years. Medical developments in the past have also changed testing requirements, for example, AIDS activists in the 1980’s succeeded in winning expedited drug approval and expanded access to new drugs for terminally ill patients. I will discuss these developments more in the next chapter, and in Chapter 9. see Carpenter, Reputation and Power. Pp. 393-464.

have cancers that are caused by a genetic mutation that involves more than two copies of the HER2 gene, which then causes the body to overproduce the HER2 protein, causing deadly tumors.\textsuperscript{66} Herceptin is an approved treatment for breast cancer, but it is only effective for patients with the HER2 mutation. There are 1,200 diagnostic tests like the test for the HER2 genetic mutation in use today, and they inform treatment decisions already.\textsuperscript{67}

Personalized diagnostics is making personalized medicine a possibility, but the current system of premarket testing will need to change. Clinical trials are the accepted standard for new drug approval. New treatments are tested either against a placebo or against the current standard of treatment to establish safety and efficacy for the general population. But many drugs may be safe and effective for particular patients, but not for enough patients to pass premarket tests, particularly efficacy requirements. Further, as Allen Roses, a GlaxoSmithKline executive noted, more than 90 percent of drugs that are approved nevertheless only work in 30-50 percent of patients, and they may have risks and side effects for all patients.\textsuperscript{68} Advances in diagnostic testing make it possible to move away from the “one drug fits all” model of development, testing, and approval. According to Roses:


By eliminating the people that we predict will be non-responders we'll be able to do smaller, faster and cheaper drug trials...If you can determine who is going to have a response (to a drug) and who is not going to have a response, you can take your next molecule and aim it specifically at the people who haven't had a response with the first one so that you can create a set of drugs that cover the population, and then you are back to selling to everybody.\textsuperscript{69}

Currently, two-thirds of drugs that are denied approval are denied due to lack of efficacy, but personalized medicine is already pushing regulators to adopt a more targeted conception of efficacy. In 2011 the FDA announced new guidelines for the regulation of diagnostic tests and targeted drug therapies; the agency now requires that each targeted therapy be approved with its associated diagnostic test, and thereby does not require that targeted therapies establish general efficacy for all patients.\textsuperscript{70} Still, critics worry that these requirements, which tie diagnostic testing to targeted medicine, will discourage innovation in both diagnostics and drugs.

In light of these new technological developments, the approval process is changing, and while standards remain strict, they are becoming more flexible. With the targeted drug regulations, the FDA approved 35 new medicines in 2011, including two personalized medicines that were approved with genetic tests, and 24 medicines that were approved before European regulatory agencies.\textsuperscript{71}

Other developments in medical technology are also challenging the prescription drug system. Unlike the United States, most other countries certify some drugs as

\textsuperscript{69} Ibid.
\textsuperscript{70} Food and Drug Administration, \textit{Building the Infrastructure to Drive and Support Personalized Medicine} (Food and Drug Administration, October 5, 2011).
\textsuperscript{71} FDA, \textit{FY 2011 Innovative Drug Approvals} (FDA, November 2011).
“behind the counter” in addition to over the counter or prescription-grade. In March 2012, the FDA held a hearing to investigate the expansion of over the counter and behind the counter options in the US.\(^72\) There have also been recent political movements to make more drugs available over the counter, including birth control, emergency contraception, and Naloxone, which reverses the otherwise fatal effects of opiate overdose.\(^73\) On at least one college campus, emergency contraception is now available in vending machines.\(^74\) A move from the two-tier system to a substantial behind the counter option for drugs is unlikely to happen quickly, but it is increasingly an option that is deployed and considered by agency officials.

This shows that on both fronts, self-medication and deregulation are gaining momentum. In April 2012, two Republican senators introduced the “Promoting Accountability, Transparency, Innovation, Efficiency, and Timeliness at FDA Act” (or the PATIENTS’ FDA Act). For our purposes, the most interesting parts of the act is section 202, which aims to “better ensure that patients have the opportunity themselves to weigh possible risks against the possible benefit of a particular drug or device.” This section doesn’t change current practice much, but it does require more formal risk-benefit assessments that are applied consistently to all drugs, rather than enabling risk-averse


\(^{73}\) “Community-Based Opioid Overdose Prevention Programs Providing Naloxone — United States, 2010”, 2010, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6106a1.htm?s_cid=mm6106a1_x.

regulatory officials to strategically deny approval for drugs. The spirit behind the bill is more radical though, the authors of the bill argue that,

Many patients accept the risks of a product because of the potential benefit it may afford them. However, too often well-intended decisions at the FDA may result in review decisions that prevent innovative products from being available to certain patients willing to accept greater risks than others.\(^{75}\)

In May 2012 the Senate passed the Food and Drug Administration Safety and Innovation Act (S.3187) as well, which would require that the FDA accept data from clinical trials conducted outside of the United States, thus making the approval process shorter and less costly. This kind of legislation and rhetoric is an early sign that self-medication may be gaining popularity in the public sphere today.

6. A Path to Responsible Self-Medication

What would the pharmaceutical industry look like if the regulatory expansions of the twentieth century had taken a less prohibitive route? How might the FDA change if it continues to expand patients’ access to new personalized drugs and behind the counter pharmaceuticals? It may seem difficult to imagine any acceptably safe version of the laissez faire polices of the nineteenth century, given the incredibly complex and dangerous drugs that are available today. A return to self-medication may also seem especially undesirable, given the above description of widespread narcotic and opiate use in the nineteenth century. Yet other regulatory agencies have taken a non-prohibitive path, and some countries are beginning to reconsider prohibitive drug policies for

\(^{75}\) This is from Senator Burr’s website. http://burr.senate.gov/public/_files/041712fda.pdf
recreational users. These modern examples can show us a path to responsible self-medication.

First consider the US Consumer Product Safety Commission (CPSC), which regulates most consumer products except for handguns, food, tobacco, and drugs. The CPSC primarily requires that manufacturers disclose all the potential risks and safety hazards of products. The CPSC also oversees some premarket safety testing to some extent, but this testing is mostly aimed at preventing the sale of children’s toys that contain toxic metals like lead or toxic plastics like BPA. In 2011, the CPSC launched an online database that catalogues and monitors consumer safety complaints, dangerous defects, and risks for all products, so that consumers can access the information necessary to make an informed choice. The CPSC also oversees voluntary recalls of dangerous products, but has never (as far as I can tell) pursued any non-voluntary recall, which would require that the agency use the legal system to force a manufacturer to comply with a recall. Because the courts play an extremely active role in holding manufacturers accountable for the adverse effects of their products, the CPSC arguably has more postmarket mechanisms to ensure product safety than the FDA.

Despite the CPSC’s apparent toothlessness, it nevertheless influences consumer safety through premarket and postmarket mechanisms. Companies almost always comply


77 A recent study of the CPSC, which included a survey of recall reports and interviews with CPSC staff, also was unable to find any examples of non-voluntary recalls by the CPSC. See Product Recalls, Imperfect Information, and Spillover Effects: Lessons from the Consumer Response to the 2007 Toy Recalls Seth M. Freedman, Melissa Schettini Kearney, and Mara Lederman NBER Working Paper No. 15183 July 2009
with voluntary recalls, and since the CPSC widely advertises safety concerns they discourage consumers from buying unsafe products. Further, the CPSC effectively enforces labeling and safety disclosure requirements, and promotes informed consumer choice.\textsuperscript{78} The CPSC works in part because companies are also legally liable for any undisclosed safety hazards posed by their products. Anticipating this CPSC oversight and potential liability, manufacturers test products for safety and voluntarily disclose risk and warnings.\textsuperscript{79}

Second, one may worry that a more liberal pharmaceutical policy would be ill suited to the current marketplace of complex and deadly drugs, with serious side effects and the potential for addiction and abuse. Yet some developed countries are already beginning to decriminalize and legalize recreational drugs. Most notably, Portugal decriminalized the use of all recreational drugs in 2001. While drug use in Portugal has increased, rates of addiction and abuse decreased.\textsuperscript{80} Further, more users enrolled in rehabilitation and treatment programs as a result of decriminalization because the stigma and fear associated with illicit drug use no longer prevented unwilling addicts from seeking help.\textsuperscript{81} The Portuguese experience points to an alternative drug policy. One where consumers can purchase and use any drugs they want, but where treatment options for addicted consumers who want help are available. While Portugal focuses on

\begin{itemize}
\item \textsuperscript{78} Ibid
\item \textsuperscript{79} Symposium: The Products Liability Restatement: Was It a Success?: Post-Sale Duties: The Most Expansive Theory in Products Liability Spring, 2009 74 Brooklyn L. Rev. 963by Kenneth Ross and J. David Prince
\item \textsuperscript{80} Caitlin Elizabeth Hughes and Alex Stevens, “What Can We Learn From The Portuguese Decriminalization of Illicit Drugs?,” \textit{British Journal of Criminology} 50, no. 6 (November 1, 2010): 999–1022
\item \textsuperscript{81} Glenn Greenwald, \textit{Drug Decriminalization in Portugal: Lessons for Creating Fair and Successful Drug Policies} (Cato, April 9, 2009).
\end{itemize}
recreational drugs, such a system could (and ought to) extend to pharmaceuticals as well. That hard drugs like cocaine and heroin are available for recreational use in Portugal, and public health outcomes have nevertheless improved, suggests that potentially dangerous pharmaceuticals ought to also be available for medicinal and recreational use, as they were in the nineteenth century.

7. Conclusion

In this chapter I have described the historical development of pharmaceutical regulation within the broader context of American history, with particular reference to evolving understandings of individual liberty. The belief in a right of self-medication reflected nineteenth-century Americans’ more general commitment to individualism and free choice, particularly free economic choice. The birth of the American welfare state in the 1930’s gave policymakers a reason to take an interest in the public health, and a series of public health disasters made citizens more open to limits on self-medication. Together, these forces in public life culminated in the strict regulatory framework that governs the pharmaceutical industry today. But new advances in personalized medicine and recent calls for the expansion of behind the counter status and self-medication, indicate that the pendulum may be swinging back towards the expansion of consumer choice. Other regulatory agencies in America and Portugal’s drug regime show that such an expansion is conceivable, even today. In the following chapters I will develop the moral case for self-medication.
II. The Consequences of Pharmaceutical Regulation

Two kinds of prohibitive pharmaceutical regulations violate citizens’ rights of self-medication: premarket testing requirements and the prescription drug system. These regulations harm patients because they discourage innovation, prevent sick patients from accessing potentially beneficial drugs, and drive up the cost of drugs. On the other hand, they benefit people because they promote informed consumer choice and keep potentially unsafe drugs from the marketplace. A growing body of economic research suggests that the harms of regulation, in terms of life lost and overall suffering, as well as the economic costs, likely outweigh the benefits of the current system. Yet we often overlook this fact. Though the harms are substantial, it not often apparent whether a particular patient dies as a result of prohibitive regulations, and though the benefits are small, the deaths that are caused by dangerous drugs are easy to see.

Earlier, I described how pharmaceutical regulation evolved in response to tragic public health disasters. Even today when dangerous drugs like Vioxx lead to patient deaths, the public and the media decry a lack of effective regulation and call for more government involvement in the industry. In contrast, few interest groups or media outlets condemn regulators when thousands suffer and die of diseases that could have been treated and cured were it not for prohibitive policies.¹ In this chapter, I will discuss the human costs and benefits of regulation. I will give many examples that illustrate the positive correlation between regulation and suffering. The claims presented in this chapter are largely empirical, but the normative implications are clear.

¹ One prominent example of an interest group that does argue for pharmaceutical policy reform is the Abigail Alliance, which I will discuss in detail in Chapter 5.
One of the few sustained philosophical defenses of pharmaceutical regulation rests on a hypothesis that the consequences of self-medication would be catastrophic. George Rainbolt argues that if we “vividly imagine the consequences of repealing prescription drug laws… even autonomy is not worth this price…. The consequences of the (self-medication) are so awful that we ought to accept hard paternalism.” Yet Rainbolt gives no evidence for this claim, and fails to consider that the costs of prohibitive policies are also substantial. The evidence suggests that anyone who is concerned with consequences ought to endorse a much less prohibitive regulatory framework than those that all developed nations have adopted. Even those of us who are not consequentialists should question our commitment to pharmaceutical regulation in light of the substantial suffering and death it causes. Perhaps the best institutional solution rests somewhere between the current system and an unconditional right of self-medication, or perhaps self-medication will be best. The following evidence can only show us the costs of prohibitions, not which institutional solution would be best, but it does tell in favor of greater rights of self-medication than we currently have.

1. Counting Harms and Benefits

Before we survey the costs and benefits of pharmaceutical regulation, we should pause to consider why they matter. While I believe that paternalism in medicine can never be justified because citizens have unconditional rights of self-medication, more moderate liberals might argue that paternalistic rights violations are justified if the self-harming consequences of exercising that right are truly catastrophic. Liberal perfectionists, for example, might hold that paternalism is warranted if it promotes human

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flourishing overall. Liberal consequentialists are also accepting of paternalism in cases where it promotes general welfare. Some liberals, like Robert Goodin, have argued utilitarian considerations are particularly well suited to address state actions.\(^3\) He argues that while individuals might not have a duty to promote good consequences overall, public officials should focus on consequences because they have a duty to be impartial with respect to all citizens and they are particularly well placed to assess the overall consequences of a policy. Finally, for anyone who might reject rights-based arguments, a review of the consequences of pharmaceutical regulation may be relevant. As David Schmidtz has argued, in the absence of any rights-based or promise-based claims about what we should do, cost benefit analysis with full cost accounting, weighing all the relevant consequences of an action or inaction, is a good candidate decision procedure.\(^4\)

Once we allow that consequences might play a role in public morality, we are still left with questions about how to judge consequences. In a world where all developed liberal societies enforce prohibitive pharmaceutical regulations, how could we tell whether fewer prohibitive regulations would have better consequences? After all economists cannot randomly assign non-prohibitive pharmaceutical policies to some liberal states and compare the consequences against a status quo control group. When all liberal states have the same kinds of policies, how can we say that some counterfactual policy would be better?\(^5\)

\(^3\) Robert E. Goodin, *Utilitarianism As a Public Philosophy* (Cambridge University Press, 1995).


\(^5\) We cannot know for sure if an alternative policy would be better or worse, but this fact does not tell in favor of the status quo either. One reason to stay the course might be risk aversion, new non-prohibitive pharmaceutical policies might have unknown and
One strategy is comparative analysis. While all developed societies enforce prohibitive pharmaceutical regulations, developing countries often do not. Though it is difficult to compare health outcomes in developing legal systems with developed nations, middle-income countries (some of which enforce regulations, some of which do not) can provide us with some data about how non-prohibitive regimes might work. Additionally, among developed liberal states, some are more prohibitive than others. The FDA is by far the most prohibitive pharmaceutical regime, while most countries in Europe designate some drugs that require a prescription in the US as behind the counter or even over the counter. These comparisons can inform our judgments about the relative safety of each system. A pitfall of this kind of comparative analysis is that less prohibitive regimes might look to the FDA for guidance about what to prohibit, but without some prohibitive agencies, non-prohibitive regimes might lack data for informed consumer choice. This worry assumes that prohibitive agencies cannot fulfill an advisory role without also prohibiting medicines. I propose that agencies can oversee testing and provide recommendations for medication and thereby empower patients to exercise rights of self-medication safely without prohibitions.

Historical analysis can also give us insight into the effects of pharmaceutical policy. Throughout history drug disasters have occurred in countries that had less unforeseen consequences whereas the present prohibitive policies at least have consequences we understand. Yet we should be wary of this logic, lest we become complacent in living with the devil we know, when the alternative might not be a devil after all. In any case, we can make judgments about which path we ought to favor, even if we do not know whether to follow the path to its end. For more on this, see Richard Layard, who argues that the public has a risk averse psychology that makes them undervalue reforms which are expected to increase happiness because people undervalue unknown but likely positive outcomes. Richard Layard, “Happiness and Public Policy: a Challenge to the Profession*,” *The Economic Journal* 116, no. 510 (February 28, 2006): C24–C33.
prohibitive pharmaceutical policies. From this, we might conclude that prohibitive pharmaceutical policies save lives. But since there are so few drug disasters in history, this conclusion cannot be established by the scarce data that exists. In fact, detailed historical analyses of these incidents will show that prohibitive policies in most cases do not prevent drug disasters. As I will soon show, drug disasters are generally not “averted” by prohibitive policies, though when disasters occur elsewhere regulatory agencies tout disaster prevention as a success of prohibitive policies. Similarly, time series analysis can shed light on the effects of regulations. Prohibitive pharmaceutical regulations emerged in the twentieth century. We can therefore see how health outcomes, drug prices, and availability changed in response to drug regulation. One difficulty of this analysis is that medical technology became more advanced and complex over time as well, and that the health care and pharmaceutical industries changed over time for reasons unrelated to pharmaceutical regulation.

These strategies are imperfect, but they can still enable us to compare the consequences of more prohibitive policies with less prohibitive policies, even if we cannot control for other factors that may also influence health outcomes. In the rest of this chapter I will present evidence that uses these strategies. The evidence suggests that prohibitive pharmaceutical regulations cost more lives than they save and also impose a significant economic cost on patients and society. I will focus on three kinds of costs: drug loss, drug lag, and economic costs.\(^6\) The evidence I will present suggests that even

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\(^6\) Alexander Tabarrok and Daniel B. Klein’s helpful bibliography informs much of this chapter’s discussion of the economic literature on drug regulation. Alexander Tabarrok and Daniel B. Klein, *Is the FDA Safe and Effective?* (The Independent Institute, September 26, 2001).
those liberals who are comfortable with paternalism ought to reject paternalistic pharmaceutical prohibitions, if only because they do not work.

2. Drug Loss

Attaining approval for a new drug is very costly. Depending on the drug type, development and approval can take up to 15 years and cost $500 million to $2 billion, with most of those costs incurred during the approval process.⁷ It is so costly to attain approval for new drugs that manufacturers have little incentive to develop helpful or potentially lifesaving drugs in situations where drugs are unlikely to be profitable (e.g. drugs for rare conditions). I will focus on two kinds of evidence for this claim. First, the Orphan Drug Act, which effectively lowered the costs of regulation in an effort to encourage innovation, indicates that a costly approval process does discourage pharmaceutical innovation. Second, social scientific and survey evidence suggests that the costly approval process discourages biotechnology innovators and investors from developing new treatments.

Consider first the general claim that drug regulation discourages innovation. Sam Peltzman developed a model to predict how many new drugs would have been introduced to the market each year were it not for the 1962 Kefauver-Harris Amendments, which gave the FDA the power to require not only safety testing but efficacy testing for new

drugs as well. The 1962 amendments also gave the FDA the power to oversee clinical trials, and together these two new forms of authority increased the costs of premarket approval significantly. Peltzman found that were it not for the amendments, drug introductions would have been more than double the actual rate of introductions after 1962. 

This hypothesis was subsequently supported by additional studies. For example, when economists compared research and development productivity in the US and UK, where productivity was defined as the number of new drugs discovered and introduced for every dollar spent on research and development, they found that productivity declined six fold in the US and only threefold in the UK after the introduction of the 1962 testing requirements in the US. This research indicates that even if innovation slowed in part because of fewer research opportunities, prohibitive testing requirements still had an adverse affect on innovation in the US. Economist

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9 Peltzman’s model predicts that 41, rather than 16 new drugs would have been introduced. Ibid.
10 This result is robust—Grabowski and Vernon, argue “In sum, the hypothesis that the observed decline in new product introductions has largely been concentrated in marginal or ineffective drugs is not generally supported by empirical analyses” (34). Henry G. Grabowski and John Mitcham Vernon, The Regulation of Pharmaceuticals: Balancing the Benefits and Risks (American Enterprise Institute for Public Policy Research, 1983). See also Steven N. Wiggins, “Product Quality Regulation and New Drug Introductions: Some New Evidence from the 1970s,” The Review of Economics and Statistics 63, no. 4 (November 1, 1981): 615–619.
Elizabeth Jensen later found more generally that regulatory stringency is inversely related to the expected number of new drug discoveries.12

While it is impossible to know how many drugs would have been introduced but for prohibitive pharmaceutical regulation, these studies indicate that prohibitive regulations do have an adverse effect on innovation. In response to worries about drug lag, Congress passed the Orphan Drug Act (ODA) in 1983, to encourage companies to develop and seek approval for rare conditions affecting fewer than 200,000 Americans. The ODA established tax incentives to develop drugs for rare conditions and seven-year market exclusivity provisions for approved drugs. The ODA worked. Significantly more drugs were developed for patients with rare diseases and patients with rare diseases were significantly more likely to access and benefit from newly available drugs.13 These results show that by lowering the initial fixed costs of drug development, the ODA encouraged pharmaceutical innovation and saved lives.

The success of the ODA therefore illustrates that costly approval processes adversely affect pharmaceutical innovation, and that efforts to mitigate the costs of approval positively affect innovation. Yet the ODA only corrected for the adverse affects of regulation on innovation for moderately rare diseases. For extremely rare diseases

even the benefits established by the ODA cannot offer manufacturers enough of an incentive to invest in development and approval.\footnote{Though some rare diseases still go under treated insofar as treatment would not be profitable. The ODA also has perverse effects on pricing, as I will argue in the upcoming discussion of P17.}

Surveys of industry leaders affirm the claim that drug regulation discourages innovation. For example, a recent study conducted by the California Healthcare Institute found that as regulatory agencies become less permissive, the biotech industry loses access to capital and innovation stalls.\footnote{“Competitiveness and Regulation: The FDA and the Future of America’s Biomedical Industry.” (California Healthcare Institute, February 2011).} Another recent study found unsurprisingly that medical technology innovators migrate to more favorable regulatory climates in Europe, and strict premarket testing procedures discourage pharmaceutical innovation.\footnote{Chris Wasden, Medical Technology Innovation Scorecard: The Race for Global Leadership. (PricewaterhouseCoopers, January 2011).}

Still more evidence of drug loss is presented in a case study of a medical device called MelaFind, published by Michael Mandel at the Progressive Policy Institute. Mandel shows that pharmaceutical over-regulation can send a signal to other potential innovators not to invest in certain drugs and technologies. Melanoma is a deadly form of skin cancer that can be prevented with early screening for precancerous skin lesions. To facilitate early detection, the biotechnology company Mela Sciences developed MelaFind, a handheld computer device designed to help physicians identify precancerous lesions. Yet despite early successes in identifying precancerous cells, MelaFind was initially denied approval by the FDA because it could not perform better than expert dermatologists.\footnote{Michael Mandel, Policy Brief: “How the FDA Impedes Innovation: A Case Study in Overregulation” (Progressive Policy Institute, June 2011).} Mandel points out several problems with this logic. First, requiring first
generation devices to outperform experts is an impossibly high task for many kinds of devices that would eventually outperform expert physicians if allowed to develop further.\textsuperscript{18} Second, devices like MelaFind are diagnostic, so they only supplement a physicians judgment by providing more information, on its own the device cannot harm patients.\textsuperscript{19} The case of MelaFind has implications beyond this particular device. By prohibiting sale and development of devices that do not outperform experts, regulatory agencies discourage biotech innovators from developing any products that do not initially improve patient care but which are expected to with further development.

One way to correct for drug loss is to decrease the costs of the approval process for \textit{all} conditions. The success of the Orphan Drug Act illustrated that policymakers can encourage innovation by compensating manufacturers for high development and approval costs. Deregulation would also lower the cost of development and approval. Evidence suggests that less regulated drug classes are more innovative, so it is plausible that less

\textsuperscript{18} As Mandel writes, “The first automobiles, for example, were both more expensive and less reliable than a horse. Similarly, the first personal computers were basically toys compared to the existing minicomputers and mainframes. But they got better and cheaper over time. From that perspective, it’s clear that a government regulatory body with “too-high standards” can have the effect of choking off innovation. Imagine how the history of computing would have been different if Steve Jobs and Steve Wozniak had to prove that the Apple I could meet government performances standards before it could be sold.” Ibid.

\textsuperscript{19} Shortly after Mandel published this case study, the manufacturers of MelaFind submitted new data to the FDA, which then narrowly approved the device with an 8-7 vote, subject to the manufacturer’s assurances that the device would not be widely used until further testing was conducted. The subsequent approval or MelaFind indicates that it did not pose a threat, so the agency’s initial failure to approve the device discouraged further innovation without protecting consumer safety. “MelaFind, Device That Screens For Melanoma With Light, Approved By FDA,” \textit{Huffington Post}, November 2, 2011, http://www.huffingtonpost.com/2011/11/02/melafind-device-that-scre_n_1071451.html.
regulation for all drugs would increase innovation.\textsuperscript{20} For this reason, Nobel-winning economist Gary Becker has concluded that:

A return to a safety standard alone would lower costs and raise the number of therapeutic compounds available. In particular, this would include more drugs from small biotech firms that do not have the deep pockets to invest in extended efficacy trials. And the resulting increase in competition would mean lower prices without the bureaucratic burden of price controls.\textsuperscript{21}

Though less prohibitive policies are compatible with programs like the Orphan Drug Act, deregulation can substitute for the current system where the public subsidizes innovative research for diseases, potentially reducing public costs.

3. Drug Lag and Efficacy Testing

Another cost of prohibitions on unapproved medicines is drug lag. Not only does a long and costly approval process discourage the invention of potentially beneficial drugs, it also delays the introduction of the beneficial drugs that are invented. As manufacturers navigate the approval process, patients with conditions that could be treated or cured by unapproved drugs suffer and die, waiting for approval. We can see evidence of drug lag by comparing approval times between countries and across time. Both methods of comparison indicate that longer approval times are extremely costly but do not save lives. In fact, long approval times cost lives. One solution to the problem of drug lag is to simply shorten the approval process. Another solution is to make the

\textsuperscript{20} Further evidence for this claim can be found in the fact that less regulated drug and device classes are more innovative. R A Merrill, “Regulation of Drugs and Devices: An Evolution,” \textit{Health Affairs} 13, no. 3 (May 1, 1994): 47–69.

\textsuperscript{21} Becker, \textit{Big Ideas}. 
approval process non-prohibitive, because no matter how short the process becomes, for some patients the wait will be too long.

In 1962 the average drug took seven months to gain approval. Five years later it took thirty months. The change was a direct result of the expansion of the FDA’s authority to require premarket efficacy testing for all new drugs. Drug lag first was raised as a concern in the 1970’s when pharmacologists William Wardell and Louis Lasagna estimated that tens of thousands of American patients’ deaths could have been prevented if the FDA had approved available lifesaving drugs sooner and faster.\(^{22}\) By then drugs took up to ten years to gain approval. In the late 1970’s American patients began traveling to European countries, which approved drugs significantly faster, because patients in Europe had access to beneficial drugs years before US patients.\(^{23}\)

In light of this evidence, concerns about the lengthy approval process grew. From 1976-1978 the National Cancer Institute (NCI) clashed publically with the FDA over the agency’s oversight of clinical trials for cancer treatments, which they alleged undermined potentially lifesaving research and subjected oncologists to unnecessary bureaucratic requirements.\(^{24}\) Then, in 1988, the HIV/AIDS advocacy organization AIDS Coalition to


\(^{23}\) Hollywood actor Rock Hudson’s traveling to Europe for AIDS treatment is a famous example of this phenomenon, which sparked patient activism for faster approval times in the US. Sometimes medical tourism backfires, like when Steve McQueen traveled to Mexico for cancer treatment that immediately killed him. See also Kenneth I Kaitin and Jeffrey S Brown, “A Drug Lag Update,” *Drug Information Journal* 29, no. 2 (April 1, 1995): 361–373.

\(^{24}\) Carpenter, *Reputation and Power*. Pg. 393.
Unleash Power (ACT UP) staged large protests to encourage the FDA to expedite approval for medications that could fight opportunistic infections like HIV.\(^{25}\)

In response to these concerns from the medical community and the public, Congress passed with the Prescription Drug User Fee Act (PDUFA) in 1992, which among other things, implemented expedited approval process for drugs that could potentially treat life-threatening diseases and relaxed premarket prohibitions for terminally ill patients. For example, terminally ill patients who were not enrolled in clinical trials gained access late stage experimental medicines on a “parallel track.”\(^{26}\) The PDUFA also gave pharmaceutical manufacturers the option to pay a user fee for expedited approval. Revenue generated by user fees funded additional staff, enabling the FDA to review new drug applications more quickly. The PDUFA shortened the approval process to some extent, but it still takes an average of eight years for a typical drug to get approved, despite the fact that the FDA has considerably more staff and funding today than it did in 1962.\(^{27}\)

Some scholars have claimed that the drug lag is shortening, because the US is catching up to European approval times.\(^{28}\) Today, medical devices are approved faster in Europe than in the US, while biopharmaceuticals sometimes gain approval in the US

\(^{25}\) Ibid.Ch. 7  
\(^{26}\) Still, drug lag is particularly devastating for patients with aggressive cancers, and the approval process still creates drug scarcity that prevents even terminally ill patients from accessing experimental drugs on the parallel track.  
first.\textsuperscript{29} Part of this variation is attributable to strategic marketing decisions, rather than policy differences, but if we understand lag as a relatively slower approval time this is true.\textsuperscript{30} Yet any delay in the availability of drugs is a drug lag in comparison to either conditional or unconditional rights of self-medication or non-prohibitive regimes. Every month that an unapproved drug remains inaccessible to patients, people suffer. While the costs in lost lives and suffering is hard to specify with precision, economists have estimated that drug lag accounts for the loss of hundreds of thousands of life-years, in addition to needless suffering.\textsuperscript{31}

Let’s pause to consider this statistic. Hundreds of thousands of life-years are lost because patients lack access to drugs that exist, but await approval. Additionally, patients suffer for years while drugs that could help them navigate premarket tests. When

\begin{flushleft}
\textsuperscript{29} In general, European regulatory agencies are still faster than the US, and Japan has a notoriously slow approval process- new drugs are often introduced in Japan \textit{seven years later} than in Europe. A survey of over 200 medical technology companies found that on average, manufacturers were able to make their products available to European patients two years earlier than U.S. patients, with device and drug lag ranging from 3 to 70 months. J. Makower, A. Meer, and L. Denend, \textit{FDA Impact on US Medical Technology Innovation–A Survey of Over 200 Medical Technology Companies} (Pricewaterhouse Coopers, New York, NY, USA (November 2010), 2010). And Kaori Tsuji and Kiichiro Tsutani, “Approval of New Biopharmaceuticals 1999–2006: Comparison of the US, EU and Japan Situations,” European Journal of Pharmaceutics and Biopharmaceutics 68, no. 3 (March 2008): 496–502.
\textsuperscript{30} Industry surveys suggest that drug lags are attributable to differences between regulatory agencies as well as strategic premarket approval decisions by manufacturers. For example, some manufacturers report that they initiate the regulatory process in the US and Europe at the same time, but that approval times varied because of different agency standards. Other manufacturers seek approval from faster and more efficient agencies first, so that sales in those markets can fund costly and lengthy approval processes elsewhere. In both cases, prohibitive pharmaceutical policies are responsible for limited access to therapeutic and lifesaving drugs in some markets. Makower, Meer, and Denend, \textit{FDA Impact on US Medical Technology Innovation–A Survey of Over 200 Medical Technology Companies}.
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premarket pharmaceutical regulations prohibit patients from accessing the means necessary to save their lives, the human cost of drug lag is particularly tragic. Defenders of pharmaceutical regulation point to the success of the PDUFA as evidence that prohibitive polices need not cause terminally ill patients to die from a lack of treatment, but this inference is mistaken. The success of the PDUFA actually shows that relaxing prohibitive policies can save lives. While terminally ill patients have more options now than they did before the PDUFA, they still lack options as a result of prohibitive policies, and non-terminally ill patients are limited in their options as well.

Consider the following example of a new drug that is awaiting approval. Steve Holl, 61, was diagnosed with glioblastoma, a deadly brain cancer that kills over two-thirds of patients with in a year. The cancer is notoriously difficult to treat because it is impossible to completely remove and after surgical removal, the cancer always quickly grows back. For other patients with glioblastoma, like Senator Ted Kennedy, the diagnosis is a death sentence. Yet Holl has survived, even thrived, with glioblastoma thanks to an experimental treatment, a custom-made cancer vaccine that has prevented the tumor from growing back. The vaccine treatment is still experimental; meaning that it patients with glioblastoma who are not enrolled in a clinical trial cannot legally access the treatment. Despite scarce trial data on the vaccine, physicians are very optimistic about the prospects of this new treatment. So far, none of the eight patients in with glioblastoma cancers have seen their cancer return after receiving the vaccine.

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Now consider the *thousands* of patients who are currently dying of glioblastoma. Each of them could potentially have enjoyed more time with their families if they had access to the vaccine. Ted Kennedy might have seen the passage of national health care reform, or the birth of the first sixth-generation Kennedy if he had access to the same treatment as Steve Holl. Though the safety and effectiveness of the vaccine is still unknown, the eight patients who are enrolled in the trial have lived while patients outside of the trial died. For this reason alone, many people with glioblastoma may judge that the benefits of an unapproved treatment outweighed any potential risks, but the treatment remains prohibited. Even after the PDUFA reforms, terminally ill patients are still required to wait for years to access lifesaving experimental drugs, and for many of them, it will be too late.

Not only does the premarket testing process cost lives, it does not prevent dangerous or ineffective medicines from reaching the market. Manufacturers can adequately screen for safety and efficacy in the absence of prohibitions.\(^{34}\) Earlier, I described a study by Sam Peltzman, which found that after 1962, substantially fewer drugs were introduced.\(^{35}\) I attributed this phenomenon to drug loss, meaning that fewer drugs were invented and developed because the cost of approval became prohibitively high. Another possible explanation for this decline in new drug introduction is that ineffective drugs were weeded out by new efficacy testing. Peltzman tested this theory, and found that while fewer ineffective drugs were introduced to the market; the *market*

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\(^{34}\) I will return to this point in Chapter 5, where I discuss postmarket clinical trials. Briefly, I argue that the success of randomized clinical trials for drugs that are already approved indicates that prohibitive approval requirements are not necessary for safety and efficacy screening.

share of ineffective drugs did not change as a result of the 1962 amendments. This study indicates that premarket efficacy testing does not increase the market share of effective drugs.

Premarket efficacy tests are not only ineffective; they are also unnecessary. Currently patients must wait until a drug has been approved as safe and effective for at least one recognized medical condition. Most of the approval lag is due to efficacy testing. However, once a drug is approved as effective for treating one condition, it is legally available to treat any other conditions as well. This practice is called off-label prescribing, and the off-label market accounts for over 20 percent of all prescriptions written.36

For example, Zofran is an anti-nausea drug that is approved for use in chemotherapy patients. Once Zofran was approved, obstetricians began prescribing it to pregnant women as a successful treatment for morning sickness. Methotrexate (MTX) is approved to treat placental cancers but is currently the only available pharmaceutical treatment for ectopic pregnancies. Doxipin is used to treat depression and anxiety, but is sometimes prescribed to treat allergies as well. Almost all cancer chemotherapy is off-label because the most effective treatments use drugs from multiple manufacturers, which do not have any incentive to facilitate approval for drugs they do not make even where there is evidence of efficacy from clinical trials. Zoloft is an anti-depressant, but it is prescribed off-label to treat premature ejaculation. Magnesium Sulfate is an off-label treatment for premature labor. In fact, almost all prescriptions for children and pregnant

women are off-label, because of the ethical difficulties of conducting clinical trials on these populations.

While physicians tend to support initial premarket efficacy testing requirements, they overwhelmingly reject any regulation of the off-label market.37 The off-label market is currently regulated by a disperse network of physician communication, and little government oversight, yet off label prescriptions are no more dangerous that on-label prescriptions.38 That the off-label market works so effectively and is capable of delivering effective drugs to patients even when those drugs have not been approved for their conditions indicates that efficacy testing is not required to deliver effective drugs to patients.39

Two justifications are generally offered in favor of efficacy testing. First, patients might forego useful treatment in favor of ineffective treatments if ineffective treatments were allowed on the market. Second, it is difficult for patients and physicians to assess the efficacy of a new drug without some premarket testing. For example, Patricia M. Danzon and Eric L. Keuffel give the following defense of premarket testing:

Regulation of market access, manufacturing and promotion arise because product efficacy and safety can be critical to patient health but are not immediately

observable. Evaluating safety and efficacy as a condition of market access and monitoring manufacturing quality and promotion accuracy over the product life cycle are public goods that can in theory be efficiently provided by an expert agency such as the Food and Drug Administration (FDA).40

I will address this argument in more detail in Chapter 9, but for now we should note that even if there is a market failure in providing information about the safety and efficacy of drugs (and the off label drug market indicates that there is not) this only tells in favor of government regulation of information, and it does not support prohibitions more generally. 41 Government agencies can overcome the problem of inaccurate pharmaceutical labeling and marketing by requiring manufacturers to conduct efficacy tests and disclose clinical trial data, without prohibiting patients from accessing drugs.

The evidence suggests that even though it might bring some informational benefits, prohibitive premarket efficacy testing costs far more lives than it saves.42 For


41 This point is also made by economist Fredric Scherer, who writes “An information market failure may need correction. But why doesn’t the regulator merely require appropriate testing and disclosure of test data, letting physicians decide from the data whether the drug is safe and efficacious? If there is an argument for regulation of whether new drugs may be marketed, it must lie in a further information market failure—e.g., from the possibility that most physicians are too busy to make well-informed independent decisions.” F. M Scherer, The Pharmaceutical Industry, Handbook of Health Economics (Elsevier, 2000)

this reason, economists who study pharmaceutical regulation, including many economists who are not generally advocates of market solutions, agree either that premarket efficacy requirements should be significantly reduced or that drugs should be available without premarket efficacy testing.\(^{43}\)

4. Drug Lag and Safety Testing

While premarket efficacy testing requirements explain most of the variation in drug lags between countries, safety requirements are also responsible for some drug lag. The evidence against premarket efficacy testing requirements is the strongest, but historical and comparative evidence also suggests that premarket safety testing may be unnecessary and ineffective as well.

For example, before 1992, the US had much longer safety approval times than Europe. If a lengthy safety testing process really did ensure drug safety, then we would expect to see fewer safety recalls in the US than in European countries during this period. Yet comparative studies found that approximately 3% of all approved drugs were recalled both in the US and in European countries with shorter approval times.\(^{44}\) This evidence suggests that a longer safety approval process did not shield the US public from dangerous drugs. When drugs were regulated solely through the courts in the nineteenth century, there were no premarket efficacy or safety testing requirements.

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\(^{43}\) This is based on a survey of the economic literature about the FDA and or economists more generally by Daniel Klein. He finds that many economists support pharmaceutical regulation, but those who study it overwhelmingly favor liberalization. Much of the research summarized in this chapter was found through Klein and Tabborrok’s reports on this topic. Daniel B. Klein, “Colleagues, Where Is the Market Failure? Economists on the FDA,” *Econ Journal Watch* 5, no. 3 (2008): 316–348.

century, new drugs were not less safe than they were following the regulatory expansion of agencies like the FDA.\textsuperscript{45} Similarly, the passage of the PDUFA in 1992, which sped approval times in the US by reducing the length of both safety and efficacy requirements, did not cause a corresponding increase in drug recalls or public health crises that resulted from dangerous drugs.\textsuperscript{46}

One explanation for the seeming ineffectiveness of premarket safety testing is that premarket tests only establish safety for a specific population, while in practice the safety of a drug varies substantially between patients. Drugs that are safe in healthy patients may be unsafe in unhealthy patients. Drugs that are safe for younger populations might have unacceptable side effects for older patients. The very concept of safety rests on a judgment about the risk of side effects relative to potential benefits, and the benefits of a drug also vary across populations. Even for safe drugs that are never recalled, hundreds of thousands of patients suffer or die each year from adverse reactions, or suffer side effects without receiving any benefit. Indeed, 90\% of drugs are only effective in 50\% of cases.\textsuperscript{47} This is not a failure of safety testing; it is a necessary limitation. As former FDA Commissioner (1990-1997) David Kessler said in his testimony to the US Congress:

\textsuperscript{45} Peltzman, “An Evaluation of Consumer Protection Legislation.”
\textsuperscript{46} For Example, Philipson et al write “‘By the most plausible measure, the [1992 PDUFA] act did not, in fact, have any effect on drug safety: neither the proportion of drugs eventually withdrawn (2 to 3 percent), nor the speed with which they were withdrawn, changed in any statistically significant way since the law’s passage.” Philipson et al., “Assessing the Safety and Efficacy of the FDA.” See also Henry Grabowski and Y. Richard Wang, “Do Faster Food and Drug Administration Drug Reviews Adversely Affect Patient Safety? An Analysis of the 1992 Prescription Drug User Fee Act,” \textit{Journal of Law and Economics} 51, no. 2 (May 1, 2008): 377–406.
If a drug is studied in a few thousand patients and a serious life threatening drug reaction occurs at an incidence of one in ten thousand, it is likely that this serious and life threatening risk will not have been seen in the clinical trials and will only emerge after the drug is on the market. In fact, it has been noted that only a fraction of adverse reactions that appear on the label occur in the first seven years. Adverse reactions continue to occur during the post-marketing period. Companies have to file adverse reaction reports. Thousands of adverse drug and device reports come in to the Agency each year.\textsuperscript{48}

Clinical trials cannot feasibly include enough patients to find every potential adverse reaction, and safety approval necessarily applies to all patients, not just the kinds of patients who are likely to receive a benefit with few side effects.

Also, clinical trials are often very different from typical use conditions. Clinical trials are useful for collecting data about drugs but the usefulness of the data applies differently depending on the circumstances of use. For example, Acomplia, a weight loss drug that was approved in Europe by the EMA was recalled from the market in 2008 due to concerns that the psychiatric side effects of the drug outweighed the potential benefits.\textsuperscript{49} The benefits of Acomplia were more significant in clinical trials because typical users of the drug were not closely monitored. Further, typical users were more likely to suffer psychiatric side effects because they used the drug less consistently and for shorter periods. The example of Acomplia shows that the safety of a drug cannot always be found in a clinical trial. This example also shows that some drugs may be safe


in certain controlled circumstances, but that regulators who are concerned with the safety of a drug on balance for typical users may nevertheless deny access to the drug. The FDA did not approve Acomplia in the first place for safety reasons, but the success of Acomplia in European clinical trials illustrates that a drug may be safe in some circumstances but not safe for all patients. Patients who would use Acomplia properly and under close supervision may have found the drug safe, but large-scale safety testing could not distinguish between patients who could safely use the drugs and patients who were likely to suffer serious psychiatric reactions.

In short, premarket safety testing can play an important role in informing physicians about the potential of new drugs, both the potential risks and benefits; but premarket trials cannot reliably ensure the safety of drugs for the patients who actually use them once they are approved. This is not to say that safety tests are unnecessary. Safety tests are useful but limited and the costs of prohibiting access to untested drugs might exceed the benefits. Another reason for skepticism about the need for prohibitive safety testing requirements is that safety tests successfully continue once drugs have been approved, so pre-approval prohibitions are seemingly not needed for successful safety testing.

Still, defenders of pharmaceutical regulation may point to major drug disasters that the US avoided because of strict regulations. Does safety testing prevent serious drug

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51 I will return to this point in the discussion of clinical trials and experimental treatment in Chapter 5.
catastrophes? A close historical analysis of the five major drug disasters in the twentieth century reveals that the lives saved were not the direct result of regulations themselves.

First, recall the 1937 Elixir Sulfanilamide disaster that I discussed in Chapter 1. This tragedy inspired greater pharmaceutical regulation, but would greater regulation have prevented the deaths caused by the Elixir? Though it was not required, Elixir Sulfanilamide was tested for safety, but the solvent was not. As soon as the dangers of the Elixir became clear, the manufacturers of the Elixir halted production and shipments of the medicine and initiated a recall. Later, FDA officials traveled the country confiscating unused shipments of the medicine and further notifying the public of its dangers. Then, the manufacturers were found liable of gross negligence in the courts for failing to disclose the deadly effects of the elixir. The first thing to notice about this case is that the manufacturers of Elixir Sulfanilamide already had high incentives to avoid the safety disaster they caused; they were legally liable for the safety risks of the drug and their reputation was destroyed by the crisis. Second, while even stricter safety-testing requirements could have prevented the disaster, the crisis in no way told in favor of efficacy testing requirements. Third, the crisis did not justify prohibitive premarket safety testing requirements. The problem with the Elixir tragedy was that the deadly effects of the Elixir were unknown, and the fact that the solvent was untested for safety was not disclosed. Were the risks known or the untested status of the solvent disclosed, perhaps the disaster could have been avoided without prohibitions, especially if the company was legally liable for failing to test and disclose the status of the drug and its solvent.

Second, the Thalidomide disaster is often cited as a triumph of regulation. To review from Chapter 1, Thalidomide was a sedative that was used widely in Europe
between 1957 and 1961 as a treatment for morning sickness, until overwhelming evidence revealed that it caused infant mortality and birth defects. The deaths and disability caused by Thalidomide did not affect many Americans because Thalidomide was not approved in the US at the time. Frances Kelsey, the FDA inspector who blocked the sale of Thalidomide in the US because of the potential for negative neurological side effects, was hailed as a heroine and received numerous awards including the President’s Award for Distinguished Federal Civilian Service. The FDA touts this as an example of the importance of pharmaceutical regulation, and historians and political scientists who study the FDA cite the Thalidomide tragedy as the chief historical justification for the 1962 expansion of pharmaceutical regulation.\footnote{\setlength\parindent{0em}FDA.gov, for example, describes the close call with Thalidomide as a triumph of regulation.\setlength\parindent{2em}}

However, it remains unclear whether prohibitive regulations can be credited for avoiding this disaster. Even today, clinical trials are not conducted with pregnant women, so the adverse effects of Thalidomide still could not have been detected by government testing. At the time Thalidomide approval was delayed because of concerns that had nothing to do with pregnancy or birth defects but rather because of potential neurological effects, even though birth defects were the primary problem with Thalidomide. The current testing requirements also would not have caught the problems with Thalidomide because drugs are not typically tested on pregnant women. Indeed, Thalidomide is still available as an approved treatment for cancer patients and people with leprosy, so it is technically still available off-label as a morning sickness drug. The drugs legal status is thereby effectively the same as when it was prescribed in the 1950’s. All morning sickness drugs are off-label, so they all potentially are untested for the risks that were
associated with Thalidomide. Today no pregnant women would take thalidomide, despite the fact that it bears the same approval status as other morning sickness drugs, because the risks are known to be greater than alternative treatments. Lastly, recall that the Thalidomide tragedy occurred before the 1962 amendments that required efficacy testing. Therefore, the tragedy cannot be cited as a triumph of the current standards of regulation because Thalidomide was one of the motivations for extensive and prohibitive safety and efficacy testing requirements; it was not a product of them.\textsuperscript{53}

Since Thalidomide, two other international drug disasters have occurred outside of the United States. The first involved Isoproterenol, an asthma drug that killed over 3,500 children in Europe and Australia in the 1960’s. The deaths were attributed to the use of inhalers that delivered concentrated doses of the drug. Though Isoproterenol was also approved for use in the US and Canada, deaths were avoided because manufacturers marketed different inhalers in these countries, not because of variations in approval procedures.\textsuperscript{54} In this case regulation did not prevent the drug disaster, rather patients in the US and Canada were the fortunate beneficiaries of an arbitrary manufacturing choice, and European and Australian patients were exposed to an unsafe product. Isoproterenol’s risks were not detected in premarket testing because no deaths were detected in any clinical trials. Rather isoproterenol deaths resulted from excessive and continued long-term use with a specific kind of inhaler. Had the deadly inhaler been tested in the United States, it would have passed the tests.

\textsuperscript{53} Carpenter, \textit{Reputation and Power}. Pg. 259

The second major international drug disaster may have been averted by the United State’s strict approval process. From 1956-1970 over 11,000 patients in Japan were severely disabled after using a drug called Clioquinol for the treatment of intestinal problems. In other countries, such as the US, over the counter sales of Clioquinol were banned and Clioquinol use was discouraged as early as 1961 out of concerns about toxicity. A popular interpretation of this case is that tragedy was prevented in the US by pharmaceutical regulation. Even if we grant this reading of the case, the example of Clioquinol does not establish that prohibitive pharmaceutical regulations are beneficial on balance, only that regulation might have prevented some significant harm. It is worth noting further that the FDA banned over the counter sales of Clioquinol in 1961 because of safety concerns, before the agency ever even gained the authority to prohibit drugs on the basis of efficacy.\(^{55}\)

The fifth major drug disaster of the last century was not prevented by prohibitive testing requirements in the United States. Over 27,000 American patients who were prescribed the popular arthritis treatment Vioxx suffered heart attacks and sudden cardiac death between 1999 and 2003.\(^{56}\) This indicates that not only did premarket safety testing not shield the US from the drug disasters described before; it was ineffective at shielding the US from the dangers of Vioxx.\(^{57}\)

This review of the evidence shows that there is a mismatch between the justification for pharmaceutical regulation (to avoid drug disasters) and their actual effects. While it is true that the United States has avoided drug disasters that struck other

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\(^{55}\) Ibid.


\(^{57}\) Epstein, “Regulatory Paternalism in the Market for Drugs.”
countries, few major drug disasters have actually occurred anywhere, and it is not clear that US style regulations could have avoided the disasters where they did occur.

Evidence from the less-prohibitive medical device market bolsters this claim that prohibitive premarket safety testing requirements may be unnecessary. The FDA oversees the manufacture and sale of medical devices, from bandages to artificial hips and joints. These devices are either subject to traditional premarket approval, like pharmaceuticals, or a process called the 510(k) process, which is designed to quickly clear medical devices without much testing as long as they are substantially equivalent to existing devices. This means that new pacemakers, artificial hips, stents and other devices can be sold and marketed with little oversight through 510(k).58 For the most part, devices that are sold after 510(k) are safe, (though 510(k) devices are subject to more safety recalls than those that underwent the traditional premarket approval process.) Between 2005 and 2009, the FDA ordered safety recalls for eighty 501(k) devices and twenty-one devices that had undergone traditional premarket approval.59 However, more devices were approved through the 501(k) process, and the proportion of 501(k) devices that were recalled (0.48%) is substantially smaller than the proportion of devices that were recalled after they were approved by the traditional premarket approval system (14.5%).60 These data are difficult to judge, because there may be other factors that make 510(k) devices safer than other devices, but this finding does indicate a less stringent system of pharmaceutical regulation does not necessarily lead to more safety risks.

58 Christine Mai-Duc, “FDA Urged to Rethink Approval of Medical Devices,” Los Angeles Times Articles, July 30, 2011.
Similarly, pharmaceuticals are usually not tested for safety in children and pregnant women, and the FDA rarely approves new drugs for these populations. Nevertheless, physicians have access to databases of patient information, privately conducted clinical trials, and other physicians’ recommendations and data. With these tools in hand, obstetricians and pediatricians routinely prescribe medicines to children and pregnant women off-label despite the fact that the drugs have never undergone FDA safety tests in these populations.

These considerations indicate that prohibitive premarket safety testing requirements might be unnecessary, since experts can and do reliably disseminate data about the safety of new medical products without extensive premarket government oversight. Further, while regulatory agencies do effectively approve drugs as safe for entire populations, networks of physicians and patient information databases can generate more targeted information about drugs that is tailored to specific populations. In this way, non-governmental safety information might be more useful than government-required premarket safety testing.

Even if premarket safety testing overcomes information deficits about new drugs, premarket prohibitions are not necessary to this end. Safety testing is a valuable public good, it is important that the public and medical experts know the relevant risks and potential benefits of products. However, prohibitive testing requirements mean that patients are forced to suffer and die while they await this information, or that patients are prohibited from accessing “unsafe” medicine that could bring substantial benefits.

In the next few chapters I will develop this argument in more detail, but the foregoing evidence indicates that the potential benefits of prohibitive premarket testing
requirements do not outweigh the costs of drug lag. This is especially true for efficacy testing, but may also be true for safety tests. A non-prohibitive testing system could provide the public good of medical information without depriving patients of important pharmaceutical options.

5. Prescriptions, Conditional Approval, and Bans

In addition to premarket prohibitions, pharmaceutical regulators also enforce post market prohibitions through the prescription drug system, conditional approval requirements, and outright bans on some drugs. The justification for these post market prohibitions is that patients will use drugs incorrectly or unsafely if granted unrestricted access. As above, the costs of prohibitions do not justify the potential benefits.

Consider first the prescription drug system. Many drugs that are ultimately approved are only available with a prescription (or in some countries, with authorization from a pharmacist). Several studies suggest that prescription drug requirements do not promote the public health and might even undermine users’ safety. These studies compare health outcomes before and after prohibitive prescription requirements, between countries that do and do not enforce prohibitive requirements, and also between drugs that change from prescription-only to over the counter. In all cases, more prohibitive policies have worse health outcomes.

If post market prohibitions on prescription drugs do protect patients, then we should expect to see higher medicine-related mortality rates in non-prohibitive countries, and higher rates of addiction and misuse, all else equal. Yet the data indicate that prescription drug systems do not actually serve patient safety where they are enforced. For example, Sam Peltzman analyzed time series data from the US vital statistics report
from 1900-1980, and found that the introduction of a prescription drug system in the 1940’s did not reduce mortality from accidental or suicidal poisonings. Instead, the introduction of a prescription-only category of drugs correlated with more fatal poisonings. Peltzman hypothesizes that consumers were more likely to consume potent and risky drugs when a physician endorsed their choice.

One explanation for the seeming ineffectiveness of a prescription drug system is that prescription-only designation coincided with an explosion of new and dangerous drugs. Perhaps fatal poisonings would have increased were it not for a prescription only system. Comparative data between countries suggests this is not the case. Peltzman also compared middle-income countries with enforced prescription drug systems (Argentina, Uruguay, Ireland, Israel, Italy Portugal, Spain, and Japan) to countries that did not enforce prescription drug systems (Chile, Colombia, Ecuador, Mexico, Peru, Venezuela, Greece, Yugoslavia, Egypt, Hong Kong, Philippines, Singapore, and Thailand). Peltzman found that controlling for the effect of income and income inequality on infectious disease mortality, enforced prohibitions on prescription drugs did not reduce mortality from infectious diseases. If anything, middle income countries that enforced prescription drug prohibitions sometimes had higher mortality rates, perhaps because prescriptions were unavailable to some patients who needed them.

In the same study, Peltzman found that poisoning mortality does not increase in non-prohibitive countries. In fact, states that enforced prescription-only drug regulations had 50-100% higher rates of poisoning mortality than non-prohibitive countries. As above, Peltzman hypothesizes that the paradoxical increase in drug misuse can be

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attributed to the fact patients use risky prescription drugs more in states that enforce prescription-only requirements, so prescription-only regimes actually encourage dangerous drug use by making licensed use of those drugs seem safe.

Peter Temin has also investigated the health effects of mandatory prescription requirements in a series of investigations into the effects of switching the approval status of cough and cold medicines and topical hydrocortisones from prescription-only to over the counter. Temin found that switching not only significantly lowers the costs of medical care for patients but also expands access and improves health outcomes.

Another kind of costly postmarket regulation is the marketing restrictions that are associated with conditional approval. While physicians are permitted to prescribe drugs off-label, manufacturers are not permitted to publish information about the off-label benefits of approved drugs. Were it not for these restrictions, we can imagine that off-label drugs might be even more effectively and widely used than they already are. Instead, marketing and labeling requirements make it difficult for patients and physicians to learn about the potential benefits of new drugs, or to learn how to safely use them.

Pharmacologists William Wardell and Louis Lasagna illustrate this point with the example of Beta Blockers. In the early 1960’s research suggested that beta-blockers, which diminish the effects of stress hormones like adrenaline, might be helpful for treating cardiovascular conditions, especially for preventing second heart attacks and lowering blood pressure. In 1965 beta-blockers were approved in the UK, but they were

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not approved at all in the US until 1968, and then only for very limited conditions and not for the prevention of second heart attacks. Beta blockers were only approved for the prevention of second heart attacks in 1981, seven months after a comprehensive study showed that 6,500-10,000 lives could be saved each year by beta blockers used in this way. Dale Gerringer points out that this implies that at least 4,000 deaths could have been prevented had approval not taken seven months, and at least 45,000 deaths could have been prevented had beta blockers been initially approved, at the advice of cardiologists, for cardiac use in 1965.64

Defenders of pharmaceutical regulation might reply that while beta-blockers were not approved for prevention of second heart attacks, they were available, and cardiologists could legally prescribe them for off label use. But this example shows that when regulators assume the power to approve drugs for safety and efficacy, an approval delay for an available drug, can also effect how physicians and patients make decisions. When approval for a certain condition takes too long, patients can suffer even if the drug is formally available. For this reason, a majority of physicians agree that conditional approval should not limit advertising about alternative drug uses.65 To some extent, online access to postmarket clinical trials is enabling physicians to become informed about off-label uses. Recall the example of combination therapy for chemotherapy, all of which is off-label. Nevertheless, off-label marketing restrictions also discourage manufacturers from contributing to postmarket clinical testing for the efficacy of their new drugs, because even if efficacy is established they cannot market their drugs for new

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64 Gieringer, “The Safety and Efficacy of New Drug Approval.”
65 Gregory Conko, A National Survey Of Neurologists And Neurosurgeons Regarding The Food And Drug Administration (Competitive Enterprise Institute, October 5, 1998).
conditions without further approval.

Some kinds of off-label prescriptions are banned full stop. For example, patients have access to prescription doses of medical marijuana in fourteen states, but those states only permit access to the drug for patients with approved conditions. This means that all fourteen states that permit medical marijuana permit its use for AIDS and cancer patients, but only seven states permit medical marijuana as a treatment for chronic pain and none permit its use for clinical depression or anxiety, despite evidence that it might be an effective treatment for these conditions that has fewer side-effects than the current standard treatments. In this case, the cost of off-label prohibitions are equivalent to the costs of an outright prohibition or drug lag for a product that may be the most effective treatment for chronic pain, depression or anxiety.

A similar kind of postmarket prohibition is the limits set on some prescriptions for controlled substances like Attention Deficit Hyperactivity Disorder (ADHD) drugs and painkillers, which are legally approved by the FDA, but the Drug Enforcement Administration (DEA) sets manufacturing quotas that are designed to limit prescription drug abuse and recreational use. In addition to the above costs of limited access, these prohibitive policies also cause drug shortages. In 2011 multiple manufacturers and the FDA announced drug shortages for ADHD drugs like Adderall. In response, the DEA argued that the quotas were appropriate and that any drug shortages were attributable to

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manufacturers over-manufacturing a greater proportion of expensive versions of drugs, causing an under-supply of generics.\textsuperscript{67} Even if this charge is true, quotas ultimately cause the shortages. Similarly, patients are finding it increasingly difficult to fill prescriptions for painkillers as a result of the DEA’s efforts to mitigate prescription painkiller abuse.\textsuperscript{68}

Prohibitions that ban drugs that failed premarket tests also harm patients, particularly those with treatment-resistant conditions that may have benefited from whatever drug failed to obtain approval. There are no systematic studies of the health effects of these prohibitions, but the hazards of drug lag apply to drugs that fail to gain approval. Additionally, criminal prohibitions of off-label use and the use of unapproved medicines also have the same substantial human costs that are associated with enforcing drug prohibitions more generally, including the social and economic costs of prosecution and punishment.\textsuperscript{69}

6. The Economic Cost of Regulation

Finally, drug regulation has a substantial economic cost. The approval process makes drugs more expensive because it is costly to conduct the required efficacy tests and trials necessary to gain approval. Additionally, pharmaceutical regulation enables manufacturers to maintain high prices for drugs. The prescription drug system also makes drugs less affordable because in order to obtain a prescription, patients must first see a

\begin{itemize}
\item \textsuperscript{67} Gardiner Harris, “F.D.A. Finds Short Supply of Attention Deficit Drugs,” \textit{The New York Times}, December 31, 2011.
\item \textsuperscript{68} Because non-medical painkiller use is criminally prohibited and enforced by the DEA, a black market for painkillers has become increasingly lucrative, causing several armed pharmacy robberies in the past year. In response, some pharmacies have discontinued the sale of painkillers, depriving medical users of easy access to prescribed drugs. See N. R. Kleinfield, “Anxious Days for Long Island Pharmacies,” \textit{The New York Times}, January 8, 2012.
\item \textsuperscript{69} Douglas Husak, \textit{Overcriminalization: The Limits of the Criminal Law}, 1st ed. (Oxford University Press, USA, 2008).
\end{itemize}
physician. Patients without insurance or affordable access to a physician then lack access to prescription drugs.

First, as I outlined above, the approval process is expensive. Manufacturers pass high costs to consumers. At first glance this might seem counterintuitive, after all, prices for easily manufactured goods like drugs are usually determined by demand. Indeed, the primary predictor of drug price is whether there is a specific demand; the most expensive drugs are those that treat chronic or fatal conditions, with high demand and low competition. But the high cost of development also contributes to the overall cost of drugs. The cost of developing any particular drug does not correlate with the market price of that drug, and more profitable drugs subsidize the development of potentially more therapeutic but less profitable treatments. Profitable drugs also cover the cost of research and development for all the drugs that either fail to gain approval or are unprofitable.

Further, the approval process presently withholds approval for drugs that are less effective (but cheaper) than existing drugs. This means that consumers who are willing to compromise effectiveness for cheaper drugs never get the chance to access those drugs. Further, this standard discourages companies from developing cheaper drugs where expensive drugs already treat a condition. This standard of approval therefore maintains high drug prices, which means that patients who cannot afford expensive drugs cannot access less effective but cheaper drugs, so they get no drugs. In other words, poor patients are left with no treatment options because they cannot afford the most effective treatment.

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70 Palmer, “The $8,000 Pill.”
71 Ibid.
Second, pharmaceutical regulation makes drugs more expensive because it decreases competition between manufacturers. Regulations slow the approval of alternate therapies and prohibit competing manufacturers from making similar drugs. The example of 17P, a drug that prevents premature labor, illustrates how pharmaceutical regulation can exponentially increase the costs of drugs. In 2003 a study conducted by the National Institute of Health found that prescribing a form of progesterone called 17P early in pregnancy could significantly reduce women’s risk of preterm birth. Unfortunately, 17P was no longer manufactured because better drugs had been developed for the conditions it was originally designed to treat (uterine cancer and hormonal problems) and 17P remained off-label for prematurity. Fortunately, physicians could still prescribe the drug to be made by individual compounding pharmacies, rather than by drug manufacturers. Sold in this form, 17P cost $10 per shot, and pregnant woman received weekly shots of 17P for four months during pregnancy if they were at risk of premature labor. As evidence grew that 17P was an extremely effective prematurity treatment, the FDA encouraged drug companies to develop and manufacturer a prematurity drug under the Orphan Drug Act (ODA). The agency then granted KV Pharmaceuticals approval and orphan drug status for their manufactured version of 17P, which is called Makena.

Once approved, KV Pharmaceuticals received exclusive rights to manufacture and market all drugs treating prematurity for seven years, and immediately sent letters to compounding pharmacies threatening FDA censure for independently compounding the

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73 Ibid.
Moreover, KV pharmaceuticals charged $1500 per weekly shot, instead of $10. KV Pharmaceuticals explained that the 150x cost increase was justified because of the cost of drug development, testing, and post-market monitoring as well as the expected benefits. Joanne Armstrong, writing for the New England Journal of Medicine, estimated that “the cost of treating all 139,000 patients who could benefit from (17P)…is $41.7 million. Substituting Makena…would bring the estimated cost to $4.0 billion.”

This example illustrates the aforementioned ways that regulation can increase the cost of existing drugs. The manufacturers of Makena claimed that they expected to spend $200 million developing 17P for sale and bringing it through the approval process, and that these development costs explained the high price. By approving Makena, regulators granted exclusive manufacturing rights to KV Pharmaceuticals, thus protecting KV pharmaceuticals from competition. Even if having a uniform manufacturing process for drugs like Makena would promote safety (there is no evidence to suggest that 17P was unsafe), the benefit of uniformity comes at a high financial price for patients and society. But there is another price as well. If the high cost of drugs like Makena discourages some patients from using it, then more high-risk pregnancies might result in premature births. Premature infants are more likely to die in their first year of life, be severely disabled, or

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suffer from conditions such as autism. In this way, the financial price translates into a devastating human price as well.

The case of Makena was so egregious that public outcry moved KV pharmaceuticals to eventually lower the price to $690 per shot, still at 69x increase over the cost of 17P. Additionally, in response to public outcry the FDA announced that it “does not intend to take enforcement action against pharmacies that compound (17P) based on a valid prescription for an individually identified patient unless the compounded products are unsafe, of substandard quality, or are not being compounded in accordance with appropriate standards for compounding sterile products.”78 This statement might seem to mitigate the harm of the FDA’s actions in the Makena case, but it really illustrates that regulation in this case was superfluous, and that its costs far exceeded the benefits. Essentially, the FDA now holds that uniform manufacturing and testing for 17P is unnecessary after all, and that compounding pharmacies could be individually monitored for safe and effective administration of 17P. Therefore, taxpayers, regulators and KV pharmaceuticals, unnecessarily spent hundreds of millions of dollars on development, testing, and approval for Makena.

Third, post market pharmaceutical regulations also increase the cost of drugs by raising the cost of obtaining a drug, whatever its price. Prescription requirements increase prices because they limit the supply of consumers to only those with prescriptions, so drug manufacturers might charge more for the drug to compensate for the depleted demand.

78 Belkin, “Prematurity Drug Price Jumps Wildly.”
Poorer patients and patients without health insurance who lack access to affordable medical care cannot afford to obtain the prescription, even if they could afford the drug itself. In other words, prescription drug requirements increase the cost of all prescription drugs by the price of a physician’s visit. Especially for uninsured patients, this cost can be prohibitive. Further, because insurance companies often reimburse patients for the cost of prescriptions, patients and physicians are less sensitive to the cost of pharmaceuticals, making prescriptions more expensive for the uninsured whose drug costs are not reimbursed. Insured patients bear these costs as well because high drug prices and costly doctors visits also cause higher insurance premiums. Though no one has estimated the exact cost of prescription requirements, there is some evidence that the cost is substantial. Peter Temin estimated that switching powerful cold medicines from prescription-only to over the counter status saved consumers over $70 million per year, and estimates the consumer surplus to be over $770 million per year.

Fourth, prohibitive regulations impose costs on the public, not just patients. On one hand, these economic costs are not as much of a concern in countries that provide all citizens with universal health insurance because governments can use their purchasing power to negotiate lower prices for pharmaceuticals. For example in Canada drugs are much less expensive than in the US because the Canadian government provides all citizens with health insurance and drug coverage. This is why many Americans purchase

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80 Temin, “Realized Benefits from Switching Drugs.”
drugs from Canadian pharmacies. On the other hand, even in countries that provide health care, pharmaceutical regulation makes healthcare more expensive because pharmaceutical manufacturers still bear the expense of undergoing premarket approval requirements, which is passed along to government and then to taxpayers. Also, prohibitive premarket approval costs in one country are borne by consumers worldwide; manufacturers do not pass on the costs of expensive testing only to countries that make testing expensive.

At the same time, strict regulatory environments do encourage meditech innovators to seek more friendly regulatory climates for development and approval. States cannot avoid the public cost of strict regulations by taxing drug makers (thereby preventing manufacturers from passing along costs to the public) because strict regulations also delay new sources of revenue and cost jobs, making regulation even more costly to the public. Whether health care is publicly or privately provided, the public bears the cost of pharmaceutical regulation—citizens either bear the costs as taxpayers or as patients.

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83 Makower, Meer, and Denend, *FDA Impact on US Medical Technology Innovation—A Survey of Over 200 Medical Technology Companies*.
84 It is estimated that for every meditech job lost, 4 other jobs are lost as well. Makower, Meer, and Denend, *FDA Impact on US Medical Technology Innovation—A Survey of Over 200 Medical Technology Companies*.
85 The practice of granting conditional approval for drugs also increases the costs and decreases availability of drugs. States with publicly provided health insurance only subsidize drugs for patients with approved conditions, and private insurers often refuse to cover expensive off-label treatments. For example, in December of 2010 the FDA withdrew approval for Avastin, a drug that restricts the growth of new blood vessels, for the treatment of breast cancer. While Avastin is still approved for a variety of other
Finally, enforcing drug prohibitions is expensive. When patients illegally access prohibited drugs, either by purchasing unapproved experimental medicines, or buying prescription drugs for recreational use, or by illegally importing pharmaceuticals from other countries, they commit a criminal offense. While it is true that the public sometimes bears the cost of drug abuse and misuse, we also bear the cost of investigating, prosecuting, and punishing patients who illegally access prohibited drugs. More troublingly, citizens who access prohibited drugs are punished and sometimes imprisoned, despite the fact that they do not act wrongly. By purchasing drugs without a prescription unauthorized users do something that millions of other patients do every day.

7. Conclusion

To sum up, even if premarket regulation does prevent some death and suffering by keeping unsafe drugs from the market, the lengthy process of safety and efficacy testing as it exists today imposes significant safety costs relative to more permissive regulatory regimes. Prohibitive regulations also are expensive. The benefits of medical regulation must be weighed against costs of drug loss, drug lag, and inflated drug prices.

cancer and conditions, the FDA cited a lack of clinical evidence that Avastin slowed disease progression or lengthened life expectancy enough to justify the risks to breast cancer patients. Because Avastin must now be prescribed off-label for breast cancer patients, insurers are reluctant to reimburse patients and physicians for the treatment, and one year of Avastin treatment can cost up to $88,000. To be clear, Avastin is an effective treatment for some individual patients with breast cancer, and for some patients it is the only treatment option available, but the FDA withdrew approval because risks, like the risk of brain hemorrhaging, outweighed the potential benefits in aggregate. Breast cancer advocacy groups have continued to plead for approval, but the agency has insisted that it will not extend approval. Other cancer advocacy groups have also advocated for Avastin approval for breast cancer, arguing that withholding approval could discourage development and innovation of Avastin-like drugs, which could not only treat breast cancer, but less common cancers as well.

Still, I have not established that unrestricted access to pharmaceuticals would be preferable, only that reform is needed and that fewer prohibitions would alleviate some of the costs of regulation. Since no developed liberal societies have adopted fully permissive policies we cannot know for sure that an unconditional right of self-medication would have better effects. Yet the bad effects of pharmaceutical regulations at least tell in favor of less prohibitive polices if not unconditional rights of self-medication. Yet these are not the only, or even the strongest reasons to reject prohibitive policies, as I will now argue—pharmaceutical regulation also undermines our objective interests, violates our rights and is inconsistent with informed consent.
III. Direct and Indirect Approaches to Health Care

All liberal societies provide at least some health care to some citizens, though particular schemes of public provision vary. One reason that liberal states might provide health care is that they believe that citizens have positive rights to health or health care.\(^1\) Another is that a healthy citizenry might be a precondition to a fair society.\(^2\) Or, perhaps people in liberal democracies simply prefer their government to play a role in providing health care as a public good, rather than a privatized system. Whatever the reason, liberal societies value health and have an interest in promoting public health either as a matter of justice or as a kind of public generosity.

One way to promote a value like health is to directly provide health care, and many political philosophers have advocated for this strategy. States might also promote health *indirectly* by allowing citizens to promote their own health and structuring choices that influence health through non-prohibitive means. In this chapter, I will explore the relationship between liberalism and health in theory and in practice. I proceed from a liberal framework because I think that justice requires some kind of liberal society. I suggest that self-medication is a viable strategy for indirectly promoting public health. I

\(^{1}\) The Universal declaration of human rights declares that an adequate level of health is a human right, and some constitutions (e.g. Spain) even go so far as to explicitly affirm that the public provision of health care is a fundamental right. By positive rights I mean rights that a good be provided, in contrast to rights against interference. Health and health care are different kinds of rights but they are both motivated by the principle that some level of healthiness is required to live an autonomous or objectively valuable life.

\(^{2}\) This seems to be the sentiment behind the French health care system. John Rawls and Samuel Freeman both make a claim like this. They argue that some health care is required to ensure that all citizens are able to develop their ‘moral powers’ and participate in fair institutions. John Rawls, *A Theory of Justice*, Revised ed. (Belknap Press of Harvard University Press, 1999); Samuel Freeman, *Rawls*, New ed. (Routledge, 2007).
also argue that indirect strategies for promoting public health are not incompatible with the direct provision of health care that is favored by most liberal political philosophers.

First I will describe how actual liberal societies have approached health care. Then I will review several of the most influential philosophical arguments in favor of the provision of health care. All of these arguments favor what I will call a “direct governmental” approach. After clarifying this distinction I will show that indirect governmentalism is also a viable strategy for promoting the public health. To some, this claim might be counterintuitive. Some might think for example that unrestricted access to dangerous medicines would undermine public health and the state’s capacity to provide health care. This empirical worry is unfounded, but even if it is true, it does not necessarily tell in favor of prohibitive policies.

I am including this discussion of liberalism and health before I go on to argue for rights to self-medication because at first glance, my arguments in favor of rights to self-medication might appear offensively libertarian to some, especially those who endorse the welfare state and rich public assistance programs that aid society’s worst off members. My goal in this chapter is to show that prohibitive policies are not required for the public provision of health care, and that self-medication may be an important element of a public health care system.

1. Liberal States and Health Care

Before I continue, it may be helpful to give some examples of the kinds of public health care systems that I have in mind. A liberal society may provide health insurance to some citizens (limited coverage) or all of its citizens (universal coverage). Further, health insurance may be provided and run by the government (public), by private firms (private)
or some combination of the two. In addition to health insurance, the actual provision of care including hospitals and physicians’ salaries may be publically or privately funded.

Most liberal societies provide health insurance to their citizens.\(^3\) Additionally, some societies that are not typically labeled as liberal, such as Singapore and Rwanda have laws that ensure that all of their citizens have some form of health insurance.\(^4\) The United States is unique—only government employees, veterans, poor people, and elderly citizens are guaranteed health insurance.\(^5\) In 2014 the United States will expand health coverage by taxing citizens who fail to buy health insurance in order to fund health insurance for people who would otherwise be too risky to insure, though this system does not guarantee that everyone will have health care.\(^6\) Most other developed countries provide public health insurance directly and also allow citizens to access to a range of private insurance options. For example, in Canada and the UK all citizens insured by the government and citizens are also allowed to buy supplemental insurance for additional

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\(^5\) Limited coverage in the United States also extends to citizens with certain conditions, such as patients with kidney disease who are in need of dialysis. For an explanation of this system see Robin Fields, “‘God Help You. You’re on Dialysis.’,” *The Atlantic*, December 2010, http://www.theatlantic.com/magazine/archive/2010/12/god-help-you-youre-on-dialysis/8221/8308/.

services, like dental care. Most German citizens are required by law to use a government-approved and subsidized health insurance company. In Australia all citizens have access to some public health insurance, but the government provides tax incentives for citizens to purchase private health insurance as well.\footnote{Additionally, the actual provision of medical services varies across societies but is generally comprised of some mix of public and private care. For example, the United Kingdom and Norway provide government run hospitals and most physicians are employed by the state. In Canada, private companies provide most medical services, though they are paid for by public health insurance.}

The provision of health insurance and medical services is a major priority for all liberal societies. All of these states also strongly limit access to pharmaceuticals, and none of them recognize rights of self-medication. This is not a coincidence. Policymakers often believe that self-medication is in tension with public health. The provision of health care is seemingly in tension with self-medication insofar as people self-medicate in ways that harm themselves, because the public will bear the cost. In this chapter my goal is to show that this intuitive story is mistaken. Public health care does not require prohibitive drug policies.

2. Why Justice Requires Health Care

Liberal states aren’t the only ones who affirm a commitment to public health care. Liberal philosophers agree that institutions ought to provide everyone with access to basic health care. I agree with mainstream liberal philosophers and policymakers that justice requires health care, and I will use this idea as a premise in my later arguments for self-medication, so in this section I will quickly review some of the philosophical justifications for the public provision of health care. In particular, I will review Rawlsian, Dworkinian, welfarist and pluralistic justifications.
The most notable advocate of public health care is Norman Daniels, who has developed a Rawlsian argument for public health care. Daniels argues that liberal societies ought to provide health care to all citizens because health care is a primary good, the kind of thing that any rational citizen has reason to want. For this reason, impartial (fair) institutions would provide all citizens with at least some health care. Daniels shows this by arguing that if impartial representatives of all groups in society chose institutions, those representatives would advocate institutions that maximize the minimum level of health care for all citizens. Daniels also argues that health care is morally required for fair institutions because citizens require at least a “normal opportunity range” to pursue their projects and develop conceptions of the good.

Daniels and others also argue that fair institutions should secure equal opportunities for all citizens, and that inequalities in health undermine citizens’ opportunities, so health care is also instrumental to achieving a society that gives all citizens equal opportunity for advantage. Amartya Sen and Martha Nussbaum also present an equal opportunity argument for health care. Sen and Nussbaum argue for a “capabilities approach” to social institutions, which holds that all citizens are entitled to some public provision of health care. Their argument is as follows. Everyone, as a matter

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8 Daniels, *Just Health*, pg 49
9 Alan Buchanan has criticized this framework because a ‘normal opportunity range’ is itself a social artifact. Theories of health care should not privilege what is a normal opportunity range in an unjust society, a more objective standard of health is required. Buchanan also points out that Daniels cannot explain how health care ought to be allocated under conditions of scarcity. Daniels, *Just Health*.
10 Brighouse and Swift, for example, argue that health is a positional good. Harry Brighouse and Adam Swift, “Equality, Priority, and Positional Goods,” *Ethics* 116, no. 3 (April 1, 2006): 471–497.
of human rights, is entitled to certain capabilities, primarily the capacity to function as a human agent and to “live a fully human life.” One capability that is instrumental to this end is bodily health, which includes not only nutrition and shelter but also a minimum of health care. Thus, as a matter of human rights, everyone is entitled to some degree of health care to secure their ability to function, whatever their ends.

In contrast to Daniels’ Rawlsian model, other theories of justice arrive at an argument for health care from the idea that fairness requires equal treatment (rather than impartiality). Most prominently, Dworkin begins with the premise that fair institutions are those that treat everyone as equal. Specifically, Dworkin asserts that fair institutions ought to ensure that people have an equal share of resources that does not reflect morally arbitrary traits, like inequalities in natural talents. Since unequal health needs are morally arbitrary, institutions ought to also protect citizens from poor health outcomes

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13 The advantage of this approach is that it calls for the provision of a sufficient minimum of health care that does not depend on a normal opportunity range but rather on an objective standard of human functioning.
15 Like Rawls, Dworkin constructs a decision procedure for deriving principles that follow from this moral premise. Dworkin proposes that we can identify an equal distribution of resources that does not reflect morally arbitrary traits by imagining what kind of distribution of resources would emerge from a hypothetical auction where everyone began with equal buying power. Such an auction would yield equal (though different) resources to all participants. To control for resource inequalities that might emerge from unequal talents, Dworkin proposes that each individual in the auction does not know the economic value of his talents, and is able to purchase insurance against the possibility that she will not have economically valuable talents. Such a scheme would ensure equality of resources, correcting for unequal talents. Dworkin, “Equality, Luck and Hierarchy.”
through some kind of public insurance program. Kristi Olson has adopted this Dworkinian approach. She shows further that even if we do not accept the premise that unequal health needs are arbitrary, (perhaps because some people are responsible for their unequal health needs) the premise that institutions ought not reflect morally arbitrary asymmetries in natural talents is sufficient to justify the public provision of health insurance.

In addition to these arguments that fairness requires the public provision of some health care, another kind of liberal argument in favor of the public provision of health care begins from the premise that institutions ought to be concerned with citizens’ welfare. For example, Alan Gibbard argues that states ought to provide access to a basic

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16 Or, in terms of Dworkin’s proposed auction procedure, imagine further that auction participants do not know their specific health needs, were equality of resources secured, most individuals would spend some of their resources on insuring against adverse health. Dworkin then argues that governments therefore ought to provide at least the level of health insurance that prudent individuals in such an auction scenario would purchase because fair institutions ought not reflect morally arbitrary asymmetries in talents or health needs. Dworkin, “Equality, Luck and Hierarchy.”

17 Kristi Olson offers an alternative to Dworkin’s auction scenario that relies solely on the imperative that just institutions ought to promote a resource distribution that does not reflect unequal talents. Olson proposes a hypothetical auction wherein citizens with equal talents bid on occupying certain occupational positions in society instead of resources. The wage that attaches to each occupational position reflects the relative burdensomeness of that position. Olson hypothesizes that every occupational position will demand at least a basic income and some minimal provision of health care, including the position of the ‘voluntarily unemployed.’ Therefore, egalitarians who believe that just institutions ought not reflect unequal talents ought to provide citizens with every occupational position with at least a basic income and some health care. Both of these accounts begin with the premise that fair institutions will correct for morally arbitrary features of individuals, like unequal health needs or talents, and argue that an institution that serves this end will provide some health care for all citizens. These theories focus mostly on the individual provision of health care, rather than more general public health initiatives, because they are concerned with the effect of institutions on specific citizens who are differentially advantaged as a result of morally arbitrary traits. Kristi Olson, “The Malibu Surfer and the (Unconditional) Right to Health Care,” *Princeton Bioethics Workshop- Working Paper* (2010).
minimum of health care because if an institutional arrangement can make everyone’s ex ante prospects better off, and no one’s worse off, then states ought to adopt that institutional arrangement.\footnote{Gibbard’s argument, roughly, is like this. P1: If an institution is ex ante pareto, meaning that it makes everyone’s ex ante prospects better off and no one worse off, then it ought to be adopted. P2: A health care minimum is ex ante pareto, C: Governments should provide a health care minimum Allan Gibbard, “The Prospective Pareto Principle and Equity of Access to Health Care,” The Milbank Memorial Fund Quarterly. Health and Society 60, no. 3 (July 1, 1982): 399–428.} Utilitarians also argue for the provision of health care because they are concerned with citizens’ welfare. Utilitarians believe that morality requires that individuals and institutions aim to maximize overall well being.\footnote{Utilitarians are not the only group that endorses a utility-maximizing approach to public institutions like health care. Robert Goodin, for example, has argued that even if utilitarianism is an inappropriate moral philosophy for deciding matters of personal ethics (because, for example, utilitarians cannot justify giving special consideration to personal projects, friends, or family if doing so would undermine overall utility), nevertheless utilitarian considerations should guide public policy because public policy ought to be detached from personal projects or relationships Robert E. Goodin, Utilitarianism As a Public Philosophy (Cambridge University Press, 1995).} They argue that greater health equality, empirically, leads to greater utility because health care, like income, yields diminishing marginal utility.\footnote{For a more detailed discussion of utilitarianism and health care and how it contrasts with egalitarian theories see Equity in Health by Alan Williams and Richard Cookson in Anthony J. Culyer, Handbook of Health Economics (Elsevier, 2000). pg 1871-1872.} In other words, spending on health care for the poor and unhealthy will yield a greater gain in utility than the same amount of spending on health care for the rich and healthy and similarly a lack of health care resources for the poor and unhealthy will have a greater negative impact on utility than an equivalent lack of resources for the rich and healthy. Therefore, the public provision of health care is a good way to promote overall well being. Moreover, utilitarians argue that
a utilitarian calculus should define the specific nature of any public health plan, including how to ration limited resources and which priorities ought to guide public spending.\footnote{Peter Singer, for example, argues for a utilitarian approach to health care spending and rationing. Utilitarian justifications for health care have come under criticism, notably by non-utilitarians like Frances Kamm, who argues that certain individual health imperatives, like the need to continue living, ought to outweigh other health needs, like the need to have surgery that would improve but not save one’s life, even if providing lifesaving care for a few would lead to lower overall utility than providing life improving care for many. Another class of criticisms alleges that this kind of calculus is biased against the elderly because it seeks to maximize not only health but the number of healthy years of life. Francis Kamm, “Letters: Why We Must Ration Health Care,” \textit{The New York Times}, August 16, 2009, sec. Magazine. Peter Singer, “Why We Must Ration Health Care,” \textit{The New York Times}, July 19, 2009, sec. Magazine. Aki Tsuchiya, “QALYs and Ageism: Philosophical Theories and Age Weighting,” \textit{Health Economics} 9, no. 1 (2000): 57–68.}

So far, I have not taken a stand on which kind of argument is the most successful. This is because, following Alan Buchannan, I favor a pluralistic justification for the public provision of health care. Buchanan writes:

[The legal right to health care is grounded] in a plurality of moral considerations, some of which need not be framed in terms of rights, including the need for coordinated, efficient beneficence. The pluralistic basis for a legal entitlement to a decent minimum developed in this essay is not only more in tune with the nature of the historical struggle to include health care among the entitlements provided by the modern welfare state; it also provides a more secure normative basis for such an entitlement than the attempt to ground it in any one moral principle, including Daniels’ principle of equal opportunity.\footnote{Allen Buchanan, \textit{Justice and Health Care: Selected Essays} (Oxford University Press, 2009). Introduction.}

There are many reasons to give people health coverage. Surely different reasons apply to different populations, but for any given person there will be \textit{some reason} that will justify
providing that person with some health care. This pluralistic approach may seem unsatisfying to those who are committed to a particular brand of liberalism, but most of us can share in the conclusion that institutions ought to provide citizens with at least some health care.

3. Indirect Means of Promotion

I’ll now proceed with the assumption that states ought to provide citizens with health care. To this end, there are two policy orientations that the state might take. Call the first direct governmentalism; this approach seeks to provide a social good through legislation and social programs.\textsuperscript{23} Policies that involve creating government agencies to administer a good and actively shaping the social order are direct governmentalist solutions. In contrast, indirect governmentalists favor policies that promote social goods by securing citizens’ negative liberties and helping citizens to access those goods through voluntary exchanges. Indirect governmentalism does not rule out public assistance programs like a basic income. Rather, the indirect governmentalist orientation favors market solutions to public problems in part because markets are more compatible with individual liberty. John Tomasi characterizes the distinction like this:

Direct-governmentalists are optimistic about the moral appropriateness and practical efficacy of targeted regulations and statutes to bring about desired changes within complex social orders. Indirect-governmentalists are more skeptical of such regulatory ambitions, on both moral and practical grounds. On its democratic variants, the first reaction of direct-governmentalism to a social

\textsuperscript{23} I am borrowing this phrasing from John Tomasi. John Tomasi, ““Can Feminism Be Liberated from Governmentalism?,” in Toward a Humanist Justice, ed. Debra Satz and Rob Reich (Oxford University Press, 2009).
challenge is to ask what might be done by means of a politically channeled public will. Indirect-governmentalists are not antidemocratic. But indirect-governmentalists tend to look first to institutions through which the desires of human wills for change can be expressed without those wills being politically channeled.\textsuperscript{24}

Tomasi goes on to point out that indirect governmentalists do not deny that government can play a legitimate social role, and direct governmentalists do not believe that government should actively intervene to solve all social problems:

Even people who assign to government architects the ambitious goal of erecting social walls can recognize the importance of open spaces in which individuals can be free… The difference between direct and indirect-governmentalism is one not of kind but of strategy.\textsuperscript{25}

Tomasi frames the contrast between direct and indirect governmentalism as an either/or strategic choice between providing a good directly or allowing its indirect provision, but both strategies can be pursued at once. For example, say that liberal states have a duty to provide all citizens with at least the opportunity to get a decent education. One way to ensure that everyone has educational opportunities is to provide all citizens with access to public schools. Another is to protect citizens’ rights to educate themselves by permitting private education and home schooling and by allowing citizens to read books and discuss ideas outside of the public education system.

Policymakers and philosophers who favor public health care tend to favor a direct governmental approach, yet indirect governmentalism can also promote health

\textsuperscript{24} Ibid.
\textsuperscript{25} Ibid.
care. A right of self-medication is one example of an indirect governmentalist approach to health care. The two approaches are not in tension; states can promote public health directly and indirectly.

This point is controversial. Direct governmentalists tend to prohibit people from privately accessing social goods that are publicly provided. They justify these prohibitions on the grounds that private access will undermine public provision. For example, Brighouse and Swift have argued that private schools will undermine the state’s capacity to provide all citizens with a decent education through the public school system. In Germany, where education is publicly provided, home schooling is prohibited. Part of the justification for this prohibition is the idea that private education in the home is incompatible with the social goods that public education provides. Berlin’s education minister, Juergen Zoeliner, put the point like this:

In our increasingly multicultural society school is the place for a peaceful dialogue between different opinions, values, religions and ideologies. It is a training ground for social tolerance. Therefore, home-schooling is not an option for Germany.  

While direct and indirect governmentalism might be incompatible in some cases, my point here is only that direct and indirect means of providing social goods are not necessarily incompatible. If you are hungry, one way that a state might provide you with food is to create a government program that distributes food. At the same time, states might also make it easier for you to access food on your own, by removing barriers to access and showing you where food is privately available.

With this distinction in hand, we can now see that there are two ways to provide health care. First, a state that seeks to promote public health care might favor direct governmental programs that provide these goods. Or, a state might indirectly ensure that health care and health are provided, at least in part, by allowing citizens to independently access health care goods, or to act to improve their own health.

In principle, these two strategies are compatible; states can provide citizens with health care goods and also allow them to independently access health care services as well. In practice, societies that have adopted direct governmental approaches have not always allowed indirect governmental approaches. For example, Canada provides government-funded health services to all citizens, but until recently the Canadian government outlawed privately financed purchases of medical services. This kind of policy was in place to limit the public cost of providing universal health care, if privately funded health services were available then market forces would determine the overall cost health services, rather than government policy, and the government might then need to pay more for medical services. Yet without private funding for health services patients faced extraordinary wait times, and the policy encountered resistance from physicians and patients who also favored indirect governmental approaches to health care. In 2005

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27 This policy was recently reversed, but only in specific provinces and for specific conditions, when the national health service consistently fails to provide timely access. See Chaoulli v. Quebec, June 2005, Amélie Quesnel-Vallée et al., “In the Aftermath of Chaoulli V. Quebec: Whose Opinion Prevailed?,” CMAJ: Canadian Medical Association Journal 175, no. 9 (October 24, 2006): 1051–1052.
the Canadian Supreme Court ruled that if a provincial government could not adequately provide a particular health service then privately funded clinics were legal.\textsuperscript{28}

In other words, patients’ basic right to health care paradoxically \textit{require} an indirect governmental approach to the provision of health care in some cases, or at least legal permission for non-governmental health care providers. Unfortunately the Canadian court’s ruling has had little impact on health outcomes. In 2006 Canadian physician and critic of the Canadian health system Dr. Brian Day told the New York Times “In a free and democratic society…the state has no business preventing you and me from spending our own money on health care,” yet the narrow ruling left many laws in place that did just that.\textsuperscript{29} Private insurance is only available today in Quebec and only for a limited range of procedure, due to existing legal barriers. Where they can afford it, many Canadians continue to seek medical care in other countries.\textsuperscript{30} Those who cannot afford to travel go without treatment for months or even years.

Widespread resistance to self-medication also reflects skepticism about indirect governmental strategies for promoting public health.\textsuperscript{31} The Canadian example showed how a state could publicly provide health care but still fail to promote public health if


\textsuperscript{31} I don’t mean to overstate this claim though. In practice, a mix of direct and indirect governmentalism characterizes most health care systems. Most countries provide citizens with health care but also allow for privately funded medical services. Similarly, most countries provide citizens with prescription drug plans but also allow for citizens to privately access some pharmaceuticals. Yet in the case of pharmaceuticals, access is still strongly limited through prescription drug systems and premarket prohibitions.
they also prohibited citizens from accessing health services through other means. Just as a liberal society can both provide all citizens with health care and medical services but also permit citizens to privately access other forms of health care and private medical services, states might also provide all citizens with access to approved pharmaceuticals through a prescription drug plan but also permit citizens to access other pharmaceuticals independently.

In states that do not have strong direct governmentalist programs that provide all citizens with health care, the case for indirect governmentalism in the form of a right of self-medication is especially strong. In the United States, for example, over 50 million people currently did not have affordable access to medical services or public health care in 2010.\(^{32}\) In many developing countries, providing universal health care to all citizens is unaffordable. Without direct-governmental provisions of health care, patients not only lack access to medical services, they also cannot use prescription-grade medicines to self-medicate because they lack access to a physician who could write them prescriptions. In the absence of direct governmental provision of health care, states have duties of remedial justice to at least implement indirect governmental policies such as a right of self-medication. Duties of remedial justice take the following form. If group A has access to a good that group B lacks through no fault of their own, then it is unfair to deny B from accessing that good through other means. This is particularly true for goods that are

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especially important for liberal citizenship, such as education, health care, and (perhaps) cultural membership or language.\textsuperscript{33}

Thus, the argument from remedial justice begins with the premise that states ought to provide access to health care and medical treatment in some way. However, if a state does not provide health care, then it at least ought not hinder the provision of medical treatment from non-state entities, absent any decisive countervailing considerations. If the uninsured do not have access to insurance and doctors, through no fault of their own, then it is unfair to deny the uninsured access to health related goods that insurance and doctors are often required for. Consider an analogy between health and education, both of which are social goods that are especially important for liberal citizenship. Liberal states have a duty to ensure that citizens are minimally educated, (e.g. promoting literacy) because justice requires some level of education. However, if the state cannot (or will not) meet this obligation for all citizens, it at least ought not forbid parents who do not enjoy state provision of education from teaching their children to read, thus providing children with primary goods that the state has failed to provide.\textsuperscript{34} Similarly, if the state cannot provide universal access to healthcare it ought not prohibit those without healthcare from accessing at least some health related goods.

This argument is especially forceful if a group of citizens who do not have access to health care lack access through no fault of their own. For example, uninsured Americans have not forfeited their right to access basic health care; they have the same claim to health care goods as insured Americans. Yet the uninsured often lack access to

\textsuperscript{33} I’m grateful to Javier Hidalgo for pointing out that these arguments applied to self-medication as well.
\textsuperscript{34} This argument is especially forceful as an argument for permitting private education and homeschooling in low-income communities where public schools fail.
important and basic health goods like prescription drugs because they lack access to employer-based drug plans. Also, seeing a doctor who can issue a prescription is often unaffordable for the uninsured. Thus, it is especially impermissible to deny uninsured Americans access to health goods through other means, such as obtaining prescription-grade drugs without authorization. For this reason, without direct governmental provisions for health care, indirect governmentalism is especially urgent. In states like the United States, pharmaceutical prohibitions doubly handicap uninsured sick people, not only do the uninsured lack the means to obtain treatment from a physician, they are further denied the means of legally treating themselves.  

4. The Direct Governmentalist Argument for Prohibition

Indirect governmentalism as a means of promoting public health might strike some as counterintuitive. For example, one might think that a protected right of self-medication would undermine public health and compromise the government’s capacity to provide health care. Even if this empirical objection is true, it does not necessarily tell in favor of prohibitive policies. In this section I will address the concern that pharmaceutical liberalization, would undermine states’ ability to directly provide health care to citizens.

An intuitive objection to pharmaceutical deregulation is that people will undermine the public health system if they are permitted to make risky medical choices. The thought is that patients will make unwise or risky decisions that are ultimately harmful to their health, and the state provides these patients with medical treatment for

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35 It is important to distinguish this kind of argument from an argument for compensation. I do not mean to suggest that self-medication rights could compensate for the injustice of a health system that failed to provide citizens with health care, only that it is even worse to prohibit private access to insurance where public access is deficient, as I also argue in the discussion of Canadian health care.
their resulting injuries, then the public health system will ultimately bear the cost of self-medication. If these costs became excessive, then they might undermine the states ability to provide health care to all citizens.

I will address worries about social costs further in Chapters 5 and 10, but for now notice that this is only a concern if people reliably harm themselves by using dangerous drugs. In the previous chapter I cited evidence that showed that this hypothesis is empirically suspect, non-prohibitive regimes are not associated with higher rates of drug misuse or abuse; in fact, the rates of misuse and abuse are lower in non-prohibitive regimes. Further, states permit all sorts of self-harming behaviors, such as failing to exercise or over indulging in fatty foods, because limiting those behaviors would also threaten an important liberty interest. In the next chapters I will make the case that self-medication is often a similarly important liberty. Insofar as this concern justifies limits on self-medication, it also justifies an extraordinary range of paternalistic prohibitions that many citizens would likely find unacceptably costly or invasive.

Further, even if the above empirical concern is warranted, and patients will reliably harm themselves by abusing or misusing dangerous pharmaceuticals, indirect governmentalists still have resources to respond to this concern. First, a right of self-medication does not mean that patients are entitled to unconditional or subsidized access. I have suggested that physicians and regulatory agencies should still play an epistemic role in endorsing medicines but that endorsement should not be backed by prohibitions. Under such a system, healthcare providers including the state can permissibly refuse to finance the use of unapproved treatments and can refuse to subsidize adverse health outcomes that result from risky drug choices. Similar to legislation that is designed to
discourage smoking, patients who use dangerous unapproved medicines might also be asked to bear higher medical premiums or to pay a tax for unapproved use. Such policies could offset the public cost and promote public health without requiring prohibitions.

Second, like all rights, self-medication is not an absolute right. If it turned out that a particular drug harmed citizens in a way that directly imposed a substantial social cost on the government or society, then prohibitive policies for that particular drug might be warranted. To say that prohibitions or limits might be warranted in a few particular cases though does not undermine the claim that states ought to promote public health indirectly by respecting a general right of self-medication. Consider this analogy. Speech might be limited in particular cases, where speaking poses risks to others or imposes an unacceptable social cost (e.g. yelling fire in a crowded theatre or hate speech), while protections for free speech are still required for social justice. Similarly, self-medication could conceivably be permissibly limited in particular cases, and this possibility does not undermine the more general claim that citizens should be permitted to access medical treatment.

5. Libertarians and Liberals

I am including this discussion of liberalism and health before I go on to argue for rights to self-medication because at first glance, my arguments in favor of rights to self-medication might appear too libertarian for some liberals, especially those who endorse the welfare state and extensive public assistance programs that aid society’s worst off members. But provision and prohibition need not go together.

One way that liberals have typically been distinguished from libertarians is in their approach to economic liberties and property. As Samuel Freeman puts the
distinction: high liberals believe that economic liberties are not basic, classical liberals believe that economic liberties are extremely weighty and basic, and libertarians hold that property is nearly absolutely valuable. Classical liberals and libertarians tend to be skeptical of direct governmental programs. Some libertarians seem to think that direct government, which almost inevitably requires redistributive taxation, is inherently unjust. While not going this far, classical liberals depart from high liberals in that classical liberals are suspicious of large government programs like most systems of universal health care that I described above. Libertarians are also skeptical of positive rights, and classical liberals sometimes argue that positive duties cannot be coercively enforced. In contrast, high liberals argue that the public provision of social services is required by justice to satisfy people’s positive rights, like the right to health care.

The right of self-medication is delivered straightforwardly from a libertarian framework. Libertarianism fundamentally maintains that government should not interfere in citizens’ voluntary choices. Libertarianism sometimes rejects the idea of government entirely. While I am sympathetic to this approach, when it comes to health care I agree with the high liberals that I described above. Government can play a valuable role in providing everyone with health care.

While liberals and libertarians might disagree about property, taxes, political authority, freedom of contract, democracy, the range of liberties that we should tolerate, and the proper role of government, I contend that the two views will converge to support a right of self-medication for several reasons. When it comes to health care, the crux of disagreement between libertarians and classical liberals on the one hand, and high liberals on the other seems to center on a) whether direct governmental programs like universal health care are permissible, and b) whether citizens have positive rights to health care.

First, notice that this disagreement reduces to a disagreement about what the government should provide, not about what government should prohibit. It is a disagreement about the role of direct governmentalism. Insofar as indirect governmentalism doesn’t undermine the state’s ability to directly deliver social goods, liberals should favor indirect governmentalism as well. In cases where direct governmentalism fails, indirect governmentalism might be an alternative path to justice, or at least a way for states to satisfy their duties of remedial justice. In some cases indirect governmentalism might even further promote those social goods that are provided by direct governmentalism. I think this is the case for self-medication.

Second, while liberal philosophers have been entirely silent on the question of self-medication, I will argue that liberals and libertarians should agree that government must tolerate a range of intimate personal decisions, particularly those that involve matters of life and death. In the following chapters, I will further defend the claim that self-medication merits this kind of protection.
6. Conclusion

In this chapter I have argued that there are two paths to promoting public health. Liberal philosophers who have argued forcefully and persuasively in favor of the public provision of health care have overlooked indirect governmentalism as a way of achieving this end. The right of self-medication might promote public health alongside a system of universal health care. Absent universal health care, self-medication will at least enable citizens to access medical treatment on their own. Both liberals who favor direct governmentalism and libertarians who value individual liberty above all else should be open to indirect governmentalist policies like rights of self-medication. Though rights of self-medication are delivered straightforwardly from a libertarian commitment to non-interference and self-ownership, in the following chapters I will make the case that liberals should also favor rights of self-medication. For such liberals, I will suggest that citizens’ interests in rights of self-medication are very weighty, particularly for patients who aim to use drugs to enhance their autonomous capacities or to save or end their lives. These weighty interests, in addition to the above consequentialist considerations, are still more reasons to favor indirect governmental polices like rights of self-medication.
IV. Liberal Paternalism and Self-Medication

While liberalism is distinguished by its reverence for individual autonomy, most liberals believe that some paternalistic restrictions on personal liberties are nevertheless permissible.¹ In particular, many liberals believe that a just state can (and maybe should) prevent citizens from making choices that undermine their autonomous capacities. Call this view liberal paternalism. Two arguments for liberal paternalism have been particularly influential. The first states that liberal states have a legitimate interest in promoting citizens’ objective interests, and that limits on personal choice are permissible to this end. The second argument states that liberalism requires an autonomous citizenry, and therefore that some paternalistic restrictions on self-harming choices might be required to secure the preconditions for fair institutions.

I am not a liberal paternalist, but I recognize that the liberal paternalist’s approach to the value of autonomy has powerful intuitive force with most liberals. I suggested in Chapter 2 that the current system of prohibitions causes a lot of death and suffering and that reform is urgently needed. Yet many liberals might balk at my claim that prohibitive pharmaceutical regulations should all be abolished. The empirical analysis I presented in Chapter 2 does not establish that prohibitions are in principle unjust, or that a non-prohibitive system would have the best outcomes. Liberal paternalists might then agree that pharmaceutical reform is necessary, but favor a more moderate system prohibitive

¹ Throughout this discussion, I use the term ‘autonomy’ interchangeably with ‘agency.’ Though some philosophers use these terms differently, I mean them both to mean, roughly, the capacity to make decisions competently and freely. Another term that is sometimes used in this way is ‘self authorship.’ The specific definition and characterization of these terms isn’t necessary to understand the following arguments, and where it is I will explain each term in more detail.
pharmaceutical regulations, perhaps with shorter approval times and more paths to access prescription drugs.

In this chapter, I will develop the liberal paternalist framework in detail and I will argue that the best liberal arguments for paternalistic restrictions do not justify the current system of prohibitive pharmaceutical policies because liberal paternalists can promote citizens’ objective interests and secure fair institutions though less-prohibitive policies. Also, less prohibitive policies in some cases are required to further citizens’ objective interests and autonomous capacities.

In section 1, I will sketch the basic idea behind liberal paternalism. In section 2, I will reconstruct what I think is the best argument for liberal paternalism in more detail, namely the view that states ought to promote citizens’ objective interests. I will address some liberal paternalist concerns about self-medication in section 3. In section 4, I will address some epistemic problems with a less prohibitive system. In Section 5 I discuss the idea that states should promote citizens’ autonomous capacities so that they can participate in fair institutions. This version of liberal paternalism also has interesting implications for self-medication. Section 6 concludes.

1. A Quick Overview of Liberal Paternalism

Liberals all agree that autonomy is important, but there are two ways of understanding how a liberal state ought to respond to the value of autonomy. Some liberals believe that states ought to respect whatever choices citizens actually make as long as those choices do not harm others. This is what I believe, but I realize that it is a minority position. Other liberals, who I am calling liberal paternalists, believe that states are not required to respect self-harming choices. These liberals are comfortable with
prohibitions on hard recreational drugs and prostitution, as well as seatbelt and helmet laws.  

The best case for liberal paternalism (setting aside consequentialist arguments, which I addressed in Chapter 2) focuses on the fact that using hard drugs, being a prostitute, or being injured by an auto or motorcycle accident will harm drug users, prostitutes, passengers and cyclists. Since liberalism purports to value autonomy and citizens other objective interests, liberal institutions should protect citizens’ health and autonomous capacities, so some paternalism is permissible. Samuel Freeman puts the argument in favor of paternalistic restrictions on liberties like this:

When the aim and effect of restrictions against self-destructive conduct is to maintain the moral and rational integrity of the person—in the sense of the capacities for rational agency and moral responsibility upon which liberalism and liberal autonomy are based—then there is nothing illiberal about imposing restrictions on conduct that is harmful only to the agent concerned.

Liberal paternalists believe that autonomous capacities are particularly valuable for a variety of reasons; I will focus on two reasons. First, the development of our autonomous capacities is in our objective interests and is integral to a flourishing life. Second, our

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4 Peter De Marneffe, for example, argues that people have an objective interest in developing capacities like the ability to deliberate, but also the ability participate in
autonomous capacities are preconditions for the functioning of a fair society. The argument from these two claims to paternalism is as follows

P1: In order for citizens to live flourishing lives and/or to participate in fair institutions, as equals, they must have at least a sufficient level of autonomous capacities that enables them to deliberate about public policy and also about what is right and what their values are.

P2: States should seek to give citizens flourishing lives and include them as equal participants in a fair society.

C: States should adopt a system of liberties that secures citizens’ autonomous capacities to the extent that is necessary.

Whether our capacities are instrumental to other liberal aims like flourishing lives or fair institutions or necessary for a fair society, what these two kids of arguments share is the conviction that in some cases, states can (and should) limit particular opportunities of autonomous choice in order to promote citizens’ capacities overall.

It is important at this point to distinguish the versions of liberal paternalism that I am sketching from a kind of capacities-maximizing consequentialism. Liberal paternalists believe that just institutions should promote citizens’ autonomous capacities, but within limits. Straightforwardly maximizing autonomous capacities risks too many restrictions on opportunities to exercise those capacities, and after all, autonomous capacities are not valuable for their own sake. They are valuable for the role they play in making a flourishing life or a fair society possible.

loving relationships, and that these interests provide the legitimate basis for laws that restrict women’s rights to become prostitutes. de Marneffe, *Liberalism and Prostitution.*
The value of promoting autonomous capacities must then be weighed against the value of actually exercising those capacities, insofar as the two compete. Surely some actual instances of autonomous choice are also required to live a flourishing life or participate in fair institutions. Like the rest of us, liberal paternalists would condemn a society that maximized the autonomous capacities of all but withheld any actual opportunities for autonomous choice.

To strike this balance, liberal paternalists argue that some choices, e.g. basic rights, must be protected from paternalistic interference even if paternalist violations of basic rights in particular cases would promote citizens’ autonomous capacities overall. The key is that the overall system of liberties, protections and prohibitions balances out to promote good lives and fair institutions, while respecting basic liberties (especially the most important of basic liberties). For example, Peter de Marneffe proposes the following four criteria for determining which liberties should be protected from paternalistic restrictions:

A necessary condition of a liberty being basic is that at least one of the following conditions is satisfied: (a) this liberty is necessary for someone to have adequate control over her own life; (b) this liberty is a necessary social condition for people to deliberate fully about what is right and good; (c) this liberty functions to symbolize someone’s status as an equal citizen or full member of society; (d) this liberty is necessary for someone freely to engage in an activity that she needs to

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engage in to have a happy or successful life (as judged by some objective list of substantive goods).\textsuperscript{7}

Conditions (a) and (b) just restate the view that institutions should do what it takes to promote citizens’ autonomous capacities, if institutional protections for certain kinds of choices tend to make people more autonomous overall, then liberal paternalists like De Marneffe favor protections. Conditions (c) and (d) reflect the underlying justifications for promoting autonomous capacities in the first place, if certain choices must be protected in order for citizens to ably participate in fair institutions and lead flourishing lives then states should secure protections for those kinds of choices as well. Notice at this point that liberal paternalists do not value actual opportunities for autonomous choice \emph{for their own sake}. Rather, choices and choice making capacities are both instrumental to the liberal paternalists’ broader goals of creating fair institutions and flourishing lives.\textsuperscript{8}

The above sketch of liberal paternalism is quite general, and it leaves room for a range of paternalistic restrictions on individual choice. Liberal paternalist arguments have been used to justify restrictions on recreational drug use, euthanasia, prostitution, and unconscionable contracts, gun control, dietary restrictions, and seatbelt laws. While political theorists have not addressed the right of self-medication, all developed liberal societies have some form of restrictions on self-medication, and liberal paternalist theorists sometimes cite these restrictions approvingly.\textsuperscript{9}

\textsuperscript{7} de Marneffe, \textit{Liberalism and Prostitution}. pg 110
\textsuperscript{8} Ibid.
\textsuperscript{9} For example, Samuel Freeman argues that the priority of liberty does not extend to a right of self-medication, citing the FDA approvingly in Samuel Freeman, \textit{Rawls}, New ed. (Routledge, 2007)., Pg. 69
In order for the liberal paternalist to endorse prohibitive pharmaceutical polices that limit citizens’ rights of self-medication, it must be the case that self-medication would undermine citizens’ autonomous to an unacceptable degree. That is, if pharmaceutical use undermined people’s capacities to pursue their projects and lead flourishing lives, or was damaging to liberal institutions in some way, then restrictions on self-medication could be justified from the liberal paternalist framework. More generally, if self-medication were a serious threat to citizens’ autonomous capacities liberal states might decide not to protect citizens’ rights to self-medication, even if pharmaceutical use did not make flourishing lives impossible or weaken liberal institutions.

In the rest of this chapter I will argue that liberal paternalists should reject many forms of pharmaceutical paternalism, even if some paternalistic restrictions on pharmaceutical choices might be warranted. The evidence I presented in Chapter 2 should move even the most paternalistic liberal to agree that reform is necessary, and in Chapter 3 I argued that reforms are compatible with other liberal commitments. These reasons make room for substantial reforms. Prescription and experimental drugs that are currently prohibited or selectively prohibited could possibly promote the objective interests of patients and enhance their capacities. Additionally, prescription drug restrictions are not necessary for liberalism to succeed. For all these reasons, liberal paternalists should favor a less prohibitive drug system.

2. Paternalism and Objective Interests

Consider first the argument that paternalistic restrictions on personal liberties are sometimes warranted if they promote citizens’ objective interests. This argument is based on the empirical assumption that some activities undermine citizens’ autonomous and
other capacities so badly, that they compromise people’s ability to live objectively valuable or flourishing lives. Several theorists have focused on the fact that self-harming behavior sets back citizens objective interests. De Marneffe, who has advanced the most developed account of this view, puts the argument like this:

When there is good reason for someone to prefer her situation with a law that limits her liberty in some way, and this reason has greater weight than anyone’s reasons to want this law not to be in place, including her own, then this reason can justify the government in adopting this law.  
That is, paternalism is warranted if an overall system of liberty that includes paternalistic restrictions is in the interest of those who are subject to the restrictions, all things considered.

De Marneffe appeals to this principle in justifying laws against prostitution. It is in the all things considered interest of women who would be prostitutes that governments enforce laws against prostitution. De Marneffe cites some evidence that shows that being a prostitute is stigmatizing, damages women’s ability to have meaningful romantic relationships, and that prostitution can undermine women’s capacities to secure other employment and to live flourishing lives more generally.

De Marneffe is quick to point out that this defense of paternalism assumes an objective conception of all things considered interests. Unlike subjective interests, which are the interests that people avow in their lives, the things they actually do want, a person

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11 de Marneffe, Liberalism and Prostitution. Pg. 65-66
12 Ibid. Pg. 33
has an objective interest in something if there is good reason for her to want it. Further, de Marneffe writes, “there can be good reason for a person to want something she doesn’t actually want,” and also there can be “good reason for her to want something even if she does not believe that there is any good reason for her to want it.”

Paternalists like de Marneffe must then make the case that a given restriction is all things considered in the interest of those who are subject to the restriction. On the other hand, these liberal paternalists also accept what Rawls calls the presumption of liberty--the idea that liberty should not be limited without good reason. This does not mean that any interference is wrong, but rather that some justification must be offered for policies that limit citizens’ choices. That a limit is in a person’s objective interests, on this view, is a good candidate justification.

For any particular case then, liberal paternalists must justify paternalist restrictions, and sometimes the justification for restrictions might not be sufficient to warrant limits on a particular liberty. For example, de Marneffe is skeptical that paternalism is ever warranted in cases where an autonomous, informed, and mentally competent person opposes a government restriction of a liberty that it is objectively important for her to have, even if the restriction is motivated out of concern for her interest. That is, sometimes the value of respecting a liberty interest, even if it is a non basic liberty, can outweigh the value of promoting objective interests.

De Marneffe’s strategy in defending paternalistic laws is then to show

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13 Ibid. Pg. 66
14 Rawls, A Theory of Justice.
15 de Marneffe, Liberalism and Prostitution. Pg. 130.
(1) That a paternalistic restriction is in a person’s all things considered objective interest and
(2) That the liberty that is limited by the restriction is not as important as the interest protected by the restriction.

For example, he gives the following defense of a hypothetical system of motorcycle helmet laws for citizens under age 21:

The freedom to ride without a helmet when one is under twenty-one is not very important and the risks to those under twenty-one of riding without a helmet are significant. Consequently, the reasons for the intended beneficiaries of this policy to want the government to adopt it arguably have greater weight than their reasons to want the government not to adopt it, despite their opposition to it. 16

Similarly, even if recreational drug users or prostitutes oppose restrictions on their rights to use hard drugs or sell sexual services, if restrictions are in their objective interest then restrictions are permissible because the countervailing interest in getting high or selling sex is not very weighty.

Conditions (1) and (2) raise questions about the content of our objective interest, the liberties that are importantly a part of our objective interests, and the system of restrictions will promote our objective interest on balance. Liberal paternalists answer these questions when they argue that that right to sell sex, get high, ride a motorcycle without a helmet, shoot an assault weapon, or eat MSG and trans fats do not have the same kind of importance as rights like freedom of speech or religion, the right to start a newspaper, or the right to choose a spouse. A system of liberties that limited the latter set

16 Ibid. Pg. 129.
of important rights, even for paternalistic reasons, would rarely if ever promote citizens' interests, whereas restrictions on the former set of rights may well do so, and therefore face a lower threshold of justification.  

More answers can be found about the content of objective interests when we look at the kinds of restrictions liberal paternalists favor. Selling sex, using recreational drugs, owning assault weapons, riding without a helmet, and eating junk are fit candidates for paternalistic restriction because they are activities that bring small economic or recreational gains but also seriously set back the interests of those who do them. Presumably paternalism is warranted then because the interest in doing the particular things that undermine one’s capacities is not that strong, and the cost of having one’s capacities undermined is high.

To sum up, liberal paternalists like de Marneffè seem to endorse a conception of objective interests that assigns great weight to citizens’ health and autonomous capacities and little weight to economic and recreational benefits. This is a normative judgment about what our interests are. Suppose we adopt this judgment and accept that the right to use pharmaceuticals for recreational or economic benefits is not very morally serious.

The first thing to notice is that not all pharmaceutical restrictions merely limit non-medical use. Premarket testing requirements prevent patients from accessing drugs for medical conditions as well, as do prescription drug requirements in cases where patients disagree with their physicians about treating a medical condition. As I will argue in the

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17 I am skeptical that such a divide between rights can be sustained without slipping into a kind of objectionable perfectionism, but even if it can, it’s not clear that self-medication belongs on the side of sex drugs and motorcycle rides, instead of on the side of religion and speech. Elsewhere, I have argued that all liberties are basic because they will be important to the development of some citizens’ capacities. I will not develop that claim more here though.
next three chapters, pharmaceutical freedoms are especially weighty, especially patients with medical conditions but also for non-medical users.

Even if we characterize all pharmaceutical freedoms as relatively unimportant compared to other liberties, we are left with an empirical question about how to which scheme of liberty will promote citizens’ interests. Does the current system of pharmaceutical restrictions promote our objective interests? I presented some evidence in Chapter 2 that suggests that pharmaceutical regulation as it stands today does not promote citizens objective interests on balance. For example, the drug lag costs more lives than it saves and the prescription drug system makes drugs unaffordable and causes patients to misuse and overdose on prescription-grade drugs. Further, the evidence suggests that unrestricted pharmaceutical use does not necessarily undermine our objective interests on balance since it seems to secure patients’ health better than the current restrictions that most developed societies have adopted.

Beyond the comparative studies of public health, more can be said to this kind of liberal paternalist argument for prohibition. First, pharmaceuticals are designed to enhance people’s health and capacities. That is the whole point of them. Further, most people value their health and autonomy, so they will be wary of using pharmaceuticals that undermine their health and capacities. People who do use pharmaceuticals to undermine their health or autonomous capacities, such as recreational painkiller users, may not benefit from prohibitive policies that punish access; in fact prohibitions may stand in their way of receiving help for drug abuse and addiction.18

18 Greenwald, Drug Decriminalization in Portugal.
Still, a liberal paternalist might defend some pharmaceutical restrictions while still accepting that the current system is seriously flawed. The research by health economists overwhelmingly suggests that less prohibitive restrictions would promote patient health on balance, but liberal paternalists might still favor some limits if in fact those limits did prevent people from undermining their health and their autonomous capacities below a minimum threshold or more generally.

3. Liberal Paternalist Limits on Self-Medication

Liberal paternalists might worry that unrestricted access to pharmaceuticals would undermine patients’ objective interests in some cases, even if it is on balance better than the current system. Insofar as patients use pharmaceuticals for non-medical reasons, liberal paternalists might also be concerned misuse and abuse or patient anxiety from too many choices.

Let us now return to the assertion that paternalistic limits on self-medication are permissible because self-medication does not protect an interest that is as objectively important as other basic rights. While liberal paternalists often appeal to the intuition that our interests in using heroin or feeling the wind in our hair at 85mph are not objectively that important, they all agree that our interest in our own health is crucial. If I am right about the empirics and prohibitive policies actually undermine our health in some cases, then in these cases paternalistic restrictions on prescription drug use not only fail to achieve their stated paternalistic aims, they seriously wrong patients by undermining an objectively important interest.

Granted, these arguments only support a qualified right of self-medication because it only protects self-medication in cases where a patient’s health could improve
with more access. Liberal paternalists who favor prohibitions on recreational drug use will similarly argue that a patient’s interest in recreational pharmaceutical use is not very important. Yet the vast majority of prescription-grade, unapproved, and experimental drugs are not used recreationally, and insofar as promoting one’s own health is an objectively important interest, so too are many rights of self-medication.

Still, some paternalists have adopted de Marneffé’s distinction between morally serious liberty interests and less serious interests to justify paternalistic pharmaceutical restrictions. For example,

[The] decision to use an untested drug is not usually based upon a fundamental tenet of the person’s belief system. Thus, an interference with this decision will not encroach upon the person’s deeply held beliefs or upon his basic approach to life.19

Yet this line of defense fails because while the decision to use experimental drugs is not generally an integral part of a person’s deeply held beliefs or approach to life 1) it could be, and 2) patients who suffer from conditions that can be treated with experimental medicines then develop the belief that using untested drugs is important, even if it is otherwise rarely a part of anyone’s more general approach to life.

Liberal paternalists might even allow for rights of non-medical self-medication if institutions can address their concerns about widespread pharmaceutical misuse and

19 Thaddeus Mason Pope, “A Definition and Defense of Hard Paternalism: A Conceptual and Normative Analysis of the Restriction of Substantially Autonomous Self-Regarding Conduct”, January 25, 2008. Cited on pg. 364 ft. 220 as “Brody (1983) pg192,” Pope also references “Goldman & Goldman (1990) pg. 73-74” where the authors explicitly contrast contrasting prescription drug laws with “others that would block central values of agents” such as rights to participate in dangerous recreational sports. Pope’s dissertation did not include a bibliography, so I am unable to verify these original citations beyond Pope’s use of them.
abuse without resorting to prohibitions. In some cases, non-medicinal pharmaceutical use is seemingly against users’ objective interests in the same way that recreational drug use is not in many users’ objective interests.\(^{20}\) In many of the standard cases like recreational drug use, liberal paternalists favor prohibitive policies because restrictions are the *only way* to avoid objectionable acts of self-harming. The thought is that the *only way* to prevent cyclists from dying because they didn’t wear helmets is to prevent them from riding without helmets. Similarly, proponents of prohibition assume that the *only way* (or at least the best way) to prevent drug users from becoming addicted is to prevent them from using the drugs in the first place.

Whether prohibitive policies are in fact warranted in these cases of risky behavior (I doubt they are), this kind of concern about pharmaceutical misuse and abuse can be addressed through non-prohibitive forms of paternalism. For example, states might require that untested and dangerous pharmaceuticals are sold behind the counter with explicit dosage instructions and only after consultation with a pharmacist or other expert. Liberal paternalists who are concerned about self-harming might even require patients to pre-consult with a pharmacist or physician before buying drugs (though I will argue against these requirements in a later chapter).\(^{21}\)

Behind the counter systems could also include voluntary registries that enable painkiller addicts to commit to avoiding painkiller use, much like gambling addiction

\(^{20}\) The empirical evidence from the Chapter 2 suggests that on balance pharmaceuticals will work as they are designed, to make people better, not worse, and in any case restrictions do not mitigate the possibility of misuse and abuse; they may even increase instances of pharmaceutical misuse.

registries at casinos. Patients who wish to avoid the possibility of misuse or who do not trust themselves to make the right decision about which drugs to use would still have the right to pay and consult with physicians and to follow physicians advice under a non-prohibitive system. Insurance companies might require patients to consult with medical advisors before taking dangerous pharmaceuticals or risk waiving certain medical services. Governments could still require and conduct clinical trials as a means of learning and disclosing all the relevant information about new drugs, without prohibiting drugs that are undergoing the trials or drugs that fail to pass government standards.

These represent only a few of the less prohibitive strategies that aim to protect patients’ health without limiting their liberties. Not only are these non-prohibitive paths more compatible with the liberal paternalists instinct to assume a presumption of liberty, they might even be more effective at promoting patients’ health than prohibitive policies if a more permissive system would bring non-medical use into the open so users could get help and be monitored. A similar problem with alcohol prohibition in the 1920’s may exist today with pharmaceutical use—the costs of prohibition outweigh the costs of permission, even though permissive policies have real costs.²²

For extremely addictive and harmful drugs liberal paternalists might even endorse limited prohibitions. For example, narcotic medications and drugs that are seriously risky and difficult to use might be withheld from patients without prescriptions while all other drugs are permitted behind the counter. I think that these more qualified policies are a mistake, especially because consequences of black markets may be on balance more harmful even to medical users, and also for reasons that I will develop in the next few paragraphs.

²² Here I am referring both to the economic costs of regulation and enforcement, which I described in Chapter 2, and the human cost of prohibitive policies.
chapters. Still, if liberal paternalists can come with me this far they have already endorsed radically less prohibitive prescription drug policies than the regulations that most countries currently enforce.

Liberal paternalists who seek to promote citizens objective interests may be concerned that the presence of an option to access medication would itself be harmful. This is premised on the idea that additional choices sometimes cause greater patient anxiety and dissatisfaction. David Velleman flags this concern about physician-assisted suicide— if deadly drugs are available, terminally ill patient might feel pressured to use them. In *The Paradox of Choice*, psychologist Barry Schwartz famously showed that having more consumer choices tends cause anxiety, and leaves consumers unhappy with whatever they choose. On the other hand, experimental economists and psychologists have also shown that people value having options in the future, and will pay irrationally high prices to preserve low-value future options. This is called diversification bias. Both of these findings are relevant to a right of self-medication. These considerations show that the presence of more consumer choice may make patients less satisfied with their treatment decisions, but patients might still value having more treatment options all the same. Even if an institutionalized right of self-medication did cause more anxiety for all patients, widespread low-level unease wouldn’t necessarily outweigh the anxiety and

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frustration that is borne by the few patients who would use options that they presently lack under prohibitive regimes.\textsuperscript{26}

Though the anxiety of choosing is a serious concern for liberal paternalists, prohibitions still aren’t necessarily the solution. A less prohibitive drug system could leave patients just as free as before to defer to their doctor’s judgments and avoid the stress of choosing. Without a prescription drug system, patients could still autonomously decide to delegate judgments about best treatment options to doctors, but those who disagree with their physician’s judgments would enjoy additional options.

4. Epistemic Worries about Unrestricted Access

Supporters of medical paternalism might reply that while the interest in health is important, the interest in using unsafe drugs is not, and paternalistic restrictions merely remove the option to use unsafe drugs, not all drugs. The thought is that safe drugs will be available over the counter or typically prescribed without much trouble. As an empirical point this is false, safety does not always align with permissions and prohibitions. Some relatively safe drugs (e.g. birth control) are prescription-only and some relatively more risky drugs (e.g. alcohol and Tylenol) are not, and experimental drugs might be on-balance safer than existing treatments or no treatment (as I suggested in the previous chapter) but merely lack approval. Liberal paternalists might then revise this claim, maintaining that the potential risks of an unapproved drug are too great to allow and that no amount of safety risk is acceptable if the prescription drug is not being used to treat a diagnosable medical condition. Still, these concerns fail to justify restrictions on access to experimental and unapproved medicines.

\textsuperscript{26} This is a contractualist point about aggregation, see e.g. T. M. Scanlon, \textit{What We Owe to Each Other} (Belknap Press of Harvard University Press, 1999).
Consider first the claim that the potential risks of untested medicines are too great to allow unrestricted access. While it is true that using untested medicines carries great potential risks, the data I presented in the Chapter 2 show that premarket prohibitions are also extremely risky. One way to mitigate the risks of drug lag is to permit access while still requiring testing. This would enable patients to learn about the risks of new drugs along with medical researchers. Such a system would not diminish patients’ ability to learn about the potential risks of new drugs relative to the current system, but it would eliminate the potential risks associated with prohibitive policies.

Further, medical researchers can often anticipate the risks of new drugs by comparing them to similar drugs and testing them on animals. Drugs are never sold to humans, even in the context of clinical trials, without first undergoing animal testing. This kind of evidence can give consumers an idea of the potential risks of a drug before any premarket testing on humans occurs.

I suspect that liberal paternalists will take little comfort in these considerations in favor of a fully non-prohibitive premarket testing system, but again, I hope that the evidence will at least bring such critics halfway. Even if liberal paternalism supports premarket safety tests on the grounds that the unknown risks associated with unsafe drugs are potentially very high, such considerations do not justify premarket efficacy testing requirements, which cause most of the time associated with approval lag. Efficacy testing requirements not only cause needless death and suffering by preventing patients from accessing medication that will benefit them, but once a drug is approved as effective for treating one condition it can legally be prescribed off-label to treat any condition.
In a recent survey physicians unanimously affirmed their support for off label drug permissions. While the very same physicians also supported efficacy requirements their reasons were grounded in the epistemic benefits of efficacy testing, not in any benefits associated with premarket prohibitions. Yet efficacy testing could still help to inform physicians even if it was not used to establish prohibitions, so this reason in favor of efficacy testing does not justify the current testing regime. Since off label drug use is widely considered in the interest of the public health, patients ought to be permitted to access drugs that have not been approved as effective for any particular conditions.

In other words, even if liberal paternalists are not moved to reject premarket safety testing, they ought to reject the premarket efficacy testing requirements that cause devastating drug lags and bring little apparent benefit since many drugs are then prescribed off-label anyhow.

Liberal paternalists may also be concerned with the known risks of drugs if they are very high. Sometimes premarket testing finds that drugs are incredibly risky; so dangerous that pharmaceutical regulators deem the risks as unacceptable and drugs are not approved for use in humans. Yet even if these kinds of unapproved drugs are generally unacceptably risky, for certain kinds of patients the risks may be worth it. I will discuss extremely dangerous drugs in the next chapter, but for now I will just note that liberal paternalists who are tempted by the view that some extremely dangerous drugs ought to be prohibited full-stop might consider the prescription-only model for these kinds of drugs. This kind of a less prohibitive policy would allow some patients to access

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heretofore unapproved drugs and would still empower physicians to determine whether using a risky drug was in a patient's objective interest. Even for the riskiest drugs, liberal paternalists should favor less prohibitive policies as alternatives to blanket prohibitions.

Now consider the claim that no amount of risk is acceptable for a drug that does not treat any approved medical conditions. Paternalists who advance this claim are arguing that patients should not be permitted to compromise their health by risking side effects or using dangerous drugs unless their health stands to benefit on balance. This claim then implicitly privileges health-concerns over other features of a patient's well being or objective interest. When physicians or regulators decide whether a drug is safe enough to be prescribed for a given condition, they do not merely assess the empirical risks and benefits of the drug. They also make a judgment about whether the risks of that drug justify the benefits, given the patient's condition. Yet this is not only a judgment about science; it is also a judgment about the patient's objective interest. But on this point we have no reason to believe that scientific experts are the experts about patients all things considered interests.

Physicians and regulators are experts about pharmaceuticals, so we ought to defer to them about empirical facts about drugs, but patients are experts about themselves and their bodies, and patients who seek to use pharmaceuticals generally seek them out to promote their own health and capacities. Liberal paternalists, who are concerned with the whole person's objective interests, should then defer to patients about whether the risks of a drug are worth it.

A related epistemic worry is that patients who are motivated to promote their own health and capacities still might fall short of doing so because they are ignorant or
unintelligent.\(^{28}\) Here liberal paternalists will argue that paternalism is permissible because patients cannot become sufficiently informed about the nature of pharmaceuticals in order to make good medical choices. Unlike hard paternalism, prescription drug regulations are therefore justified as soft paternalism because uninformed and ignorant patients choices cannot be truly voluntary.

In *Harm to Self*, Feinberg puts the worry like this:

> As a general rule, if a layman disagrees with a physician on a question of medical fact, the layman may safely be presumed wrong . . . Hence the state intervenes to protect him not from his own free choices, but from his factual ignorance.\(^{29}\)

Therefore, Feinberg argues, prescription requirements are justified on the grounds of soft paternalism. Should we accept this hypothesis about patient ignorance? Certainly physicians and medical experts have real epistemic advantages over the ordinary patient. Not only does medical training and experience make experts uniquely qualified to evaluate the scientific properties of pharmaceuticals, but also experts devote more time to learning about pharmaceuticals than the average patient.

On the other hand, the immediate response to patient ignorance ought to be to inform patients so that they may consent to treatment, unlike other medical choices the prescription drug system does not attempt to educate patients about the risks and benefits of treatment as a precondition for consent. Also, patients are much more motivated to investigate their own particular treatment options than a physician who sees 40 patients a


\(^{29}\) Feinberg, *The Moral Limits of the Criminal Law.*, pg 128
day. While patients may have been unable to research their medical options in the past, technological advances such as online databases of drug information and websites that give targeted health advice may make this more of a possibility. Also, the current state of patient ignorance might be a result of learned helplessness in the face of restrictive policies. In any case, a move to behind-the-counter status for prescription and experimental drugs could encourage patients to learn more about the medicines they take then they currently know.

Patients might even know their medical interests better than physicians. A recent “pragmatic trial” conducted by British medical researchers tested how different asthma treatments fared in typical use. Clinical trials indicated that some asthma controllers preformed better than others, but in the pragmatic trial researchers found that the choice of controller did not matter because most asthma sufferers did not use their controller medication every day anyhow.30

Similarly, in some cases the best treatment for a condition, like coronary artery narrowing, also carries the highest risks if patients do not effectively use their medication.31 Physicians cannot know whether a given patient is capable of benefiting from a medicine that is difficult or costly to take, but on this point patients themselves are the experts about their own likelihood to use medicine properly. Patients who know they are likely to misuse a medication or who are confused by complicated schedules might opt for treatment plans that are less vulnerable to patient error while more capable

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patients might choose treatments that have better clinical results but are prone to error. Under the current system, patients are not empowered to make these kinds of decisions for themselves, even though they have an epistemic advantage at assessing their own prospects with a given treatment.

If patient ignorance is a severe problem today it is not clear that the current prohibitive prescription drug system is justified. If patients who are using prescription drugs today truly are ignorant of the nature of the drugs, then these patients are not able to give informed consent for the drugs they use. However, most physicians and pharmacists and everyone else seems to think that patients who currently take prescription drugs do consent, so they must be sufficiently informed about the drugs that they take. Since there is no reason to think that only those patients who currently receive prescriptions are capable of understanding the prescription drugs they take, patient ignorance does not seem to be a concern for prescription drug use more generally.

Even if patient ignorance were a problem for ordinary prescription drug users today, restrictions would not be the solution anyhow. Physicians, regulators, and pharmacists should aim to treat consenting patients, not to withhold treatment from patients who cannot consent because they lack information. A prohibitive policy in this case is akin to citing a lack of patient information before a surgical procedure as a reason to commit medical battery. Instead of prohibitive policies, liberal paternalists who believe that patients are too ignorant to understand pharmaceuticals should first favor information disclosure requirements, informed consent, and patient education programs.

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32 Imagine that a surgeon took out a patient’s kidney without the patient’s consent, and then offered as his justification, “he had no idea what losing a kidney entailed!” That’s not a justification for coercion; it just makes the coercion worse!
5. Paternalism and Participation in Fair Institutions

Another argument in favor of paternalistic restrictions is that sometimes paternalism is warranted in order to secure the conditions necessary for a fair society. For example, John Rawls and Samuel Freeman argue that basic rights are distinctive because they are preconditions to participation in fair institutions.

As above, capacities are crucially but instrumentally important to liberal paternalism. In this case the importance of autonomous capacities depends on the fact that an autonomous citizenry is required for a fair society, not that autonomous capacities are required for an objectively valuable life. Liberal paternalists of this sort then advance whatever system of liberty, restrictions and permissions, would best enable a fair society. Freeman states this argument as follows:

My position is that liberalism is not incompatible with certain restrictions on self-destructive conduct, even if such conduct is informed, voluntary, and rational in the ordinary sense… citizens in a constitutional democracy have a duty to maintain the degree of competence necessary to exercise the capacities of agency that enable them to reflect on their good and observe the moral requirements of social life. 33

We can see the argument for this kind of view most clearly with the examples of freedom of religion and rights of drug use. In order to participate in fair institutions citizens must be able to freely debate political matters in public, and develop their own views about which policies would be best. For many people religious matters directly bear on their assessments of policy, and they find it important to consult with religious

33 Freeman, “‘Liberalism, Inalienability, and the Rights of Drug Use’.”
communities before deciding how to vote or whether to accept a new law. Given this fact, states should protect freedom of religion in order to ensure that everyone can participate in fair social institutions. On the other hand, some choices actually undermine citizens’ capacities to participate in fair institutions, and so a system of liberties can rightly limit these kinds of choices. Freeman makes the case for prohibitions of intrinsically debilitating drugs like heroin and cocaine partly on these grounds, while acknowledging that the level of incapacitation matters for whether prohibition is justified—marijuana use should probably be permitted. 34

The justification for such a system is empirically contingent. We can imagine a relatively unfree society that did not protect freedom of religion or prohibit recreational drugs. In such a society citizens may nevertheless develop their own informed views about public policy and participate in fair institutions. We might also imagine that religion truly was “the opiate of the masses” such that it undermined citizens’ capacities for reflective agency, in which case liberal paternalists like Freeman would presumably support limits (assuming also that limits did not undermine the strains of commitment and cause everyone to reject liberalism.) 35 Or, we might imagine a society where using drugs like LSD enabled citizens to think more creatively about political issues, to the extent that all citizens affirmed the importance of LSD use for their participation in fair institutions. 36

34 Ibid.
35 Marx famously compared religion to an addictive drug. Karl Marx and Joseph O’Malley, Critique of Hegel’s “Philosophy Of Right” (CUP Archive, 1977). pg. 131
36 Steve Jobs and members of the Beatles famously claimed that LSD made them more creative. The scientific evidence on this claim is mixed, but some studies have found a link between moderate acid use and creativity. See for example, W. McGlothlin, S. Cohen, and M. S McGlothlin, “Long Lasting Effects of LSD on Normals,” Archives of
The standard liberal constellation of liberties is then justified by the assumption that in most societies drugs do undermine people’s autonomous capacities, and people’s religious views do seem to bear on whether coercive laws are justifiable to them, so a state that is concerned with making justifiable policies will need to take religious toleration seriously and limit drug use given these facts.  

Does this form of liberal paternalism tell in favor of prohibitive pharmaceutical policies? Likely not in the case of most prescription drug and premarket testing policies. Prescription drugs are widely available to anyone with a prescription, and experience with these drugs has shown that they are not intrinsically debilitating for those who use them properly for therapeutic uses. Further, only premarket safety testing is designed to address the potentially debilitating aspects of new drugs, so prohibitive efficacy tests cannot be justified on this basis unless using an ineffective drug is seriously debilitating. And so once again, liberal paternalists ought to if nothing else endorse fewer testing requirements for new drugs.

Even if pharmaceutical use isn’t necessary for citizens’ autonomous capacities, liberal paternalists like Freeman who wish to defend the current prohibitive regime must show further that such policies are necessary to promote citizens’ moral powers or

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37 Freeman, “‘Liberalism, Inalienability, and the Rights of Drug Use,’.”
promote other social justice ends. Otherwise, restrictions on access to medication violate
the Freeman’s own interpretation of the presumption of liberty. 38

Still, liberal paternalists of this sort might still argue in favor of restrictions in two
cases where self-medication undermines citizens’ capacities to develop and pursue their
projects and to participate in fair institutions. These cases are drug abuse and unsafe
experimental drugs.

First, liberal paternalists like Freeman, those who support some restrictions on
recreational drugs, might worry that some prescription drugs are relevantly similar to
drugs like heroin or cocaine. Already black markets for prescription-grade painkillers
have emerged that mirror the black markets for street drugs. I will address concerns about
addiction in more detail in Chapter 11, but for now I will flag a specific worry about
Freeman’s argument in favor of prohibiting addictive drugs.

If Freeman’s concern is that the debilitating effects of prescription drug abuse and
addiction will undermine citizens’ ability to participate as equals in a fair society, then

38 Unlike de Marneffe’s understanding of the presumption of liberty which holds that
paternalism is not warranted if it limits an objectively important right, Freeman argues
rights cannot be limited except for the sake of other rights or social justice. A right of
self-medication does not generally bear directly on matters of distributive equality in the
way that the positive provision of health resources would, so liberal paternalists like
Freeman must show that the right of self-medication undermines citizens’ other liberties
in some way. Since self-medication is a self-regarding choice, this case is unlikely to
succeed. This is why Freeman accepts limits on liberties that prevent citizens from
jaywalking or loitering in the park, despite the fact that such limits might offend against a
more general right of free choice. Unlike de Marneffe who accepts these kinds of limits
on the grounds that one’s interest in jaywalking or loitering is not very important,
Freeman accepts these kinds of limits on because they serve a broader social purpose
(safer roads and parks). Alternatively, if loitering or jaywalking violated other liberties,
particularly basic liberties, Freeman would also accept limits. In these ways Freeman and
de Marneffe will accept similar extensions about what the presumption of liberty entails,
but for different reasons. I am grateful to Annie Stilz for helpful conversation on this
interpretive point.
liberal paternalists like Freeman should not favor prohibitions that create black markets, instead they ought to treat the problem head on. Pharmaceuticals are uniquely suited for oversight because they are currently sold in a regulated market that enables monitoring and intervention in cases of misuse and abuse.\textsuperscript{39} Instead of prohibiting the use of addictive pharmaceuticals for all citizens, states can monitor recreational drug use to anticipate cases of abuse that are so severe that addicts will lack the capacity to act as citizens of a just society. Once identified, extreme addicts can be provided additional resources that will ensure that their autonomous capacities do not fall below whatever relevant baseline is required for them to participate as equals. In short, even if some prescription drugs do have troubling addictive and debilitating properties, non-restrictive systems that provide support for addicts to ensure that no one’s autonomous capacities are unacceptably damaged or destroyed by drug use might limit these effects better than prohibitions.

Under a non-prohibitive pharmaceutical system, untested drugs would be required to carry a label that disclosed experimental status, and also that disclosed any potential ill effects based on previous research and available information about the drug’s components. Still, drugs that have not been tested for safety still carry the risk that they could incapacitate those who use them. For experimental drugs like these we must

\textsuperscript{39} Unlike hard street drugs, prescription drugs are manufactured by recognized corporations and distributed through pharmacies. This feature of pharmaceuticals enables non-prohibitive regulation that can soften the depilating effects of drug abuse and addiction without criminalizing the drugs themselves. Above I mentioned addiction registries, similar to gambling registries at casinos, unrestricted access to methadone treatment and counseling might also help addicts and painkiller abusers.
consider the magnitude of the harm with respect to citizens’ overall autonomous capacities.  

Presumably, few people currently desire or attempt to use experimental medicines that have not been tested for safety. The only substantial constituency that has systematically lobbied for access to experimental drugs is terminally ill patients. If Freeman’s worry is that certain drugs will damage people’s capacity to participate in fair institutions, he ought to also worry conditions like terminal illnesses will damage the relevant capacities as well. If the goal is to promote people’s autonomous capacities on balance then the incapacitating effects of a deadly drug lag surely outweigh the potential damage of unsafe drugs. If nothing else, terminally ill patients ought to be permitted to opt out of prohibitive testing requirements in order to have the chance to maintain their autonomous capacities.  

More generally, I am skeptical that even a liberal paternalist like Freeman should endorse most actual prohibitive pharmaceutical policies. Anyone who is concerned with patients’ ability to stand as equals in a fair society ought to reject policies that limit people’s rights on the basis of their health or ability level and let thousands of patients needlessly die. Freeman is also a Rawlsian, and so we might ask whether impartial institutional designers in the original position would choose to limit the pharmaceutical freedom of terminally ill patients for paternalistic reasons.

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40 Experimental drugs that have not been tested for safety are generally unavailable, so I cannot make any empirical claims about the effects of making them available.
41 I also think that everyone should have access to unapproved drugs, even internal to Freeman’s own framework. While some non-terminally ill people will use untested experimental medicines, just as people engage in all sorts of life threatening or risky behavior, like rock climbing, for bad reasons, but when the numbers of people who face these risks are small and the cost of lessening the risk is prohibiting a good for legitimate users, even liberal paternalists do not favor prohibitions.
Still, there are some aspects of self-medication those liberal paternalists like Freeman will not allow. Dangerous drugs that permanently undermine autonomous capacities will be disallowed within Freemans framework, as will deadly drugs that obliterate autonomous capacities. Most drugs are not permanently debilitating or deadly though, so liberal paternalists who are concerned with citizens’ ability to participate as equals in a fair society should reject pharmaceutical paternalism in most cases.

6. Conclusion

In this chapter I have argued that liberal paternalists, those liberals who favor restricting citizens’ rights to engage in self-destructive behavior, should nevertheless favor less prohibitive pharmaceutical restrictions. Even if we grant the liberal paternalists’ premise that some kinds of paternalistic prohibitions are permissible, the case for the current system of regulation is weak, especially in light of the empirical evidence and the liberty interest at stake. Even a liberal paternalist ought to endorse my call for substantial reform. Still, this evidence does not establish that a fully non-prohibitive system is the best approach, so in this chapter I have tried to reconstruct how a liberal paternalist might approach pharmaceutical regulations and suggest that liberal paternalism tells in favor of fewer prohibitions.

This chapter has been an attempt to persuade liberals who, unlike me, are comfortable with paternalism in other policy areas that paternalism in pharmaceuticals isn’t justified for the standard reasons; pharmaceutical use does not undermine our objective interests or capacity to participate in fair intuitions. Hopefully I have convinced at least some liberal paternalists that we as liberals should rethink the paternalistic justification for prohibitive pharmaceutical regulations.
Later, I will develop the further argument that paternalistic pharmaceutical regulations are always seriously unjust. While I have shown that liberal paternalists ought to endorse less prohibitive pharmaceutical policies, even those prohibitions that a liberal paternalist would allow would violate our rights to self-medication. Therefore, not only does the liberal paternalistic justification for the current system of pharmaceutical restrictions fail, almost all pharmaceutical restrictions are wrong.
V. Self-Medication as Self-Defense

Innocent people have rights to defend themselves against threats, even if those threats come from the state. This principle has been widely affirmed and dates to Hobbes, who argued that the sovereign could not prohibit its citizens from accessing “food, air, medicine, or any other thing necessary for life.” Hobbes argued further that people had no obligations to obey laws that threatened to deprive them of the necessary means for sustaining their lives, and that it was permissible to use force against the state for the purposes of self-defense. It is particularly noteworthy, for our purposes, that Hobbes includes medicine as one of the things necessary for life. Today, all developed countries deprive people from accessing experimental drugs that could save or drastically improve their lives. In this chapter I will argue that states cannot permissibly prohibit terminally ill and severely unhealthy patients from accessing unapproved drugs that could save their lives, and that patients can permissibly access unapproved drugs illegally. Further, I will argue that states ought to actively facilitate and provide access to dangerous and experimental drugs and help people to make informed decisions, in contrast to the prohibitive policies they currently enforce.

To motivate this chapter, consider this case. Abigail Burroughs was 21 when she died of cancer. In the last stages of treatment Abigail’s oncologist suggested that an experimental drug, Cetuximab, might treat the kind of cancer cells that were killing her, but the drug was only available in clinical trials for colon cancer, and Abigail had head

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2 I am grateful to Annie Stilz for pointing out this helpful reference.
and neck cancer. Abigail died in 2001. In 2006, Cetuximab was approved for treating head and neck cancer as well.³

Abigail’s story, and hundreds like hers, shows that pharmaceutical regulation stands in the way of patients using lifesaving drugs. Abigail suffered from a treatable cancer, and the means to cure her cancer existed at the time of her death. Abigail and her doctors could have improved her health and possibly saved her life were it not for prohibitive approval policies that threatened steep penalties for anyone who provided patients like Abigail with experimental medicines. Many patients with terminal illnesses, even patients who are participating in clinical trials, would risk these penalties for the chance to save their own lives. It is more difficult for them to convince physicians to take personal and professional risks of their own on a patient’s behalf, so patients have few options. Thus, as a result of policies that effectively interfere with the consensual treatment decisions made by patients and provider, patients like Abigail die.

In section 1 I will argue that people with terminal illnesses have rights of self-preservation that entitle them to legal exemptions from bans on unapproved drugs. In section 2 I argue that patients who are severely sick and people with degenerative illnesses also have rights of self-preservation. In section 3, I argue that it is permissible to illegally assist patients in accessing unapproved medicines. In section 4 I will argue for a duty to provide access to potentially lifesaving and unapproved drugs. Last, I will consider the objection that these exemptions for terminally ill and severely sick patients would impose unacceptable costs on others because they would compromise the clinical

1. Medical Self-Defense

The right to defend one’s own life through non-lethal means is relatively uncontroversial.\(^4\) Further, we have rights use lethal force to preserve our lives against villainous attackers and active threats, and some philosophers, like Judith Thomson, have argued that it is also permissible use lethal force against innocent aggressors.\(^5\) For now, let’s assume only that we have rights to use non-lethal force to preserve our own lives and I will return to Thomson’s conception of self-defense shortly.

Self-defense doesn’t come up much in medicine, because in general physicians and medical staff aim generally to work with patients to save lives, so patients’ rights against life-threatening interventions do not arise. Yet there are a few intersections between self-defense and medicine. First, the doctrine of informed consent to a limited extent protects patients’ rights against interventions that the patient deems unacceptably risky to her life or health. Second, if a pregnant woman’s life or health is threatened by continuing a pregnancy she has the right to abort a viable fetus if doing so is the only way to avoid the risks associated with continued pregnancy.\(^6\) This right applies even if the woman’s risk of death from continuing the pregnancy is relatively low, and even if the pregnancy only poses a serious threat to her health but does not threaten her life.\(^7\)

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\(^4\) Some consequentialists and utilitarians may disagree.
Third, Abigail’s story, and the court case that followed, raises the possibility that a broader right of self-defense may entail access to experimental medicine. Before Abigail died, she and her father, Frank Burroughs, founded the Abigail Alliance for Better Access to Developmental Drugs. After her death, Frank sued the FDA and the Department of Health and Human Services on her behalf, alleging that the failure to permit terminally ill patients to access experimental drugs violated the fundamental right to preserve one’s own life. In 2004 a D.C. district court ruled against the Abigail Alliance, but in 2006 a three-judge panel of the DC Circuit Court of Appeals overturned the ruling and found that terminally ill patients do have a constitutional right to purchase experimental medicines that had successfully passed Phase 1 safety testing.\(^8\) There, the judges argued:

The prerogative asserted by the FDA — to prevent a terminally ill patient from using potentially life-saving medication to which those in Phase II clinical trials have access . . . impinges upon an individual liberty deeply rooted in our Nation’s history and tradition of self-preservation.\(^9\)

Then the FDA petitioned the court of appeals to rehear the case en banc, whereupon a divided court denied that access to experimental drugs was a fundamental right.\(^10\) The

\(^{8}\) Abigail Alliance v. Von Eschenbach, 445 F. 3d 470 - Court of Appeals, Dist. of Columbia Circuit 2006


\(^{10}\) In part, this reversal was justified by the argument that greater patient access would undermine the clinical trial system. I will address this objection later in this chapter. For a discussion of this argument see Rebecca S Eisenberg, “Role of the FDA in Innovation Policy, The,” *Michigan Telecommunications and Technology Law Review* 13 (2007 2006): 345.
Alliance’s legal options were exhausted in 2008 when the Supreme Court declined to accept further appeal.

This episode points to a tension within medical ethics. On one hand, patients have rights of medical self-defense, including the right to refuse treatment that they deem too risky and also the right to have a therapeutic abortion, insofar as it is necessary to preserve one’s own life or health, at any point in a pregnancy. On the other, patients like Abigail are not permitted to save their own lives by using unapproved but potentially lifesaving drugs.

Eugene Volokh has argued that the panel was correct and that the en banc ruling was wrongly decided in Abigail because patients’ rights of medical self-defense in experimental drug cases is not morally different from patients’ rights of self-defense in other cases. Volokh poses the following analogy. Imagine a woman, Katherine, is trying to use a gun to kill an attacking grizzly bear, though there is some chance that in firing the gun she will miss the bear, angering him further and making her own death quicker, more painful, and more certain. Still, Katherine has a right to use the gun to try to protect herself from the attacking bear. Similarly, imagine that Ellen is trying to use experimental drugs to kill otherwise treatment-resistant cancer cells. Even if Ellen’s drug use does pose a risk of making her death quicker, more painful, or even more certain, she has a similar right to use the drugs if they have a chance of saving her life when she is otherwise in grave danger. As Volokh writes,

This is not a general autonomy argument, premised on the theory that all people should be free to put whatever they choose into their bodies. Rather, the argument

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11 Volokh, “Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs.”
focuses specifically on the right to medical self-defense, a right supported both by the Supreme Court’s case law (Roe and Casey) and by the longstanding acceptance of the right to lethal self-defense.\(^{12}\)

While a more general right of medical autonomy or bodily autonomy also supports rights to use experimental drugs, a much less controversial normative premise supports rights of access for patients like Abigail.

As a first pass, this argument justifies *at minimum* expanded rights to access drugs for patients with terminal illnesses. That is, terminally ill patients have the right to use drugs that could save their lives even if the drugs have not passed the required tests, either because the drugs were not approved or because the drugs are still being tested. Another reason to endorse such an expansion of rights for terminally ill patients is that the traditional justification for premarket safety requirements, and for an approval process more generally, is to preserve patients’ lives and health. But patients with treatment-resistant terminal illnesses face certain death without access to unapproved medicines, so prohibitive policies that aim to protect patients from risky drugs are not justified in these cases where the risks of the drugs, whatever their magnitude, cannot outweigh the risks of non-treatment.

This argument points to two kinds of institutional solutions that would facilitate terminally ill patients’ rights of self-preservation. First, people with treatment-resistant terminal illnesses ought to be granted *exemptions* from premarket testing requirements and bans on experimental and unapproved drugs. For example, if a patient is given less than a year to live and her illness is not responsive to any available treatments, and then

\(^{12}\) Volokh, “Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs.”
she ought to be permitted to access any drug that could potentially treat her illness without fear of any legal penalties or sanction.

Second, terminally ill patients ought to be permitted to waive their rights against risk, that is, to exempt manufacturers from legal liability for adverse drug effects. This second institutional solution is warranted if, in practice, waiving liability for adverse effects is necessary to induce drug manufacturers to sell risky experimental and unapproved drugs to terminally ill people. In these cases, waiving one’s rights against risk are a necessary means to self-preservation, so terminally ill patients should also be permitted to waive their rights against risk.

2. Self-Defense and Minimum Functioning

People have rights of self-defense even when their lives are not in danger, but when their condition threatens their health so severely that they live (or will soon live) below a critical level of well-being. For example, the basic rights theorists that I discussed in the previous chapter all affirm that citizens have negative and positive rights to whatever health care is necessary for adequate level of well being or capacities. Henry Shue frames these rights in terms of security and subsistence—people have rights against any threats or deprivations that would make them unable to exercise their other rights. This sufficientarian conception of rights expands on the above conception of self-defense to include 1) rights to preserve one’s health to some extent, and 2) rights against deprivations.

Consider (1). Not only do people have the right to defend themselves against life threatening forms of interference, they also have rights to defend themselves against forms of interference that could severely undermine health and capacities. That is, even if
a victim is sure that her attacker will only leave her injured or disabled, she still has a right to defend herself in these cases. Similarly, even if a patient suffers from a debilitating but non-terminal disease, or a degenerative condition that threatens to become debilitating, such patients still have rights to access any medicine that could prevent their health from compromising their capacities or well being below a minimum baseline of human functioning.

Consider for treatment resistant clinical depression as an illustration of disease that undermines a person’s well being and capacities below a critical level of well being. Depression is a debilitating disease, many people who suffer from it cannot maintain steady employment, and cannot pursue or enjoy any other projects. Further, depression causes extreme suffering for long periods of time. Clinical trials have indicated that patients with severe treatment resistant clinical depression respond favorably to Ketamine, and that in some cases, Ketamine can quickly alleviate all depression symptoms. However, Ketamine (also known as the recreational drug Special K) is not approved to treat severe depression, in part because it can cause severe adverse side effects including hallucinations. In some cases, Ketamine use can even cause death. And so, patients with treatment resistant clinical depression continue to suffer from their illness despite the fact that Ketamine might help them, because Ketamine is not approved except for veterinary use or as an anesthetic that can only be accessed by anesthesiologists. If patients do attempt to access prohibited treatments despite the risks, they even face criminal penalties. For example, in the US Ketamine is a schedule III

substance, and people who attempt to sell, purchase, or use Ketamine are subject to investigation and punishment by the Drug Enforcement Administration.\textsuperscript{14}

Patient safety is cited as the justification for Ketamine restrictions, even though patients with treatment resistant clinical depression are left otherwise to suffer below an adequate baseline of human functioning. More cruelly, those patients who might attempt to improve their capacities are prohibited from trying on the grounds that the risks are unacceptably high. As in the case of Abigail Burroughs, prohibitive pharmaceutical policies ensure that patients will suffer below an adequate baseline of human functioning, and in this way, prohibitive policies violate the rights of patients with treatment-resistant depression. Further, as above, the traditional patient safety justification will often fail to justify prohibitions for patients who suffer (or will soon suffer) below a baseline level of adequate health because the costs of non-treatment are extraordinarily high.

And so, each person has a right to access drugs that could save her life and also a right to access drugs that would lift her above a minimal baseline of human functioning. This argument has further implications. Even if regulatory officials judge that the risks and side effects of treatment \textit{generally} outweigh the benefits, those patients who suffer below an adequate baseline of functioning or well being are also entitled to access dangerous and experimental treatments, insofar as the drugs could potentially help and they would continue to suffer needlessly otherwise.

Specifically, this argument tells in favor of extending the aforementioned exemptions and liability waivers to patients who are severely sick or who have degenerative illnesses that will eventually make them severely sick, if untreated. For

\textsuperscript{14} “National Drug Intelligence Center Bulliten- Ketamine,” (US Department of Justice,, July 2004).
example, imagine a patient has been diagnosed with early Alzheimer’s disease, and who will become incapacitated without treatment. Such a patient ought to be exempt from bans on experimental and prohibited drugs that could potentially halt or slow the progression of Alzheimer’s. Further, patients with degenerative diseases like these ought to be permitted to waive their legal rights against the risks of these treatments, insofar as such liability waivers are required for patients to gain access to experimental drugs.

3. Legal Authority

So far I have argued that if a person or some force of nature threatens your life or health, you have a right to defend yourself against that threat. Sometimes prohibitive pharmaceutical regulations threaten patients’ lives or severely endanger their health, and in these ways the regulations violate patients’ rights. Therefore states do not have the moral authority to enforce prohibitive regulations that threaten patients’ lives. Nevertheless, there are currently prohibitive approval policies for drugs in all developed countries. Given these policies, what are the boundaries between state power and citizen obligation? Are patients obligated to obey the law even when it threatens their lives, or are they exempt from legal requirements in cases where the requirements violate their rights in these ways?

Return to the analogy of direct threats. Imagine that it is illegal to kill an endangered species of grizzly bear, but Katherine finds herself under attack from such a bear. Even if the law protecting endangered grizzly bears is in general a justified law, it is not justified in Katherine’s case because it violates her right to defend herself from bear attacks. Similarly, even if prohibitive approval laws were justified for drugs that treat non-terminal illnesses or non-debilitating conditions, for patients who are extremely sick
or terminally ill the laws are not justified. If a prohibitive law jeopardizes a person’s survival, she is exempt from that requirement even if the requirement is justified more generally.\textsuperscript{15}

For these reasons, if patients do manage to illegally access experimental drugs that can potentially save them from death or debilitating illness, they should not be prosecuted or punished. This is a similar claim to the argument that battered women who use force to defend themselves from domestic abusers should not be prosecuted or punished, even if in general it is impermissible to use private force against wrongdoers. To make a familiar Hobbesian point, in these cases, the law is not normatively binding on lawbreakers because adherence to the law seriously endangers their safety.

More generally, physicians are also permitted to break the law to help patients survive in the face of terminal and debilitating illnesses. Imagine that the endangered grizzly is attacking Katherine, and her brother Ken is holding a gun. Even though it is illegal to kill endangered animals, Ken can permissibly break the law if it would save Katherine from death or serious injury. Similarly, physicians can ought to be exempt from legal sanctions when they help patients to access dangerous and experimental drugs that are otherwise illegal.

For example, at the height of the AIDS epidemic some physicians and patients subverted the clinical testing process to distribute potentially beneficial doses of AZT to multiple AIDS patients, despite the fact that the drugs were only prescribed to a few.\textsuperscript{16}

These buyers clubs were illegal, but at the time AZT was the only treatment option for

\textsuperscript{15} I am grateful to Annie Stilz for helping me to develop this point.
\textsuperscript{16} Steven Epstein, \textit{Impure Science: AIDS, Activism, And the Politics of Knowledge} (University of California Press, 1998).
AIDS patients, and so patients and physicians broke the law for the mere chance of survival. Physicians who illegally assisted AIDS patients in preserving their own lives in this case acted permissibly, in the same way that Ken acted permissibly when he illegally shot the endangered grizzly.

This further step also has revisionary institutional solutions. Currently, physicians who provide their patients with experimental and prohibited medicines are subject to legal and professional sanctions. Such sanctions are unjust, because physicians act permissibly when they break the law to help their patients to preserve their own lives. Therefore, just as severely sick and terminally ill patients are entitled to exemptions from bans on unapproved and experimental medicines, so too should their physicians be exempt from legal and professional sanction when they provide unapproved drugs in these cases.

Further, insofar as physicians provide and facilitate the use of unapproved drugs with their patient’s consent, physicians should also be protected from malpractice penalties if the drugs ultimately have bad consequences. This additional provision ensures that physicians are not punished through tort law for facilitating a person’s attempt at self-preservation, since in doing so physicians acted permissibly.

4. Provision of Experimental Drugs

A right of self-preservation might have positive and negative elements. Namely, people are entitled to freedom from life-threatening or unsafe interference and entitled to freedom from depravation. If so, then this conception of the right of self-preservation has even more revisionary implications for pharmaceutical policy. Not only are prohibitive
policies unjust, but also physicians and policy makers are \textit{morally required} to provide life
saving treatments in some cases.

Return to the grizzly bear analogy. Imagine that a bear is attacking Katherine and
Ken is able to provide her with a bear-killing handgun. Ken knows that the gun is
Katherine’s only shot at avoiding death or severe disability as a result of the attack, but
he also knows that the gun may only anger the bear more, thus making Katherine’s death
more painful. Despite the risks, if Ken retains the gun and allows Katherine to die he has
done something wrong. Another analogy- imagine that a some members of a village are
starving due to a poor harvest, and public officials are able to raise taxes and redistribute
food to the starving villagers. Officials and citizens have an obligation to provide for the
starving villagers even if they are not responsible for the famine.

Disease is a natural event like poor harvest, starvation, or grizzly attack. One
might think that no one has any duties to mitigate the bad effects of natural causes, but if
one accepts the premise that there are some positive obligations to assist people who are
greatly in need, whether from natural or intentional causes, then disease is not morally
different from bear attacks or famine. In all these cases, if it is relatively easy to alleviate
great suffering or to save a life, one has an obligation to do so.

This additional premise, that self-preservation sometimes entails positive duties as
well as negative duties, has still more revisionary conclusions for pharmaceutical
approval policies than the foregoing arguments. Not only do policymakers, physicians,
and regulators have an obligation not to interfere with a patient’s attempts to save her
own life and preserve her health above some level adequate functioning or well being,
and not only is it *permissible* for them to assist a patient’s attempts to save her own life, it may also be morally required.

Three specific institutional solutions follow from this argument. Foremost, policymakers ought to lift the bans on access to unapproved drugs, at least for terminally ill and severely sick patients. The easiest way to fulfill the positive duty to assist people in preserving their own lives is to refrain from violating their negative rights to do so.

Second, pharmaceutical policy ought to actively help patients to find access to potentially beneficial but unapproved drugs, rather than actively prohibiting access. For example, regulatory agencies or professional organizations may maintain a public database that contains information about unapproved drugs that nevertheless have shown some success in treating terminally ill patients and people with severe or degenerative diseases. Policy makers may also introduce an additional category of approval specifically for patients in these categories, where extremely dangerous drugs are generally prohibited except as a last resort for the purpose of self-preservation.

Third, insofar as public institutions subsidize and provide sick citizens with drugs, they ought to subsidize and provide any unapproved drugs that stand to enable patients to save their lives or preserve their health above an adequate level of well being or capacities.\(^\text{17}\) This policy solution may seem like too radical of a reversal, not only should states *permit* access but they must *provide* access to dangerous and unapproved drugs as well? But within the broader context of self-preservation it follows from the relatively uncontroversial premise that there are some positive duties to provide people with the necessary means to save their own lives, even if those means also carry significant risks.

\(^{17}\) Some minimal testing may be required before subsidies help patients to access experimental drugs, as a way of establishing that there is at least *some* potential benefit.
5. Harm to Others

So far I have argued on the assumption that using unapproved medicine for self-preservation only puts the terminally ill patient at risk, and that it does not have any negative externalities. Yet this assumption is false, or at least it could be in some cases. In *Abigail Alliance v. Von Eschenbach* the FDA asked the DC circuit court of appeals to reconsider the panel’s judgment that that terminally ill patients’ rights of self-preservation entailed rights to access unapproved drugs, on the grounds that such an expansion of access would compromise the approval process if many patients insisted on using unapproved drugs because the agency and researchers would then be unable to use randomized trials to test the drug’s effectiveness. If people with terminal illnesses were permitted to purchase potentially lifesaving medicines, there would be little incentive for them to enroll in clinical trials and risk receiving a placebo or the standard treatment instead of the drug. In light of this argument, the DC court overturned the ruling in a special *en banc* hearing.

This case raises the possibility that a patient’s right of self-preservation in these cases may impose significant costs on others. There are several responses to this argument. First, as Volokh has argued, this argument does not justify blanket prohibitions on the use of experimental drugs by the terminally ill; it only justifies limits on access in cases when serious social externalities trump rights of medical self-defense.  

18 This means that drugs that were tested but failed to gain full approval, like Ketamine, cannot be prohibited on the grounds that permitting access would undermine clinical trials, because trials have already been conducted.

18 Volokh, “Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs.”
Volokh argues further that blanket prohibitions are not required to ensure that clinical trials are able to test for the safety or efficacy of new drugs:

(This) argument justifies limiting medical self-defense only when such limits are necessary for conducting clinical studies and no other alternatives will do. For instance, if the studies require 200 patients, and there are 10,000 who seek the experimental therapy, there is little reason to constrain the self-defense rights of all 10,000. Likewise, if the drug is now being studied only on people who suffer from a particular kind or stage of a disease, the drug should not be legally barred to those who fall outside those studies. If we must strip people of self-defense rights to save many others’ lives in the future, we should impose this tragic constraint on as few people as possible and to as small an extent as possible.  

In any case, as I argued in an earlier chapter, it is not clear that efficacy testing should be prohibitive at all, since once a drug is approved as an effective treatment for any condition it can be permissibly prescribed for all other conditions without efficacy tests. Since the need to conduct efficacy tests for every particular condition that a drug could treat is not weighty enough to justify prohibiting the off-label prescription of drugs, I am skeptical that the need to conduct efficacy tests justifies prohibiting the sale of potentially life saving drugs.

People whose lives are threatened are often permitted to act in ways that impose costs on others if doing so would preserve their own lives. Many philosophers even

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19 Volokh, “Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs.”
20 For example, citizens are often considered exempt from prohibitions on the private use of force when aggressors threaten their lives. In these cases, the social costs of prohibiting private force are outweighed by people’s interest in self-defense even if there
believe that harmful action is warranted if it is necessary for self-preservation. Judith Thomson has argued that it is permissible to use lethal force against *multiple innocent threats* to preserve one’s own life. For example, imagine that a temporarily drugged but non-blameworthy person is driving a truck with a passenger and the truck is about to hit you. You have a gun, and you could shoot the truck in a way that would make the truck explode, thus preserving your own life but killing the two innocent occupants. In this case, it is permissible to shoot the truck to protect yourself even if the driver and passenger are innocent. If the use of lethal force is permissible for self-preservation in this case, then it may be permissible for patients to access unapproved medicine even if doing so will impose *deadly* risks and costs on others.

Still, there are limits to the costs we can impose on others in the course of saving our own lives. Imagine you are terminally ill and only a liver transplant will save your life. A right of self-preservation would not entitle you to forcibly remove someone else’s liver. To what extent can the right to use lethal force against innocent bystanders for self-defense justify self-preservation in medical contexts? Thomson draws the line between bystanders who are threats (e.g. they are causally responsible for the threat to your own life) and bystanders who are not. In the organ case, the bystander with the lifesaving liver is not a threat, so it is impermissible to kill him. That is, the bystander is not the cause of your potential death, were it not for him you would still be dying of liver failure.

Are beneficiaries of clinical trials more like innocent threats or mere innocent bystanders? Say patient A needs a lifesaving drug, but that drug is being tested for the

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are social costs to permitting private force Annie Stilz suggested this analogy in comments on an earlier draft.

21 Thomson, “Self-defense.”

22 Ibid.
sake of patient B. Were it not for patient B patient A would have access to the lifesaving
drug. In this way, patient B is more like an innocent threat than an innocent bystander
because his actions (or actions on his behalf) are the cause of A’s potential death.
Therefore, since it is permissible to use lethal force against innocent threats to preserve
one’s own life, it may also be permissible to compromise a clinical trial if doing so saves
lives. I will return to these kinds of questions in Chapter 8, but for now I mean only to
raise the possibility that it is permissible to expose innocents to deadly risks in order to
preserve one’s own life if the presence of those innocents is directly threatening. So in the
case of medical self-defense, even if there are serious social costs to permitting terminally
ill patients to access experimental drugs, some lives lost may be justifiable insofar an
alternative system would prevent patients from using drugs to save their own lives.

Even if permitting the sale and use of unapproved drugs for self-preservation
would undermine clinical trials in ways that imposed costs on innocent bystanders, the
mere presence of social costs is not sufficient to justify denying patients their rights of
self-preservation. For example, Udo Schuklenk has argued forcefully that terminally ill
AIDS patients have rights to access experimental medicines even if there are serious costs
to third parties.23 The right of self-preservation is so powerful that health care providers
(e.g. insurers and states) might be asked to absorb the costs in the same way that society
bears the costs of other basic rights.

One objection to this line is that the social costs of permitting unrestricted access
to experimental drugs may be catastrophic, or at least high enough that even rights of
self-defense cannot entitle people to use untested drugs, and that states have no

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obligations to bear the costs of protecting rights of self-preservation. For example, if the death of one innocent is required to prevent a deadly virus from wiping out humanity, then that person’s right of self-defense may be outweighed by impersonal considerations. Analogously, if self-medication made clinical trials impossible and undermined the entire system of medical testing and data collection, then limits to self-medication for the sake of clinical trials would be justified to avert extreme catastrophe. Even if this objection succeeds, it rests on a false empirical assumption.

For one thing, many randomized clinical trials occur today after approval. The FDA itself uses post-approval trial data to extend conditional approval to drugs that are already approved as effective for particular conditions. Post-approval trials are also standard in cancer research, where drugs are generally approved as effective for one kind of cancer, and then tested for other kinds of cancers in post-approval trials. Eric Topol recently described post-approval trails that were designed to assess whether statins (cholesterol lowering drugs) could effectively lower the risk of heart attacks and strokes for relatively low risk patients. These trials included tens of thousands of patients, and at least half of them received potentially inferior treatment despite the fact that the drugs being tested were already available to anyone with a prescription. Patients were informed of this possibility, but enrolled in the trials to receive the other benefits of clinical trials,

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24 This objection was initially posed by Joanna Masel, by way of Peter Singer.
25 I am grateful to Alex Tabarrok for conversation on this topic and for providing some of the following references and examples, which have helpfully informed my response.
including close monitoring and high quality subsidized medical care. All these examples indicate that an end to at least some premarket testing requirements, or expanded access to unapproved drugs, would not catastrophically undermine the clinical trial system since many clinical trials are successfully conducted even when patients have access to the drugs that are being tested.

Another reason to suspect that expanded access to experimental drugs would not make medical testing impossible is that many consumers would not necessarily have sufficient reason not to participate in clinical trials for drugs that have not been tested in clinical trials. That is, if evidence from randomized clinical trials is not available for a drug, it is unclear that patients will push as strongly for access to that drug (rather than participating in a clinical trial, which brings other benefits) unless that patient has no other options. This hypothesis is especially plausible when we consider that clinical trials, if they are ethical, require that patients receive either the standard course of treatment or the drug that is being tested. This standard only requires that patients receive a placebo when no standard course of treatment yet exists. For patients with treatable illness, there is often some chance that the control group will receive the more effective treatment, so incentives to participate in trials remain. Were patients given access to experimental drugs, testing for pharmaceuticals may begin to look more like surgical clinical trials, which are conducted without regulatory oversight. Despite an absence of prohibitions, I haven’t found any evidence that researchers confront difficulties in recruiting patients for surgical clinical trials.

Alex Tabarrok recently pointed out another example that indicates that randomized clinical trials can continue even if patients are free to access experimental
Before the WHI, anecdotal evidence strongly suggested that HRT could reduce heart attacks for women, but the WHI conducted randomized clinical trials of the therapy, which was approved and widely available and prescribed off-label. The WHI successfully enrolled patients in the trial, and the results showed that HRT actually increased women’s risks of heart attack and other ailments, effectively changing the standard of care through postmarket testing. Tabarrok cites this example in making the case that other government agencies could play an important role in conducting randomized clinical trials and educating patients and physicians, but that prohibitive premarket policies are not necessary to this end.

All these examples are meant to show that even if rights of self-defense are not absolute, even if self-defense can not justify granting patients access to unapproved treatments when it would have extreme social costs, that is not a likely scenario for unapproved pharmaceutical today. Still, there are some costs that could plausibly justify limits on access to unapproved drugs, and we must weigh these costs against patients’ rights to save their own lives.

6. Conclusion

To review, my argument has unfolded from the premise that people have rights to preserve their own lives. Terminally ill patients have rights of self-preservation that justified exemptions from experimental and unapproved drug bans and the right to waive rights against medical risks. Patients with severe and degenerative diseases which compromised their health below some necessary baseline level of functioning or well

\[29\] This example was described in an email conversation.
being also had rights to exempt themselves from drug bans or waive liability. In addition, physicians and policy makers may permissibly break the law to assist severely sick and terminally ill people in accessing banned drugs. Indeed, states and physicians have positive duties to facilitate and provide access to many drugs that are currently banned. Even if permitting terminally ill patients to access unapproved medicines would compromise the clinical trial system to the detriment of others, this objection does not justify many of the current prohibitions. In any case, rights of self-preservation may justify imposing some costs, even deadly costs, on innocents insofar as the innocents threaten terminally ill patients’ ability to preserve their own lives.
VI. Deadly Drugs on Demand

Iris and Don Flounders were married for over 60 years. Don had terminal and incurable mesothelioma, a painful form of lung cancer. Iris was not terminally ill, but she had long held that she did not want to live without her husband. As Don’s illness progressed, both Don and Iris wanted to die.

The Flounders traveled to Mexico to obtain Pentobarbital, which is used to euthanize animals and is not available in most developed countries, including their home country, Australia. Before their deaths, Don and Iris recorded a video explaining their choice and arguing for a right to die. In it Don said,

I knew that I would want to have the choice at the end as to how and when I die.

We both very much resented the fact that we had to travel halfway ‘round the world just to have the choice. We should have been able to get this drug at our local pharmacy, to be put safely away just in case, for the future. Iris added, “When we got the drugs I thought I might not want to live on without Don. Three years on, my thinking is the same. We decided this together. No one encouraged us, quite the opposite.” The couple was found dead in their home, arm in arm.

Some critics of the right to die might argue that neither Iris nor Don ought to have been permitted to use deadly drugs. More often, proponents of physician-assisted suicide defend limited legal rights to die. For example, they argue that deadly drugs ought to be available to terminally ill patients like Don (and perhaps patients with severe, painful, pain).

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1 “British Suicide Couple Release Internet Video Calling for Right-to-die Laws’,” Daily Mail, May 1, 2011.
3 ibid
and debilitating illnesses,) but not to all patients. This is the extent of most prominent defenses of physician-assisted suicide. In contrast, few philosophers have considered Don Flounders claim that he should have been able to get deadly drugs at his local pharmacy. In this chapter I will take up such a proposal, and I will argue that suicide drugs ought to be available to any patients who competently choose to end their lives.

I first argue that suicide is always permissible even if some patients seemingly have better reasons for committing suicide than others. Second, I propose that deadly drugs ought to be regulated like handguns or other consumer goods that have deadly potential. Third, I show that legalizing the sale and use of deadly drugs would not have bad consequences. Fourth, I address empirical and moral objections to this proposal. Fifth, I consider the objection that even if suicide is always permissible, limited legalization is a form of justified hard paternalism because some patients may be better off if they are prevented from killing themselves. Sixth, I argue further that unconditional rights to die are required by a principle of non-discrimination. Seventh, I discuss the special case of consumers with depressive reasons for suicide, and I argue that even clinically depressed patients ought to be permitted to use deadly drugs to commit suicide in most cases. Section 8 concludes.

1. The Right to Die

In 1997, John Rawls, T.M. Scanlon, Thomas Nagel, Ronald Dworkin, Robert Nozick and Judith Thomson jointly penned The Philosophers’ Brief, an amicus curae brief for two cases arguing for a constitutionally protected right to die. In it, they argued that the constitution ought to protect patients’ right to die, because the interest in making end of life decisions “is so central a part of the more general right to make ‘intimate and
personal choices’ for himself that a failure to protect that particular interest would undermine the general right altogether. They argued further “death is, for each of us, among the most significant events of life” and therefore merited special institutional protection.

The authors of the Philosophers’ Brief, and most other proponents of physician-assisted suicide, take care to limit their policy proposal to terminally ill patients and to exclude, for example, healthy young adults who have just endured bad break-ups. The argument in the Brief, for example, is that the Constitution protects rights to make intimate decisions, that a protected right to die for terminally ill patients would improve end of life care, and that a protected right to die would not lead to a ‘slippery slope’ to either widespread suicide or non-voluntary euthanasia. The brief supports regulated rights to die. Psychiatric and medical evaluation requirements must establish that the patient is severely sick but mentally healthy and the patient must undergo a waiting period. The administration of deadly drugs is subject to direct oversight in each particular case. The authors also argue that any difficulty of protecting patents’ rights and regulating deadly drugs cannot outweigh the liberty interest at stake when terminally ill people choose to die.

There are political reasons for the choice to limit rights to die to the terminally ill. Selling suicide to any kind of consumer is a deeply offensive proposal to religious conservatives who value the sanctity of life in a way that prohibits suicide for any reason.

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6 Dworkin et al., “Assisted Suicide.”
Also, limits on access may assuage the fears of those who (mistakenly) believe that legalizing access to suicide drugs will set society on a slippery slope to non-voluntary euthanasia, particularly of elderly and disabled patients. As the authors of the brief mention, evidence from states and countries that have legalized physician-assisted suicide strongly suggests that this empirical worry is unfounded but it may impair support for rights to die more generally. Advocating for the terminally ill, whose lives will surely end within six months either way, is good compromise between those who reject suicide in all its forms and those who believe that suicide is permissible.

If the reasons for drawing a moral distinction between terminally ill patients and others are grounded in strategic considerations, we should still address the merits of arguments against any form of suicide. David Velleman has developed an innovative and principled argument against the moral permissibility of suicide in a series of essays. Velleman argues that patients do not have the right to die because rights derive from the value of personal autonomy, and choosing to obliterate autonomous capacities is inconsistent with that value. My response is that even if choosing to die is in some way offensive to the value of autonomy, limiting that choice might be similarly offensive to the value of autonomous choice. As Velleman points out, it is a further question whether

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10 Velleman, “Against the Right to Die.”
interference in deadly choices is warranted in the absence of a right to die, institutional prohibitions on suicide may be more wrong than allowing suicide.

Aside from strategic political reasons for drawing a moral distinction between terminally ill patients rights to die and all other suicidal people, philosophers have cited various principled defenses of this distinction. For the terminally ill, the badness of death cannot be avoided, but they can be harmed by death all the same. In these cases, deadly pharmaceuticals give patients who face very few remaining options, people who have tragically little control over their lives, one final autonomous choice that they can make for themselves. I agree that the strongest case for physician-assisted suicide is often on behalf of terminally ill patients, but suicide is a permissible choice even for patients who do not have terminal illnesses.

There are several reasons that tell in favor of rights to physician-assisted suicide for all kinds of patients. First, the decision to die is an incredibly intimate and important choice. Like other decisions about our own bodies, it is incredibly invasive when policymakers or those around us seek to prohibit a person from choosing to end her own life. Since choosing to die does not violate anyone else’s rights, it is an essentially self-regarding choice as well. Death is a personal decision that no one takes lightly or

11 Ben Bradley discusses how death can be bad for someone who dies, but elsewhere he defends a conception of harm that shows that death can additionally be a harm in some sense (as can continued suffering) if it makes the harmed comparatively worse off than she would have been otherwise. This account of harm is problematic, but for our purposes it illustrates the relationship between the badness and the wrongness of death, and how wrongness and harm doesn’t always align with the badness of death. Ben Bradley, Well-Being and Death, Reprint. (Oxford University Press, USA, 2011).
approaches with indifference. For these reasons, limits on the right to die are invasive interventions into a personal and important decision.\textsuperscript{12}

The philosophers writing the Philosophers’ Brief make this kind of point explicitly when they argued that a right to die merits protection as \textit{basic} (like the decision to use contraception or have a child.) This argument is inconsistent with the limited policy conclusions in the Brief, which are to permit rights to die only in some circumstances. If a right is basic for some then it is basic for all. Some basic liberties merit protection because limits to those liberties would require interventions that offended against the dignity of persons.\textsuperscript{13} Limits on end of life choices also require a kind of invasion of privacy because end of life choices are especially intimate choices, so coercive policies that limit these choices are offensively invasive.\textsuperscript{14} Other basic rights are distinguished because they are subjectively important to people, even if those choices are not in a person’s objective interest. For example, some religious practices may make religious worshipers objectively worse off, but religious citizens value those practices so strongly and religious identity is centrally tied to their identities that freedom of religion

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\item This argument rests on the familiar idea that respect for persons sometimes requires respecting their self-destructive decisions. The libertarian interpretation of this idea obviously supports a right of self-medication as well, but the premise is controversial. Still, the presumption of liberty isn’t the only reason to support a right to die.
\item For example, if limiting people’s right to choose their sexual partners empowered the state to send police officers into people’s bedrooms, then the general right to privacy would also protect a right to choose one’s sexual partners. Laurence H. Tribe, “Lawrence V. Texas: The ‘Fundamental Right’ That Dare Not Speak Its Name,” \textit{Harvard Law Review} 117, no. 6 (April 1, 2004): 1893–1955.
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nevertheless warrants protection as basic. End of life choices are among the most significant choices many of us will make, many people think that the value of their life as a whole can only be understood in light of their death, and therefore limits on the right to die also threaten citizens’ rights to further their overall interests, as they understand them.

Relatedly, many people have religious convictions that shape their end of life choices, or other reasons to make certain choices about dying that are influenced by beliefs about spirituality or sacredness. A just society must be neutral with respect to these kinds of questions, and so states should give citizens room to make whatever choices comport with their religious or spiritual views at the end of their lives. For this reason, states also should not endorse a particular understanding of life and death via its euthanasia and drug policy.

Most importantly perhaps, when a person gets to the point where they have competently decided to choose death, it is because she judges that their life is on balance

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16 David Velleman, who himself has described many of the problems that might be associated with institutionalized rights to die, also points to one of the advantages of enabling people to choose the time and manner of their own death. He argues that the meaning of one’s life can only be fully understood at the time of his death, and that is why Velleman would prefer to be conscious at the time of his death, so he can more fully appreciate the meaning of his life as a whole. David Velleman, “Dying,” Think Magazine, forthcoming.

no longer worth living.\textsuperscript{18} To get to this point, she must be experiencing extraordinary physical or psychological suffering. Death is not the decision that any person of sound mind takes lightly, so when someone’s considered and reflective judgment is that death is her best option she is entitled to make such a choice, and it is especially cruel to take that option away from her. This is especially true for patients who suffer from degenerative, debilitating, and painful terminal illness, but need not be limited to these kinds of patients a priori.\textsuperscript{19} Even a healthy person’s life could go so badly that continuing to live is worse than the alternative.

None of the above reasons for the right to choose death or for the permissibility of suicide depend on whether the suicidal patient has a terminal illness. Therefore, these arguments support what I am calling unconditional rights to die meaning that suicide is permissible regardless of a person’s medical condition. The decision to die remains an intimate, important, self-regarding decision whether or not the suicidal patient has a terminal illness. Just as the state ought not take a stand on whether religious reasons for a choice are valid, similarly states ought not take a stand on whether other kinds of reasons for a choice, such as a patient’s relative level of health or remaining life, are valid.

2. Handguns, Deadly Drugs, and Externalities

Most countries and US states prohibit the sale and purchase of deadly drugs. I have argued that suicide is permissible, so states should not limit the sale of deadly drugs on the grounds that suicide is wrong. Still, people may have rights to kill themselves, but


\textsuperscript{19} This consequentialist claim supports a right to die for epistemic reasons, as in the previous chapter it relies on the premise that patient’s are in the best position to decide if choosing to die is in their interest, all things considered.
not have rights to access the means to do it if ready access to poison had significant negative externalities. There is some support for this concern, 13 percent of all accidental deaths in the US are already due to poisoning, though less than 1 percent of all homicides are due to poison.\textsuperscript{20} Consider an analogy to recreational drug use. Even if people have rights to use drugs for fun, and even if it is not wrong to do so, states may claim that legal prohibitions on buying and selling recreational drugs are nonetheless permissible as a way of preventing negative social externalities.

Concerns about negative externalities have been used to justify limits on other deadly products as well. Handguns are the clearest example. Arguments for handgun prohibitions rarely center on the concern that people will use handguns to kill themselves. Rather, the worry is that people will use handguns to kill others, either accidentally or on purpose. For this reason, governments either prohibit handguns full stop or impose regulations on handgun sales that are designed to prevent criminals, psychopaths, and children from purchasing and using handguns to kill other people.\textsuperscript{21}

In the case of handguns, there are two good reasons to reject full prohibition. First, prohibitive policies are unlikely to be effective. In the United States, for example, a ban on handguns would entail that for every handgun that would eventually be used in a crime, at least 50 non-criminals would be prevented from owning a gun. Furthermore, the groups with the highest gun ownership rates have comparatively lower rates of violence than other groups, most gun owners own guns either for self-defense or sport. In any

\textsuperscript{20} Troublingly, most homicidal poisonings are used against socially vulnerable populations such as infants and the elderly. The most recent study of homicidal poisoning found that it is less often used against competent healthy adults. \textit{National Vital Statistics Report, Volume 50, Number 15} (Bureau of Justice Statistics,, September 2002).

case, most guns that are used in crimes are stolen or purchased on black markets. Prohibitions are unlikely to eliminate the existence of stolen guns and black markets, so they are unlikely to be effective. Second, prohibitive policies have substantial costs. As Douglas Husak argues, prohibitive policies would exacerbate the problems of overcriminalization and punishment by criminalizing behavior that is not itself harmful but which merely carries a risk of harm.\textsuperscript{22} States should take punishment very seriously, and therefore ought to avoid prohibiting or criminalizing behavior that never actually harms anyone. Gun prohibitions also limit important liberties and potentially violate citizens’ rights to self-defense or self-protection. For these reasons, few philosophers have endorsed prohibitive gun policies; instead most endorse a system of licensing and registration, and holding gun owners strictly liable for any harm that is caused by their guns.\textsuperscript{23}

Handgun licensing, registration, and liability policies can provide a useful guide to limiting malicious use of deadly drugs. Public policy may permissibly regulate the sale of deadly drugs for the sake of public safety, but full prohibitions on deadly drugs are also unlikely to effectively prevent suicide.\textsuperscript{24} Further, such prohibitions would be overinclusive if they ruled out legitimate uses of deadly drugs, namely permissible suicide. Gun licensing laws require that potential owners submit to a background check and psychiatric evaluation and wait for several weeks before receiving their guns. Similar

\textsuperscript{22} Ibid.


\textsuperscript{24} For example, in the next section I will discuss the comparatively low rates of suicide in places where deadly drugs are available, especially relative to ‘shame societies’ that prohibit deadly drugs but nevertheless have high suicide rates.
licensing requirements may be applied to the sale and possession of deadly drugs to mitigate the danger of mentally incompetent people using the drugs to harm themselves or others. Gun registration requirements ensure that guns can be tracked if they are stolen or used in crimes. Registrations for deadly drugs can play a similar role. Standards of strict liability for gun owners ensure that people will store their guns safely to prevent theft, accidental injury, or misuse. Again, standards of strict liability may also apply to the possession of deadly drugs to prevent accidental or non-consensual poisonings.

None of the above gun regulations aim to paternalistically prevent people from killing themselves with handguns, so from the perspective of the foregoing arguments, gun regulations do not offend against peoples’ right to die. Rather, these kinds of regulations are for the sake of public safety, not paternalism. If a person of sound mind uses a handgun to end her life, states could not permissibly limit her right to use a handgun on those grounds because to do so would violate her right to die. So too, deadly drug regulations should not aim to prevent people from self-poisoning, they should instead aim to prevent the malicious use of deadly drugs. As in the handgun case, if a person of sound mind seeks to use deadly drugs to end his life, states ought not violate his right to die.

Institutionally, how would these considerations inform laws about physician-assisted suicide? Since some regulations are needed for the sake of public safety, perhaps deadly drugs should not be available over the counter. However, deadly drugs should be available to anyone who would seek to use them to end her own life because suicide is permissible and states should not limit citizens’ permissible choices, especially when those choices are particularly intimate and important as suicide is. I propose that deadly
drugs ought to be sold behind the counter, rather than over the counter, next to aspirin and other medicines. By putting deadly drugs behind the counter they can be regulated for the sake of public safety without limiting self-harming behavior. This retail model is similar to the current market for handguns. Pharmacists who sell deadly drugs behind the counter can enforce licensing and registration regulations just as retailers are required to abide by handgun regulations. A less radical version of this proposal would rely on physicians to perform the psychological screening necessary for the licensing requirements, thus making deadly drugs available by prescription rather than behind the counter.

This proposal calls for a change in the current approach to deadly drugs and physician-assisted suicide. Instead of a system where the status quo is a widespread prohibition on deadly medicines with perhaps a few exceptions for the terminally ill, the regulatory framework ought to permit most people to access deadly drugs, with exceptions only for mentally incompetent people and some criminals.

3. Practical Objections

There are two kinds of objections to the above proposal. First, one might object that nearly unconditional access to deadly drugs will have bad consequences, including an epidemic of suicide, homicide, and abuse. A second objection is that the above proposal would make pharmacists, physicians, manufacturers, or even society complicit in killings.

First let us consider the empirical objection. While no developed countries have instituted the proposal that I outlined, non-medical right-to-die organizations are permitted to provide and administer deadly drugs and euthanasia in Switzerland. Exit
International and Dignitas are the two organizations that provide these services. Both are subject to some government oversight. A recent study of these organizations found that both organizations provided assistance in dying for patients, only after an evaluation process to establish that the wish to die is deliberate and stable.\textsuperscript{25} The authors of the study conclude that weariness of life rather than terminal illness may be a more prevalent reason for suicide.\textsuperscript{26} This finding indicates that the demand for deadly drugs exceeds the current level of legal access in most places. One concern that the study raises is that women are overrepresented in the Swiss organizations compared to other more regulated legal regimes, like the Netherlands, which require that patients have a terminal illness in order to use deadly drugs. This suggests that women may disproportionately choose suicide for non-medical reasons, which raises concerns about women’s vulnerability to social coercion or pressure to choose death. On the other hand, women in the Netherlands do request assistance in dying more than men, which may suggest that the equal gender distribution of assisted suicide in more regulated systems is a result of paternalistic refusal by physicians, which raises similar concerns about women as a vulnerable social group.

More evidence about the potential effects of legalizing deadly drugs can be found in Mexico where patients have de facto access to deadly drugs. There, pentobarbital is available over the counter in veterinary supply stores. Although the drug is technically illegal without a veterinary prescription it is widely available. In contrast to the Swiss suicide law, Mexican veterinary supply stores are far less regulated than the above

\textsuperscript{25} S. Fischer et al., “Suicide Assisted by Two Swiss Right-to-Die Organisations,” \textit{Journal of Medical Ethics} 34, no. 11 (October 1, 2008): 810–814.

\textsuperscript{26} Ibid.
proposal because any adult can easily purchase deadly drugs like any other consumer good. Yet the US suicide rate is three times the Mexican suicide rate. One explanation is that suicide rates depend far more on cultural factors than on the availability of easy methods of suicide. Countries with comparatively high suicide rates such as South Korea, China, and Japan also have strong shame societies, where suicide often a response to some kind of humiliation. Mexico’s prominent Catholic cultural ethos likely discourages suicide despite the availability of deadly drugs. Further, while Mexico does have a notoriously high rate of murder, instances of homicidal poisoning and non-voluntary euthanasia are also low.

The examples of Switzerland and Mexico suggest that relatively widespread availability of deadly drugs does not lead to widespread abuse or disaster. While there is little evidence about the effects of the above proposal, existing evidence suggests that empirical worries about suicide epidemics and widespread poisoning and abuse are unsubstantiated.

A related empirical argument, which has been cited by Velleman and other critics of euthanasia, is that patients would feel pressured to choose death either as a result of explicit or implicit encouragement from their physicians or loved ones. Terminally ill patients use a lot of hospital resources and are very expensive to care for. Were patients

28 Oregon physicians who provide access to euthanasia take special care to ensure that patients do not choose to deadly medical treatment as a result of financial pressure or coercion from family members. see M. A Lee et al., “Legalizing Assisted Suicide—views of Physicians in Oregon,” New England Journal of Medicine 334, no. 5 (1996): 310–315.
legally permitted to access suicide drugs they might feel pressure from people around them (even if no one ever explicitly pressures the patient) to end the burdens of continuing care. This objection is also empirical. The worry is that on balance patients at the end of their lives would be less autonomous with a legally protected right to die than they would without it because institutional rights to die would reliably lead to coercion.

There is reason to doubt this empirical worry, patients rarely complain about pressure or coercion in countries that allow physician assisted suicide and indeed these countries often accommodate foreign suicide tourists who were coercively prevented from accessing deadly treatment in their home countries. Further, as I argued above, prohibitive policies are not well suited to prevent the possibility that some will be wrongly coerced because they are over inclusive, they also limit the options of willing users of deadly drugs. Instead, strict regulations to ensure competence and voluntariness are warranted. In some cases patients may not be pressured to choose to die, but they may wish to die in order to spare their family of the financial burden. Insofar as the patient’s choice is informed, free, and competent, the patient is simply responding to the reasons he has in the same way that other patients who choose death to spare themselves future suffering are responding to their all things considered reasons. Even if financial burden is a main reason for choosing to die, in these cases the choice ought to be respected.

A third empirical objection to the above proposal is that the availability of deadly drugs will compromise medical care, especially for terminally ill patients. Critics of legal euthanasia and physician-assisted suicide cite the fact that the rise of legal euthanasia for terminally ill patients in the Netherlands was correlated with lower quality medical care

29 Fischer et al., “Suicide Assisted by Two Swiss Right-to-Die Organisations.”
for patients who chose palliative options. Critics also worry that if deadly drugs were available within a for-profit health care system like the United States, then insurance providers may deny disabled and sick patients pain relief and palliative care options, citing the availability of deadly drugs instead. Further, critics fear that widespread acceptance of suicide will diminish social support for providing health services to sick and disabled patients, and will encourage insurance providers to refuse to cover treatment with low expected survival. These empirical concerns are controversial. Oregon allows euthanasia in some cases and has relatively good health outcomes compared to similar states, and Oregon ranks ninth in the use of hospice, despite the availability of deadly drugs for terminally ill patients. Even if these concerns are warranted though, the objections are addressed not to the use of deadly drugs but to the potential side effects related to patient care. Proponents of widespread access to deadly drugs may accept all these criticisms and affirm that sick and disabled patients are entitled to quality medical care and the option to use deadly drugs.

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4. Killing and Complicity

Critics of voluntary euthanasia might also push a more principled objection to the behind the counter model for deadly drugs. Some argue that there is an important moral difference between letting a patient die from a disease and providing him with deadly drugs.\(^{33}\) Even if we accept that there is a moral difference between killing and letting die at this point, we should not discount the role of consent. Killing is generally wrong because killers bypass the will of their victims. But not all killings have this feature. Euthanasia is importantly different from murder because patients consent to euthanasia. The wrongness of euthanasia is silenced by the patient’s consent. Instead, euthanasia enables patients to reassert their autonomous will when intolerable suffering or terminal illnesses have otherwise deprived them of the ability to autonomously shape their own lives.\(^{34}\) In this way, the moral significance of autonomy both makes killing generally worse than letting die, and also tells against prohibitions on deadly drugs and counts in favor of permissible voluntary euthanasia.

Another principled objection to the sale of deadly drugs is that it makes the provider of the good complicit in destructive acts.\(^{35}\) There are three lines of response to this kind of objection. First, Consider Susan Wolf’s moving description of the anxiety of making decisions on behalf of a terminally ill loved one. In her insightful account of her own father’s death, Wolf writes:

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33 In a later chapter I will defend a moralized distinction between killing and letting die, and I will argue that killing is only generally worse because patients’ rights not to be killed are stronger than their rights to assistance.
34 Brock, “Voluntary Active Euthanasia.”
It was he who traveled that road, not me. I paid my own price, though. I felt the heavy weight of his trust and the obligation to fight for him. I was scared I might fail. I felt very close to the jaws of death.  

Wolf ultimately chose palliative care for her father, and her choice affirmed her qualified opposition to euthanasia. But as Wolf points out, loved ones are complicit in end of life decision making, as are medical professionals, whether they choose to facilitate someone’s death or not.

Second, this objection assumes that ending one’s life is a destructive act. As I argued above, some patients see ending their life at the time and in the manner that they chose as valuable, and being required to die slowly from natural causes is destructive. In this way policymakers who ban the sale of deadly drugs are complicit in destructive acts, not the physicians and pharmacists who provide deadly medicine.

Third, providing access to a deadly drug isn’t itself destructive or wrong, even if using the drug to die were destructive or wrong. For example, it is not wrong to sell someone alcohol and sleeping pills, or handguns, or razors, even if consumers might use these products to harm themselves or end their own lives. If anything, enabling patients to end their own lives with deadly medicine might make fewer people complicit in a patient’s death because many patients are able to drink deadly medications without any assistance, whereas palliative care requires that others become involved in actively managing a death.

5. Justified Hard Paternalism?

Edward Gorey wrote “The Suicide, as she is falling/ Illuminated by the moon, / Regrets her act, and finds appalling/The thought she will be dead so soon.” Gorey’s verse points to a deeper objection to the widespread sale of deadly drugs; if people could buy suicide drugs at their local pharmacy they may mistakenly choose to die when upon further reflection, perhaps months or years of refection, they would realize that suicide was a poor choice.

Danny Scoccia has recently raised this concern about using deadly drugs. He argues that even if suicide is permissible and legal suicide would not be open to abuse, restrictions on deadly drugs are a form of “justified hard paternalism.”\(^\text{37}\) Recall that ‘hard paternalism’ refers to paternalism against mentally competent people. Scoccia acknowledges that extremely sick and terminally ill patients may have rights to use deadly drugs, but Scoccia explicitly argues against the legalization of non-medical uses of deadly drugs, which I have proposed. Scoccia motivates his argument with the example of Frank:

Imagine that Frank suffered a shoulder injury a year ago that will prevent him from ever again playing competitive golf, his life’s passion. He is no longer depressed about his situation but feels certain that he has nothing to live for and would be better off dead.\(^\text{38}\) Scoccia argues for “legalization with limits,” which would deny Frank’s eligibility to use deadly drugs even though he is mentally competent and willing. He claims that patients


\(^{38}\) Ibid. Pg 367.
like Frank “should be denied suicide assistance and hard paternalism explains why: the vast majority of them are better off alive than dead notwithstanding their belief to the contrary.” Scoccia’s argument is for hard paternalism, which I am against in all cases. But his argument merits consideration as an important objection to the proposal that I advanced above.

Briefly, Scoccia’s argument is as follows. First, Scoccia argues that a person’s right to make decisions about his own body is not absolute. Even if all violations of autonomy are pro tanto wrong, they can be outweighed by welfare-oriented considerations. To illustrate that the value of autonomous choice is not absolute, Scoccia appeals to precommitment laws wherein people voluntarily limit their autonomous choices in the future for the sake of their future selves’ welfare. Since people can reasonably limit their future autonomy for the sake of well being, public officials can also reasonably limit autonomy for the sake of well being. Douglas Husak pursues a similar strategy for justifying hard paternalism. This strategy has several problems. First, we generally assume that people are entitled to make autonomy-limiting decisions for themselves but not for others, so there is an important asymmetry between precommitment and state paternalism. Further, precommitment contracts can be dissolved if both parties (e.g. a gambler and a casino owner) consent to dissolve the contract. The reason for this condition on contracts is that the autonomous choices of both existing parties to a contract take priority over the autonomous choices of their former selves.

39 Ibid.
Scoccia goes on to argue that some autonomy-claims are stronger than others. Jehovah’s Witnesses have strong claims against paternalistic interferences in medicine because they experience the violations to their autonomy as severe and it is unlikely that they will later approve of the paternalistic intervention. In contrast, people like Frank are less likely to experience paternalistic limits as severe and more likely to retroactively approve of the paternalistic intervention. This kind of argument is bolstered by the effectiveness of small paternalistic interventions, such as suicide guards on bridges that effectively lower overall rates of suicide by raising the costs. Since a person like Frank will be grateful for paternalistic interference if prevented from using deadly drugs, limits on Frank’s choice are warranted even if he objects at the time. Scoccia considers the possibility that Frank may know that he will later be glad for the prohibition but nevertheless regard the idea of adapting to a life without golf as a kind of selling out. Still, Scoccia maintains that the benefit of paternalism towards Frank would nevertheless be great by Frank’s own lights, despite the violation of Frank’s autonomy.

Another objection to Scoccia’s argument is that Frank’s example, which gives Scoccia’s policy argument intuitive force, misrepresents suicidal people’s reasons, which are typically more credible than Frank’s. Once we recast the example to better reflect the experience of real people who choose to commit suicide when they are relatively healthy Scoccia’s case is less intuitive. Imagine that Frank played golf since early childhood,

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41 It’s telling that Scocca doesn’t consider any actual cases of non-medical suicide. A brief review of publically available suicide notes reveals that unlike Frank, many suicidal healthy people have intuitively good reasons for their choices, generally chronic pain, weariness with life, or a desire to avoid living without a loved one. Consider for example the film director James Whale, who wrote, “The future is just old age and illness and pain…. I must have peace and this is the only way.” Or Kurt Cobain who wrote “I don’t have the passion anymore, and so remember, it’s better to burn out than to fade away.”
and that competitive golf is the only community he knows. Not only can he no longer play, but also he will no longer be able to participate in the sport at all. Without access to his friends, his work, or anything he values, Frank decides to end his life. Now imagine that Frank is evaluated and certified as mentally competent. After a brief waiting period he reaffirms his decision to die. With this thicker rendering of Frank’s case his reasons seem more plausible, and while most of us would still counsel Frank against ending his life, interfering in his choice would impose substantial costs on him as it would in the Jehovah’s Witness example.

Say we accept Scoccia’s claim that the value of autonomy is not absolute and that paternalism is warranted when people would later be grateful for benevolent paternalistic interventions. There are still two reasons to reject Scoccia’s argument for hard paternalism. First, Scoccia’s argument faces serious epistemic difficulties. On his proposal institutions are to allow that terminally ill and severely sick people have a sufficiently weighty interest in choosing death that is not outweighed by benevolent considerations, but patients like Frank do not. Yet the permissibility of using deadly drugs hangs on patients own subjective experiences in the future, so institutions must have a way of assessing which kinds of patients will reliably be grateful for paternalism and which would not. Scoccia’s proposal therefore requires that policymakers or

The famous conductor Sir Edward Downes ended his life at a Swiss suicide clinic alongside his wife, who was diagnosed with terminal cancer because he did not want to continue to live with deteriorating health and without his wife. When the inventor George Eastman killed himself after two years of suffering from a chronic but non-terminal painful illness his note read “To my friends: My work is done. Why wait?” I’m not saying that all of these people ought to have ended their lives, only that their stated reasons for suicide were more reasonable than Frank’s, and Scocca’s policy argument for limits on access to deadly drugs should address the kinds of reasons that actual suicidal people give.
physicians assess each patient’s circumstances and reasons to determine whether they would in the future regret their choice. At this point though, Scoccia has not given any reasons to think that physicians and/or policymakers would have better epistemic credentials to evaluate a patients expected subjective experiences, if he lived. No one has better access to the experience of living a life than the person who is living it, as a rule it stands to reason that we are therefore the experts about our own present and future well being, even if our judgment is unreliable it may still be more reliable than anyone else’s.

Second, there is a deeper metaphysical worry about Scoccia’s argument. On whose behalf are hard paternalistic limits in the case of deadly drugs? Paternalistic limits will surely harm Frank because they limit his autonomous choice, but they don’t benefit anyone because if Frank chooses to die his Future self will not be harmed because he will no longer exist. That Frank’s future self would be happy if Frank continued to live does not mean that Frank ought to continue to live.42 Perhaps it is true that on balance there will be more happiness in the world if Frank chooses to live, namely the happiness that Frank will experience in his future, but paternalistic restrictions on Frank’s right to die cannot be justified on Frank’s behalf because his choosing to die is not harmful to anyone.

Return to Gorey’s verse about the falling suicide. David Rosen has studied suicide survivors and people who make serious attempts at suicide (in contrast to non serious

42 This problem is parallel to the non-identity problem. That a person would be happy to exist if her parents decided to have her doesn’t mean that her parents ought to decide to conceive or continue a pregnancy. Derek Parfit, Reasons and Persons (Oxford University Press, 1984).
attempts that are more typically understood as cries for help rather than attempts to die).\textsuperscript{43} He found that people who make serious suicide attempts that fail often succeed in a second attempt. This indicates that suicidal impulses are often robust over time, and that unlike Gorey’s suicidal jumper, many people who attempt to die but fail will not regret their decision but will try again.\textsuperscript{44} That said, Rosen’s work also found that many suicide survivors also are transformed by their experience and claim to have spiritual insight into the precious nature of life that non-survivors lack.\textsuperscript{45} The fact that some suicide attempt survivors would not re-attempt suicide does not change the foregoing arguments though because had they not survived they would not have been in a position to regret their choice. This is true even for non-deadly choices that irreversibly change us, like the decision to marry or divorce. As David Velleman argues, when a prior choice changes the person you are (or even whether you are a person) regretting that choice is in some sense unintelligible from your present perspective because had that choice not been made, you would not have been who you are today so you are not in a position to regret that choice.\textsuperscript{46}


\textsuperscript{44} Ibid.


\textsuperscript{46} This is just a sketch of an argument that Velleman develops in much greater detail. He writes, “We can perhaps envy the [versions of ourselves] for whom things might have gone differently, as we envy any other person. But we cannot think of them as our more fortunate selves, because they aren’t selves of ours in the relevant sense, and so we cannot regard what they have as something that we ourselves might have had.” J. David Velleman, “Forget What Might Have Been,” \textit{SSRN eLibrary} (August 16, 2011), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2088344.
6. Discrimination

So far I have argued that suicide is permissible regardless of a person’s medical condition, and that attempts to justify legal restriction on access to suicide drugs fail. Here I will develop a further argument in favor of unconditional access to deadly drugs. Laws that regulate access to deadly drugs on the basis of a person’s medical condition are discriminatory. States and countries that allow for conditional rights to die only permit terminally ill and (in some cases) disabled patients to access deadly treatment. These laws wrongfully discriminate against both disabled and healthy patients.

Disability rights advocates and some bioethicists argue that extending legal access to deadly drugs only to sick and disabled patients offensively expresses public disregard for the lives of the unhealthy. For example, Diane Coleman, the founder of the disability rights organization Not Dead Yet writes, “It is the ultimate form of discrimination to offer people with disabilities help to die without having offered real options to live.” Not Dead Yet opposes the legalization of euthanasia not based on an objection to euthanasia in principle, but because the few laws that permit euthanasia in the US discriminate on the basis of a patient’s health status. In this case, disabled people are victims of discrimination in an interesting way—having rights and privileges that others lack is what harms them. But the fact that others lack the freedom to choose to use deadly drugs stigmatizes disabled people by sending the message that their deaths are more acceptable than the deaths of abled people.

47 Golden and Zoanni, “Killing Us Softly.”
48 NotDeadYet.org
There are two available responses to Coleman’s complaint. Coleman suggests prohibition of deadly drugs for everyone. Alternatively, the proposal that I developed above also mitigates the harm of discrimination by expanding access to deadly drugs for everyone. Disability rights advocates who are concerned by stigmatization ought to favor my proposal over Coleman’s. To see why, I will need to introduce a further normative premise: laws that only allow for conditional access to deadly drugs are also a form of discrimination against the healthy.

Though stigmatization is a troubling feature of discrimination, another problem with discrimination is that it deprives people of important freedoms. At base, anti-discrimination laws are premised in the idea that if one person has the right to make her own decisions for herself then others should be given that right as well. Conditional right to die laws extend the freedom to end one’s life to sick and disabled people, but do not extend that freedom to everyone. Above I argued that the permissibility of suicide does not depend on a person’s medical condition, so conditional laws prohibit people from making a permissible choice on the basis of their medical condition (in this case, their relative health). Often, laws that discriminate on the basis of health or ability are wrong because they limit disabled people’s employment or housing options on the basis of their medical condition, even when their medical condition has nothing to do with their employment or housing choices. Laws that discriminate on the basis of ability are

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50 This argument draws on Sophia Moreau’s account of why discrimination is wrong. I will draw on this account further in Chapter 10, where I make a similar argument in favor of access to any drugs. Ibid.
wrong for the same reason; they limit healthy people’s options to use deadly drugs even though their relative health does not bear on the permissibility of their choice.

With this additional premise in hand, Coleman’s proposal is therefore inadequate. Even if prohibiting the use of deadly drugs did cure the problem of stigmatization against disabled people, it reinforces the very problems that healthy people faced as a result of discriminatory laws. Consider an analogy to gay marriage. Arguments for marriage equality are premised on the idea that heterosexual couples legitimately have the *right to marry.* \(^{51}\) Marriage equality advocates then argue that this right should also be extended to gay couples because sexual orientation is a normatively extraneous trait that shouldn’t limit one’s deliberation about whether to marry. It would be an inadequate response to then deny that anyone is entitled to marry. The elimination of marriage or marriage privatization would be to extend the harm of discrimination (that it limits an important freedom) to everyone, such a response would not mitigate the harm. \(^{52}\) Similarly, further limiting disabled people’s options in order to avoid extending the right to die to healthy people merely compounds one of the initial harms of the discriminatory policy.

This reasoning explains why Swiss right-to-die policy forbids discrimination on the basis of a person’s medical condition except insofar as a medical condition impairs a patient’s ability to consent (e.g. mentally ill, severely mentally handicapped, and unconscious patients are not permitted to access physician assisted suicide.) The clinics have rigorous procedures to ensure that the patients who choose to die decide freely, but

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\(^{52}\) This is a kind of ‘leveling down’ that not only has bad expressive properties, but also responds to a wrongful limit on deliberative freedom by further limiting deliberative freedom on the basis of some people’s normatively extraneous traits, so it does not solve the problem of discrimination. Moreau, “What Is Discrimination?”.
it they not take a stand on which kinds of patients have the most reason to die. At least 21% of people who use these clinics do not have progressive or terminal illnesses.53

7. Clinical Depression

My argument so far has unfolded on the assumption that patients who are licensed to use deadly drugs are mentally competent. This proposal does not extend to children or mentally incompetent patients, such as patients suffering from schizophrenia or dementia. Those who use deadly drugs to end the lives of children or mentally incompetent people under their care ought to be subject to criminal penalties for manslaughter or homicide.

There are some cases where a suicidal person’s competency is less clear. Patients with clinical depression pose a challenge to this proposal because in some ways they seem mentally competent to decide to die, but their reasons also seem unfounded and irrational to an outsider. More information is needed about how clinical depression affects a person’s psychology to assess whether depressed patients should be permitted to use deadly drugs. One way of understanding clinical depression is as an illness that affects a patient’s motivational states, her feelings and desires. Terminally ill patients might be depressed because they are in pain and they may feel hopeless because their lives will soon be over, and for this reason they might want to make deadly or risky choices. Insofar as clinical depression is like this, depressive impulsive ought to be given as much credence from the standpoint of informed consent as other motivational influences. A preference to die because of emotional pain merits as much respect as a preference to die because of physical pain.

53 Fischer et al., “Suicide Assisted by Two Swiss Right-to-Die Organisations.”
Another way of understanding depression is as an illness that gives patients false beliefs. False beliefs undermine a patient’s ability to consent. This is why paranoid schizophrenic patients are not fit to give consent for refusal or access-based medical decisions. Hypochondriacs also systematically have false beliefs that undermine their ability to consent to or refuse treatment. In some cases clinical depression seems to operate like this. People who are depressed sometimes cannot realize that their lives are going relatively well, that their jobs and marriages are stable, that people do like them. Instead they develop false beliefs about their lives, careers and relationships and cannot see that the real reason that they are depressed is because of clinical depression, not their circumstances.\(^\text{54}\) Yet we should be wary of inferring that depressed patients are delusional just because we disagree with their assessment of their lives. Depressed people often hold more accurate beliefs about their situation than non-depressed patients and make better predictions about the likelihood of future events, especially negative events.\(^\text{55}\) Depressed people are also instrumentally rational, able to plan, and responsive to incentives.\(^\text{56}\) For this reason, clinically depressed patients are generally considered capable of giving medical consent, even though they experience their lives very differently than a non-depressed person would. Since depression does not generally


undermine a patient’s ability to consent to risky treatments like cosmetic surgery or hip replacements, it does not undermine one’s ability to consent to deadly treatment either.

This assessment comports with the following description of suicidal depression by David Foster Wallace:

The so-called “psychotically depressed” person who tries to kill herself doesn’t do so out of quote “hopelessness” or any abstract conviction that life’s assets and debits do not square. And surely not because death seems suddenly appealing. The person in whom its invisible agony reaches a certain unendurable level will kill herself the same way a trapped person will eventually jump from the window of a burning high-rise. Make no mistake about people who leap from burning windows. Their terror of falling from a great height is still just as great as it would be for you or me standing speculatively at the same window just checking out the view; i.e. the fear of falling remains a constant. The variable here is the other terror, the fire’s flames: when the flames get close enough, falling to death becomes the slightly less terrible of two terrors. It’s not desiring the fall; it’s terror of the flames. And yet nobody down on the sidewalk, looking up and yelling “Don’t!” and “Hang on!” can understand the jump. Not really. You’d have to have personally been trapped and felt flames to really understand a terror way beyond falling.⁵⁷

In this passage Wallace shows that depressed peoples’ interest in ending their lives with deadly drugs is the same as the interest of people who suffer from extremely painful physical illnesses. Like patients with painful physical conditions, depression is a disease

that causes extreme psychological and physical suffering. In this way people with clinical depression, like anyone who is sick, ought to have access to any treatment that could dull or cure any suffering. Some people with clinical depression are resistant to treatment, and in these cases depression is a chronic and painful incurable condition. Given that patients with clinical depression are able to consent, they too should be given access to deadly drugs despite the fact that they suffer from a mental illness which is responsible for their decision to use deadly drugs.58

David Foster Wallace suffered from clinical depression and took medication for it for twenty years. In 2007 Wallace discontinued treatment because the only effective treatment for his depression caused severe side effects. According to his father, “He was being very heavily medicated…He’d been in the hospital a couple of times over the summer and had undergone electro-convulsive therapy. Everything had been tried, and he just couldn’t stand it anymore.”59 On September 12, 2008, Wallace hanged himself. His sister Amy described her reaction as, “inevitably our thought was, if only he could have held on a little bit longer, and then we realized, he did. How many extra weeks had he hung in there when he just couldn’t bear it? So we’re not angry at him. Not at all. We just miss him.”60 For people who suffer from treatment-resistant clinical depression, suicide is still a terrible loss, but Wallace’s family’s reaction affirms that suffering associated with the disease may on balance be worse from the patient’s perspective.

58 If anything, people with treatment resistant clinical depression have a more weighty claim than those who seek non-medical suicide. Instead, depressed patients who seek deadly drugs have a claim that is more similar to a person with a clinical illness. Once depression is understood in this way then, expanding access to deadly drugs for depressed people is less controversial than expanding access for non-medical suicide cases.
8. Conclusion

Death is not a decision that anyone takes lightly. Even though most of us could violently kill ourselves at any moment, the thought of it is usually less appealing than almost anything else we could do. So we do not deliberate between suicide and another cup of coffee, as a Camus character would, we unthinkingly continue on and don’t even appreciate how lucky we are to be spared from the kind of suffering that would make someone want to die. Expanding access to deadly drugs need not mean that we the lucky ones will ever be exposed to deadly poisons. Only the unluckiest among us confront circumstances that compel them to kill themselves, the right to die therefore protects the interests of the most badly off.

Suicide is always a tragedy. It is devastating to families and it is tragic that people suffer so badly that they seek to end their own lives. Still, the fact that someone’s life is so full of suffering, even if it is depressive suffering, is not a reason to further limit his or her options. By all accounts the use of deadly drugs is one of the most reliable and least painful ways to die. Without the option to use deadly drugs, people like David Foster Wallace or Iris Flounders are driven to violent ends like jumping off bridges, drowning, gunshots, and hanging. These kinds of deaths not only risk further pain and suffering; they can be especially traumatic for a person’s family members. Also troublingly, prohibitions on deadly drugs force slow and painful deaths on severely disabled terminally ill patients who cannot kill themselves in other ways.

The prevalence of right to die organizations in most countries and suicide tourism to Switzerland and Mexico shows that there is considerable demand for effective legal

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options to end one’s life. Terminally ill, clinically depressed, and otherwise suicidal patients often affirm Iris Flounders’ call for a legal right to die, suggesting that at least some people are not eventually grateful for paternalistic prohibitions of deadly drugs as proponents of hard paternalism suggest.\(^6^2\) Rather, prohibitive policies do not prevent the tragedy of suicide; though they do compound the misery of people who are suffering the most by further limiting their options. For these reasons, deadly drugs ought to be widely available subject only to regulations and oversight that prevent criminal use of deadly drugs. Access to deadly drugs should not be limited based on medical status or policymakers’ assessment of whether a person has good reason to commit suicide.

\(^{62}\) Scoccia, “In Defense of Hard Paternalism.”
VII. Informed Consent and Self-Medication

In this Chapter I argue that the doctrine of informed consent, a central tenet of medical ethics, implies a robust right of self-medication. Therefore, we ought to reject paternalistic prohibitions of experimental and prescription drugs, and respect the right of self-medication in almost all cases, even if self-medication is medically inadvisable. In earlier chapters I argued that patients have rights to make risky and deadly treatment decisions in particular cases. Namely, terminally ill patients have the right to use risky experimental drugs and everyone has the right to use deadly drugs to end their lives. Here I will advance a more radical conception of rights of self-medication: whenever as a patient is entitled to refuse treatment she is entitled to access medication as well, regardless of her medical condition and the risks of using medication. Call this more extreme conception an unconditional right of self-medication.

In section 1 I frame the puzzle of unconditional self-medication; why don’t the same considerations that tell in favor of informed consent also justify a right of self-medication, regardless of the risks of medication or a patient’s medical condition? In section 2 I describe the doctrine of informed consent in more detail. I sketch three justifications for informed consent in section 3; that the doctrine of informed consent promotes good medical outcomes, good consequences overall, and that patients have the normative authority to make medical decisions. All three of these reasons, I contend, tell in favor of self-medication as well. In section 4 I will suggest the medical outcomes associated with self-medication would be better than the medical outcomes associated with prohibitions. In section 5 I argue that self-medication would be better for patients overall welfare, and in section 6 I argue that patients’ normative authority to make
medical decisions includes a right of self-medication as well as informed consent. In section 7 I will discuss some asymmetries between self-medication and informed consent. Section 8 concludes.

1. The Puzzle

Consider the following two cases:

**Risky Refusal:** Debbie has diabetes and her physician advises her to start insulin treatment. Debbie understands the risks of refusing insulin, but is also unwilling to live by a schedule and monitor her medication. Against medical advice, Debbie decides to try to manage her diabetes with diet and exercise. Debbie’s physician is morally and legally prohibited from injecting Debbie with insulin against her wishes.

**Risky Access:** Danny has diabetes and his physician advises him to treat his condition with diet and exercise. Danny doesn’t want to invest the time or energy in diet and exercise, and would prefer to just begin using insulin right off. Against medical advice, Danny wishes to try to manage his diabetes with insulin. However, Danny cannot legally access diabetes medication without a prescription from his physician.

In risky refusal, Debbie has the right to refuse insulin treatment against medical advice. Indeed, it would be immoral for Debbie’s physician to coercively administer the treatment without her consent because all physicians are obligated to respect the doctrine of informed consent, which states that patients are entitled to refuse any medical treatment, even against advice. Yet in risky access Danny’s authority to make treatment
decisions is not similarly protected, and in most developed countries Danny is legally prohibited from carrying out his treatment plans.

This discussion raises the following puzzle. If patients have a right to refuse medical treatment against medical advice, then why don’t competent patients also have rights to access medical treatment against medical advice?

At first, it may seem unclear why this is a puzzle. The bare fact that competent patients have the right to refuse medical treatment does not entail or imply that patients have the right to access that medical treatment as well. After all, people have rights to refuse all sorts of goods and services that they do not have the right to access. Everyone has the right to refuse sex with celebrities, but that doesn’t entail that people have the right to access sex with celebrities. You might have a right to refuse to participate in an exclusive club or fraternity that you don’t have a right to access independently. People have the right to refuse to be killed, but a right to die doesn’t follow. The right to refuse heroin does not entail that prohibitions on heroin are wrong. Similarly, the bare right to refuse medical treatment is like the right against battery, and a right against battery does not establish a right to access dangerous bodily interventions.

Yet the puzzle arises when the right of refusal is understood within the doctrine of informed consent, and medical practice as a whole. The approval process and prescription drug systems entail a degree of paternalism that is sharply at odds with the rest of medical practice. Limits on rights of self-medication, such as testing requirements and the perception system) are not merely failures to grant access (like other positive rights violations) they also are themselves a form of paternalistic interference (i.e. negative rights violations). Given that paternalistic interference in medicine is generally wrong,
this anomaly cries out for justification or explanation. Presumably limitations on patients’ access to pharmaceuticals are intended to promote patients’ best interests, yet if paternalist treatment interventions are impermissible, why aren’t paternalist limitations on self-medication also impermissible?

All developed countries face this puzzle, because all developed countries enforce prohibitive pharmaceutical policies and affirm the doctrine of informed consent. Physicians are empowered by governments to limit patients’ access to medicines out of a concern that patients with unrestricted access will make inadvisable treatment decisions, or misuse or abuse potentially dangerous medicines. Manufacturers are prohibited from providing experimental drugs to patients and patients are forbidden from accessing them. As I argued in Chapter 1, these limits on access were historically for paternalistic reasons, patients might harm themselves if not for premarket testing requirements and a prescription drug system.

These requirements all violate patients’ rights to self-medication. Today, legal restrictions paternalistically limit access to drugs while other kinds of paternalistic medical interventions violate core principles of medical ethics. I will argue that paternalistic limits on access are wrong for the same reasons that other paternalistic forms of interference are wrong, and so for this reason I favor an almost-fully non-prohibitive drug system—pharmaceuticals should be widely available without a physician’s notice or agency approval, meaning that patients should have rights of unconditional rights of self-medication.
2. The Doctrine of Informed Consent

The doctrine of informed consent states that patients have the right to refuse medical treatment, even against medical advice. Further, the doctrine of informed consent also maintains that physicians have a duty to inform free and competent patients about their condition, the risks and benefits of treatment, and alternative treatments.¹

At its core, the doctrine of informed consent requires that providers receive a patient’s expressed consent before administering any medical treatment or performing any procedures. This means that even if a medical procedure is in a patient’s medical and overall interest, physicians cannot perform unwanted procedures on patients, even during surgery, without the patient’s expressed pre-consent.

Additionally, the doctrine also maintains that it is impermissible to withhold diagnostic information, such as news of a terminal illness, simply because the patient would be happier not knowing. It is also wrong to withhold information about the risks and benefits of a treatment in order to encourage patients to make medically advisable choices. Thus, the doctrine of informed consent rules out a range of paternalistic practices in the administration of medical treatment because it prohibits physicians from making or shaping treatment decisions on behalf of a patient without the patient’s consent, even if treatment is intended to benefit the patient.

In the twentieth century, the doctrine of informed consent has been continuously reaffirmed in professional codes of ethics and in the courts.² Further, the doctrine of

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² See for example American Medical Association ‘Physician Resources- Informed Consent’ and Janet L. Dolgin, “The Legal Development of the Informed Consent
informed consent, and the rejection of hard paternalism, has been widely accepted in philosophical discussions of clinical ethics and patient care. As Miller and Wertheimer write,

If we look at the literature on the ethics of medical care, we will encounter vigorous and (almost) unanimous arguments against paternalism. The dominant philosophical view has privileged respect for autonomy as a guiding principle over the ancient Hippocratic tradition that the physician is entitled to decide what treatment is best for his patients. There is a near universal consensus that patients have the right to refuse treatment even if the physician (rightly) thinks that the patient is mistaken, and that physicians should not deceive or withhold information from patients, even when they think it is in the patient’s interests to do so. Anti-paternalism appears to reign.\(^3\)

Physicians who fail to recognize patients’ rights of informed consent are subject to legal and professional censure, even if their actions ultimately benefit the patient whose rights were violated.

Today, a patient must meet three criteria in order to give informed consent.\(^4\) First, she must be mentally competent. For this reason, unconscious, severely mentally disabled, intoxicated, and underage patients are often not considered capable of giving informed consent. At the margins, it is often difficult to assess competence. Are laboring women competent to consent to treatment during childbirth? Are addicts able to consent

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\(^3\) Franklin G Miller and Alan Wertheimer, “Facing up to Paternalism in Research Ethics,” Hastings Center Report 37, no. 3 (January 8, 2012): 24–34.

\(^4\) Young, “Informed Consent and Patient Autonomy.”
to their drugs of choice? These are difficult questions that largely can be settled by empirical research. What is generally agreed upon though is if a patient with a given condition can consent to a particular treatment, then he is competent to consent to or refuse treatment more generally. This claim is controversial though. Teenagers are competent to refuse chemotherapy and consent to heart surgery, but are not considered competent to consent to cosmetic surgery or to refuse all unwanted medical interventions. I will return to this point in the last chapter, but for now let us limit our discussion to patients that are clearly competent to consent to or refuse treatment.

Second, she must be informed, meaning that any information that a reasonable layperson would find relevant to a treatment decision has been disclosed and explained. While there is some disagreement about just how much information this requires, the standard definitely requires that patients are informed of their diagnosis, prognosis, and the risks and benefits of the best available treatment options relative to treatment refusal.

Third, she must give her consent freely. If a competent, informed patient only consents because of manipulation or coercion, the physician still has not secured

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5 Ibid.
6 Presently, states are divided regarding the strength of disclosure standards. About half of all US states require physicians to disclose any information reasonably prudent physician would give and half require physicians to disclose any information a reasonable patient would find relevant. Nevertheless in practice the ‘reasonable patient’ standard has defined the standards of care despite legal variation. For more information about this divide see Jaime Staples King and Benjamin W Moulton, “Rethinking Informed Consent: The Case for Shared Medical Decision-making,” American Journal of Law & Medicine 32, no. 4 (2006): 429–501.
7 For example in Salgo the court held that “a physician violates his duty to his patient and subjects himself to liability if he withholds any facts . . . necessary to form the basis of an intelligent consent by the patient to the proposed treatment.”Salgo v. Leland Stanford Junior University Board of Trustees, 317 Pacific Reporter 2nd 170 (California Court of Appeals 1957). The court lifted this language from an amicus brief from the American college of surgeons. Dolgin, “The Legal Development of the Informed Consent Doctrine.”
informed consent. Sometimes it is difficult to tell if a choice is free. For example, if a religious patient refuses treatment only because his community would shun him if he accepted it, does he freely refuse treatment or is his refusal coerced? If a father only consents to donate his blood because his daughter requires it did he really have a choice? Still, we can bracket these borderline cases and still see that in most cases of informed consent, patients cannot give informed consent when they are being influenced by coercion.

Initially, the justification for the expansion of patients’ rights was derived from the idea that people had rights against assault and battery, or more generally, rights to bodily integrity. For example, in the United States, the doctrine of medical consent emerged in 1914 with *Schloendorff v. New York Hospital*, which characterized unwanted medical interventions as a kind of battery. In this case, Mary Schloendorff, a patient at New York Hospital, consented to be examined while under sedation but explicitly requested that she not undergo surgery. Despite this request, her physicians did perform surgery and removed a tumor as well as her uterus. Schloendorff sued for damages, and the courts ruled in her favor, characterizing the case as a form of battery. In their decision, the courts declared that physicians could not perform invasive medical procedures against patients’ wishes because,

Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation

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8 Coercion can come from social norms, see Aaron James, “Power in Social Organization as the Subject of Justice,” *Pacific Philosophical Quarterly* 86, no. 1 (January 24, 2005): 25–49.

9 *Schloendorff v. New York Hospital.*
without his patient’s consent commits an assault, for which he is liable in damages. ¹⁰

Yet Scholendorff did not justify a more general right of informed consent because the courts did not hold that physicians were required to disclose information about the risks of medical treatment, treatment options, or even diagnoses. For this reason, medical professionals continued to paternalistically withhold information from patients well into the twentieth century.

As legal and ethical standards of treatment expanded from consent to informed consent, the justification for expansion of patient authority has changed as well. Informed consent emerged as legal doctrine in 1957 with Salgo v. Leland Stanford, Jr. University.¹¹ In this case Martin Salgo was rendered permanently paralyzed by an operation that he consented to, though he claimed that his consent was compromised since he had not been informed of the risks associated with the procedure. The California Court of Appeals agreed, and determined that doctors had not only a duty to secure consent for medical treatment, but also to provide patients with any information about a medical decision necessary for consent. A series of cases followed in other states that confirmed this ruling, such that all states now require that doctors inform patients of the risks and benefits of treatment. ¹²

¹⁰ See Benjamin Cardozo’s decision in Schloendorff v. New York Hospital.
¹² Dolgin, “The Legal Development of the Informed Consent Doctrine.”
Physicians are now required to disclose any information that a reasonable person would find relevant to medical decisions, in addition to securing consent.\footnote{Alan Buchanan defends this practice and attacks the paternalistic withholding of information. Allen Buchanan, “Medical Paternalism,” \textit{Philosophy & Public Affairs} 7, no. 4 (June 1, 1978): 370–390.} Before the doctrine of \textit{informed} consent emerged patients only had the authority to refuse treatment, but new disclosure requirements developed with the doctrine to enable patients to play a more active role in choosing or declining a particular treatment over alternatives.\footnote{Salgo v. Leland Stanford Junior University Board of Trustees, 317 Pacific Reporter 2nd 170 (California Court of Appeals 1957).} The courts have affirmed this doctrine time and again—“a physician violates his duty to his patient and subjects himself to liability if he withholds any facts . . . necessary to form the basis of an intelligent consent by the patient to the proposed treatment.”\footnote{Salgo v. Leland Stanford Jr.}

In practice, this means that physicians cannot withhold information of a terminal diagnosis for which there is no treatment, even if the patient would have been happier and medically no worse off without the diagnosis. Physicians cannot withhold information about the risks and benefits of potential treatments in order to encourage good decision making. It is impermissible for physicians to withhold information from parents of disabled children, as was once common practice, in order to alleviate parents from the pressure and guilt associated with making treatment decisions on behalf of their children. While physicians who paternalistically withhold information from patients usually have the best intentions, their behavior nevertheless violates patients’ rights.
3. Three Justifications for Informed Consent

I will focus on three reasons that have been widely cited in favor of the doctrine of informed consent:

**Medical Outcomes**: In general, DIC leads to better medical outcomes

**Epistemic Authority**: Physicians ought to treat the whole patient, not just the condition. Patients can assess what is in their overall interest better than physicians, so physicians should defer to patients’ judgments about treatment decisions.

**Normative Authority**: Patients have the sole authority to make self-regarding treatment decisions even if it is not in their overall interest to do so.

The first two justifications are broadly consequentialist. The medical outcomes justification is based on the empirical premise that institutional protections for DIC will promote patients’ medical interests on balance, even though it enables patients to make medically inadvisable treatment decisions in particular cases. R. Gillon puts the argument like this:

Far more harm than good would result from a social or moral system that permits, let alone requires, compulsory medical treatment—even life saving treatment—of competent adults in cases where those adults have competently and voluntarily rejected that treatment.\(^{16}\)

This is an empirical conjecture, which I will not assess here except to note that there are several ways that a disregard for DIC might lead to worse medical outcomes. Good

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medical care requires collaborative relationships of trust between physicians and patients. Patients who know that their physicians won’t coerce, trick, or mislead them are more likely to seek medical care and honestly disclose relevant information to their physicians. Further, patients are generally much more satisfied with medical services and medical outcomes themselves are better where physicians abide by DIC.

The epistemic justification for the doctrine of informed consent is grounded in the idea medicine ought to aim to treat the *whole* patient, not just her condition, and while physicians are experts about health, patients are experts about their overall well-being. Therefore, physicians ought to defer to patients’ judgment about treatment options. This idea originates with Mill, who famously argued in On Liberty:

Neither one person, nor any number of persons, is warranted in saying to another human creature of ripe years, that he shall not do with his life for his own benefit what he chooses to do with it. He is the person most interested in his own well-being, the interest which any other person, except in cases of strong personal attachment, can have in it, is trifling, compared with that which he himself has.

Bioethicists have affirmed this sentiment. Robert Veatch writes,

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There is no reason to believe that a physician or any other expert in only one component of well-being should be able to determine what constitutes the good for another being.\textsuperscript{20}

The following examples illustrate the sentiment behind the epistemic justification. First imagine a patient who is deeply religious and believes that it is wrong to accept blood transfusions. While a physician might correctly judge that a blood transfusion is in the interest of her health, she might also agree that it is not in her interests all things considered, given her cultural identity and religious commitments. Second, we might imagine a cancer patient who refuses chemotherapy in an effort to preserve her fertility, even though chemotherapy is in her medical interest. Third, some patients might refuse to schedule medically necessary treatment as soon as possible in order to participate in important life events, like a child’s wedding or a vacation with a spouse. In cases like these the doctrine of informed consent holds that a patient’s judgment about her \textit{overall} interests ought to prevail because health is only one among many values that are relevant to a patient’s medical decision making.

The strongest most widely cited justification for the doctrine of informed consent is the normative authority justification, which states that patient autonomy is morally valuable even if respecting a patient’s decisions isn’t in her medical or overall interest.\textsuperscript{21} For example, according to DIC, even hearing news of a terminal diagnosis would make a patient’s remaining days medically worse off and objectively worse overall, and indeed if


a patient would prefer that she never found out about the diagnosis, physicians still must disclose diagnostic information to their patients.

This justification for DIC relies on the premise that patient autonomy is a value and, importantly, that physicians ought to foremost respect patient autonomy, not promote it. That is, according to DIC physicians are charged first with respecting the autonomous choices their patients make, and only furthering a patient’s autonomous capacities in ways that accord with due respect. Even if a patient’s treatment decision makes her less autonomous in the long-term, physicians still are prohibited from interfering with that decision.22

For example, if a patient decides to refuse lifesaving treatment her decision will fully destroy her autonomous capacities, physicians cannot permissibly override such a decision or mislead or coerce her to accept lifesaving treatment according to DIC. Examples like these abound, patients have the right to refuse operations that will save their limbs, refuse treatment that will extend their lives, and refuse therapy that will preserve their cognitive capacities. In all these cases, DIC protects a patient’s right to refuse treatment even when refusal will undermine her autonomous capacities in the long run.

There are several reasons to accept this justification for DIC. First, the idea that autonomous people have the normative authority to make self-regarding decisions without coercive or deceptive interference rests on a solid base of support in normative

22 Ibid.
ethics, particularly the neo-Kantian and contractualist that have been well developed by Christine Korsgaard, Stephen Darwall and T. M. Scanlon, respectively.²³

Whatever the normative ethical underpinning, the core of the moral justification for informed consent appeals to the widespread beliefs each person is entitled to power over the proceedings for decisions that effect her, and that the right to make intimate and personal decisions about one’s own body is fundamental.²⁴ As Tom Beauchamp has argued, the value of autonomy is affirmed by a plurality of moral theories, and is one of our moral convictions that inspires widespread confidence with little apparent bias.²⁵ This sentiment is also reflected in legislation and court decisions that affirm other basic rights to make self-regarding intimate and personal decisions, particularly those that are especially important to people. Like other basic rights, self-regarding decisions about our own bodies warrant particularly strong protections from state interference, even if said interference is designed to promote citizens’ own welfare or overall autonomous capacities.

This interpretation of patient autonomy, as a value that physicians should respect, comports with more widely held intuitions about the value of autonomy. While some hard-nosed neo-Kantians disagree, most affirm that our autonomous capacities are not so

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²⁴ Korsgaard, *The Sources of Normativity*.

valuable in themselves that the moral importance of an autonomous will trumps the value of respecting autonomous choices.\textsuperscript{26}

Importantly, this interpretation of the doctrine of informed consent values autonomy as a trait that one should respect and only promote in ways that accord with due respect. There are several advantages to this interpretation of the value of autonomy. First, to say otherwise and endorse the view that one ought to foremost promote autonomy seems to deny that people can permissibly choose to get drunk, ride roller coasters, stand on their heads for a long time, binge eat, fail to exercise, or watch reality television, because all these activities also can undermine or alter one’s autonomous capacities either temporarily or permanently. This interpretation reduces an autonomy-based principle to a kind of consequentialism that merely focuses on autonomous capacities rather than well-being. Instead, I am suggesting that autonomy it is a thoroughly non-consequentialist constraint on the conduct of physicians.

Second, this interpretation of the value of patient autonomy is also the best explanation for DIC in theory and practice. An essential commitment of DIC is that a physician acts wrongly if he misleads or coerces a patient into having an operation (say, taking out a few non-vital body parts). DIC prohibits such actions even if an operation on patient A would benefit patients B and C (by redistributing A’s organs to them), and even if on balance the violation of patient A’s normative authority to refuse treatment made the set of patients (A, B and C) more autonomous overall.\textsuperscript{27} For the same reason physicians act wrongly and violate DIC if they coerce or mislead a patient at time $t_a$ in order to ensure that the patient is maximally autonomous over the extended time of $t_a$, $t_b$, and $t_c$.

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\textsuperscript{26} Velleman, “Against the Right to Die.”
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DIC therefore is committed to the idea that patient autonomy is not a value that physicians should maximize or promote between patients or over the course of a patient’s life; it is a value that physicians should respect.  

One asymmetry between the synchronic and diachronic cases above is that patients cannot permissibly decide to undermine other’s autonomous capacities, but patients can make decisions that limit the autonomous capacities of their future selves. For example, if a patient pre-discloses that she doesn’t want to know her diagnostic or treatment information, this kind of practice is not incompatible with the normative authority justification for informed consent. Just as patients are entitled to autonomously make risky or dangerous decisions that have long term consequences for their well being, so too are patients entitled to autonomously make decisions that have consequences for their level of autonomy. For example, GT Laurie has argued that patients have rights not to know genetic information if they give advanced consent that the information be withheld. On the other hand, advanced directives only go so far, and a patient’s prior wishes not to know are not authoritative if the patient competently changes her mind.

For these reasons, even if a patient’s refusal decision would make her medically worse off, worse off all things considered, and less autonomous, patients are nevertheless entitled to refuse medical treatment and any coercive or deceptive interference in the patient’s refusal-decision is wrong.

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28 Parfit goes the other way on paternalism. Derek Parfit, Reasons and Persons, Reprint. (Oxford University Press, USA, 1986). Pg. 321
Before I continue, a note about methodology is in order. While I maintain that the normative authority justification is the strongest, my goal in this essay is to show that all three credible justifications for DIC tell in favor of self-medication. I will therefore show that a right of self-medication does not rely on any particular (and for some, controversial) normative premise but rather that a right of self-medication is as broadly supported as DIC. Both consequentialists and non-consequentialists have reason to support self-medication. For this reason, patients have rights of self-medication even if self-medication would lead to worse medical and overall outcomes. Yet a right of self-medication would promote patients’ medical and overall well-being, so the case for self-medication is even stronger.

I will now argue that the consequentialist and non-consequentialist reasons that I have presented in favor of DIC also justify a right of self-medication.

4. Medical Outcomes

The first justification for the doctrine of informed consent posits enabling patients to refuse treatment decisions leads to better medical outcomes in general, even if it enables poor decision-making in particular cases. This justification rests on an empirical hypothesis about the effects of informed consent. Setting aside the question of whether the data tell in favor of informed consent, what can this justification say about the prescription drug system? In Chapter 2, I presented some evidence to suggest that a right of self-medication wouldn’t necessarily have worse public health consequences than prescription drug and premarket testing systems; in fact, consequences might be better. Briefly, I will review these considerations here.

First consider the prescription drug system. In the United States, the prescription
drug system emerged in 1938 and was firmly in place by 1941. To review, Sam Peltzman’s analysis of time series data from the US vital statistics report from 1900-1980 found that the introduction of a prescription drug system in the 1940’s did not reduce mortality from accidental or suicidal poisonings. Instead, the introduction of a prescription-only category of drugs correlated with more fatal poisonings. Peltzman hypothesizes that consumers were more risk-acceptant about drug use when a physician endorsed their choice. Similarly, in a comparative analysis of middle-income countries that enforced prescription drug prohibitions to varying degrees, Peltzman found that enforcement was correlated with higher mortality rates. States that enforced prescription-only drug regulations had 50-100% higher rates of poisoning mortality than non-prohibitive countries. As above, Peltzman hypothesizes that the paradoxical increase in drug misuse can be attributed to the fact patients use risky prescription drugs more in states that enforce prescription-only requirements, so prescription-only regimes actually encourage dangerous drug use by making the authorized use of dangerous drugs seem safe. Another explanation for these poor public health outcomes is that prescriptions were unavailable to some patients who needed them in countries that enforced prohibitions.

I describe this history in more detail in Chapter 1.

One explanation for the seeming ineffectiveness of a prescription drug system is that prescription-only designation coincided with an explosion of new and dangerous drugs. Perhaps fatal poisonings would have increased were it not for a prescription only system. Comparative data between countries suggests this is not the case. Peltzman compared middle-income countries with enforced prescription drug systems (Argentina, Uruguay, Ireland, Israel, Italy Portugal, Spain, and Japan) to countries that did not enforce prescription drug laws (Chile, Colombia, Ecuador, Mexico, Peru, Venezuela, Greece, Yugoslavia, Egypt, Hong Kong, Philippines, Singapore, and Thailand). Peltzman found that controlling for the effect of income and income inequality on infectious disease mortality, enforced prohibitions on prescription drugs did not reduce mortality from infectious diseases. Sam Peltzman, “The Health Effects of Mandatory Prescriptions,” Journal of Law and Economics 30, no. 2 (September 1, 1987): 207–238.
The poor outcomes associated with premarket prohibitions are more difficult to test because the prohibitive premarket testing standards in Europe and North America determine availability of drugs worldwide.\textsuperscript{33} Still, the effects of drug loss, drug lag, and high pharmaceutical costs all must be counted as poor medical outcomes of testing requirements. Even though clinical trials promote good medical outcomes, prohibitive policies are not necessary to this end, as I argued in Chapter 5. Further, even if prohibitions did drug disasters (and I have suggested that they do not,) prohibitive premarket testing requirements likely cause more death and suffering on balance. The balance of evidence that I presented in Chapter 2 strongly suggests that prohibitive systems have poor medical outcomes relative to less prohibitive systems. This evidence does not show that a fully non-prohibitive system would be best, but it does show that stronger rights of self-medication would likely improve public health outcomes.

One response to these studies is that they mask a more general medical cost of non-prohibitive regimes. As I discussed in chapter 4, the option to access any medication, particularly deadly medication, would cause greater patient anxiety and dissatisfaction.\textsuperscript{34} If more medical choices caused an epidemic of choice-induced patient anxiety, then patient anxiety might be counted as a poor medical outcome associated with self-medication.\textsuperscript{35} Still, in order for this cost to justify prohibitive policies it must on balance outweigh the benefits of stronger rights of self-medication. Consider this analogy. Adopting DIC may have enabled medically inadvisable refusal decisions and caused a


\textsuperscript{34} Velleman, “Against the Right to Die.”

great deal of anxiety for patients who learned of diagnoses they wouldn’t otherwise have
known; but the macro-effects of DIC caused better medical outcomes on balance and
many patients were spared unwanted medical interventions. Similarly, adopting a right of
self-medication would enable patients to access medically inadvisable treatments and
may cause patients to experience more anxiety about their medical choices, but on-
balance prohibitive pharmaceutical policies make patients medically worse off.

Further, prohibiting some treatment options is not necessary to mitigate the
anxiety caused by more medical options. Alternatively, patients can access counseling to
help them make decisions about medical treatment. Patients can also defer to their
physicians if they are anxious about choosing alone. Also, some pharmaceuticals are
specifically designed to treat anxiety, and a right of self-medication would make those
drugs, like Valium or Lexapro, available to patients who might otherwise suffer from
anxiety as a result of having pharmaceutical options. In a non-prohibitive prescription
drug system patients could even fully autonomously decide to temporarily delegate
medical authority to doctors and avoid any pressure and anxiety associated with choosing
from many different treatments. Yet with a right of self-medication, those who disagree
with physicians judgments would enjoy additional options and avoid any anxiety
associated with lacking choices.

In sum, the bad medical outcomes associated with self-medication can be avoided
but the bad medical outcomes associated with prohibitive premarket testing requirements
cannot because they are intrinsic to the system. Perhaps countries could take some
measures to discourage overly risk acceptant decision making where prohibitive
prescription drug systems are enforced, but a right of self-medication avoids these poor
outcomes as well. While a right of self-medication might cause bad medical outcomes in particular cases, e.g. when patients use dangerous drugs to harm themselves, I have suggested that prohibitive drug requirements *on balance* have worse medical outcomes than self-medication would. Still, a more nuanced approach to drug regulation may have the best medical outcomes of all three choices, (prohibition, quasi prohibition, permissive policies.) In response to this possibility I will now argue that medical outcomes are not the *only reason* to favor self-medication; just as the doctrine of informed consent developed in part to make patients and society better off, so too should a right of self-medication, but even if self-medication did not have good health outcomes it is still required by justice.

5. Epistemic Authority

The epistemic authority justification for DIC stated that while physicians might be experts about a patient’s medical well being, patients are best suited to make decisions about their all things considered well being. This principle was grounded in part in Mill’s famous arguments against paternalism in On Liberty. It is therefore unsurprising that Mill affirmed a right of self-medication when he argued that it was wrong to require in all cases prescriptions for the use of potentially dangerous drugs because “no one but the person himself can judge the sufficiency of the motive which may prompt him to incur the risk.”36 The current restrictions on pharmaceuticals are designed to promote patients’

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36 Mill writes “Nevertheless, when there is not a certainty, but only a danger of mischief, no one but the person himself can judge of the sufficiency of the motive which may prompt him to incur the risk: in this case, therefore, (unless he is a child, or delirious, or in some state of excitement or absorption incompatible with the full use of the reflecting faculty) he ought, I conceive, to be only warned of the danger; not forcibly prevented from exposing himself to it. Similar considerations, applied to such a question as the sale of poisons, may enable us to decide which among the possible modes of regulation are or
health, but not their overall well-being. For this reason, a prescription drug system is incompatible with this justification for informed consent.

To see how the prescription drug system privileges physicians’ judgments about treatment over patients’, consider the example of Adderall. While Adderall is only prescribed for the treatment of Attention Deficit Disorder, a growing number of students and workers without ADD have found that taking Adderall increases their performance and productivity. Those without a diagnosis of ADD cannot legally buy Adderall because they do not have a physician’s prescription for the drug. Consequently, black markets for Adderall have formed at college campuses, but those who purchase the drug without a prescription do so illegally.

Just like patients with ADD who give informed consent to take Adderall, black market Adderall consumers judge that the potential benefits of taking Adderall outweigh the risks. Physicians and pharmaceutical regulators permit access to a drug if they judge that the medical risks outweigh the medical benefits. When drugs don’t provide any medical benefit, no amount of risk can justify their prescription, so patients without medical conditions lack access to potentially beneficial drugs. For example, we can imagine that the overall benefit of Adderall for some kinds of students and workers without ADD would be even greater than the overall benefit of Adderall for patients with ADD. Compare for example a college student in a highly competitive and stressful...
environment, who must complete projects that require a great deal of focus, to an independently wealthy man of leisure who has ADD, but no pressing deadlines or goals. While the wealthy man of leisure might have more of a *medical* reason to use Adderall, the benefits of the drug for his life as a whole don’t exceed the benefits that the college student would enjoy. A similar argument can be made against experimental drug prohibitions. Even if it is medically inadvisable for a patient to use an untested drug, if the potential benefits of the drug are high enough then patients may judge that the known and unknown medical risks of using untested drugs are worth it for the potential benefits.

The doctrine of informed consent is justified in part by the idea that patients are in a better position than physicians to judge whether the overall benefits and risks of consenting to a treatment are justified given their life as a whole, and to refuse if they are not. If a patient decides that consenting, though medically advisable, isn’t advisable given her projects and commitments, the physician ought to defer to her judgment about the treatment decision. The prescription drug system deprives patients of that deference. Prescription-only prohibitions privilege physicians and regulators judgments about what is medically advisable over a patient’s judgments about which treatment decision makes the most sense given her life as a whole.

These prohibitive policies are not only at odds with informed consent, but also with other areas of medicine like cosmetic surgery. Even though cosmetic surgery doesn’t provide patients with any medical benefit and carries significant risks in many cases, physicians still provide patients with cosmetic procedures because their patients are willing to accept some level of medical risk for an overall, non-medical benefit. If patients can assume medical risks for overall benefits in this case, why not for
prescription drugs as well? Other areas of medicine, like sports medicine, also embrace the idea that health is one of many values and that medical professionals can rightly make trade-offs between health and career gains. Some drugs are explicitly designed and marketed for potentially non-medical reasons, and non-medical conditions can be re-characterized as medical conditions for the drugs to be legally sold.\(^{37}\) In some ways any condition qualifies as a medical condition insofar as it can be treated with medicine, but the very definition of disease or dysfunction is defined in part by addressing the necessity of particular capabilities for a patient’s broader projects and goals.

When a physician makes a decision about whether to allow a patient to access a prescription-only drug, the decision is based on a risk/benefit ratio of the drug that depends on the severity of the condition it treats. Similarly, when a regulatory official decides to designate a drug as prescription-only, or unapproved, or to withhold approval until further tests are completed, she also makes a decision on the basis of a particular risk/benefit judgment. In both cases gatekeepers accept more risk for conditions that are particularly painful or dangerous, because the potential benefits are greater. Similarly, when regulators decide to withhold approval for a drug it is based on the judgment that unknown risks and side effects are too dangerous to allow given the potential but also unknown benefits of the experimental drugs. These judgments are normative judgments, not a scientific judgment.

\(^{37}\) For example, psychiatrists have recently debated whether premenstrual disphoric disorder was a real medical diagnosis or a symptom of normal menstruation. This decision will effect whether drug companies can legally develop and market new drugs to treat menstrual symptoms. See “The billion-dollar battle over premenstrual disorder: Long-suffering women and big pharma make uneasy allies as the American Psychiatric Association nears a call on PMDD” NATASHA VARGAS-COOPER, Salon, FEB 25, 2012
For example, patients display differential levels of tolerance for conditions and side effects. One patient may be extremely bothered by restless leg syndrome but tolerate dizziness with ease, whereas another may find that a side effect like dizziness is worse than a condition like restless leg syndrome. These patients will come to different judgments about whether taking a drug that is associated with dizziness to treat restless leg syndrome is worth it for them. This variation is one reason to affirm the doctrine of informed consent, because it enables patients to judge for themselves whether treatment is worth it given the potential costs and benefits. Self-medication also empowers patients to make these kinds of judgments for themselves. Medical experts might be best placed to accurately determine the risks and benefits associated with a drug, but it doesn’t follow that they are best placed to determine whether the medical risks are worth the potential medical benefits for a particular person.

Still, medical experts do have a significant epistemic advantage, and their advice is relevant to a patient’s judgment about her overall interest. Many of us have a strong interest in preserving our health, and it is therefore important that information about whether a treatment is medically advisable is an important public good. However, prohibitive policies are not necessary for the provision of the public good of medical advice. Pharmaceutical regulators and physicians might certify new drugs as safe, effective, or advisable without prohibiting patients from accessing unsafe drugs. Or, as a less extreme proposal the behind the counter model might be extended to all drugs,

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38 This kind of concern is addressed in the ‘overtreatment literature’ in medical ethics, which asks whether physicians ought to be gatekeepers to treatment even when patients have conditions that to some extent merit treatment. P. Franks, C. M Clancy, and P. A Nutting, “Gatekeeping Revisited—protecting Patients from Overtreatment,” New England Journal of Medicine 327, no. 6 (1992): 424–429.
meaning that in order to access a drug patients must consult with a pharmacist or physician about the expected risks and benefits (or opt out of these information requirements and perhaps waive the legal right to sue in case of adverse effects.) In this way, patients can still access the judgment of medical experts, but where patients judge that their overall well-being departs from an expert’s judgment about their medical well-being, they can still access their chosen treatment.

6. Normative Authority

The third and strongest justification is based on the non-consequentialist premise that physicians ought to respect patients’ autonomous self-regarding choices about what they do with their own bodies. This justification maintains that physicians ought to respect a patient’s autonomous decisions, even if they are not in the patient’s medical or overall interests. As I described above, there are many reasons to accept that patient autonomy is a value that medical practice ought to respect; here I will argue that the value of patient autonomy also tells in favor of self-medication.

Most clearly, this justification supports the doctrine of medical consent, which protects patients from forced medical interventions. The value of patient autonomy is also the basis of informed consent: physicians cannot mislead or coerce patients into consenting to treatment. Even if a physician never forces a treatment on a patient, he can still violate her right to make decisions about her own body if threatens her, or withholds relevant information, or lies. The right of informed consent has negative and positive elements. DIC establishes a negative right against coercion, deception, and bodily interference, and a positive right to access necessary information to make an informed
decision. The normative authority justification also supports both negative and positive elements of a right of self-medication.

DIC prohibits physicians from deceptively or coercively undermining a patient’s ability to make treatment decisions. In contrast, the prescription system legally empowers physicians and regulators to coercively limit patients’ ability to make treatment decisions. DIC holds that physicians cannot stand in patients’ way of making their own treatment decisions by withholding information. In contrast, the prescription drug system stands in patients’ way of making their own treatment decisions by withholding access. These tensions should be resolved on the side of self-medication. The value of patient autonomy prohibits interference with medical decision-making. Pharmaceutical regulation is a form of coercive interference. Prescription drug regulations therefore offend against the value of patient autonomy and are inconsistent with the normative authority justification for DIC.

Above I argued that according to DIC physicians ought to respect, not promote the value of patient autonomy. Even when a patient autonomously chooses to make refusal-based decisions that will likely undermine or destroy her autonomous capacities in the long run, physicians must respect those decisions. Similarly, even if a patient seeks to make a medically inadvisable access-based decision that will undermine or destroy her autonomous capacities, regulators, pharmacists and physicians are not entitled to coercively prevent her from accessing risky treatments. Patient autonomy is not the kind of value that physicians should merely promote within some consequentialist calculus. Rather, the value of patient autonomy places deontic constraints on the conduct of medical professionals. Public officials can only permissibly act to promote patients’
autonomous capacities in ways that accord with due respect for the patients, just as it is impermissible for physicians or pharmacists to interfere by forcing a patient to accept treatment. Coercively interfering with a patient’s treatment decisions, whether they are refusal-based or access-based, does not accord with due respect and is therefore impermissible even when interference would preserve the patient’s autonomous capacities in the long run.

Like other negative rights, informed consent and self-medication have positive elements in that they require accommodation and non-interference. If a citizen has a negative right that people not interfere with her personal property and public officials fail to enforce her property claim, then public institutions fail to protect her property rights. This doesn’t mean that officials need to provide citizens with personal property. Rather, this example shows that negative rights sometimes require the positive provision of some kind of accommodation.

If DIC has a positive element like this, public institutions must not only affirm DIC they must legally enforce it as well. In this sense, the value of patient autonomy also tells in favor of institutions that ensure effective access to treatments, including a legal right of self-medication and legal access to medication itself. For example, if a patient seeks to use a medically inadvisable treatment, not only is she entitled to purchase and use the treatment, but her right merits enforcement. Public institutions should therefore accommodate citizens’ rights of self-medication and require pharmacists and physicians to allow universal access to treatments that they provide, though not to provide particular treatments. 39

39 See eg painkillers and birth control
DIC also protects patients’ rights to access all relevant information about treatment options, and in this sense the positive provision of some treatment-relevant goods are required for patients to make informed treatment decisions. Information isn’t the only thing required to make a treatment decision, in some cases the treatment itself is required as well. That is, just as physicians are required to provide information, to fully insure that patients are the one’s making their own treatment decisions they must also provide access. Yet this positive element of self-medication only goes so far. While consumers are entitled to effective access, self-medication does not require that manufacturers or the government to actually provide patients with pharmaceuticals— it only requires that they not stand in patients’ way when patients wish to access what is available to others and that they protect the right to access pharmaceuticals.

**7. Asymmetries Between Consent and Self-Medication**

I have argued that the same reasons that justify the doctrine of informed consent are also reasons to support an unconditional right of self-medication. Still, lying to patients is a form of fraud, and performing unwanted medical interventions is a form of battery, but standing in a patient’s way when he seeks treatment or failing to provide treatment do not amount to fraud and battery. In this section I will address some asymmetries between consent and self-medication.

Failing to obtain informed consent is wrong for many reasons. In some cases it is a kind of battery, when a physician does something to the patients’ body without her consent. In some cases it is a form of fraud, when a physician knowingly misinforms a patient about her treatment options in order to promote one treatment over another. But not all cases of informed consent reduce to cases of fraud or battery, and the wrongness
of violating informed consent requirements is not fully reducible to the wrongness of fraud or battery. Consider this objection:

Different Rights: Informed consent is qualitatively different from the right of self-medication. If a right to informed consent is violated then a patient has been assaulted or mislead, whereas if the right to self-medication is denied then a patient has not been similarly harmed, if there is any harm at all.

There are two interpretations of this objection, first that violating the requirements of informed consent is worse than denying rights to self-medication (I agree,) and second that patients do not have rights to self-medication more generally (I disagree.)

Consider first the claim that denying patients’ right to give medical consent is almost always worse than denying a right of self-medication. Not only do failures of medical consent violate patients’ right to make medical decisions autonomously, performing a medical procedure without a patient’s consent is battery. This response is warranted, but it fails to get the conclusion that self-medication isn’t a right. The shift from consent to informed consent showed that medical paternalism is wrong for reasons that don’t include battery. Just because failing to obtain informed consent doesn’t reduce to battery doesn’t mean that informed consent isn’t a right. Similarly, failures to secure informed consent are probably worse than denying a right of self-medication in many cases, but violations of self-medication are still wrong. When physicians mislead patients about the risks of treatment fail to respect the practical and epistemic authority of patients, they also commit a form of fraud. In other words, failures to obtain medical or informed consent are typically wrong for several reasons, because they are a form of battery or fraud and also because they fail to respect the epistemic and practical authority
of patients. Yet not all cases of informed consent reduce to cases of fraud, and not all failures of medical consent constitute battery.

Failure to disclose is the clearest example of how informed consent requirements are not reducible to prohibitions on fraud. Physicians can violate patients’ rights of informed consent without misleading them about their treatment options when they fail to disclose information that the patient would have found relevant to her treatment decision. For example, in Johnson v. Kokemoor and Whiteside v. Lukson the courts found that physicians have a duty to disclose their experience and performance data, even though this information isn’t information about the risks and benefits of a particular treatment.  
40 Cobbs v Grant, a case that defined the present standards of informed consent law, found that physicians must disclose the risks and benefits not only of a particular treatment, but also the potential risks and benefits of alternative treatments and of no treatment.  
41 In these cases, physicians can accurately describe the risks and benefits of a treatment, and thus they do not commit any acts of fraud, but they still violate patients’ rights of informed consent. Such practices are wrong even if all medical procedures are refused and no fraud or battery is committed. They still violate DIC. These considerations show us that that the epistemic and practical authority of patients does real work in justifying the doctrines of medical and informed consent.

Therefore, violating patients’ rights to give medical or informed consent is wrong for additional reasons beyond fraud and battery. These additional reasons also make violations of rights to self-medication wrong. The fact that violating a patient’s right to refuse treatment is typically worse than denying a patients right to information about

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40 Johnson v. Kokemoor and Whiteside v. Lukson
41 Cobbs v Grant, For more on the ethics of this case see Weisbard, “Informed Consent.”
treatment which is typically worse than denying rights to self-medication, does not establish that patients do not have rights to information or self-medication.

Now consider the second form of the objection, that patients don’t have rights to access medical treatment because the right to access treatment is qualitatively different from the right to refuse. This objection is true, but misplaced. While our rights against fraud and battery are qualitatively different from our rights to self-medication, the more general right to make medical decisions isn’t qualitatively different when it applies to refusal-based decisions or access-based decisions. As I showed above, neither refusal choices nor access choices necessarily hinge on a right to bodily integrity or a right against fraud, what unites them is the conviction that the patient is the ultimate authority in medical decision-making. This authority doesn’t distinguish between the authority to refuse and the authority to choose, refusal is a sub-species of the general authority to decide.

One way to see how informed consent requirements are not qualitatively different from the right of self-medication is to consider the parallels between failures to disclose information and failures to provide access. In both cases, physicians are liable for failing to provide a good that is required for a patient to make a treatment decision, whether the good is information about the treatment or the treatment itself.42 When a physician or official acts in ways that deprive a patient of any good that is necessary for patient autonomy they violate the patient’s right to make his own treatment decision.

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42 For similar reasons, fraudulent pharmaceutical advertising is wrong because it misleads a patient in ways that undermines her ability to make her own treatment decisions. I will discuss this case in more detail in Chapter 10.
8. Conclusion

This argument calls for radical changes in the practice of medicine. Self-medication requires that agency officials, physicians and other experts cannot act as gatekeepers for most medical treatments. In addition to the qualified, conditional rights that I argued for in the previous chapters, I have argued here for an unconditional right of self-medication. Still very little needs to change in practice despite the revisionary nature of this argument. Patients still can consult with expert’s physicians and pharmacists about the risks and benefits of medication, and will in most cases choose the medically advisable treatment options that would have been chosen for them under the current system. The right of self-medication only departs from the current practice of medicine in cases where patients disagree with physicians’ judgments about what the patient ought to do. Yet in these cases, just as in the case of informed consent, medical experts should defer to patients because patients are epistemic authorities about their own all-things-considered interests and practical authorities over their own bodies.

My argument has been developed from current medical practice, and does not rely on a broader rejection of all forms of paternalism. Rather, I have argued that existing anti-paternalistic principles that are central to medical ethics also support self-medication. Enabling patients to refuse medical treatment against medical advice has expanded patients’ choices and medical autonomy; the right of self-medication continues this expansion of patient rights. The relatively recent adoption of the doctrine of informed consent is evidence of moral progress in medicine; self-medication is the next step.
VIII. Doing, Allowing, Regulating

In light of the foregoing discussion of the costs of regulation, both consequentialist and rights-based theorists ought to disapprove of the current regulatory regimes that are present in developed liberal societies.¹ So far I have argued that pharmaceutical regulations likely cause more death and suffering than they prevent and violate rights. Still, many philosophers and ordinary citizens recognize that there is a moral difference between allowing people to suffer or die from their diseases and directly harming or killing people by exposing them to dangerous drugs. From this intuitive distinction between doing and allowing, killing and letting die, we can reconstruct a defense of regulation that might succeed despite the grim empirical findings.

Briefly, defenders of regulation might argue that drug manufacturers are responsible for death and suffering that results from dangerous drugs. In contrast, when people suffer and die for a lack of drugs their diseases cause suffering and death, not the drug regulations that block access to helpful or curative drugs. In this way, manufacturers’ actions are more morally serious because their actions are more similar to killing, while regulators do not kill patients; they merely let patients die from their diseases. Thus, since killing is morally worse than letting die, even if regulation results in more deaths on balance, it is still justifiable if it prevents manufacturers from killing patients with dangerous drugs.

This defense has intuitive force for those of us who believe that there is a serious moral difference between killing and letting die, and I suspect that such a defense

¹ In earlier chapters I reviewed the history of pharmaceutical regulation and recent work in health economics. There, I argued that pharmaceutical regulation costs many more lives than it saves and causes much more suffering than it prevents.
explains much of the public support for drug regulation. Yet the defense fails under closer scrutiny because the best available defense of the distinction between killing and letting die does not support prohibitive pharmaceutical regulations. The reason that killing is generally worse than letting die is that killing is generally a violation of people’s negative rights and a primary manifestation of the killer’s agency. As long as manufacturers disclose all known risks, hazards, and expected efficacy of drugs, releasing dangerous drugs neither violates patients’ rights nor does it constitute a primary manifestation of the manufacturers agency. On the other hand, when public officials’ actions lead to thousands of deaths, because they coercively prohibit access to drugs, their actions do violate patients’ negative rights and are to some extent a primary manifestation of the government’s agency. While the deaths that regulators cause do not rise to the level of murder, they are certainly more morally serious than merely allowing patients to die from their diseases. Therefore, the actions of regulators are morally worse than the decision to sell dangerous drugs.

This conclusion is counterintuitive. Patient advocates and the public condemns manufacturers whose drugs kill patients, but few would accuse pharmaceutical regulators of killing the public. While the folk defense held that pharmaceutical regulation was permissible because killing is worse than letting die, I will show that the distinction between killing and letting die actually shows that pharmaceutical regulation is even worse than the empirical record suggests.
1. Killing and Letting Die

In this section I will defend what I take to be the best justification and explanation of the distinction between doing and allowing, (and killing and letting die.) After a brief introduction to the distinction, I will argue against a non-moralized account of the distinction between killing and letting die. Then I will defend a moralized justification for the distinction. I will also consider some psychological explanations for the distinction.

The moral distinction between doing and allowing can be illustrated with the following case.

*Organ Redistribution:* Imagine you are a physician, and five patients are in your care. One patient is expected to live and four are expected to die, but if you secretly kill the one who you expect will live you can redistribute his organs to the four who would otherwise die of their diseases, thus saving their lives. No one will ever know that you killed the one to save the four, so your action will not have any systematic negative consequences, like undermining doctor-patient relationships or causing widespread paranoia and anxiety. ²

Most people have an intuition that it would be wrong for you to kill the one to save the four, even if on balance more people will live as a result of your actions and the consequences would be better.

There have been a variety of attempts to characterize the distinction between doing (and killing) and allowing (and letting die). Many of these attempts rest on some metaphysical distinction between what we cause and what we allow. This strategy

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² This case was posed by Judith Thomson and is a variant of the famous ‘trolley problem,’ developed first by Philippa Foot and Thomson. See Thomson, Judith Jarvis, “The Trolley Problem” The Yale Law Journal, Vol. 94, No. 6 (May, 1985), pp. 1395-1415
reflects the observations that when we *act* we take ownership of the causal chain that originated with us whereas when we *allow* we do not take ownership of the events that are already in play.\(^3\) In paradigm cases, killing involves initiating a causal sequence that results in death whereas letting die involves failing to stop an existing causal sequence that will result in death.\(^4\)

These causal strategies run into troubling counterexamples. For example, people can kill through inaction; when a nurse fails to feed the incapacitated patients under his care, our intuitions suggest that he kills them.\(^5\) Defenders of this approach might revise, and argue instead that one kills when she is a *but-for* cause of death, whereas she lets die when the death would have happened whether she was involved or not.\(^6\) But again, counterexamples emerge.

*Certain Death*: Imagine that Mr. Orange is badly wounded from a failed heist, and will surely die from his injuries. As he lay in Mr. White’s arms, Mr. Orange

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\(^3\) Examples of this strategy can be found in ethics and in the law. The legal requirement of proximate cause as a requirement for assessments of harm states that a defendant must be a ‘but for’ cause of the harm that occurred in order to be held liable. See for example, Will Cartwright, “Killing and Letting Die: A Defensible Distinction,” *British Medical Bulletin* 52, no. 2 (April 1, 1996): 354–361.; Weisbord, “Informed Consent.”


\(^6\) This view is reflected in the law, and also Shelly Kagan discusses a version of this view where an agent kills only if the death only would have occurred if he existed, and would not have occurred had he never existed. Put this way, there are obvious problems with this account and few would defend it. See Shelly Kagan, *The Limits of Morality* (Oxford University Press, USA, 1991).
confesses that he has betrayed Mr. White because he is actually an under cover police officer. Mr. White shoots Mr. Orange in anger and Mr. Orange dies.  

Surely in this case Mr. White has killed Mr. Orange, even though Mr. Orange would have died from his injuries had Mr. White not been involved. Yet in this case Mr. White was not a but-for cause of Mr. Orange’s death because had Mr. White not shot Mr. Orange he would have died still. We might revise to say that Mr. White was a but-for cause of Mr. Orange’s particular death, and that is why it still qualifies as killing, but this revision seems too inclusive, because it will characterize cases that are intuitively instances of letting die as killing. For example:

Rock Climbing: Imagine you and I are rock climbing. You slip, but I catch your rope. Then, seeing that you are too heavy for me to hold, I let you go.  

Intuitively, I did not kill you this case, I allowed you to fall, even though I was in some sense a cause of your particular death.

Together, these examples suggest that no purely causal or metaphysical account of the distinction can capture our intuitions about the moral distinction between doing and allowing. Nor can a theory of intention or bodily action explain the distinction, since in rock climbing I intentionally caused your fall by physically letting go. For these reasons, I am skeptical that non-moral distinctions can give us much insight into the doing and allowing distinction because I think that the distinction between doing and allowing actually tracks a distinction in circumstances that in general neatly aligns with other moral distinctions we care about.

7 Spoiler alert! This is the plot of Reservoir Dogs.
8 Cartwright, “Killing and Letting Die.”
The failure of causal explanations for the distinctions points to the need for a moralized conception. Warren Quinn develops a moralized defense of the distinction. Quinn argues that “doing” cases are those where the agent’s primary contribution to the bad outcome is an action, whereas “allowing” cases are those where it is an inaction. Yet the rock climbing case above illustrates the difficulty with this approach, sometimes our actions are intuitively cases of allowing. Also, sometimes our inactions are intuitively cases of doing:

*Crosswalk:* Imagine your car is coasting down a hill towards a crosswalk full of people. You decide not to press the breaks, and several people are run over by your car. Still, something in this neighborhood seems true.

Quinn goes on to say that positively contributing to harm violates people’s negative rights, their rights against being harmed for example. In contrast, negatively contributing to harm violates people’s positive rights, such as their right to assistance. Since it is worse to violate people’s negative rights than positive rights, acts of doing are worse than allowings.

This, I think, is the truth in Quinn’s analysis. Whatever the distinction between doing and allowing, it will rest on a theory of right and wrong. Usually, acts of doing/killing are more wrong than acts of allowing/letting die because doings/killings violate people’s negative rights not to be harmed, whereas allowing/letting die violates positive rights to assistance. Attributions of responsibility also neatly align with the distinction between doing and allowing. In general, we consider ourselves (and others)

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9 Ibid.
more responsible for what we do than for what we fail to do. Thus, people are typically more responsible for doing/killing than allowing/letting die, which makes their role in any suffering morally worse.

What can we say about the distinction, in light of this framework? At minimum, a moralized reconstruction of the distinction is committed to the following:

**Doing and Allowing:** It is generally worse to kill or make someone worse off than to allow her to suffer or die, because it is worse to violate negative rights against being killed or harmed than positive rights. Further, we are generally more responsible for what we do than what we allow.

One way to interpret this reconstruction is that causal sequences that are intuitively cases of doing reliably align with violations of negative rights and responsible action, whereas causal sequences that are intuitively cases of allowing reliably align with violations of positive rights.

A stronger interpretation of this moralized reconstruction is that our intuitions about the distinction are moralized all the way down. Experimental evidence tells in favor of this strong interpretation, Joshua Knobe and others have shown that moral appraisals influence our judgments about causation.\(^\text{10}\) That is, where the above strategies sought to find moral significance in a theory of causation, our intuitive theory of causation depends largely on moral appraisals, particularly in cases of doing and allowing. This evidence indicates that attempts to make sense of distinctions between doing and allowing that rest

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on metaphysical distinctions are misguided, instead we must consider the morality reasons in favor or against each kind of act, instead of an act’s causal origin.

I will now consider several justifications for a moralized reconstruction of the distinction. First, the idea that it is worse to violate negative rights than positive rights, and that actions are more morally serious than inactions, has strong intuitive appeal. Those who would deny the distinction face the following forceful challenge from Francis Kamm:

You can’t seriously believe that you have a duty to give almost all your money away to help others in need, or even a duty to kill yourself to save two people…. and then when we ask why you don’t live up to that say, “Well, I’m weak. I’m weak.” Because if you found yourself killing someone on the street to save $1000 you wouldn’t just say, “Well, I’m weak!” you would realize that you’d done something terribly wrong. You would go to great lengths not to become a person who would do that. That’s a serious sign that you believe you have a moral obligation not to kill someone. But when someone says “Our theory implies that you should be giving $1000 to save someone’s life and if you don’t do it, that it’s just as bad as killing someone,” and he says, “I don’t give the $1000 because I’m weak!” then I can’t believe that he thinks that he really does have that obligation to aid or that his not aiding is equivalent to killing. Imagine him coming up to me and saying “I just killed someone for $1000, but I’m weak!”¹¹

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If negative rights violations were not morally worse than positive rights violations then failures to provide lifesaving would, in principle (setting aside negative externalities) be as much a blemish on one’s character as murder. I view this extension as too high an intuitive price for views that deny the moral distinction between violations of negative and positive rights, so I assume that negative rights violations are worse, though this claim remains controversial.

Quinn echoes Kamm’s challenge when he argues that to deny the distinction between doing and allowing is to embrace an unacceptable moral theory. Without a distinction between negative rights (against being harmed) and positive rights (against suffering) then our bodies and projects would be fully subject to the community’s cost-benefit analysis. If harming you led to less suffering overall, then morality would say you ought to be harmed. Act consequentialists believe this, but most of us believe that we have a special claim to control our bodies, even if exercising that control is in some sense worse for everyone. This special claim explains the greater weight of negative rights; they protect our unique entitlement to control our own lives and our own bodies in addition to our entitlement to escape death or suffering, whereas positive rights only protect the latter.

Samuel Scheffler makes a similar point, that denying the distinction between doing and allowing is unsustainable. Unlike Quinn, who focuses on a victim’s perspective, Scheffler develops this point from the perspective of the moral community. Scheffler argues that some distinction between doing and allowing is an essential feature of any non-instrumental conception of responsibility. That is, if we are going to have a

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12 Quinn, “Actions, Intentions, and Consequences.”
moral theory that assigns responsibility to people *at all*, it must recognize this distinction.

Scheffler gives two reasons for this point. First, he writes,

In order to regulate one’s life by reference to a normative standard that requires one to always make optimal use of the causal opportunities one has available, one must take a purely instrumental attitude toward one’s own actions. But in order to view oneself as subject to norms of individual responsibility at all…one must see oneself as having non-instrumental reasons to hold oneself to the normative standard…. (Furthermore,) in order to see other people as subject to norms of individual responsibility one must see them as having non-instrumental reasons to conform to the relevant norms and as subject to reactive responses that cannot be understood in purely instrumental terms.¹⁴

In other words, the very practice of acting as an autonomous and independent agent requires that we view our actions noninstrumentally, that our actions amount to more than the rote carrying out of impersonal moral requirements, that we refrain from seeing ourselves, or being, cogs in a consequentialist machine.

Imagine that we internalized a moral theory that denied the distinction between harming and allowing suffering. Such a moral theory would then require individuals to always eliminate suffering as much as possible. If we accepted this moral theory, people could not express their distinctive character and values, we would all become suffering-minimizes. Consequentialists may reply that it doesn’t matter if we have distinctive characters as long as we all do what is moral.¹⁵ Scheffler’s argument does not rule out such a response; but he suggests that a moral theory that views each person’s actions as

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¹⁴ Ibid.
¹⁵ For example, Peter Singer raised this objection in comments on an earlier draft.
instrumental to broader social goals, a theory that does not make room for individual
deliberation, (besides deliberation about which action would minimize suffering) will
also undermine norms of personal responsibility because those norms require that we see
ourselves and others in non-instrumental terms.

Scheffler then goes even further to suggest that if we internalized a moral theory
that denied the distinction between doing and allowing it would not be possible to define
ourselves as distinctive persons at all. Part of being a person consists in being able to
decide which reasons to take as relevant for action and to act on the basis of those
reasons. Moral theories that denying the distinction between our acts and our failures to
act, and theories which antecedently specify which reasons (consequences) are relevant to
our actions are theories that deny us this opportunity for self-expression and character
development.¹⁶

The relative wrongness of killing can be explained by the above considerations.
Killing is especially wrong because:

(a) It is worse to violate a person’s negative rights than positive rights

And,

(b) It is worse to cause death through primary manifestations of one’s agency (e.g. actions) than secondary manifestations of one’s agency (e.g. inactions)

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¹⁶ One objection to this view, (also raised by Peter Singer) is that it may suggest that
morality must allow people to torture innocents, so that the torturers could distinguish
themselves as distinctive persons. Yet Scheffler’s argument that some measure of
distinction is necessary for personal responsibility does not require that any kind of
distinction is necessary. Indeed, the theory aligns with a moral theory that prohibits
interference with other people’s actions (because it’s morally worse to violate negative
rights) so it is possible for such a theory to rule out the torturing of innocents while still
maintaining that requiring that everyone always maximize good consequences at all times
would rob us with an important precondition of responsibility, namely, the capacity to
deliberate and see oneself noninstrumentally.
Above I presented some justifications for these claims, though they remain controversial. From now on, I will proceed from the assumption that killing is relatively worse than letting die for the above reasons.

Whatever justifies the distinction between doing and allowing, rights or a theory of responsibility, this distinction has widespread appeal. Scanlon proposes two psychological explanations for the appeal of this distinction—conservatism and mistrust. First consider conservatism. It has been well established that people have a bias towards accepting the status quo. We accept that our current situation includes some measure of risk that we will suffer or die, but we are reluctant to introduce any additional risk beyond the natural order that we might be killed, even if introducing that risk minimizes our risk of suffering overall. For example, we accept that we could die or organ failure, but we are reluctant to accept a mandatory organ redistribution scheme that would risk killing us to save others of organ failure, even if such a scheme improved our ex ante prospects overall.

Alternatively, mistrust may explain the appeal of the distinction. Scanlon writes that we are reluctant to believe that decisions really are made for our benefit unless we have a role in making those decisions. So, for example, many people accept paternalistic acts of self-binding (like gambling addiction registries) but not coercively enforced paternalism (like the abolition of casinos). Similarly, we do not trust others to make important decisions for us, even if ceding this authority puts us at a higher risk of

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17 T. M. Scanlon, *The Difficulty of Tolerance: Essays in Political Philosophy* (Cambridge University Press, 2003), pg. 40
suffering or death. These considerations are not justifications for the distinction; instead they are possible explanations for its intuitive force.

2. The Prevention Argument

Regulatory agencies that prohibit access to dangerous medicines, like the FDA, justify their prohibitive power by citing instances when pharmaceutical manufacturers caused patients’ deaths by allowing dangerous drugs on the market; defenders of these agencies then argue that government must be empowered to prevent drug disasters by conducting premarket testing and prohibiting the sale of unapproved drugs. In the previous chapter I showed that prohibitive regulations probably cannot prevent dangerous drugs from reaching the market, but even if pharmaceutical regulators could prevent drug disasters with premarket regulation, these benefits are outweighed by the cost of premarket testing, including drug lag and drug loss.

Defenders of pharmaceutical regulation might nevertheless hold that prohibitive regulations are permissible, and perhaps even required, because the government can rightly prevent people and companies from killing its citizens, even if doing so costs lives overall. In this section I will show how the moral distinction between killing and letting die has been used to justify prohibitive pharmaceutical regulations.

The following case illustrates what I will call the Prevention Argument:

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18 When decisions are subjectively less important, like seatbelt decisions, people more readily cede control. We can imagine a society that highly valued freedom of movement and freedom from bodily restraint. Such a society would not cede authority in the seatbelt case, just as our society would not cede authority to make spousal choices to matchmaking experts, even if it would lead to happier marriages, because spousal choices are especially important to us.
**Prevention:** Mark intends to kill Patty and redistribute her organs to save five people. Gloria intervenes to prevent Mark from killing Patty. Patty lives, and five people die.

The moralized analysis of killing and letting die can explain why Gloria acts rightly in preventing Mark from killing Patty. Even though on balance Mark would have saved more lives than he took, he still would have acted wrongly because 1) killing Patty was a primary manifestation of his agency, so he would have been (more) responsible for Patty’s death than for the deaths of the five patients who perished from their diseases, and 2) killing Patty violated Patty’s negative right not to be killed, whereas letting the five die only violated their positive rights to assistance.

Because Mark intended to do something wrong, Gloria’s action to prevent Mark from killing Patty is permissible, and perhaps even morally required. This holds even though Gloria’s actions are implicated in the deaths of the five patients. In this way, Gloria lets the five patients die by ensuring that they will die from their diseases, rather than letting Mark kill Patty to avoid the death of the five. Since killing is generally worse than letting die, then just as Mark’s decision not to kill Patty would have been the right call even though it guaranteed five deaths, so too is Gloria’s decision to prevent Mark from killing Patty.

Now consider the following analogy to pharmaceutical regulation:

**Preventative Regulation:** Manufacturer intends to release a drug that will cause one patient to die for every five lives it saves. Government agency intervenes to prevent Manufacturer from killing patients, and other patients die from their diseases.
Defenders of pharmaceutical regulation might press this analogy. Like Mark, manufacturers are responsible for the deaths they cause, and when they give patients dangerous drugs they violate patients’ negative rights not to be killed. Similarly, just as Gloria was required to intervene to prevent Mark from killing Patty, even though doing so meant that five patients would die, government agencies like the FDA are required to intervene to prevent manufacturers from killing patients with dangerous drugs, even if those drugs would save lives on balance.

Just as in *Prevention*, even though the government is implicated in the deaths of patients who die from their diseases, they prevent manufacturers from *wronging* patients by releasing dangerous and deadly drugs. This analogy grounds the *prevention argument*, it states:

P1: Killing is generally morally worse than letting die, even if on balance killing would result in fewer lives lost.

P2: Pharmaceutical manufacturers kill patients by selling dangerous drugs.

P3: Government can rightly prevent individuals and companies from acting wrongly, even if on balance those wrongful actions would result in fewer lives lost.

C: Government can rightly prevent manufacturers from selling dangerous drugs.

In other words, the prevention argument states that government agencies can permissibly let some patients die of their diseases in order to prevent drug manufacturers from killing patients with dangerous drugs, even if such a policy results in more deaths on balance.
Examples of the prevention argument can be found in the media and in policymakers’ justifications for pharmaceutical regulation. For example, Barack Obama defended pharmaceutical regulation at a healthcare summit in 2010:

We could set up a system where food was cheaper than it is right now if we just eliminated meat inspectors, and we eliminated any regulations on how food is distributed and how it's stored. I'll bet in terms of drug prices we would definitely reduce prescription drug prices if we didn't have a drug administration that makes sure that we test the drugs so that they don't kill us, but we don't do that. We make some decisions to protect consumers in every aspect of our lives.  

19 FDA officials also invoke the prevention argument as a justification for prohibitive policies. 20 Referring to untested and unapproved drugs that are often marketed as nutritional supplements, Michael Levy, acting director of the F.D.A.’s office of drug security, integrity and recalls said, “These products may work, … but if you take them, they could kill you.” 21 Levy went on to complain that the agency’s resources were limited, and public officials could therefore only prohibit a fraction of untested and unapproved drugs from being sold, clearly citing killer drugs as a justification for prohibitive regulations.

19 Bipartisan Health Care Reform Summit February 24, 2010
20 See for example FDA.gov.
Consumer advocates and the media also reinforce the perception that drug companies kill patients by manufacturing and marketing dangerous drugs. A 2004 article by the New York Times criticized the FDA for failing to detect deaths caused by Vioxx and suggested that “the delay in uncovering Vioxx's dangers cost 55,000 Americans their lives…an adequate system for monitoring side effects may have prevented some of the deaths.” These examples illustrate the popular perception that drug manufacturers kill, meaning that they wrongfully cause patients’ deaths.

3. Why Manufacturers Don’t Kill

The prevention argument is one commonly cited justification for pharmaceutical regulation. This argument underlies the public’s approval and support for regulatory agencies. If we accept the causal account of the distinction between killing and letting die, the intuitive force of this argument is clear because dangerous drugs are a direct cause of patients’ deaths whereas pharmaceutical regulations are only a secondary cause of death and disease is the primary cause. Yet for reasons I explained above, the moralized account of killing and letting die is a better reconstruction of the distinction. I will now show that under this account, the prevention argument doesn’t hold up for two reasons. First, drug manufacturers don’t kill the patients who die from using dangerous drugs. Second, regulatory agencies don’t act permissibly by allowing patients to die from their diseases.

The first way that the prevention argument fails is that it drug companies aren’t killers. When patients die from using dangerous drugs the public and media often say

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things like “Merck killed over 50,000 people by selling them Vioxx,” as if this action is similar to a situation like “Mark killed Patty by removing her vital organs.”

When the two situations are presented beside one another like this, the flaws in the comparison are obvious, yet in public discourse people rarely question the use of words like kill to describe the actions of drug companies. So entrenched is the presumption that drug companies wrongly kill patients that several Hollywood movies begin with drug companies recklessly maiming and murdering people, and no one questions this premise.23

But unlike Hollywood scripts, this dissertation doesn’t aim to entertain, so we can question the premise that pharmaceutical companies kill patients. The main asymmetry is that when drug manufacturers release dangerous drugs, their intention isn’t to cause patients to die. Cynically, why would drug companies intend to kill their customers? Even when a company kills through blameworthy negligence, for example by using a solvent or manufacturing process that is deadly (as in the case of the Elixir Sulfanilamide disaster) or by failing to disclose the known risks of a treatment, the death they cause is more akin to manslaughter than murder. Yet in most cases companies do use good manufacturing processes, conduct safety testing and disclose all known risks.

One of the features that makes killing morally worse than letting die is that acts of killing are primary manifestations of the killer’s agency. The deaths caused by dangerous drugs, even if they are caused by blameworthy negligence or fraud, are certainly not the

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23 See Fugitive, The Constant Gardener, Resident Evil, the forthcoming Wonder Woman TV show, the videogame Bioshock, and Rise of the Planet of the Apes for examples of murderous pharmaceutical companies in popular culture.
primary manifestations of the companies’ agency. At their worst they are merely foreseen but unintended side effects, but in most cases patient deaths are unforeseen as well.

Also, manufacturers have huge incentives to make the prevention of patient deaths a primary manifestation of their agency. For one thing the whole point of pharmaceuticals is to minimize patients suffering and extend their lives, the more drugs that pharmaceutical manufacturers make that achieve these goals the higher their profits will be. For another, a single drug disaster can ruin a drug company, both because its public image will be compromised and its stock will fall, and also because the cost of litigation can bankrupt the manufacturers of dangerous drugs.

These considerations show that one of the features of killing that makes it worse than letting die, that killers are more responsible for the deaths they cause, does not obtain for pharmaceutical companies. In this way then, drug manufacturers don’t kill. Put like this it may seem obvious that the manufacturers of dangerous drugs don’t kill consumers, but this thought seems to give the prevention argument much of its intuitive force. Since the prevention argument is widely accepted, my goal has been to clarify here that pharmaceutical companies aren’t killers even when drugs cause patients to die.

Another asymmetry between Prevention and Preventative Regulation is that when Mark killed Patty, presumably Patty did not consent to Mark’s actions, whereas when pharmaceutical manufacturers sell dangerous drugs to patients, patients consent to take the drugs in light of the risks. Prohibitive pharmaceutical regulations like the premarket approval process and prescription drug system forbid patients from accessing dangerous medicines, but if a patient did take dangerous medicines she would consent to the risks.

A closer analogy to pharmaceutical regulation would be a case like this:
The Gamble: Patty and five others lie in a hospital room dying from a disease. They invite Mark to their room to administer a risky treatment which must be given to all six patients at once, and is expected to kill 1 in 6 patients who use it but cure the other five. Mark delivers the drug and it does in fact kill Patty by causing organ failure but cures the other five.

In this case, Mark’s killing of Patty doesn’t seem as wrong as it did in Prevention. Even if Mark’s giving Patty the deadly drug still strikes some people as wrong, we should accept that the fact that Patty consented to some risk of death by joining the scheme mitigates the wrongness of Mark killing her. Similarly, when patients consent to take any dangerous drug, knowing that the drugs carry some risk of harm but a greater chance of benefit, if they are subsequently injured their consent mitigates the wrongness of the harm. 24

In addition to the responsibility condition, the other feature that makes killing morally worse than letting die is that killing violates the victim’s negative rights not to be killed, whereas letting die only violates a person’s positive rights to assistance. But in cases where the victim consents to the killing, it is not clear that killing actually does violate her negative rights not to be killed because by consenting the victim waives her right against being killed. Take the example of euthanasia, which I discussed in Chapter 6. Patients have rights not to be killed by their physicians but when patients choose euthanasia they waive that right, and indeed, people have a negative right choose to die.

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24 One objection to the consent argument is that the risks and potential hazards of some treatments are too difficult to understand, and people reliably misjudge small probabilities and large payoffs that are associated with most medical treatments, so consent is impossible. I addressed this concern in an earlier chapter, where I discussed the symmetry between the right to self-medication and informed consent.
If we accept that our negative rights against interference, including the right against murder, are ours to waive, then we are committed to the principle that patients can consent to a 100 percent chance that a treatment will kill them when they opt for voluntary euthanasia. Now consider medical treatments that carry a 1 percent risk of death or injury (which is a higher risk than any available pharmaceuticals). If a patient can consent to a deadly treatment that will surely kill him, it seems he should similarly be able to consent to a risky treatment that might kill him. Since consent mitigates the wrongness of assisting in a patient’s death, consent also mitigates the wrongness of exposing a patient to a risk of death. Therefore, the two things that distinguish killing as genuinely worse than letting die, that killing is a primary manifestation of the killers agency and that it violates the victim’s negative rights, do not hold in the case of dangerous pharmaceuticals because manufacturers do not intend to cause patients’ deaths and patients consent to the risks posed by dangerous drugs.

At this point, one might object that patients cannot waive their rights against risk when they voluntarily take dangerous drugs, either because patients don’t have rights to die or to injure themselves or because doing so is wrong. David Velleman, for example, has argued that patients don’t have the right to die and Samuel Freeman and Peter de Marneffe have argued that citizens don’t have the right to engage in self-harming practices like recreational drug use or prostitution.25 One argument in favor of these kinds of views is that citizens are not entitled to autonomously choose to damage their autonomous capacities. If such rights do not exist, then they cannot be waived. In the previous chapters, I addressed these kinds of arguments, and I argued that rights to die

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and self-harming rights do exist and that they are powerful constraints on our behavior. Yet for now let us assume that patients do not have especially strong rights to engage in risky behavior, so they cannot waive their rights against risk. Even still, a patient’s consent might mitigate the wrongfulness of harmful drugs for other reasons. If people take grave risks that also carry greater benefits, allowing extreme medical risk taking stands to promote overall patient welfare. Further, since manufacturers, only risk harm when patients consented to the risk of harm, providing access to potentially dangerous drugs might have better consequences overall, in the same Millian way that respecting people’s decision usually has better consequences.\textsuperscript{26}

Another way of reading Velleman, Freeman, and de Marneffe is that even if people have rights to self-harming, it is nevertheless wrong for someone to kill himself, or to expose himself to a risk of harm. If so, patients might nevertheless have the right to engage in self-harming in the same way that we have other rights to do wrong.\textsuperscript{27} For example, if I own a rare work of art and I destroy it by painting over the canvas, I may have acted wrongly, but I had the right to do so because I owned the art. Whoever sold me the paints facilitated my wrongful action, but did not act wrongly. If abortion is wrong, women might still have the right to do it, and those who provide abortions do not act wrongly by assisting women in exercising their rights. If so, then when manufacturers provide dangerous drugs to consenting patients, they might facilitate patients in doing wrong but not do wrong themselves.


One objection to this argument is that selling a product that one knows will be used in self-harming is morally different from the painting case. Consider the example of tobacco companies. Some people think that employees at tobacco companies are complicit in wrongdoing, even if self-harming tobacco users are fully informed of the risks of smoking and fully consent. Even if this is true, consumers’ consent substantially mitigates the wrongdoing, and insofar as the tobacco companies do act wrongly to any extent the wrongness of their actions do not rise to the level of justifying prohibitions. In other words, tobacco companies may also have rights to do wrong if their actions are in fact wrong. Similarly, even if it is in any way wrong to sell dangerous drugs, the balance of moral reasons still tell in favor of allowing pharmaceutical companies to sell drugs to informed and willing customers who consent to the risks.

This is not to say that manufacturers cannot wrong patients by selling them dangerous drugs. I have argued that P2 is false; drug manufacturers do not necessarily act wrongly when patients die from using dangerous drugs. But in some cases, patient deaths are a result of a manufacturer’s wrongful actions such as fraud and blameworthy negligence. In these cases it follows from P2 and P3 that government can rightly prevent manufacturers from acting wrongly in these cases. Still, the conclusion that prohibitive pharmaceutical regulations are justified doesn’t follow because the wrongness of the manufacturers actions is not distributing the drug, but lying to consumers about the nature of the drug.

To see why, consider a classic illustration of blameworthiness. Imagine I serve you tea, not knowing that the tea in fact contains a toxin that will make you sick. You

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28 Annie Stilz posed this objection in an earlier draft.
drink the toxic tea and become ill. In this case, my action harmed you, but my ignorance of the toxin excuses me from blame. Now imagine that I serve you tea knowing that the tea has a toxin in it, and I tell you that your drink contains only tea, in this case I am subject to blame because I poisoned you and I also wronged you by lying about the contents of your drink. Finally, imagine that I knew there was some chance that the drink I was serving was toxic, but I failed to investigate whether it was or not, and I didn’t disclose to you that toxicity was a possibility for your drink. In this case, I also acted wrongly, and if you get sick I am to blame, because I was negligent in preparing your tea and I failed to disclose the risks.

In all these cases, you consented to drink the tea, but your consent doesn’t waive your negative rights against being poisoned if it is based on fraudulent statements I’ve made. Similarly, patient consent doesn’t mitigate the harm of negligently manufactured drugs that turn out to be dangerous.

Does this consideration justify prohibition? The wrongful act in these cases is that manufacturers are negligent or fraudulent. If manufacturers carefully prepared a dangerous drug such that they could accurately predict the risks, and then disclosed the risks, patients would be capable of consenting to the drugs. This consideration therefore doesn’t necessarily tell in favor of prohibitions, rather it tells in favor of securing the conditions necessary for patient consent, namely accurate labeling and good manufacturing practices.

Further, in the last chapter I will argue that in cases like these where manufacturers act wrongly, they should be held liable for harming patients through the tort law. Postmarket regulations like these will also provide manufacturers with
incentives to continue to monitor manufacturing procedures and the effects of drugs once the drugs have been released, whereas premarket prohibitions do not give manufacturers these incentives.

4. Why Pharmaceutical Regulators Act Wrongly

With the moralized distinction between killing and letting die in hand, I have shown that drug manufacturers do not kill patients, so the prevention argument fails because it is unsound. In most cases, patients waive their rights not to be harmed when they consent to use dangerous drugs. Even when drug manufacturers do act wrongly in ways that violate patients’ negative rights, the wrongful actions are not the primary manifestations of their agency. Further, while these cases of wrongful death are more morally serious than the other deaths that are caused by dangerous drugs, prohibitive policies are still not justified because they do not address the nature of the company’s wrongdoing.

Defenders of pharmaceutical regulation might find it counterintuitive that the manufacturers of dangerous and deadly drugs don’t kill the patients who die by using the dangerous drugs. In this section I will show that the moralized distinction between killing and letting die yields another counterintuitive conclusion about pharmaceutical regulation as well—pharmaceutical regulators act wrongly when they prohibit patients from accessing lifesaving or therapeutic medicines because they violate people’s negative rights and are responsible for the deadly effects of prohibitive policies.

There is an important asymmetry between manufacturers whose products cause death and regulators whose policies cause death. Though dangerous drugs cause patients’ deaths, manufacturers often do not foresee these deaths. When the deaths are foreseen,
manufacturers disclose these risks to patients who are considering the dangerous drugs. In any case, manufacturers don’t intend that drugs kill patients since most drugs are designed for therapeutic use and are intended to save lives, not cost them. Further, drug companies have huge incentives to minimize the number of lives lost as a result of their actions. For these reasons, I have argued that the deaths that result from dangerous drugs are not the primary manifestations of manufacturers’ agency.

Now consider regulators. The prevention argument held that pharmaceutical regulation did not cause death in the way that dangerous drugs causes deaths, rather, regulatory agencies allow some patients to die of their diseases in order to prevent dangerous drugs from killing other patients. But just as manufacturers are not killers like Mark, government regulators aren’t heroes like Gloria either. Recall that Gloria intervened to prevent Mark’s from killing Patty and saving five others from dying of preexisting conditions. The prevention argument held that like Gloria, when a pharmaceutical intervenes to prevent manufacturers from killing some patients with dangerous drugs in order to save others, even if more lives are ultimately lost, the regulator is the hero of the story.

Yet *Prevention* was flawed in part because it overlooked the role of patient consent, *The Gamble* more closely represents how drug manufacturers act. So, in actual cases of pharmaceutical regulation, regulators’ actions are importantly different from Gloria’s. First, Gloria intervened in Mark’s killing of Patty against Patty’s wishes, and while no one who takes a dangerous drug wishes to die from it, patients do consent to some risk of death in exchange for a potential benefit or cure. Second, Presumably in *prevention* when Gloria intervened on Patty’s behalf Patty didn’t then die from a disease
anyhow, or in any case the value of saving a patient from being killed is diminished if she was going to die anyhow. 29 We can modify Prevention in light of these asymmetries, and then the case looks like this:

Prevention 2: Patty and five others lie in a hospital room dying from a disease. They invite Mark to their room to administer a risky drug that is expected to kill 1 in 6 patients who use it and will cure the other five. If Mark delivers the drug it will in fact kill Patty by causing organ failure but cure the other five. But while Mark is en route, Gloria intervenes and delays Mark’s visit, so the six patients die of their diseases.

This case is more similar to The Gamble, where Mark doesn’t violate Patty’s negative rights because she consents to the treatment. It seems that in this case Gloria isn’t a hero at all, Mark is.

I argued above that even when Mark’s actions did actively lead to the death of one patient, the moral features that distinguish acts of killing as morally worse than letting die did not hold in Mark’s case. But when we recast the prevention case in this way, the moral features that distinguish acts of killing as morally worse also seem to distinguish Gloria’s actions as especially wrong, even though they are strictly an example of letting die. First, even though Gloria doesn’t kill the six, she does violate their negative rights to seek a cure for their condition. Second, the deaths caused by a regulator’s actions are more closely linked to the regulator’s agency than the deaths that are caused

29 Recall the example of Mr. White and Mr. Orange above, would it have been permissible for an ambulance driver to let five people die (who could have been saved) in the name of preventing Mr. White from killing Mr. Orange, only to allow Mr. Orange himself to die from his injuries?
by a manufacturer’s actions, though neither regulators nor manufacturers intend that anyone die.

In this way the prevention argument mistakenly characterizes the actions of Gloria and of pharmaceutical regulators as (at worst) a violation of positive rights. But Gloria and regulators actually interfere with people’s negative rights.  

Gloria interferes when she delays Mark, and as I argued in an earlier chapter, pharmaceutical regulation interferes by delaying people’s access to therapeutic medicines. Regulations also violate citizens’ fundamental negative right of self-medication, a patient’s right to use drugs and a manufacturer’s negative liberty to sell them.  

Even if one doesn’t accept that commercial rights or rights of self-medication are basic, consumers more generally have a negative right to against interference which regulation limits. Economic rights and self-medication might rightly be subject to constraints, but the rights to make voluntarily

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30 A quick approximation of the distinction between negative and positive rights is that negative rights are rights against interference whereas positive rights are rights to assistance. In cases where some interference makes a person worse off her negative rights are violated, and in cases where assistance is available and it is withheld, her positive rights to assistance are violated. Killing violates negative rights and letting die violates positive rights.

31 I’m not saying this negative liberty is absolute or basic, only that commercial exchange is entirely negative, it’s a right against interference rather than a right to assistance. Imagine you ordered a book online and as the manufactures are preparing to ship the book to you someone cancels your order. It’s true that whoever canceled your order in some sense didn’t make you any worse off than you were, because you never had the book. By canceling your order he didn’t violate your property rights either, because he only denied you something that you hadn’t yet possessed. Still, there is a sense in which his intervention not only violated the manufacturer’s right to sell you the book but your right to receive it as well. This is because presume that people have rights to access goods freely, and canceling the order violated this right.
exchanges and bodily choices are negative liberties—a species of the more general negative right against interference.\textsuperscript{32}

In light of these considerations, by recasting \textit{Prevention} to look more like \textit{Prevention 2}, it becomes clear that Gloria, and by analogy, regulatory agencies do interfere in patients’ lives in ways that violate Patty and the other patients’ negative rights. Gloria’s intervention in Mark’s delivery violated Patty and the other patients’ rights to self-medication and their more general right to access the good Mark was bringing. If we accept then that negative rights violations are especially morally serious, then even though Gloria doesn’t violate Patty and the other patients’ rights not to be killed, she does violate their rights to self-medication and consensual commercial exchanges.

As we saw above, consent can mitigate negative rights violations, if a person consents to be killed or to accept some risk of being killed, than killing or exposing someone to a risk of death is not (as) wrong. But in the example of \textit{Prevention 2} and in the case of pharmaceutical regulations, citizens do not consent to the violation of their negative rights to access medication. We can imagine a scheme where consent is possible, if patients could opt in to a system wherein they pre-committed to waive their rights of self-medication and consented to prohibitive pharmaceutical policies, or to opt out of the present prohibitive system and accept the risks of using dangerous drugs, but at present no one can consent to prohibitive pharmaceutical regulations so the harmful nature of this negative rights violation cannot be alleviated.

\textsuperscript{32} For a defense of this view see John Tomasi, \textit{Free Market Fairness} (Princeton University Press, 2012).
The above arguments show that while Gloria and regulator’s actions don’t violate a negative right that is as important as patients’ rights not to be killed, they still violate negative rights. Further, by violating their negative rights she contributed to their deaths. According to the moralized distinction, the wrongness of killing is explained in part by the fact that negative rights violations that result in death are morally worse than positive rights violations that result in death. In this way, the same things that make killing especially wrong when compared to letting die, also describe the actions of Gloria or of pharmaceutical regulators. It is not that pharmaceutical regulation kills people, but it does violate their negative rights in a way that contributes to their deaths. Regulation prevents patients from accessing opportunities that would save or prolong their lives, and in this way regulators don’t merely let patients die of their diseases either. Preventing manufacturers from providing assistance stands somewhere between killing and letting die. It is especially wrong because patients’ deaths are caused by a violation of their negative rights as well as by a positive rights violation. On the other hand, the negative rights that pharmaceutical regulation violates aren’t as urgent as the negative right against killing.

The other feature of an act of killing that distinguishes it from letting die is that killings are the primary manifestations of the killer’s agency, whereas letting die is at worst a secondary manifestation of agency, or not an act of one’s agency at all. Like Scheffler, I am skeptical that the distinction between primary and secondary manifestations of agency can be cast neatly without appealing to a normative concept like moral responsibility. Earlier I argued that drug manufacturers are not usually responsible for the deaths they cause by providing dangerous drugs because they generally do not
foresee the patients’ deaths and even those deaths that are foreseen are not intended. In other words, even if dangerous drugs do cause patient deaths, the manufactures are excused by their factual ignorance.

Pharmaceutical regulators also do not intend the deaths that are caused by the regulatory process, but the deaths caused by drug lag do implicate the officials’ will more than the deaths that result in many cases of ‘letting die’ because the deaths would not have occurred were it not for the intentional actions of regulators. Still, the regulators will is not implicated in the way that a killer wills the death of his victim because the deaths were not as closely a manifestation of a regulator’s agency as they would be for a murderer. The extent that deaths are a manifestation of one’s agency is a matter of degree, that a regulator’s will is implicated does not make him a murder but it does make him more of a killer than an ordinary bystander who had no role in deadly prohibitive policies.

Regulators are therefore fit to be held responsible for the deaths that are caused by their intentional actions, namely by prohibitions on therapeutic medicine. Unlike manufacturers, regulators are not excused by factual ignorance when patients die as a result of their actions because regulators are not ignorant about the deadly effects of regulation in the way that manufacturers are ignorant about the deadly effects of experimental medicine. Once manufacturers are able to estimate the potential benefit of a drug, regulatory agencies can estimate many patients will suffer or die because they lack access to the unapproved drug during the approval process. The deadly effects of drug lag
are well known by legislators and regulatory officials.³³ At least by the time Phase III efficacy testing begins, patient advocacy groups like the Abigail Alliance supply the public with good estimates of the harm caused by drug lag, and these estimates are continuously affirmed when patients subsequently die while waiting for drugs.³⁴ In this way, the deaths that result from the actions of agency officials cannot be excused by factual ignorance.

In other words, when dangerous drugs cause patients to die, manufacturers can often claim to be blamelessly factually ignorant of the harmful effects, but regulators are usually not factually ignorant of the harms of regulation. Perhaps though, because the prevention argument carries such force, regulators are blamelessly ignorant of the moral facts. This could be the case if, for example, they believe that drug lag is not morally wrong. Gideon Rosen has argued that accepting blameless factual ignorance as an excuse might have radical implications for assessments of moral culpability; if regulators are blamelessly ignorant of the moral wrongness of causing patients to die while waiting for drugs, assuming they discharged their epistemic duties, then they might be excused from blame for regulation.³⁵

³³ For example, in light of the deadly effects of drug lag regulatory officials and legislators have introduced institutional reforms like the Prescription Drug User Fee Act and ‘fast track’ approval for drugs that treat terminal diseases. These reforms are specifically designed to shorten the approval process and mitigate the loss of life caused by drug regulation, though the human cost of drug lag remains far greater than the cost of dangerous drugs. I discuss these effects in more detail in Chapter 2.

³⁴ The Abigail Alliance is a patient advocacy group that has unsuccessfully sued on behalf of terminally ill patients for access to therapeutic medicines. The Alliance has advocated specifically for access to fourteen lifesaving medicines, all of which were eventually approved by the FDA after a lengthy testing process, while terminally ill patients died waiting for access. See Chapter 5 for a more detailed discussion of this case.

Elizabeth Harman disagrees. Harman argues that blameless moral ignorance is not an excuse, even though blameless factual ignorance is exculpatory. If Harman is right, then regulators are morally responsible for the deaths they cause through regulation even if they do not know that it is wrong to cause deaths in this way. Yet even if pharmaceutical regulators are personally excused from responsibility because they are ignorant of the fact that it is wrong to cause patient deaths by withholding access to therapeutic medicines, the actions of regulators are still wrong. The deadly effects of prohibitive policies call out for an excuse because withholding access to drugs is wrongfully harmful in the first place. Even if the fact that the public and public officials do not generally recognize that causing death through regulation is wrong excuses pharmaceutical regulators from blame, it doesn’t change the fact that intentionally withholding access to therapeutic medicine is wrong.

5. Conclusion

Return to the psychological considerations that explained the distinction between killing and letting die. Interestingly, these considerations cut both ways in the case of dangerous drugs and regulation. On one hand if people have a bias against putting their fate in other people’s hands (mistrust) then we might think citizens would be opposed to ceding the authority to decide if a medicine could be therapeutic or harmful. On the other, since people also have a bias towards accepting the natural course of events even if interventions might improve their ex ante prospects, (conservatism) we would expect citizens to see death from disease as more acceptable than deaths from dangerous drugs.

That pharmaceutical regulation enjoys such widespread support indicates that conservatism explains more of our moral thinking than mistrust.

Should we accept the conservatism behind the prevention argument? As Scanlon points out “conservatism… is uncomfortably close to a bias of the lucky insofar as it rests on a conscious turning of attention away from the prospect of our being one of the unlucky ones.”37 The prevention argument mistakenly turns our attention away from the deaths that are caused by disease, and instead, focuses our attention on the deaths caused by dangerous drugs. The unlucky that have diseases then die from their conditions, and citizens are left to hope for good luck.

These considerations support the counterintuitive conclusion that the deaths that are caused by dangerous drugs in most cases do not rise to the level of killing, while the deaths that are caused by pharmaceutical regulation are not mere instances of letting die.

The prevention argument therefore fails for several reasons. Even if we accept that killing is in many cases morally worse than letting die (P1) and some policies can justifiably prevent wrongful killing even if doing so results in more deaths overall (P3), so the prevention argument could succeed in principle. But P2 is false. Pharmaceutical manufacturers don’t kill their patients by selling dangerous drugs, and so the conclusion does not follow. Further, pharmaceutical regulation is wrong in itself because it violates people’s negative rights. While regulatory agencies don’t kill patients, their actions are more morally serious than simple cases of letting die because by prohibiting unapproved medicines regulators deny manufacturers the ability to provide potentially lifesaving assistance and patients the ability to access them.

37 Scanlon, *The Difficulty of Tolerance*. Pg. 41
IX. Is Pharmaceutical Regulation a Public Good?

Public goods arguments are also used to justify prohibitive pharmaceutical regulations. Proponents of pharmaceutical regulation sometimes support prohibitive policies because they believe that medical experts provide a valuable public good by ensuring the safety and efficacy of drugs. We might state this public goods argument like this:

P1: Expert public officials ought to promote citizens’ interests.

P2: When it comes to pharmaceutical use, medical experts are experts about citizens’ interests.

P3: Medical experts can effectively regulate pharmaceuticals in ways that comport with their expert judgment

C: Medical experts ought to be empowered to regulate pharmaceutical use.

In Chapter 7, I argued that P2 is false, while medical experts might be experts about people’s medical interests they are not experts about people’s interests all things considered. There, I also suggested that we ought to be skeptical of P1, at least as a justification for prohibitive policies because prohibitions constitute a kind of coercion that violates our normative authority.

Still, even if we accept P1 and P2, I will argue in this chapter that the institutional context of pharmaceutical regulation threatens medical expert’s ability to make pharmaceutical policy in ways that comport with their expert judgment. My hypothesis is that the public indirectly influences regulatory agencies, thereby entrenching the very cognitive biases that the agencies were designed to mitigate. For this reason, institutions like the FDA cannot effectively play the epistemic role for which they were designed.
This empirical hypothesis raises a challenge for liberal theorists who endorse paternalistic institutions but also believe in democratic oversight of regulatory agencies.¹ I conclude that such theorists ought to question their support for prohibitive agencies and democratic institutions alike.

In section 1, I will give some examples of the public goods argument and I will develop it in more detail. In section 2 I will describe the institutional context of pharmaceutical regulation. In section 3 I will argue that in equilibrium pharmaceutical experts are indirectly constrained by the public in ways that compel them to make decisions that do not comport with their expert judgment. In this section I will sketch a model of agency independence that I develop formally in the Appendix. In section 4 I will discuss the implications of this model for democratic theory and paternalism. Section 5 concludes.

1. The Public Goods Argument

Public goods arguments for pharmaceutical regulation argue that regulators provide the public with services that would otherwise go underprovided by market forces. Proponents of pharmaceutical regulation focus on two kinds of public goods- information and security, which are allegedly provided by agencies like the FDA. Economists, pharmacologists, industry insiders, and the public have all cited the public goods argument as a justification for prohibitive pharmaceutical policies. In this section I will describe several kinds of public goods arguments for pharmaceutical regulations.

Public Goods are non-rival and non-excludable; meaning that one person’s use of the good doesn’t diminish anyone else’s ability to benefit from the good, and that the providers of the good cannot effectively prevent people from accessing that good. Clean air is an example of a public good; one person’s enjoyment of clean air doesn’t diminish other’s ability to enjoy clean air as well, and in order to provide clean air to some one must provide it to everyone. Some public goods, like clean air, roads, and national defense, are physical goods. States provide these kinds of public goods by converting cities to wind power or building highways and missile shields. The thought is that some things are good to have, even if the market won’t provide them, so states can intervene and use taxes to fund underprovided goods in cases of market failure.  

Other public goods are less tangible, more like ideas. States provide epistemic public goods, for example by funding space research or by notifying people that a hurricane is coming. The market failure justification also explains these kinds of policies. Providing these goods is costly, and while everyone might benefit from their provision, no one is willing to privately provide it because of its non-excludable nature, once the good has been provided no one who uses it has an incentive to pay for it.  

Defenders of pharmaceutical regulation argue that regulatory agencies provide this kind of a public good by conducting premarket testing. Together with the prevention argument, I believe that this defense explains much of the public support for pharmaceutical regulation. Industry insiders, economists, and health policy experts have

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2 Dan Klein has explicitly addressed market failure and drug approval. Here I will address the question further, and argue that market failure justifications for public institutions succeed in some ways (to justify informational functions) but not others (prohibitions do not solve informational failure). I argue for the same conclusions as Klein and Tabarrok but I develop the point more formally and argue more directly that public goods arguments fail. Klein, “Colleagues, Where Is the Market Failure?”.
all cited the public good of pharmaceutical regulation as a justification for agencies like the FDA, and these justifications fall into two categories. First, some proponents of pharmaceutical regulation cite the *epistemic* function that regulatory agencies play as a public good. Here the argument is that without regulation, it is too costly to require physicians and patients to evaluate information about drugs, and it is unlikely that market forces will accurately provide such information anyhow. In light of this market failure, government officials can provide the public good of generating and disseminating information about new drugs. Second, some proponents of pharmaceutical regulation also cite a *drug security* as a public good.

Consider first information as a public good. In a recent survey on this topic, economist Kenneth Arrow wrote,

*The dissemination of the relevant information is too costly* for the patients (and the doctors) to permit the sale of drugs that have not met the appropriate standards.  

Economist Jonathan Karnon argued that

*Consumers are not best placed to interpret the safety information, and the full burden should not be placed on physicians.*

F.M. Scherer, the Aetna Professor Emeritus at Harvard’s Kennedy School of Government also cited the informational goods provided by regulation while conceding that there are nevertheless some problems with the approval process:

*The historical record is clear: FDA has made serious errors, and physicians have*

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4 Ibid.
in large numbers prescribed the approved drugs. So the system is imperfect. But without the *informational function* the FDA performs, there would be even more prescribing errors.\(^5\)

Other prominent economists have echoed this defense of regulation. For example:

It is a source of *market failure* when other mechanisms for informing consumers prove costly, inadequate, or create perverse incentives. In the case of medications, information is lacking among buyers and sellers alike, and systematic trials (along with the accompanying publicity) may be the best way to develop and organize information so that doctors and patients can understand the benefits/drawbacks of new drugs…. I am much less concerned about asymmetric information than I am about the public good nature of research. Systematic clinical trials will facilitate learning by physicians. It is not at all obvious whether a manufacturer will wish to promote learning in a way that maximizes social welfare.\(^6\)

Economist Patricia Danzon focuses on the public good of drug regulation most explicitly when she writes,

> There is a strong argument that structuring and interpreting such data analysis is a **public good that is best delivered by an expert regulatory agency**. The existence of regulatory systems to perform these functions and control market access in all industrialized and most developing countries is strong evidence for consensus opinion on this basic proposition.\(^7\)

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\(^5\) Ibid.

\(^6\) David Dranove Professor of Health Industry Management, Kellogg School of Management, Northwestern University  Ibid.

\(^7\) Ibid.
As Danzon observes, most governments seem to agree with this argument, and have assumed the role of providing the public good of pharmaceutical testing.

Though these arguments vary in their particulars, they all are backed by a suspicion that manufacturers don’t have sufficient incentives to test their products before bringing them to market and consumers will lack the expertise to evaluate new drugs. These circumstances are then cited as an example of market failure, and so they require government intervention to correct the market failure and provide the public good of accurate pharmaceutical information.

Yet agencies like the FDA do far more than overseeing clinical trials and disseminating information, they also prohibit people from using unapproved drugs. This function of pharmaceutical regulation has also been justified in terms of public goods since the agency’s infancy. The idea is that there is market failure for drug security as well as information. For example, as early as 1959 the media framed the FDA’s function as a kind of police power, and the public and members of the pharmaceutical agency were explicitly grateful for an organization that protected people from poisonous or ineffective medicines.8

The security justification for prohibitive polices persists today. Marc L Berger, a vice president at Eli Lilly and Company emphasized the public interest that was served by giving agencies like the FDA the power to police new drugs when he wrote:

The government has a legitimate interest in the public health and safety. If a new product is less effective and is associated with more harms than available

treatments, the government appropriately should not allow it to be marketed.  

Even members of industries that would seemingly benefit from more patient options, like the medical information technology industry, seemingly favor prohibitions and cite the public good of policing policies. Karl A. Matuszewski, the vice president of a medical information firm wrote that, “The safety of the general public requires the ability to determine that certain risks are to serious to allow”.  

And so in the same way that public police services protect the public from serious risks, so too can an agency like the FDA. 

Pharmacologist Paul Grootendorst gives the following justification for pharmaceutical regulation that cites both the informational and security function of regulatory agencies:

In [the] case of [non prohibitive policies], it would be necessary to introduce the concept of risk sharing to make manufacturers, rather than government, responsible for the market behavior and consequences in terms of cost-effectiveness, safety profile and budget impact related to health care professionals’ choices on new drugs and devices…if drug was worse in every aspect compared to already approved therapies, and in particular, was deleterious, then I see no gain in approving it. 

The policing function of regulatory agencies is seen as especially important as a way of protecting terminally ill patients who would be especially susceptible to unsafe medicines because they would misjudge the potential benefits and under appreciate potential risks. 

Democratic majorities affirm both public goods functions of pharmaceutical 

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9 Jason Briggeman, “44 Transcripts.”
10 Ibid.
11 Ibid.
12 Pharmacologist C. Daniel Mullins, as quoted in Ibid.
regulation. The FDA is one of the most popular government agencies. Where there is public outcry about FDA policies, it is often accused of failing to provide informational public goods or to ensure drug safety, not for delaying approval for the sake of drug safety.

As I argued in chapter 1, part of the historical justification for the pharmaceutical regulation was that unsafe and ineffective drugs posed a public health hazard and so government was needed to ensure safety and efficacy. State power to regulate drugs in these ways only came after drug disasters like the Elixir Sulfanilamide and Thalidomide scandals caused public outcry for more government oversight of drugs. Today, the primary threats to the public’s approval of the FDA stem from concerns about its failure to provide informational public goods and security. The aforementioned Vioxx recall illustrates this point. While few members of the public worry about the pain that patients suffer for lack of Vioxx, the public outcry surrounding the dangers of Vioxx was swift and continues today.

It is important to notice at this point that the security justification relies on the premise that the informational justification is successful. Expert regulators are only able to promote the public health and security if they can make policy that comports with their own judgments about what is medically best. The safest course of pharmaceutical policy

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is one that genuinely comports with expert’s judgments, not only about particular drugs, but also about the safest approval course that balances the potential risks of a drug against the risks of failing to approve a drug.

Earlier, I argued that the FDA does not promote public health through prohibitions because its efforts to ensure that drugs are safe and effective cause patents to suffer and die waiting for drug approval. In the rest of this chapter I will argue that informational argument fails, and further that the failure of the informational public goods justification further explains why the policies of the FDA do not in fact promote the public health and security on balance.

2. The Institutional Context of Pharmaceutical Regulation

Public goods arguments for pharmaceutical regulation all rest on the assumption that agency officials are able to craft pharmaceutical policy in the interest of the public’s health, according to their expert medical judgment. Yet pharmaceutical decisions are not necessarily made in this way. Pharmaceutical regulators’ power rests on public support, and their reliance on public support can undermine officials’ ability to set policy in the interest of the public health, even if they know which policies would promote the public health and even if they sincerely wish for the agency to promote public health overall. In this section I will describe the institutional context of pharmaceutical regulation.

Any discussion of the institutional environment of agencies like the FDA must begin with Dan Carpenter’s recent investigation into the FDA, which is the most comprehensive study of the FDA to date.\textsuperscript{15} He argues that the FDA expanded its power by cultivating a reputation of vigilance and by using pharmaceutical disasters like the

\textsuperscript{15} Carpenter, \textit{Reputation and Power}. 

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Thalidomide and Elixir Sulfanilamide crisis to gain public support. Nevertheless, Carpenter also frames the FDA as a relatively independent institution. Carpenter’s argument is that the FDA is insulated from congressional limits because it often enjoys higher levels of public support than the Congress, and that the FDA’s relatively powerful role is affirmed from a plurality of powerful American political factions. Carpenter writes,

The prospect of a vigorous and independent “protectorate” was made possible, in part, because politicians, consumer safety advocates, and even some insiders nagged the FDA incessantly and complained publicly of industry bias commingled with regulatory negligence. The political reality of a scientifically deliberate body of medical specialists was constructed in part through the laments of pharmaceutical firms and libertarians despairing of “over caution” and the wrong kind of conservatism. The toughness of the agency’s police functions and the stringency of its review practices was amplified, perhaps unintentionally, by physicians and specialists who complained weekly of interference in the holy and autonomous practice of medicine. Every criticism embedded a portrait. And every portrait displayed an organizational capacity that someone in the pluralistic soup of American national politics could admire.\textsuperscript{16}

Carpenter’s argument is that the FDA benefited from critics and supporters alike, and that conflicting responses to the agencies policies balanced to cement the agency’s role as an independent institution of medical experts. Paradoxically, in explaining its relative independence Carpenter affirms the FDA’s dependence on public opinion.

\textsuperscript{16} Ibid.
Carpenter does not provide a formal framework for understanding the relationship between public oversight of the FDA and its relative independence, except to say that the FDA can consistently issue its judgment about what is medically best despite the fact that the FDA’s power rests on public and is constrained by congressional oversight.\footnote{17}

In some cases this story likely does explain FDA independence, either when elected officials and the public support the FDA’s policies or when there is enough disagreement about the FDA’s policymaking that the electoral message is unclear. In other cases it is plausible that Carpenter’s own account the FDA allows for the possibility that the FDA will alter its decision away from what is medically best when the public’s judgment of medical advisability departs from the FDA’s, if in these cases the agency’s reputation, and therefore its power is threatened.

Whether the FDA acts independently of elected officials and the public is difficult to test empirically, since whenever the FDA issues a decision it will inevitably justify it as if that decision is medically advisable, even if it is in fact a response to public or congressional pressure. It may seem difficult to question the FDA’s assertion that all their policies are in the interest of the public’s health because agency officials are experts where the public is not. For this reason, I develop a formal model in the Appendix that illustrates how in equilibrium the FDA will not necessarily pursue policies that are medically best but will sometimes issue judgments in anticipation of public or congressional backlash. I will now describe the institutional context behind this model,

\footnote{17 Ibid.}
then I will explain how FDA approval policies might depart from official’s judgments about medicine even if the public and elected officials never explicitly propose limits.

Congress and the President influence the FDA’s power directly. The FDA is not constitutionally protected from congressional influence like the courts are, and its power is granted and can change by statute. For example, the FDA recently approved an over the counter contraceptive (Plan B) for sale to adult and adolescent women, but their decision was blocked by President Obama’s cabinet secretary Kathleen Sebelius. Commentators accused the President of overriding the agency’s decision for explicitly political reasons, but the ruling remained because it was entirely legal for executive authorities to override the agency. Plan B is not available over the counter today.

The FDA’s power is also subject to congressional oversight, and in this way both elected branches of government can constrain the agency. Carpenter affirms the view that the public and congress influence the FDA, and that pharmaceutical regulators are aware of the public’s importance:

In some cases… pressures came from the government itself, not least the National Cancer Institute and other NIH organs. In some cases, particularly well-heeled and legitimated companies could bring pressure from Congress and medical communities for drug approval. Yet the pressure for approval—and the calculus of reputation so central to the FDA’s drug review behavior—was never so apparent as in the Administration’s response to criticisms that it was responsible for the “drug lag” …Even as top FDA officials publicly denied the existence of a drug lag, even as they minimized its significance or justified American skepticism …their organization was systematically reviewing drugs so as to present its
audiences with a mechanical portrait of continuous innovation.\textsuperscript{18}

The evolution of the Prescription Drug User Fee Act (PDUFA), which I described in Chapter 1 and 2, also illustrates how this kind of public pressure and congressional influence can shape regulatory decisions. Cancer researchers and AIDS advocacy organizations petitioned Congress to instruct and then empower the FDA to approve drugs more quickly. If FDA officials were implementing their judgment about which approval policy was medically best before the PDUFA, then they shifted away from their judgment of medical advisability by implementing faster approval times. If the FDA’s lengthy approval times were not thought by officials to be medically advisable, then agency officials were initially pursuing a medically inadvisable approval strategy in order to avoid public criticism for adverse drug effects.

Either way, the public backlash surrounding Vioxx (rofecoxib) approval shows that FDA officials are right to worry that their power could be threatened if they quickly approve drugs that have bad effects, even if faster approval times would save lives on balance. After the Vioxx scandal, some critics even called for institutional limits on the FDA’s power and more congressional oversight, or pushed for agency officials to resign.\textsuperscript{19} This criticism has real institutional implications beyond a single decision. If the FDA’s power rests on its reputation with the public, then the Obama administration may have been emboldened to block FDA approval for over the counter access to Plan B.

On the other hand, the FDA does seem to enjoy independence from public pressure in other cases. For example, breast cancer patient advocates recently petitioned

\textsuperscript{18} Carpenter, \textit{Reputation and Power}. Pg. 528
the FDA to approve the use of Avastin as a treatment for breast cancer. The campaign was extremely public and the agency was criticized in Congress and in the media as well. Nevertheless, the agency denied approval despite threats of congressional censure, and the controversial decision still stands. In this case, the FDA seemed to maintain genuine independence from public opinion.

This discussion of institutions and agency independence would not be complete without a brief mention of the courts. Traditionally, the judicial system is empowered to act against the public’s wishes. Yet the courts have historically been either unable or unwilling to tie the hands of the FDA. An attorney who works on drug approval litigation wrote, “The courts in this area of the law tend to equate the Food and Drug Administration with God, motherhood, and country.”20 Return to the case of Abigail Burroughs that I described in Chapter 5. When Abigail’s family sued for cancer patients’ rights to access experimental medicines in Abigail Alliance v. von Eschenbach, the DC court of appeals found that the US Constitution protected patients’ rights to access potentially lifesaving unapproved treatments. The FDA then asked the court of appeals to rehear the case en banc, where the court then reversed its decision. This aspect of the Abigail Alliance case illustrates the FDA’s power to evade judicial oversight. Though the Abigail Alliance appealed to the Supreme Court, justices declined to hear the case, effectively securing the FDA’s power to prohibit unapproved drugs.

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3. A Model of Agency Independence

The public goods justification for pharmaceutical regulation rested on the premise that an official faced with an approval decision would simply choose to approve a drug in a way that comports with her medical judgment. Yet an official may also choose an approval policy that minimizes the medical risks of the drug and comports with the public’s demand for safer drugs. Or, officials might choose to delay approval even if it doesn’t minimize risks in order to give the public the impression of safety, (even if delay will ultimately cost lives.) Alternatively, officials may attempt to balance concerns about the public against their medical judgment and approve drugs in a way that takes into account the need for speedy approval and the public’s desire for maximally safe drugs.

Recently the FDA has decided in all of these ways, depending on the institutional context. In some cases the FDA has been explicitly punished for advancing its medical judgment contrary to political considerations, but evidence suggests that other decisions depart from what is medically advisable in order to avoid limits on the agency’s power. In these cases the agency’s decisions might reflect the public’s judgments, and this fact might explain its appearance of independence despite public oversight. If public officials’ and the public’s preferences over FDA policy are often met, in equilibrium, few restrictions of agency independence will occur even though the agency is not genuinely independent.

The FDA is subject to elected official’s oversight and the public indirectly influences them. For this reason, officials are constrained by their political environment and unable to issue genuinely independent and medically advisable judgments. Therefore, P3 is false and the public goods justification fails. My claim is that Carpenter’s argument
that the FDA is an independent agency might reflect the fact that the FDA acts in anticipation of public backlash and sanction from elected officials, giving the illusion of independence when in fact the FDA’s behavior is highly influenced by the public.

There is some empirical support for this hypothesis. As a motivating case, consider the following account of FDA decision making from former FDA employee Henry Miller:

In the early 1980s, when I headed the team at the FDA that was reviewing the NDA for recombinant human insulin, . . . we were ready to recommend approval a mere four months after the application was submitted (at a time when the average time for NDA review was more than two and a half years). With quintessential bureaucratic reasoning, my supervisor refused to sign off on the approval—even though he agreed that the data provided compelling evidence of the drug’s safety and effectiveness. “If anything goes wrong,” he argued, “think how bad it will look that we approved the drug so quickly.”

Miller’s boss was formally insulated from public pressure, but was indirectly constrained by the possibility that adverse drug reactions could lead to limits on the agency’s authority. This case illustrates the kind of public oversight that I will develop in the following model. Even though the public did not exercise direct oversight over Miller’s boss, and even though public influence would require congressional action in order to directly influence the FDA’s power to make approval decisions, officials at the FDA made decisions in anticipation of public oversight in order to preserve their long-term power.

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21Henry I. Miller, To America’s Health, First ed. (Hoover Institution Press, 2000). Pg. 41
The Swine flu vaccine’s approval process also illustrates this dynamic. The FDA approved the vaccine in the 1970’s to treat and prevent swine flu. Though the vaccine effectively treated thousands of patients and may have averted a swine flu pandemic, the vaccine also caused several hundred cases of death or paralysis from Guillain-Barre Syndrome.22 This approval decision can be understood in terms of Type I and Type II errors. A Type I error occurs when an agency mistakenly approves a dangerous drug, whereas a Type II error occurs when the agency mistakenly fails to approve a beneficial drug.23 For any approval decision, some harms will occur if the drug is approved and some benefits will be lost if it is not. In the swine flu case, the FDA initially committed a Type I error by approving a drug that was later deemed unsafe. Type I errors by the agency often have identifiable victims, and therefore attract significant media attention and public criticism of the agency. In the wake of the Guillain-Barre deaths the agency’s credibility was seriously damaged, and the adverse effects of the drug has undermined the credibility of subsequent vaccine-based public health campaigns.24 On the other hand, had the FDA failed to approve the swine flu vaccine they may have committed a Type II error by failing to approve a drug that would on balance provide more benefits than harms. The public and media often overlook the deaths caused by Type II errors, and had the vaccine been delayed the agency would not have paid a political price for the deaths

22 This example is taken from an unpublished amicus brief in the Abigail Alliance case, which was submitted by several economists including Alex Tabarrok, Daniel Klein, and Sam Peltzman. There, the Amici economists also discuss the role of Type I and Type II error in these kinds of approval decisions, given the institutional constraints and public influence over the FDA.
23 This characterization of the institutional context was suggested by Annie Stilz, and also appears in the aforementioned amicus brief for the Abigail Alliance case.
caused by swine flu, even if they could have been prevented. In this institutional context
the agency therefore has incentives to minimize Type I errors even if doing so is more
harmful on balance. Rather than pursuing an approval strategy that promotes the public
health on balance, since the agency is often held responsible for Type I errors but not
Type II errors, regulators often have incentives to pursue a risk-averse approval strategy
rather than the strategy that best promotes the public health.

These examples can be used to inform a theory and model of agency
independence. In the rest of this section I will sketch such a model, equilibrium, and
some empirical conclusions. In the Appendix I develop this model more formally.25

Assume that medical experts at the FDA sincerely wish to make policies that will
promote public health as much as possible. Still, institutional actors can influence the
agency’s decision-making in ways that cause agency officials to make medically
inadvisable decisions in order to avoid institutional limits. In other words, the
institutional context of pharmaceutical regulation might cause expert officials to decide
strategically, not in the interest of the public health. We can think these kinds of drug
approval decisions in terms of policy space. Imagine that the FDA judges that quickly
approving a drug (e.g. Avastin, Plan B, rofecoxib, Swine flu vaccines, or insulin,) is in
the interest of the public health. Or, imagine that the FDA judges that approving AIDS or
Cancer treatments slowly will best mitigate the dangers of potent new drugs. In all these
judgments, the public might support a different approval strategy, either that the FDA
makes a different approval decision entirely or that the FDA decides more quickly or

25 This model is based on a model of institutional constraint and judicial independence
that I developed in an earlier essay. That model was helpfully improved by comments
from Chuck Cameron and Lee Epstein.
slowly. To use a spatial analogy, in many cases the public’s judgment about drug approvals departs from the FDA’s.

However, the public does not have direct oversight over agencies like the FDA. Rather, the public can constrain elected officials, and officials in turn constrain the FDA. For many issues the public’s position on drug approval will not be salient enough to truly motivate elected officials to take a stand on the agency’s drug approval policy. But in some cases elected officials may be moved to signal their expectations (which are driven by the public’s judgment of the issue’s importance) to the FDA. The FDA may then interpret the signals from elected officials and issue an approval decision in light of congressional or presidential input.

In some cases, the FDA has pursued approval policies that departed from the preferences of elected officials despite their warnings; such as the decision to withhold approval for Avastin to treat breast cancer, or the decision to designate Plan B as an over the counter treatment. The FDA’s controversial Avastin decision stood, but the Plan B policy was overridden. Ignoring elected officials’ signals is therefore politically risky. If the FDA cares most about implementing the most medically advisable policy it might be rational for officials nevertheless to compromise on approval decision in response of public pressure, thus avoiding the possibility that their decision will be overturned entirely.

Besides the obvious public health costs, there are other reasons that the agency would want to avoid their decision being overridden and replaced with elected officials’ judgments about drug approval. First, the whole purpose of the FDA is to correct for widespread biases about new drugs, but if elected institutions consistently override their
decisions then drug approval is a matter of politics, not of medical expertise, and the FDA is essentially ineffective. Second, every time political actors exercise control over the FDA it threatens to compromise the FDA’s reputation (and thus its power) as an independent regulatory body.

In other words, congress and the president constrain the policy-making ability of the FDA and they are themselves constrained by the public. In this way, the public indirectly influences the FDA’s approval decisions. With this framework in mind, I develop a formal model of agency independence in the Appendix, and I will describe it informally here.

Members of the FDA have partial information about the whether elected officials will override an approval decision or otherwise limit the FDA’s power in response to pharmaceutical policy. Elected officials do not overrule FDA decisions every time pharmaceutical policy departs from their most preferred pharmaceutical policy, rather they will tolerate a range of acceptable policy decisions that are sufficiently close to their ideal policies.

Depending on the public salience of a particular pharmaceutical decision, elected officials will tolerate differential levels of FDA departure from their most preferred policies. For low-salience decisions elected officials might not care how the agency decides, and the FDA could decide independently without fear of institutional censure. In other cases, elected officials can send signals to the FDA about an acceptable range of pharmaceutical approval policies or approval times, and the FDA interprets the signals and decide in anticipation of further institutional action should they depart from the “acceptable” policy space indicated by elected officials. This variation in
levels of tolerance for independent pharmaceutical policy is a way of modeling uncertainty about the extent to which the FDA is free from electoral institutions, even when each institution’s ideal policy are known.

We can imagine that these institutional constraints might play out over the course of a game where the public informs elected officials of the salience of an issue and determine the elected officials’ ideal policy. Elected officials then signal to the FDA a level of deviation from the elected officials’ ideal policy that they will tolerate. The FDA observes this signal, and might set policy that departs from the FDA’s judgment about the ideal policy in order to avoid censure from elected officials, which would result in an even worse policy by the FDA’s lights.

In other words, both the FDA and elected officials would adopt strategies that would result in a final judgment on a pharmaceutical policy (or set of policies, perhaps) that is closest to their own ideal points. Elected officials will signal levels of constraint that aim to move FDA policy closer to their and the public’s ideal policy. Since it is also costly to override an agency policy, in some cases elected officials may signal that they will tolerate less than they actually will (as in the case of Avastin approval) and if the FDA calls their bluff, then elected officials pay a legitimacy cost for ineffectively reigning in a regulatory agency. In these cases, elected institutions lose credibility with the public and their future signals to agencies become less effective.

Depending on signals from elected officials, the FDA may or may not change policies in light of electoral oversight. FDA policy making depends on the cost of setting a compromise policy relative to the benefits associated with their ideal policy, and the probability that whatever policy they do set will be overridden.
If the FDA would ideally take a long time approving drugs because it judges that longer approval times are necessary for public health, and congressional pressure pushes for shorter approval times (as with the PDUFA) then the FDA may adopt shorter approval times to avoid further intervention in pharmaceutical policy making from elected officials. In cases like Plan B approval where the FDA’s strategy yields a policy outcome that is truly intolerable to elected officials’ given public and media opinion, then elected institutions will overturn the policy set by the FDA because the utility of overriding will be greater than the utility of accepting the policy set by the FDA, even when overriding is costly.

Two types of pure strategy equilibrium can emerge from the game as it is specified above—a separating and a pooling equilibrium. A separating equilibrium is one where each type of the sender chooses a different signal to send, and upon observing the senders signal, the receiver knows the senders type.

In this case, a separating equilibrium will exist when elected officials honestly signal the true level of deviation from their ideal policy that they will tolerate and the FDA sets a policy within that range to avoid being overridden.

A pooling equilibrium exists either when elected officials send no signals or if they always signal that they will tolerate nothing less than their ideal policy. In these cases, signals are uninformative so agencies have little guidance about how to set policy in light of public influence. In these cases the FDA will set policy by guessing how much congress will tolerate. This equilibrium result indicates that absent any information from elected branches, the public influence can still become entrenched in FDA policy making because the FDA will advance policy that departs from their own judgment about what is
medically in anticipation of public responses that motivate elected officials to override the policies. This equilibrium result thus characterizes the FDA policy as Henry Miller described them above. When Miller’s boss withheld approval in anticipation of public backlash if the drug had adverse effects he was pursuing an equilibrium strategy that sought to protect the agency’s power from public backlash that would insight institutional limits. 26

However, these are not the only equilibrium that could emerge. Elected officials can also signal false levels of override distance and a mixed strategy equilibrium may exist where agencies like the FDA to assign a probability distribution to the likelihood that electoral signals are false and thereby attempt to predict being overridden given the possibility of false signals. Examples of these types of mixed strategy equilibrium are developed further in the appendix.

Several substantive conclusions emerge from this model. The primary empirical conclusion is that modeling the public as constraints on elected officials facilitates a better understanding of how the FDA sets policy. The partially informative mixed strategy equilibrium showed that when elected official’s judgments depart from that of the FDA, and the override range of elected officials varies around their ideal policy, the FDA will choose a particular policy between both actors ideal policies, not simply what the FDA judges to be medically best.

Another empirical conclusion that emerges from the model is that without making any assumptions about elected official’s strategies given the state of public opinion, or about the FDA’s strategies given the electoral climate, a pooling equilibrium emerges

26 For a further explanation of this equilibrium, see proof 1 in the appendix
wherein the FDA always plays it safe and picks policies further than the policy which emerges in the partially informative mixed strategy equilibrium. Therefore, if neither the FDA nor elected officials held any beliefs about the strategies of the other player, then policy outcomes would systematically favor elected officials and the public.

This result is illustrates that in equilibrium, even when the FDA doesn’t receive much electoral oversight or public attention, FDA decision makers move policy to reflect public judgments about pharmaceutical policy.

4. The Failure of the Public Goods Justification

The public goods argument rested on the idea that the FDA made decisions independently and on the basis of health-oriented considerations. I have suggested that the FDA makes decisions strategically, in light of the institutional environment and the public mood. Therefore, what is considered safe and effective is determined not solely by medical data, but also by the strategic decisions of the FDA. In these cases, agencies may be pushed to delay or speed approval based on the political climate instead of expert judgments. This undermines agencies ability to provide informational public goods and to ensure drug safety.

Carpenter’s analysis of the FDA paints the agency as relatively independent of public and political pressure. Carpenter notes that there are few examples of agency curbing by elected officials. Still, Carpenter’s main thesis is that the FDA’s power rests on its reputation with the public, which gives elected officials few reasons to interfere. This thesis motivated the model that I sketched above. Insofar as the FDA’s power rests even indirectly on public approval, and public approval can lead to agency curbing, then in equilibrium the FDA will not render independent judgments even when elected
officials don’t even threaten to impose limits. Further, when elected officials send signals to the FDA about pharmaceutical policy the FDA will also make decisions strategically, meaning that the agency will consider the public health effects and the political effects of their decision.

The lesson of this model therefore is that medicine and politics don’t mix. When an agency is charged with making decisions on the basis of scientific and medical information but also situated within an institutional context where their power rests on public opinion, decisions will reflect both medical and political judgments. Agencies like the FDA must try to serve two masters, science and the public, and the policy that emerges therefore not the medically best policy. This explains why some of the most vocal critics of the FDA come from the scientific community, who accuse the agency of making decisions in ways that are overly political. The relative independence of the FDA is then explained by the fact that interference is rarely warranted because the FDA makes strategic decisions to mitigate the likelihood of interference.

There is a particular irony in the conclusions of this model, which is that the very problem that the FDA is designed to solve for citizens cannot be solved by the FDA because of citizens’ influence. That is, the public goods justification relies on the premise that the public has an epistemic deficit when it comes to pharmaceutical decisions that a regulatory agency is needed to correct. However, as long as the FDA’s power rests on its

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27 Carpenter, Reputation and Power. chapter 7. Recently scientists have criticized the FDA for failing to regulate BPA, for failing to ensure safety for some drugs, and for rejecting Plan B approval for unscientific reasons. The Plan B approval was then reversed by the FDA, and then overturned by the Obama Administration. For more on these cases see Carpenter, Reputation and Power.

and “FDA: Harsh Criticism From Within By Rebecca Leung, CBS News and Staff scientists opposed FDA reasons to reject Plan B contraceptive Critics of move see political pressure By Marc Kaufman, Washington Post
reputation with the public, the agency entrenches the very biases that it was designed to correct.

As I discussed above, the bias for avoiding Type I errors, which contributes to drug lag is a particularly striking example of this phenomenon. When people die from using a dangerous drug, the deaths are very public - the media reports the deaths and the FDA is subjected to enormous criticism and even threats to its authority. However, when people die waiting for a drug to become approved the immediate cause of their death is their disease. In this case the public has a status-quo bias that overlooks the harm of lifesaving medicines being withheld and emphasizes the harm of dangers medicines being sold.

The public’s status quo bias is then entrenched in regulatory policy when the FDA takes longer to approve new drugs than would be advisable as a matter of public health, both to ensure that new drugs are safe and effective and also to give the appearance of scientific authority (which is different from straightforwardly implementing the medically optimal policy,) so that if a drug does turn out to be deadly the agency will look as if they did everything they could to prevent the deaths.

Another reason to doubt the informational component of the public goods justification is that many physicians don’t know the approval status of the drugs that they prescribe anyhow. 28 In a recent survey, physicians were able to identify the FDA approval status of only 55 percent of all drug-indication pairs. In some cases physicians could not identify the approval status of new drugs but did know whether evidence based

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medicine supported drug-use for a particular condition. More troublingly, a small minority of physicians also could not distinguish between drugs with evidence supported indications and those that were surely ineffective. Despite the efforts of agencies like the FDA to provide informational benefits to physicians by overseeing efficacy testing, the public good of pharmaceutical information, in whatever form it is provided, may not be effectively communicated anyhow.

This insight is important for pharmaceutical regulation worldwide. The FDA provides guidance to pharmaceutical regulators in other countries, and the FDA ultimately settles most questions about what is safe and effective, even if other regulatory institutions move first.29 While it is true that most approval decisions are relatively straightforward and can be are decided without incident, the time to approval might be politically motivated and decisions regarding popular, risky, and controversial drugs are especially susceptible to institutional considerations. In this way, the institutional context of the US sets the standard of approval for all agencies. Other regulatory agencies also make approval decisions within broader political environments, and may thereby be influenced by strategic consideration in their own institutional context as well.

5. Institutional Solutions to Public Goods Failures

The public goods argument for pharmaceutical regulation fails to justify the current system because the institutional context of agencies like the FDA entrenches the public’s biases in pharmaceutical policy. Further insulating regulatory agencies from public influence would solve this problem for informational public goods, but we should be wary maintaining the policing function of the agency even if it is independent from

29 Carpenter, Reputation and Power. Chapter 11.
public influence. Another way to free the FDA from public influence is to privatize it completely; this solution also is incompatible with a prohibitive role for pharmaceutical regulators.

Consider first the proposal that regulatory agencies ought to be further insulated from public influence in order to avoid agency curbing. After the White House’s decision to block approval for Plan B, Dan Carpenter proposed that the FDA be reformed to act more like the Federal Reserve. He writes,

A cabinet secretary — and by extension, a president — has overruled a drug-approval decision by the Food and Drug Administration. The precedent risks placing the real power for drug approval not just with a cabinet secretary, but also with the White House itself. The only solution, then, is to make the F.D.A. truly independent. Americans have already done this, through the Federal Reserve, to protect our money supply from political meddling; it’s time to do it for drugs… We would never allow this sort of second-guessing when it comes to our financial health. We should have the same standards when it comes to our public health.30

In other words, in order to enable the FDA to set pharmaceutical policies in ways that promote public health, the agency’s power should be more fully insulated from its reputation.

Reforming the FDA to be even further insulated from public influence would not only solve the problem of agency curbing, but would also free the FDA to make policy that promotes the public health more generally. Without the possibility of agency curbing and the need to bow to public opinion the FDA would no longer be required to play it

safe by deciding strategically, rather, it could issue judgments that were solely based in medical considerations.

If Carpenter’s proposal for reform successfully insulated the FDA from public pressure, it would seemingly enable the agency to set policies that it judged medically advisable. In other words, the public goods argument for pharmaceutical regulation wouldn’t fail. However, such a solution would be radically anti-democratic. Unlike the Federal Reserve, which regulates monetary policy in a way that doesn’t limit any individual’s particular options, pharmaceutical policies do determine what each individual can and cannot purchase.

At this point we should rethink the “security as a public good” argument. Pharmaceutical regulators can ensure that manufacturers disclose safety information about new drugs, thereby protecting patient health, without prohibiting patients from accessing dangerous drugs if they choose to. One problem with the public goods argument as a justification for pharmaceutical prohibitions is that as they stand today pharmaceutical prohibitions entrench the biases of the public, so even unbiased medical experts are subject to prohibitive policies that do not reflect medical expertise.

Yet even if the FDA were freed from public influence, experts might still disagree with the judgments of regulators. When experts disagree with the judgments of an agency like the Federal Reserve, the Fed’s practical authority can still be justified by the fact that the nation needs some unified monetary policy in order to maintain economic growth. No similar public good is served by prohibitive pharmaceutical regulations though because it is not true that the nation needs a fully unified pharmaceutical policy. Experts who disagree with the experts at the FDA might choose to use and prescribe unapproved
drugs, and if patients consent their departure from the agency’s judgment doesn’t undermine the national economy or cause a public health crisis, it is mainly self-regarding.

For this reason, the “security as a public good” justifications for prohibitive FDA policies fail. The analogy to police power is mistaken because police are provided to prevent people from harming others, while regulatory agencies aim to prevent people from harming themselves. Still, experts can provide security as a public good through prohibitions insofar as they aim to prevent drug manufacturers from harming consumers by selling misbranded or adulterated products, but not by preventing consumers from accessing drugs when they know the risks.

In chapter 1, I described the Consumer Product Safety Commission (CPSC) as a model of non-prohibitive regulation that serves an informational public good. This agency is an example of how the FDA might be reformed to be both more independent and less prohibitive. To review, the CPSC maintains a database of safety concerns and oversees voluntary recalls for those products that it deems unacceptably dangerous, though the CPSC cannot recall products unless manufacturers agree to a recall. Manufacturers typically do agree to recalls, not because the CPSC has any punitive power but because CPSC recalls reliably indicate that products may be so unsafe that manufacturers can be held liable for any injuries that result from their products, and punished in civil courts. The CPSC promotes informed consumer choice by setting standards for consumer safety, advertising any safety concerns about particular products, and overseeing labeling and safety disclosure requirements, not by exercising prohibitive power.
Were Carpenter’s proposal of insulating the FDA from public pressure to succeed, the FDA might become more like the Fed or the CPSC. Since there isn’t a public good that is served by giving the FDA prohibitive power over consumers, the FDA ought to be more like the CPSC. This proposal also is responsive to worries that it is antidemocratic to insulate the FDA from public opinion. Once the FDA’s role is limited to an epistemic function, rather than a prohibitive role, then citizens will have less of a claim to be involved in policies that potentially limit their rights because they could just as easily ignore the FDA’s advice whenever they disagree.

For these reasons, pharmaceutical regulators ought to be situated in institutional contexts that are insulated from public opinion and political pressures, and they should not have prohibitive power.

Another solution to the failure of the public goods argument is to take politics out of the process even further. For example, legislators could designate private companies to advise consumers about pharmaceuticals. There’s no reason to think that only a government organization can provide informational public goods. In other industries private organizations enable consumers to make informed choices and to learn about the safety and efficacy of products and services. Klein and Tabarrok call these kinds of companies knower organizations. 31

For example Kelly’s blue book helps consumers to assess the value of used cars, Consumer Reports enables consumers to easily find information about the safety and efficacy of a range of products, including household appliances and cars. Expert reviews from Consumer Reports have lead car manufacturers to issue product recalls and to make

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31 Tabarrok and Klein, *Is the FDA Safe and Effective?*. 314
design changes. For some products that are particularly important and expensive, like computers, volunteer reviewers and specialized publications conduct extensive testing and issue personalized recommendations for different kinds of potential customers. Good Housekeeping issues its seal of approval for household products that have been tested by the Good Housekeeping Research Institute, and products bearing the seal carry a two year warranty and Good Housekeeping will replace it if defective. Other magazines offer similar seals of approval for make up and sports equipment.

Some knower organizations rate services as well. Angie’s list and Sitter City rate handymen and babysitters, respectively. Even health goods are monitored by private knower organizations, Health Grades and Vitals rate physicians and the American Medical Association and American Dental Association certify physicians and dentists. In some cases, knower organizations can inform shape public policy in non-prohibitive ways. Moody’s and Standard and Poor’s rate debt, which informs government decisions about where to invest and also about their own budgeting and development. In this way financial ratings agencies provide an epistemic public good that even governments use.

One worry about privatizing pharmaceutical regulation is that private agencies will be susceptible to industry bias. Yet government agencies are also susceptible to industry bias, and independent agencies might reasonably be required by law to disclose all industries ties and sources of funding, as should public officials for that matter. Additionally, it is unclear that industry influence does translate as bias, since pharmaceutical industries also have a genuine interest in making safe and effective products.

A second worry about privatization is *market failure*, that demand in the market
will not generate enough support for an independent knower organization for pharmaceuticals. This hypothesis is suspect, given the importance of health care information for most people’s lives, but in cases of market failure government officials or manufacturers might subsidize independent agencies to certify drugs as safe and effective. Such a system would not necessarily cause industry bias any more than licensing requirements are influenced by the fact that shipping countries pay commercial drivers to become certified.

In either case, informational public goods can be provided by public or private (and perhaps publically subsidized) agencies, but neither has the authority to prohibit patients from using drugs in the name of public health, because the security as a public good argument does not justify preventing self-harm.

6. Conclusion

In this chapter I argued that public goods justifications fail to justify the current system of pharmaceutical regulation. Regulatory agencies cannot provide informational public goods as long as their power rests on popular opinion. Agencies like the FDA can be reformed to provide informational public goods, but the security argument still fails to justify prohibitive policies. For this reason, pharmaceutical regulators ought to have more power in some sense, to certify drugs freely without considering the political environment, but less in another sense, because they do not have the authority to prohibit consumers from using unapproved drugs.
X. Institutional Solutions

Prohibitive limits on access to medicines not only have terrible consequences; they violate our rights and cause wrongful death as well. Further, prohibitive policies do not provide any public good, and they may even undermine state’s ability to provide informational public goods by entrenching the public’s biased views. States therefore ought to protect citizens’ rights of self-medication and abandon prohibitive pharmaceutical regulations. In practice, what would this entail?

In this chapter I will review a range of policies that could respect citizens’ rights of self-medication but also mitigate the bad effects of this right. These policies include non-prohibitive premarket testing requirements, public certification mechanisms, legalization, tort reform, and public health campaigns.¹ I will also describe a cultural ideal that I find attractive, given the foregoing arguments about the right of self-medication. Not only should official policies be more in line with citizens’ rights of self-medication, but also liberals should endorse and promote a broader cultural shift from medical paternalism to respect.

Some of the policies I propose will strike readers as extreme. Revisionary solutions are required to right the serious injustice of prohibitive pharmaceutical regulation. For the unconvinced, I also propose some policy solutions that are more moderate. My hope is that these solutions, if not the more revisionary proposals that I

¹ A difficulty of this approach is that I cannot argue definitively that these policies will achieve the same desirable public health outcomes as the prohibitive policies that most liberal societies currently enforce, because no existing society has in fact adopted these policies. But there is some sense in which the public health outcomes are of secondary concern, since citizens have a basic right to self-medication. Like other basic rights, even if they lead to lower overall happiness and well-being, they still deserve institutional protection.
advance, will show even the most hard-nosed skeptics of a right of self-medication that a more just pharmaceutical policy is possible.

First I will describe some political reforms, then a new cultural ideal for medicine. I then argue for the consumer-provider understanding of the doctor-patient relationship, and propose some tort reform that would better accommodate rights of self-medication.

1. Legalization

Pharmaceuticals are prohibited before they are approved and once approved they are selectively prohibited. I have argued that these prohibitions cause needless death and suffering, violate our rights, and are discriminatory. Here I will describe a range of less prohibitive policies. I believe that justice requires a non-prohibitive drug system; my hope is that readers who are skeptical of this claim can at least see that a significantly less prohibitive system is morally imperative.

Presently, medicine is not available until it has been approved for safety and efficacy; patients are prohibited from accessing untested medicines. These kinds of prohibitions offend against the right of self-medication. I propose a conservative, a moderate and a radical policy solution. John R. Graham at the Pacific Research Institute, a conservative think tank, has recently proposed that any medicines that have been approved by the European Medicines Authority ought to be available in the United States as well, (and presumably, drugs that gain approval first in the US ought to be available in Europe). Graham cites recent approval data to show that prohibitive efficacy requirements need not be enforced separately by specific regulatory regimes, and that the cost of placing approval solely in the hands of a single regulatory body are substantial. Graham writes,
During a 12-month period in 2008 and 2009, the European Union’s European Medicines Authority (EMA) and the FDA approved a total of 39 new medicines. Fifteen were approved only by the FDA, 11 were approved only by the EMA, and 13 were approved by both regulators. In five of the 13 cases where the FDA and EMA both approved the medicine, the EMA was the first to approve, and it issued those approvals 552 days faster than the FDA, on average. Even if we include all 13 medicines approved by both the FDA and the EMA, the EMA approved them 97 days faster, on average. If the U.S. government had allowed American patients to use new medicines that were approved by the EMA, but not yet by the FDA, American patients would have had faster access to 17 new medicines, out of the entire set of 39. Clearly, Congress’s grant of a regulatory monopoly to the FDA is creating a significant obstacle to Americans’ timely access to new medicines.\(^2\)

Insofar as efficacy testing is a requirement of access, patients ought to be permitted to access drugs that have passed efficacy tests in other major regulatory regimes even if their own country’s regulatory authority has withheld approval.

A somewhat less modest solution is that efficacy testing should not be a requirement of access at all. Presently, premarket efficacy testing comprises most of the approval process. As I showed in Chapter 2, passing the FDA’s efficacy trials in the United States is a lengthy and costly process that potentially raises the cost of medication and discourages pharmaceutical innovation. Efficacy requirements also prevent sick patients from accessing potentially helpful drugs until they have been proven effective.

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Prohibiting drugs that have not passed efficacy testing violates patients right to self-medication because some patients might choose to take potentially ineffective drugs, given the chance that they might be effective, were these drugs not prohibited.

For these reasons, premarket efficacy testing should not be a requirement of access. This is not to say that efficacy testing cannot play a role, drugs that have not been shown to be effective ought to carry labels that indicate as much, insurance providers may choose not to reimburse patients for the use of potentially ineffective drugs, and governments might even play a role in discouraging companies from marketing drugs that are potentially ineffective.

More radically, I also endorse unrestricted access to drugs that have not undergone premarket safety testing. Patients, especially terminally ill patients, ought to be permitted to access dangerous and potentially dangerous drugs. When a treatment undergoes premarket safety testing, government officials weigh the potential risks and benefits of a treatment, and make a judgment about whether the benefits are worth the risks. I will argue that governments are not entitled to make these kinds of decisions about medical treatment; rather, patients should be allowed to decide whether the risks of treatment outweigh the benefits.

Again, this is not to say that safety testing should not play a role. States can still provide a valuable public good by overseeing safety trials and certifying drugs that are safe so that consumers can make informed medical choices. States can also pass and enforce requirements that manufacturers disclose whether a drug has been tested or certified as safe and states can require that manufacturers disclose the safety risks associated with particular treatments. All of these premarket policy reforms are based in
the idea that states that oversee premarket testing can provide an important service by promoting informed consumer choices, without taking any choices off the table.

I have also argued for an end to post market prohibitions. Most liberal societies designate some treatments as prescription only and some as over the counter. With a few exceptions, including the United States, most societies also designate some treatments as behind the counter meaning that in order to access the treatment, patients must consult with a pharmacist about the purpose, risks, and dosing requirements of a treatment, but physicians and pharmacists do not have the authority to prohibit patients from accessing the treatment. The arguments that I developed in the previous chapters show that prescription-only status for drugs is unjust because it is discriminatory and it violates patients’ rights of self-medication.

A right of self-medication and rights against discrimination therefore require that almost all pharmaceuticals be reclassified as behind the counter. Once behind the counter, patients ought to be permitted to access drugs by either obtaining a prescription from their physician (and in these cases nothing would change from the current system) or by consulting with a pharmacist about the risks and benefits of treatment, or by signing a waiver accepting full responsibility for the risks associated with treatment.

A system where patients are encouraged to talk to pharmacists about the risks and benefits of treatment, but are still able to opt out in cases where they would prefer to access treatment without learning about potential risks respects a right of self-medication, would give patients rights to decide not to know medical information. This proposal balances these rights not to know against the real costs of making uninformed treatment
decisions. Opt out systems like this are designed to “nudge” patients to make good and informed decisions without violating anyone’s rights.

One part of legalization is decriminalization. Citizens who self-medicate should not be subjected to criminal penalties because self-medication is not wrong (insofar as it is exclusively self-harming). An act is prohibited by the criminal law if it is investigated, prevented, prosecuted or punished on behalf of the public interest. Medical treatment regulated by the criminal law in several ways, here I will focus on prescription drugs.

Possession of prescription drugs is criminally prohibited for those not possessing a prescription. In some cases, it is also illegal for physicians and pharmacists to prescribe prescription drugs for patients without specific approved conditions. These prohibitions lead to black markets for prescription drugs, which are investigated by police and prosecuted and punished in criminal courts.

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3 This is a necessary but not sufficient condition for something to qualify as criminal law. Regulatory law also meets these conditions. So, while this definition serves nicely to distinguish criminal law from private law, which I will discuss in the next subsection, it is not a comprehensive definition. Also, sometimes private law is used in the public interest, but only when the government takes on the role of a private actor on the public’s behalf, such as using the courts to enforce contracts that concern public land. In this case, the government has the same standing and interest as any private landowner, though the land ultimately belongs to the public.

4 For example, the unauthorized provision of medical treatment is criminally prohibited, including not only practicing medicine without a license, but also distributing prescription drugs without authorization.

5 Criminal law intersects with medical treatment perhaps most clearly in the case of medical marijuana. Physicians are permitted to prescribe medical marijuana but only for certain conditions, only medical professionals are permitted to sell marijuana and only patients with prescriptions are permitted to purchase marijuana. The sale, position, and use of marijuana is otherwise criminally prohibited.

6 More generally, off-label prescribing is not prohibited, but physicians are criminally prohibited from prescribing or over-prescribing certain prescription drugs such as ADHD medication and painkillers to patients without medical conditions that warrant the prescription. Further, patients are prohibited from purchasing prescription level drugs for which they do not have a prescription. Though the purchase of prescription drugs without
The first reason to reject these kinds of prohibitions is that they criminalize behavior that isn’t wrong. As Douglas Husak has forcefully argued, it is impermissible for states to criminally punish behaviors that are not wrong.\(^7\) Insofar as pharmaceutical use is essentially self-harming it is not wrong for patients to use prescription-grade drugs. Insofar as patients consent to the risks of dangerous drugs, their physicians do not wrong patients by providing them with unsafe drugs.

A stronger reason, which I have developed in the previous chapters, is that they criminalize behavior that ought to be legal. Patients have *rights* of self-medication, so not only is self-medication not wrong, criminal penalties for pharmaceutical possession, provision, and use violate patients’ rights. Stronger still, I argued that prohibitions of medications violated other basic rights like the right to save one’s own life or the right to die. These prohibitions are also discriminatory and they limit patients’ freedom to deliberate about their options without consideration of normatively extraneous traits.\(^8\) For all these reasons, it is especially wrong to use criminal penalties to enforce prohibitions that should not exist in the first place because they violate people’s rights.

Two specific cases of criminalization merit special mention at this point. First, in many parts of the United States it is a criminal offense to provide patients with physician

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\(^8\) Moreau, “What Is Discrimination?”.
assisted suicide. Most notoriously, Dr. Jack Kevorkian, a physician who assisted the death of terminally ill patients, was sentenced to 10-24 years in prison (of which he served eight) for second-degree murder. The arguments in favor of a basic right to die that I developed in Chapter 5 suggest not only that these kinds of criminalization ought to be abolished, but also that enforcing criminal penalties for physicians who assist patients in dying violates terminally ill patients’ basic right to die.

Second, criminal law intersects with medical treatment perhaps most clearly in the case of recreational medicines, like medical marijuana. Physicians are permitted to prescribe medical marijuana, but only for certain conditions. Only medical professionals are permitted to sell marijuana and only patients with prescriptions are permitted to purchase marijuana. The sale, possession, or use of marijuana is otherwise criminally prohibited. This policy is an especially stark example of wrongful discrimination on the basis of medical condition. Other pharmaceuticals are not regulated in this way. For example, the law permits physicians to prescribe other drugs off-label but not marijuana. In this way the law takes a specific stand against off-label recreational use but not other off-label uses. Today physicians are also subject to criminal penalties for prescribing or over-prescribing some prescription drugs such as ADHD medication and painkillers to patients without medical conditions that warrant the prescription. In this way the use of pharmaceuticals for recreational use is becoming increasingly criminalized. The arguments I have developed call for full legalization of recreational drugs including marijuana, and other recreational pharmaceuticals, including street drugs, though the

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government ought to play a role in certifying recreational drugs as safe (and maybe even effective) in order to promote informed consumer choices.

2. Rethinking Do No Harm

In Chapter 7 I suggested that the doctrine of informed consent also justifies a right of self-medication. But the doctrine of informed consent is not the only ethical constraint that physicians presently face. Not only are doctors ethically required to respect patients choices to refuse treatment, even when it is medically inadvisable, they are also bound by professional codes like Hippocratic Oath. Self-Medication might seem to conflict with these precepts, depending on how harm is understood. First I will suggest that self-medication doesn’t necessarily conflict with an ethical prohibition on harming like the Hippocratic oath. Then I will suggest that even if self-medication does conflict with a prohibition on harming, physicians ought to favor self-medication.

Physicians take the Hippocratic oath as part of their medical education. The oath is often associated with its original version, which states that physicians are bound to “prescribe regimens for the good of my patients according to my ability and my judgment and never do harm to anyone.” The contemporary version of the oath, which is presently taken by medical students states that physicians ought to “apply, for the benefit of the sick, all measures [that] are required, avoiding those twin traps of overtreatment and therapeutic nihilism,” but it does not include a strict prohibition of harming. It is notable that neither version of the oath makes reference to facilitating a patient’s chosen

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11 Many discussions of professionalism in medical ethics cite this version of the oath; see for example David Hunter, “Am I My Brother’s Gatekeeper? Professional Ethics and the Prioritisation of Healthcare,” Journal of Medical Ethics 33, no. 9 (September 1, 2007): 522–526.
course of treatment or considering patients judgments at all. _Primum non nocere_ is another ethical precept that is taught to medical students. It states _first do no harm._

The doctrine of informed consent maintains that physicians cannot administer treatment without a patient’s informed consent. Understood only as a patient’s right of refusal, at first glance does not conflict with a physician’s duty to do no harm because it always leaves the physician with the option to do nothing. Yet in some sense, failing to act can be harmful, such as if a physician fails to remove the entire tumor. In other cases, providing information is seemingly harmful on-balance, like when a patient learns of an incurable terminal illness and spends his last days in a state of depression and dread. Whether the doctrine of informed consent actually conflicts with an ethical prohibition on harming depends on how harm is defined.

Self-medication also does not conflict with physicians’ duty to do no harm at first glance, except in cases where formal barriers to access, in the form of premarket prohibitions and a prescription drug system, require that physicians actively provide patients with potentially risky treatments. These considerations show that it is not clear how either a patient’s right of informed consent or the right of self-medication square with an ethical prohibition on harming. A more sophisticated account of harm is needed to assess whether informed consent and self-medication are compatible with prohibitions on harming.

In the case of informed consent, can a failure to provide treatment be harmful? In some cases of self-medication, medical professionals are still required to facilitate risky decisions, someone must sell the treatment, and in some cases, someone must connect a patient to an IV or inject medicine into the patient’s veins. Whether respecting rights of
informed consent and self-medication is harmful will depend on what we mean by ‘harm’.

Two popular accounts of harm define harm either as an absolute, non-comparative bad or as comparatively bad, relative to some relevant counterfactual. Consider first a non-comparative conception of harm. This definition of harm states that A harms B if A causes B to be in an intrinsically bad state, for example by causing him pain, injury, disability, or death. This definition states sufficient conditions of harming, but does not inform any all things considered judgments about the permissibility of harm. According to this definition of harm, physicians cause harm as a matter of course—any kind of surgery, physical exam, or shot involves the physician causing pain. If first do no harm referred to a non-comparative account of harm, then the Hippocratic Oath would require doctors in most cases to first do nothing, so it is unlikely that this account of harm implicit first do no harm since it seems to define most of medicine as harmful.

The second definition of harm, the counterfactual comparative account, states that A harms B if A causes B to be all things considered worse off than he was had A not acted. This definition seems closer to what the Hippocratic Oath means; physicians have an obligation not to leave their patients in a worse off condition. Thus, physicians seemingly do not violate the Hippocratic Oath by respecting a patient’s right to refuse

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12 This discussion of harm is informed by Ben Bradley’s helpful analysis of the concept. Ben Bradley, “Doing Away With Harm,” Philosophy and Phenomenological Research (Forthcoming).
14 Bradley, “Doing Away With Harm.”
treatment against medical advice because in respecting a patient’s choice to refuse treatment the physician does not cause the patient to be in a worse state than before, the disease does.\textsuperscript{15}

Yet if we adopt this definition of harm, physicians also don’t necessarily violate the Hippocratic Oath by providing patients with access to treatment against medical advice. This definition of harm states that B has been harmed by A if he is worse off, \textit{all things considered}, as a result of B’s actions. By providing a patient with access to treatment against medical advice a physician likely does make his patient medically worse off, but as I showed above, a patient’s medical welfare and his all things considered well-being might differ. While a medical opinion is usually the best indicator of whether a treatment will make a patient medically worse off, an informed patient’s opinion is usually the best indicator of whether a treatment will make him all things considered worse off. This principle, which grounds the right of refusal as well as a right to access, also shows that the Hippocratic Oath need not conflict with providing access to treatment against medical advice. Physicians might make patients medically worse off by

\textsuperscript{15} Notice this extension does not necessarily follow from the counterfactual comparative account. As Ben Bradley writes, sometimes omissions or a failure to act might leave patients worse off than they would have been counterfactually had someone acted. So, if A intends to benefit B, but then decides not to, according to this account of harm A has harmed B by deciding not to act. Or, as Bradley puts it “Suppose Batman purchases a set of golf clubs with the intention of giving them to Robin, which would have made Robin happy. Batman tells the Joker about his intentions. The Joker says to Batman, “why not keep them for yourself?” Batman is persuaded. He keeps the golf clubs. The comparative account entails that Batman has harmed Robin, because Robin would have been better off if Batman had not kept the clubs.” That failure to benefit can count as harming is a problem for this account of harm, according to Bradley. Whether it is a problem or not, failure to benefit cases illustrate that the Hippocratic oath is potentially in tension with informed consent. Ben Bradley, “Doing Away With Harm,”
providing medically inadvisable treatment, but physicians do not harm patients by providing access to treatments that make the patient better off all things considered.

Perhaps the definition of harm implicit in the Hippocratic Oath and Primum non nocere lies somewhere between the non-comparative and comparative conception of harm. Consider this definition of harm: A harms B if A causes B to be medically worse off. If this limited conception of harm is the subject of the duty to do no harm then it is true that self-medication, insofar as it requires that someone provides the treatment, conflicts with a medical professional’s ethical obligation to do no harm in a way that the right to refuse medical treatment does not. If this definition of harm is the subject of do no harm though, then physicians ought to abandon do no harm as an ethical constraint. In some ways, this definition of do no harm is already absent from some medical specialties, like cosmetic surgery.

What could motivate the idea that physicians have a duty not to make patients medically worse off? One argument is that a physician’s job is to make patients medically better off, in which case, self-medication does conflict with this understanding of do no harm. One reason to interpret do no harm in this way is that a physician’s job is to act as a medical caretaker, so doing medical harm would be contrary to the purpose of a physician. If this is the justification for this conception of harm though, it seems misguided. The nature of any job ought to be constrained by independently justified principles; ethical principles should not be derived from the nature of the job.16

16 For example, imagine an unjust combatant who argues, “I ought to kill my enemies because it is my job!” or a bank robber who derives his ethical code from a conceptual analysis of robbing banks. We ought to bring ethical principles to bear on a how a profession is defined, the definition of a profession ought not inform ethical principles.
Further, it is unclear why making patients medically worse off, if doing so would make them better off all things considered, would be wrong. As I argued in the previous chapter, health and medical well being are instrumental to a flourishing life, but health is not intrinsically a part of a flourishing life any more than money or power. If a patient's conception of the good life doesn’t include being as medically well off as possible (and many people seemingly do not value health in this way), then health isn’t a value for him.\(^{17}\) Also, attentiveness to patients’ medical well being over all things considered well being is inconsistent with the doctrine of informed consent, as I argued above. If the doctrine of informed consent is justified in requiring physicians to defer to a patient’s judgments about his all things considered well being over his medical well being for refusal decisions, then it is justified to permit physicians to defer to all things considered well being in providing access as well.

Last, this interpretation of do no harm is inconsistent with current practices in medicine. Already, physicians perform procedures that make patients medically worse off, but all things considered better off, and neither the medical community or society judge these kinds of physicians as violating their duty to do no harm. For example, cosmetic surgical procedures are medically unnecessary and they expose patients to a substantial risk of infection and other medical complications.\(^{18}\) Sports medicine also treats patients with the aim of facilitating athletic abilities, sometimes at the expense of

\(^{17}\) In the previous chapter I alluded to the idea that liberalism is especially compatible with a constructivist theory of value, and that this kind of theory of value delivers the conclusion that health outcomes are not uniquely valuable. Yet you don’t need to be a constructivist about value to get on board with this. For example, a preference utilitarian should also favor this position, insofar as expanded access to medical treatment satisfies people’s preferences to a greater extent.

\(^{18}\) Bradley, “Doing Away With Harm.”
the patient’s overall health. In this sense, cosmetic surgery and sports medicine often make patients medically worse off. Nevertheless, cosmetic surgeons and team physicians are not considered unethical because their services make their patients better off all things considered. Therefore, it is implausible that this interpretation of do no harm does or ought to ethically constrain medical practice.

To sum up, I have argued that an independently plausible interpretation do no harm doesn’t conflict with self-medication even in those cases where physicians and pharmacists are required to administer risky treatment. Interpretation of do no harm that do conflict with universal access but not informed consent ought to be rejected. If however self-medication were to conflict with do no harm, then so does the doctrine of informed consent, and so much the worse for do no harm. Internal to the doctrine of informed consent is the rejection of paternalism in medicine, but do no harm as I have characterized it, insofar as it conflicts with informed consent or universal access, is a paternalistic doctrine.

Thus, either physicians must reject the prohibition on medical paternalism that is central to the doctrine of informed consent or reject do no harm. Rejecting informed consent is too high a price to pay to preserve do no harm. To abandon informed consent is to undo fifty years of ethical progress in medicine and return to the era where physicians were permitted to withhold diagnoses and mislead patients in the name of the patient’s medical well being. In other words, if the Hippocratic oath conflicts with self-

20 Some physicians have called for a return to the glory days of the Hippocratic oath. For example Edmund D. Pellegrino, MD writes, “Also unique to our times is the erosion of the foundations of professional ethics, which might have energized a mitigation or
medication it is because do no harm is paternalistic, and the principle therefore also conflicts with the doctrine of informed consent. Given the choice between preserving do no harm and informed consent, I have suggested that physicians ought to adhere to the doctrine of informed consent foremost.

3. The Consumer Model

Suppose medical practice changed to respect patients’ rights of self-medicating, as it changed in 1914 when the doctrine of medical consent emerged, and in 1957 when informed consent requirements became a standard feature of medical practice. When these changes occurred, the bulk of medicine didn’t radically shift. Patients still trusted their physicians to choose the right procedures and treatments for them, and even today most patients give their informed consent unreservedly for whatever treatments their physician recommends. Instead, medicine changed at the margins. In those rare cases where a patient would not consent to treatment, the doctrines of medical consent and informed consent vested patients with that authority.

Similarly, a right of self-medicating would not require a revisionary shift in the practice of medicine. People might still consult with experts, heed the warnings of reversal of those current trends to deprofessionalization. The Hippocratic Oath has been denied historical credibility; each of its precepts is challenged, and its content is negotiable or understood simply as a changeable construct of societal mores. Underlying those challenges is the pervasive moral skepticism that denies the validity of any stable moral truth and even the capacity of reason to apprehend such truth even if it were to exist. All of this is exacerbated by cultural diversity, which induces a strong tendency to moral relativism. Clearly, the confluence of those forces makes the current cycle of moral confusion and deprofessionalization much more difficult to reverse than previous cycles. Indeed, critics of medicine - some physicians among them - say that, ultimately, the end of ethics is at hand. On that view there is nothing special about medicine.” Pellegrino goes on to worry that increased openness in medicine is intrinsically at odds with the ethical practice of medicine. See E D Pellegrino, “Medical Professionalism: Can It, Should It Survive?,” The Journal of the American Board of Family Practice 13, no. 2 (March 1, 2000): 147–149.
regulatory agencies like the FDA and follow their doctor’s advice. Self-medication only changes medical practice in those cases where patients choose to make treatment decisions that their physicians and other medical experts would advise against. Most patients have an interest in maintaining their health, and can recognize that medical experts are often right about which treatments are medically best, so most patients would probably still defer to physicians and medical experts even if they had rights of self-medication.

In some sense these changes are already underway. Medical culture is changing; physicians are seen more and more as advisors than caretakers. Some critics object that these changes undermine the doctor-patient relationship or force physicians to be complicit in facilitating medical choices that they think are wrong. In this section I will argue that the shift to the consumer model of patient care is a good thing because it reflects patients’ rights of self-medication, and that physicians are not entitled to act paternalistically towards patients even though they may disagree with their patients’ choices.

A right of self-medication can be framed as call for more patient choice. Recent debates about the provision of health service have begun to raise the question of patient choice. For example, recall that Canadian health care providers have recently begun to accept private payments for health services, which has been illegal so far, so that patients can choose to obtain treatment outside of the system of universal health insurance.21 In the United States, where health care policy is in flux, some policymakers and health care

professionals have argued that government programs and insurance providers should facilitate greater patient choice over physicians and treatments.

In these debates, policymakers and medical professionals who favor patient choice make two claims. First, patients should be permitted to use their own money to access available medical services. In 2006 Dr. Brian Day criticized Canadian health care system’s prohibitions on privately funding health services, (which was only partly overturned in 2005,) arguing that: “this is a country in which dogs can get a hip replacement in under a week and in which humans can wait two to three years.” 22 Few other systems restrict patient choice in this way, and in Canada these policies are changing. The second claim is that systems that provide services should provide more, or that services should be more affordable so that patients can pay for them on their own. Here too the language of patient choice is finding force with policymakers in states that have public and private health care systems. More generally, this increasing demand for patient choice is changing the medical profession. Health care workers are now called providers in many contexts and patients are asserting not only their rights as patients, but their rights as consumers as well.

The right of self-medication is in part consistent with this trend. Self-medication empowers patients as consumers to privately choose and purchase whatever treatment they want. In this way a right of self-medication is inconsistent with prohibitions on privately funding medical treatment. Yet self-medication doesn’t require that the public subsidize all patient choices, nor does it require that patients and physicians conceive of themselves as consumers and providers.

22 Ibid
What the right of self-medication does require is that physicians and medical professionals rethink their role as gatekeepers, and it is this sense in which perhaps the right of self-medication makes medicine less about care giving, since gate keeping is seen by many as a way of protecting patients from their own bad treatment decisions. The above arguments for a right of self-medication do therefore fundamentally alter the physician-patient relationship in this way—physicians can act as advisors, but that their advisory bark shouldn’t have any bite. Medical experts should no longer have a say about which medicines are provided to patients, instead they should facilitate or support patients’ informed treatment decisions even when they are medically inadvisable. But as I have said before, I am skeptical that principled change very much would change in the physician-patient relationship in most cases because most patients will make medically advisable treatment decisions based on their physician’s expert judgments.

At this point one may object that a right of self-medication recasts physicians as mere providers and patients as nothing more than consumers. For example, in a recent New York Times opinion piece Paul Krugman wrote,

How did it become normal, or for that matter even acceptable, to refer to medical patients as consumers? The relationship between patient and doctor used to be considered something special, almost sacred. Now politicians and supposed reformers talk about the act of receiving care as if it were no different from a commercial transaction, like buying a car — and their only complaint is that it isn’t commercial enough. What has gone wrong with us?  

Krugman goes on to say,

The idea that … doctors are just “providers” selling services to health care
“consumers” — is, well, sickening. And the prevalence of this kind of language is
a sign that something has gone very wrong not just with this discussion, but with
our society’s values.24

Medical professionals have echoed this concern. In a recent editorial, published in the
New England Journal of Medicine, Pamela Hartzband, M.D., and Jerome Groopman,
M.D. reject what they call “The New Language of Medicine,” which frames physicians
as health-care providers rather than as caretakers.25 They worry that if medical
professionals come to see patients as consumers, the caregiving relationship will suffer,
medical care itself will suffer, and such a practice would demean both patients and
doctors and “dangerously neglect the essence of medicine.”26

Before we address this critique directly, notice that self-medication might actually
make medical experts more valuable to patients. If patients assume more responsibility
for their medical choices medical information might become more valuable. Patients’
rights of self-medication wouldn’t diminish the epistemic authority of medical experts
when it came to the risks and benefits of treatments, but patients with more options are
likely to have more questions for which medical expertise is relevant. Also, a right of
self-medication enables patients to focus on which treatment option is best, not which
treatment option is available. Such a change might strengthen the patient-physician
relationship insofar as physicians will be required to consult with patients about their all-

24 Ibid.
25 Pamela Hartzband and Jerome Groopman, “The New Language of Medicine,” The
26 Ibid.
things-considered interests, rather than their medical interests alone. By respecting patients’ rights of self-medications physicians can treat the patient, not the condition.

Still, even if a right of self-medication were part of the shift to patient choice that I described above, do we have any reason to believe that self-medication, insofar as it recasts the physician-patient relationship in this consumerist light, will degrade patients and medical professionals? If anything, insofar as paternalism constitutes an insulting judgment about the patients’ ability to make decisions for himself, as some theorists have suggested, the current system is more degrading to patients than self-medication.

Nor would a shift to self-medication be degrading to professionals. Physicians and medical experts need not be recast as mere providers, like auto mechanics or car salesmen, but they should be recast as advisors rather than gatekeepers. (Anyhow, what’s degrading about being an auto mechanic or car salesman?) Today physicians and medical experts in regulatory agencies like the FDA have the power not only to advise patients about which treatment is medically best, but also to prevent patients from accessing medically sub-optimal treatments. The above arguments in favor of a right of self-medication show us that physicians and medical experts are not entitled to play this gatekeeping role, but they still can play an important role as experts.

Another objection is that legal protections for self-medication would make physicians and medical experts complicit in providing treatments that they deemed morally repugnant. Recall that self-medication might require behind the counter status for some particularly dangerous drugs. This means that some drugs might require consultation with a medical expert as a condition of access. In some cases, medical experts might rightly believe that a patient’s treatment decision is a horrible mistake, and
providing the treatment will go against the expert’s conscience. Does self-medication mean that physicians and pharmacists have a duty to provide treatment they deem medically inadvisable?

An extreme case—imagine a patient who would like to access suicide drugs in a state where they are legal, and a pharmacist who believes that doing so would be wrong. A real-life case—imagine a pro-life physician who is asked to provide medication that would induce an early abortion. A hypothetical case—imagine that a pharmacist doesn’t believe in providing dangerous steroids to young athletes. Another hypothetical—imagine a pharmacist who doesn’t believe in providing addictive painkillers to willing addicts. Do physicians and pharmacists have the right to avoid being complicit in medical treatments that they consider wrong or harmful? Absent any formal barriers to access, physicians and pharmacists can decide to some extent (as they already do) whether to offer certain treatments or not. This principle of contentious refusal to provide treatment is already reflected in the law; in 1973 the Church Amendment established that physicians couldn’t be legally compelled to perform abortions if doing so violates the physician’s conscience.27 Other branches of medical practice reflect this principle as well. Some family practitioners do not treat infants under a certain age, or provide obstetric services to pregnant women. Some cosmetic surgeons only treat burn patients while others only provide breast augmentation. Physicians are not obligated to provide access to every kind of treatment they are qualified to administer. Therefore, a patient’s right to self-medication doesn’t force physicians to be complicit in providing treatments that go against their conscience. Similarly, retailers, including

pharmacists, are entitled to decide which products they will sell. That consumers have a right to buy guns, for example, does not mean that retailers are required to sell guns.

One worry about this response is that physicians and pharmacists are still enabled as gatekeepers for treatment, in a sense, because someone is still necessary to provide or sell treatments to patients. Yet respect for a provider’s conscience is not necessarily incompatible with a patient’s access to medical treatment if other providers who do not have conscientious objections to providing a treatment are available. Thus, this worry only arises in those situations where no physicians will provide a particular treatment for any price. At present, I cannot think of any existing kinds of treatments that are so repugnant that a patient might want to access but no provider would sell it for any price.

Still, some kinds of provider-choice might be forbidden if the right of self-medication also rules out patient-based discrimination. If a physician or pharmacist is comfortable providing or selling a treatment in general, then is not entitled to stand in the way of particular kinds of patients accessing the treatment. This means that providers of dangerous suicide drugs must provide them to suicidal patients who might have good reason to live, and that providers of steroids must provide them to young athletes, providers of painkillers must provide them to addicts if they provide them to people with back pain, and providers of birth control must provide the treatment to married and unmarried women alike. In all these cases though, providers retain the right to not sell suicide drugs, steroids, painkillers, or birth control, but insofar as providers do sell these treatments their conscience cannot justify discrimination.
4. Tort Reform

In this section I will address how legal protections for self-medication would affect physicians’ rights and duties to provide treatment. Patients’ rights of informed consent are legally protected. If a physician performs a procedure without a patients’ consent then the physician is legally liable, and can be punished for violating his patient’s rights. This kind of regulation happens in the courts, not by legislation. The right of self-medication should be legally protected in a similar way. If a medical expert like a physician or a pharmacist stands in a patient’s way of self-medication by misinforming the patient about the risks and benefits of treatment or by withholding the medication directly, he is similarly liable and should be punished for violating patients’ rights.

Unlike the current system of pharmaceutical regulation, which applies to all citizens equally in the form of prohibitions, tort law enables those citizens who have been injured to sue for compensatory or punitive damages while permitting other citizens to privately contract for whatever goods or services they like, as long as all parties agree on the terms. In this way, tort suits are investigated and prosecuted on behalf of a specific victim, not in the public interest.\textsuperscript{28}

Medical malpractice law is the clearest example of how tort law intersects with access to medical treatment. Physicians who provide medical treatment are liable for any adverse interactions or side effects of that treatment. Providers of medical treatment can be held to standards of strict liability if they fail to comply with a general duty not to injure patients (regardless of blameworthiness), or fault liability if adverse medical effects are due to negligence. Strict liability standards are often invoked in consumer

\textsuperscript{28} Coleman and Mendlow, “Theories of Tort Law.”
protection cases too. For example, even if manufacturers of a dangerous medical device took all necessary precautions to ensure that the device is safe, if the device injures a group of patients then the manufacturers are liable to compensate the injured patients for their injuries. In contrast, fault liability is more commonly invoked in medical malpractice cases. For example, if a physician’s negligence causes injury to a patient, then that physician is liable to pay damages to the patient to compensate for the injury, but physicians are not generally held to standards of strict liability. In most cases in the United States, medical malpractice holds physicians responsible for wrongful injuries, not all kinds of injuries.\textsuperscript{29} Nevertheless, patients and physicians do not have full rights to contract for any procedure. Namely, patients cannot waive their right to hold physicians accountable for any injuries that result from risky procedures.\textsuperscript{30}

Pharmaceutical regulation is not generally handled through the courts in terms of liability in the United States. Rather, many medical decisions involving drugs are not permitted like other kinds of contracts—even if the consumer is willing to buy and the vendor is willing to sell a drug, the transaction is often illegal.\textsuperscript{31} This policy is similar to


\textsuperscript{31} Similarly, patients are not permitted to privately contract with physicians for particular medical treatments and set standards of negligence (e.g. to only hold physicians to standards of gross negligence.)
the legal status of a rare number of medical treatments, which are de facto prohibited full-stop.\(^{32}\)

Both models of liability have advantages over the legislative restrictions on access to pharmaceuticals. Rather than prohibiting patients from accessing dangerous drugs, a right of self-medication requires that states permit patients to access dangerous drugs. When injuries then result from dangerous drug use, states that respect rights of self-medication may treat those injuries like other kinds of injuries and address them through either strict liability programs or universal health care. Further, states should continue to enforce standards of fault liability for adverse drug effects that are a result of blameworthy wrongdoing.

The first alternative to current system of pharmaceutical regulation is a move to strict liability, or no-fault compensation programs.\(^{33}\) Under such a scheme, injuries resulting from medical care would be compensated regardless of physician negligence or wrongdoing, just as workmen’s compensation law compensates workers for injuries that result from workplace accidents. Some states have already adopted strict liability standards for certain kinds of medical injuries. For example, Virginia and Florida have a strict liability compensation regime for birth related neurological injuries.\(^{34}\) Sweden and New Zealand also use strict liability standards of compensation for medical injuries in

\(^{32}\) For example, physicians who provide elective amputations to patients with Bodily Identity Integrity disorder, even if patients competently request the procedure and accept the risks, are still liable for any damages because elective amputation as a treatment for this condition is considered an injury in itself. Tim Bayne and Neil Levy, “Amputees By Choice: Body Integrity Identity Disorder and the Ethics of Amputation,” *Journal of Applied Philosophy* 22, no. 1 (March 24, 2005): 75–86.


many cases.\textsuperscript{35} Drug manufacturers may be required to contribute to a compensation pool, as employers sometimes are, to compensate patients who suffer serious adverse reactions from drugs.

Another option is to simply treat drug related injuries like other kinds of injuries, and to treat injured patients through a system of universal health care. Just as some citizens make risky consumer choices by buying sailboats, guns, or taking rock-climbing classes, other citizens will make risky consumer choices by using drugs that cause further health problems. Just as the courts need not hold sailboat and gun manufacturers or rock-climbing instructors responsible for the injuries that predictably result from their products and services, courts need not designate any particular drug provider to bear the cost of injuries from self-medication. Patients are entitled to quality health care for adverse drug reactions just as they are entitled to care for other kinds of injuries.

Another alternative is a private-contract model of medical malpractice. Richard Epstein proposes this option for all medical services. He suggests that patients ought to be permitted to contract with physicians to privately agree upon specific standards of liability and negligence, even if patients would then decide to waive their rights to sue for malpractice in some cases. Current systems of medical liability limit legal access to medical treatment because under a fault or strict liability malpractice regime, physicians are de facto legally prohibited from providing certain treatments to patients, since even willing and consenting patients who accept the risks of treatment cannot legally assure physicians that they will not later successfully seek damages. A private-contract system would also increase the availability of risky but potentially beneficial medical services,

\textsuperscript{35} Ibid.
because physicians could use contracts to protect themselves from lawsuits and damages. A private-contract model might also make medical care more available and affordable, because the high cost of medical malpractice insurance disincentives many physicians from offering certain medical treatments, leaving patients without affordable access to potentially beneficial treatments.

Epstein’s private-contract model for medical malpractice could also be extended to pharmaceutical sales. Manufacturers who are concerned with the potential risks of drugs could require consumers to sign liability waivers before purchasing the drugs. Such waivers could be subject to some regulations, for example consumers cannot waive their rights against fraudulent advertising and labeling. However, insofar as consumers are informed about the nature of a product, a private contract model of pharmaceuticals sales could potentially increase the availability of affordable drugs just as Epstein’s contract proposal stands to make medical care more available and affordable. This model of medical care also has a moral advantage insofar as it enhances patients’ economic liberties, though insofar as such contracts are unconscionable some liberals might find it objectionable.  

Reforms to the legal status of informed consent can also inform other new legal principles that protect patients’ rights of self-medication. Informed consent requires (depending on the particular system) that a physician inform a patient of any information that the particular patient or a reasonable person would find relevant to a given treatment option. This includes in some cases information about alternative treatments, as well as

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36 For example, liberals like John Tomasi will view this as a moral advantage but liberals like Seana Shiffrin will not. See Tomasi, Free Market Fairness; Seana Valentine Shiffrin, “Paternalism, Unconscionability Doctrine, and Accommodation,” Philosophy & Public Affairs 29, no. 3 (January 11, 2005): 205–250.
information about the patient’s diagnosis and prognosis and the physician’s experience. Physicians who fail in this duty to inform can be held liable for malpractice. Part of the reason that physicians are required to obtain informed consent from patients is that they are providing the treatment, but if patients were no longer required to provide treatments, would duties to inform remain? While physicians are currently required to obtain informed consent for drug therapy, informed consent is not required for over the counter medication. If all medication were over the counter or behind the counter, how would this change informed consent law? While physicians cannot be liable for treatment decisions they played no part in, physicians who act as medical experts and advisors can be held liable for giving misleading or false information to patients. Malpractice would change in this way. Physicians would not be liable for treatment decisions but those who provided false information about treatments could be held liable. Not only must physicians inform patients about the risks and benefits of available treatments, physicians and providers also must not stand in patients’ way when they seek to access medication.

Like other rights of this kind, self-medication does rely on other’s willingness to provide it to some extent, but with the foregoing arguments I have suggested that provider’s willingness need not be shaped by concerns about liability when patients are willing to waive their rights against the risks associated with treatment.\(^{37}\)

\(^{37}\) Say that people have rights to self-expression, including freedom of the press. We might imagine a society that technically protects these rights, but where no one will sell a particular group the materials necessary to start their own press or publish their ideas. Imagine for example a community (before the invention of the internet) that refused to sell printing materials, paper or ink to Marxist organizers, effectively limiting their ability to spread their message. Even though the Marxists retained their freedoms in some technical sense, the community effectively denied them of their freedom of the press by refusing to provide them with the necessary means to print. Similarly, if patients have
5. Funding Pharmaceutical Regulation

Those who are concerned by slow approval times, but also concerned about dangerous drugs, may reply to this proposal that drug lag could be effectively addressed by giving the FDA more resources, rather than limiting the agency’s power.\(^\text{38}\) Indeed, this was the justification for the regulatory expansions that followed historical drug disasters, and some progressive critics of the FDA have responded to the Vioxx deaths with calls for even stronger regulatory agencies.\(^\text{39}\) In response to this argument, Congress already passed the Prescription Drug User Fee Act (PDUFA), which enabled manufacturers to speed the approval process by paying a fee. Since the passage of the PDUFA, approval times for all drugs have shortened, which indicates that lengthy approval times are caused in part by a lack of agency resources. Still, though the FDA has substantially increased its resources over the past two decades, approval times still substantially lag behind European counterparts. John Graham writes,

Many believe that this failure is due to a lack of money for the FDA, but this is not the case. The number of personnel conducting drug reviews doubled, from 1,300 to 2,600, between 1992 and 2007. More recently, the FDA went on a hiring surge, taking on 2,500 more employees in 2008 and 2009. Indeed, the agency exceeded its hiring targets last year. In FY 2011, the FDA’s spending on regulating human drugs will have increased by 20 percent over two years,

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\(^\text{38}\) For example, Rep. John Dingell recently argued for more funding and regulatory power for the FDA in order to ensure pharmaceutical safety. See “Are we sure our drugs are safe?” By John Dingell, Special to CNN, Wed February 1, 2012

\(^\text{39}\) See for example “The Hidden Lesson of the Vioxx Fiasco: Reviving a Hollow FDA” by Rena Steinzor and Margaret Clune, Center for Progressive Reform, October 2005
according to the agency’s budget. Yet even if a lack of resources is a reason for drug lag, it is not clear that increasing agency resources could ever adequately solve the problem. Above I noted that while the clinical trial system has real benefits, it cannot ensure patient safety for particular populations, efficacy testing is seemingly unnecessary to determine drug effectiveness, and effectiveness might not be a necessary standard for approval in any case. Further, pharmaceutical manufacturers’ resources so greatly outmatch those of any regulatory agency, that no politically feasible allocation of resources could enable an agency to comprehensively oversee all pharmaceuticals. Even former FDA Commissioner Kessler, who is obviously a proponent of pharmaceutical regulation, testified that government regulators themselves recognize that more resources are unlikely to effectively secure the safety and efficacy of new drugs and devices:

FDA doctors and scientists share this view—many believe that the FDA lacks sufficient resources to protect the public health, and many worry that the FDA is not adequately monitoring the safety of drugs once they are on the market. The FDA has long been hamstrung by resource limitations. Even if FDA’s funding were doubled or tripled, its resources and ability to detect emerging risks on the thousands of marketed drugs and devices would still be dwarfed by those of the drug and device companies who manufacture those products.

It is for this reason that Kessler affirms the above suggestion that states use tort law as a mechanism to ensure patient safety and to give manufacturers incentives to disclose the

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41 House Oversight and Government Reform Committee Hearing, May 14, 2008
potential risks of new drugs.\textsuperscript{42}

This is not to say that more funding for agencies like the FDA could not improve drug safety. Public funds might subsidize expert reviews and trials for new drugs, and even pay companies to invest in research that would improve the safety of existing drugs. In these ways, more agency resources could improve drug safety in ways that are compatible with rights of self-medication.

6. Commercial Speech, Advertising, and the Internet

I have argued that government ought to focus on promoting informed patient choice without limiting patients’ options. Foremost, this requires the legalization of most pharmaceuticals, but giving patients more choices may not promote \textit{informed} choice. In this section I will discuss several ways that public officials can ensure that patients have access to any available information that is necessary for making informed pharmaceutical choices.

First, regulatory agencies ought to continue to play an epistemic role by certifying drugs as safe and effective, without prohibiting untested, unapproved, unsafe, or ineffective drugs. In this way patients who favor the current system can continue to defer to their physicians’ and agency officials’ judgments as they do today. Regulators can also continue to oversee clinical trials to ensure that the information obtained and disclosed by manufacturers is accurate. Further, public officials also ought to continue to inspect and oversee manufacturing procedures and inspect labels to ensure that manufacturers do not make fraudulent claims about their products.

\textsuperscript{42} Kessler states “For that reason, the tort system has historically provided a critical incentive to drug and device companies to disclose important information to physicians, patients, and the FDA about newly emerging risks.”
Rights of self-medication also may require that public officials play an even stronger role in disseminating and policing information about new drugs. As I argued in Chapter 9, agency officials ought to further invest in playing an epistemic role as a ‘knower organization. As a knower organization, agencies like the FDA may maintain consumer databases of adverse drug reactions and increase postmarket surveillance of available drugs. Agency officials may also conduct epidemiological studies to supplement the information gained in clinical trials.

One worry about rights of self-medication is that patients will be especially vulnerable to advertisements for unapproved drugs. My arguments have not ruled out marketing restrictions and limits of pharmaceutical manufacturers’ commercial speech. While I am skeptical that prohibitions of off-label marketing are in the public interest, courts and regulators can and should prohibit manufacturers from making misleading or fraudulent claims about their products. Foremost, patients are entitled to freedom from coercion and deception, whether from physicians or drug manufacturers. Just as it is impermissible for physicians to paternalistically mislead patients about the risks and benefits of their treatment options, it is equally as wrong when drug manufacturers mislead people about the nature of their products. Both kinds of deception ought to be punished through the tort system.

Another concern about rights of self-medication is that patients will use the internet to gain information about treatment decisions. The presence of medical

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43 My skepticism about ‘off label’ marketing restrictions is informed by the example of Beta-blockers that I discussed in Chapter 2. There I reviewed some evidence that suggested that conditional approval can have deadly effects even though the drugs are technically available ‘off label’ if physicians and patients cannot access information about off label benefits due to marketing restrictions.
information on the internet is both dangerous and promising. Poor quality information can lead patients to make terrible treatment decisions. Public officials or private ‘knower organizations’ can therefore provide an important service by certifying patient information websites in addition to new drugs, and by subsidizing independent websites that provide credible and reliable information.

On the other hand, the internet is a promising resource both for patients and their physicians. Today physicians are finding that the internet is a powerful tool for diagnostic medicine, and that online resources are enabling physicians to make increasingly personalized and targeted treatment recommendations, in contrast to the overly general textbooks that were used by earlier generations of doctors. Internet resources are also outpacing regulatory agencies in providing physicians with information about the safety of approved drugs. Most importantly, as patients are increasingly going online to learn about their treatment options, the doctor-patient relationship is becoming more collaborative and patients are becoming ever more empowered to play an active role in their own treatment decisions. Whereas responsible self-medication may have been impossible in an era of patient ignorance, the rise of the expert patient and “Dr. Google” may make consultation with a physician unnecessary in some cases. Those patients who do not trust internet resources, and patients who do not trust themselves to evaluate information online, retain the ability to consult with a physician. Hopefully though, as medical information on the internet improves physicians can focus on advising and

treat patients who are genuinely incapable of treating themselves, rather than providing information that is readily available online and treatment options that patients should be permitted to access independently.

7. Conclusion

To sum up, a right of self-medication calls for radical changes to pharmaceutical policy. Almost all drugs ought to be fully legalized. Physicians who facilitate risky pharmaceutical use should not be concerned with violating their duties as physicians. In fact, a more consumer-based approach to medicine is potentially more respectful of patients and would free physicians from excessive concerns about medical liability. The tort reforms that I propose may facilitate this kind of a shift in medicine, as would the expansion of health services more generally. Instead of focusing on prohibitions, pharmaceutical regulators ought to invest resources in overseeing drug testing and providing consumers with the information necessary to make informed choices.
XI. The Limits of Self-Medication

I have argued that radical regulatory reforms are needed in order to respect patients’ rights of self-medication. Namely, prohibitions on access to pharmaceuticals are unjust and harmful, and all liberal societies should abandon them. But there are some situations where prohibitive regulations might be justified. In this final chapter, I will describe two such situations.

Medical paternalism is not justified, but not all prohibitive pharmaceutical policies are designed to prevent people from harming themselves, some policies are designed to prevent people from harming others. For example, mandatory vaccination policies might conflict with the doctrine of informed consent, since patients cannot refuse vaccination, but their justification departs from other policies that violate informed refusal rights because mandatory vaccinations are designed to prevent people from spreading disease. In cases where exercising a right of self-medication or informed consent directly harm others, I am open to the possibility that prohibitive policies might be justified. However, I am skeptical of prohibitive policies that purport to mitigate some indirect harm to the public welfare. I propose a standard contractualist weighing of harms to assess whether the harms posed by prohibitive policies would outweigh the harms caused by patients’ exercise of self-medication rights.

Paternalism might also be justified in cases where patients are incapable of consent. While I cannot argue for this claim fully in the remaining space, I will suggest most patients are capable of consent, including teenagers, addicts, and the mentally ill, so paternalism is not justified in these cases. However, there are some cases where patients
are genuinely incapable of consenting. In these cases, paternalism in medicine is warranted.

Finally, some theorists and public intellectuals have argued that paternalism in medicine is a way of controlling medical costs, especially in societies that provide universal health care. I argue that prohibitions do not themselves reduce medical costs, and in any case, patients who want to make inadvisable medical decisions at least should be permitted to waive their rights to public resources in exchange for self-medication rights.

1. Direct Harms to Others

While the right of self-medication cannot be limited for paternalistic reasons, if self-medication was harmful to others it might rightly be limited. In almost all cases self-medication is not harmful to others, but the cases of vaccines and antibiotics show that refusal and self-medication choices aren’t necessarily victimless. Direct harms are harms that are caused by self-medication itself, not just harms that are reliably associated with self-medication given broader social considerations. The direct harms of antibiotic use give us sufficient reason to limit self-medication in these cases.

First consider direct harms more generally. Sometimes the exercise of a particular liberty is harmful to others. For example, I exercise my freedom of speech to say something insulting the exercise of my liberty harmed someone. If I exercise my freedom of movement to trespass on someone else’s property the exercise of my liberty was also harmful. We generally accept that people have rights of free speech and free movement, but that while speech rights protect people’s rights to say insulting things, movement rights do not protect the right to trespass.
There are two ways to explain the asymmetries in these two cases. First, we might focus on the victims’ entitlements, people don’t have rights to avoid insult but they do have rights o their property. Second, we might distinguish between direct and indirect harms. The speech case was indirectly harmful; the insult was not harmful in itself but only contingently given facts about the victim. In contrast, trespassing was directly harmful; trespassing intrinsically violates someone’s property rights whatever the background social facts.

Direct harms are more morally serious. While public institutions can mitigate the costs of indirect harms without limiting liberty, for example by changing the social conditions to make the exercise of a liberty less costly, direct harms can only be avoided by limiting liberty. Turning to self-medication, antibiotic use is directly harmful, so the only way of avoiding the costs of antibiotic overuse is by limiting citizens’ rights of self-medication. Other effects of self-medication are indirectly harmful, and these costs can be avoided with good social policy without violating citizens’ rights of self-medication.

Turning to antibiotic use, we should bear in mind that the right of self-medication is not absolute. If self-medication choices like antibiotic use would cause public health disasters like antibiotic-resistant contagious superbugs then the right of self-medication can rightly be limited to mitigate the harm of contagious illness. Recently, antibiotic resistant forms of tuberculosis, syphilis, strep, and staph infections and also antibiotic resistant forms of Salmonella and E. coli have been documented. Many antibiotic resistant infections develop in hospitals, where antibiotics are routinely prescribed, and some experts suggest that hospital-based overuse (along with agricultural antibiotic use) is a primary contributor to antibiotic resistance. Were antibiotics as widely available in
consumer markets as they are in hospitals, resistance might become even more problematic.

For this reason, antibiotic use is not a self-regarding choice. Every time a patient uses antibiotics to treat a condition she risks contributing to antibiotic resistance. My arguments for self-medication were premised on the idea that self-medication was self-regarding (even if it was correlated with harms to others,) but insofar as a pharmaceutical choice is itself harmful to others it is rightly limited.

This caveat does not undermine the deontic force of a right of self-medication. Even informed consent and informed refusal are sometimes permissibly outweighed by public health risks. For example, when contagious illnesses prompt quarantines people’s rights to make medical decisions for themselves are compromised along with freedom of movement and almost all other liberties. Mandatory vaccination policies bypass informed consent and refusal requirements but are justified to avoid public health disasters. When exercising a particular liberty is directly harmful to others such that it violates others’ entitlements to health and security, then limits on that liberty are permissible even if the liberty is extremely important.

2. Indirect Harms

A related objection is that patients who are permitted to make dangerous treatment decisions will reliably impose costs on others. When seemingly self-regarding behavior undermines other social goals or imposes costs on people then limits might be permissible. First I will draw on Seana Shiffrin’s work to develop a framework for understanding the relationship between paternalism and indirect harms, then I will
address the social costs of self-medication and the possibility that self-medication would undermine egalitarian social goals.

Shiffrin argues that not all paternalistic policies rely on the premise that paternalism itself is permissible. Rather, she argues that sometimes protecting particular liberties requires public enforcement. Focusing on the liberty to make unconscionable contracts, Shiffrin argues that when a liberty leads to self-harm then, protecting that liberty requires the public to be complicit in self-harming through public enforcement institutions. Shiffrin writes:

Some may object that their autonomy is compromised when they have to bear the costs of and lend assistance to projects and endeavors that they have not chosen and morally disapprove of. This is the sort of claim I argued could provide a non-paternalist rationale for the unconscionability doctrine\(^1\)

Here the justification for paternalistic prohibitions is itself is not paternalist, in that it is not in the interest of the person whose options are limited, but rather in the interest of others. If members of a society do not wish to bear the costs and provide assistance for self-harming behaviors, they can rightly refuse for their own sake. In this way, Shiffrin argues in favor of limits on self-harm by reframing them as being harmful to others.

Shiffrin’s argument then goes something like this:

P1: In a cooperative, interconnected society, self-harming behavior often imposes costs on others.

P2: The cost of self-harming can only be mitigated by becoming less cooperative and interconnected, or by legally discouraging self-harming.

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\(^1\) Danzon, “‘Liability for Medical Malpractice’.”
P3: Citizens are entitled to refuse to bear the costs of other’s self-harming.

C1: Citizens are entitled to become less cooperative or to legally discourage self-harming.

P4: Becoming less interconnected and cooperative is an unacceptable outcome.

C2: Citizens are entitled to prohibit self-harming by refusing to accommodate dangerous choices.

Shiffrin points out that in many cases, liberal societies don’t avail themselves of their entitlement to refuse to bear the costs of other’s self harming behaviors. Even though smokers and overeaters cause others to bear higher medical premiums, most public and private insurance plans accommodate these choices despite their public costs. Since liberals are principally concerned with autonomy and human development, Shiffrin argues that intimate and personal self-harming choices that are closely linked to our sense of self are fit candidates for accommodation even if they are costly. When liberals choose nevertheless to accommodate bad choices, they are still entitled to refuse to give accommodation whenever accommodating self-harming carries a public cost.

Does self-medication carry significant social costs? Before I continue with this argument it is worth pointing out that not all pharmaceutical choices are necessarily self-harming even if they are medically inadvisable, as I argued earlier in the discussion of do no harm. Further, even self-harming medical choices do not necessarily impose costs on others. For example, the case that self-harming pharmaceutical choices impose costs on others is particularly hard to make with regards to uninsured pharmaceutical users.

Even if pharmaceutical choices are the kinds of self-harming choices that carry public costs it is not clear that states ought to refuse to accommodate such choices. On
one hand, pharmaceutical choices are intimate and personal decisions, even when they are self-harming, and so insofar as society accommodates poor dietary choices and cigarette smoking, for reasons of consistency self-harming pharmaceutical choices ought to be accommodated as well. On the other hand, Shiffrin also argues that the best candidates for liberty-restrictions are those liberties whose exercise is self-harming in a way that we find morally objectionable. That is, if a self-harming choice involves relations of dominance and servitude, like a slave contract, liberals can rightly refuse to enforce the contract. If owning a certain product, like a recreational drug, undermines the autonomy of those who use it, some liberals like Shiffrin and Freeman might deem these kinds of choices morally objectionable. In cases like these, according to Shiffrin’s argument, a liberal society could fail to enforce property rights for that product.

Another way that pharmaceutical use might impose costs on others is if users harm themselves and then expect public health providers to pick up the tab. Some critics of non-prohibitive systems seem to think that this kind of concern merits restrictions. When Boston University Economist Randall P Ellis was asked why he didn’t favor a non-prohibitive pharmaceutical system, Ellis wrote,

Consumers do not pay the full cost of the drugs they use. Insurers and the government do. Hence it is appropriate for the government to play a role in deciding what they are willing to pay for.  

Here Ellis is saying that the government can refuse to accommodate self-medication because the government will bear the cost. Of course, the government needn’t subsidize

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unapproved drugs in the way that it currently subsidizes approved pharmaceuticals, so the
direct economic cost of self-medication wouldn’t necessarily fall on society. But Ellis
might be concerned with other costs associated with self-medication that will ultimately
fall on the government and society. If society is forced to bear some costs as a result of
accommodating self-medication, the argument goes, then policymakers can permissibly
refuse to accommodate self-medication.

This kind of an argument doesn’t necessarily tell against pharmaceutical use, but
it does tell against providing health care to patients who consistently use pharmaceuticals
in a medically inadvisable way and then demand but refuse to pay for the medical costs
of their choices. Notice that this is a more general problem. People make all sorts of self-
harming decisions that burden the public health system when they refuse to pay. We
accommodate these choices because we think that people have rights to make them. Since
I have argued that self-medication is a right, it ought to be accommodated even if it does
burden public health providers.

Somewhat implausibly, one might worry that unrestricted access to
pharmaceuticals would impose public health costs that were *so substantial* they hindered
states’ ability to fulfill their duties of justice in aiding society’s worst off citizens. In an
earlier chapter I described a way that the provision of universal health care might be
compatible with unrestricted access to pharmaceuticals, and I discussed Peltzman’s
analysis, which found that in non-prohibitive regimes patients are actually more cautious
when accessing highly potent pharmaceuticals and *less* prone to misuse. Further, in states
that do not provide universal health care to all citizens states have duties of remedial
justice to enable citizens to treat themselves.
Another relevant social cost that might accompany unrestricted access to pharmaceuticals is that bystanders might become complicit in acts of self-harming that they find morally objectionable. Liberal theorists often cite this kind of worry about self-harming drugs and contracts. Many are motivated by the belief that everyone should be an autonomous, capable, participant in a fair democratic society. For reasons developed in the earlier chapters, they then are averse to permitting others to inhibit their autonomous capacities. Therefore, many liberals would be uncomfortable in enforcing or contributing to institutions that enabled people to undermine their autonomous capacities.

Schifrin focuses on the example of slave contracts as a primary instance of permissible refusal to accommodate. We find coercive relationships of domination and servitude objectionable, so we might rightly reject any system of liberties that enforces unconscionable contracts and thereby refuse to enforce contracts that have these features. Similarly, while all liberal societies protect a general right of personal property, even those liberal states that have decriminalized recreational drugs do not enforce citizens’ property rights in drugs. Unlike other goods, when drugs are stolen citizens have little legal recourse, perhaps because the state doesn’t want to become complicit in helping people to possess goods that could damage their capacities.

In the previous chapters and above I made the case that pharmaceuticals typically don’t damage people’s capacities in a way that most liberals would find objectionable, but even if they did, Shiffrin’s argument wouldn’t justify paternalistic restrictions. In a sense, contracts and property rights rely on a system of public power for their enforcement. Indeed, property and contract are two concepts that many would argue presuppose the presence of some impartial institutional arbiter that sets the terms of
economic exchange. Contrastingly, pharmaceuticals use doesn’t presuppose or rely on public power. Citizens who permit others to use dangerous pharmaceuticals are not made complicit in acts of self-harming because pharmaceutical use is not the kind of activity that depends on a system of social cooperation.

Finally, the public might balk at a society where pharmaceuticals were treated like other consumer goods. Some people have an almost aesthetic aversion to pill-popping and people who are overmedicated and favor a society that values clean living. People with these preferences will surely be harmed by a more open market for pharmaceuticals. Arguments in favor of other prohibitions might be used to justify pharmaceutical prohibitions; perhaps pharmaceutical use will undermine the family or make the labor force less productive. I doubt these worries about social cost are empirically justified, though I don’t have the space here to show this definitively. Even if these costs do exist, prohibitive policies carry great costs as well, which I outlined in Chapter 1, so liberals who might make the accommodation argument against pharmaceutical use must weigh the social costs they bear against the cost that prohibitive policies or even just a lack of accommodation would impose on patients.

Last, a merely aesthetic aversion to a society of pill poppers is an objectionably perfectionistic reason for prohibition. Ronald Dworkin puts this point as follows:

[Citizens have a right] not to suffer …disadvantage in the liberties permitted to them by the criminal law, just on the ground that their officials or fellow-citizens

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3 Though the research has shown it I think, as I discussed in Chapter 2.
think that their opinions about the right way for them to lead their own lives are ignoble or wrong.⁴

I believe that such an impulse underlies many people’s intuitions against unrestricted access to pharmaceuticals, but the fact that many users’ fellow-citizens think that making self-harming pharmaceutical choices is disagreeable in some way does not entitle those citizens to criminalize self-medication.

3. Equality and Enhancement

So far I have focused on the liberal concern that citizens will undermine their autonomous capacities through pharmaceutical use, thereby imposing social costs on their fellow citizens. Yet the opposite worry also finds force with some liberals as well so I will address it here. This objection to self-medication is that unrestricted pharmaceutical use will enhance people’s capacities in a way that undermines the liberal commitment to equality. This is another variant of the thesis pharmaceutical use harms others, which I addressed in the last two sections, but in this case the harm occurs from people self-helping rather than self-harming.

Liberals might be especially concerned with the possibility that some citizens’ self-medication choices will undermine other’s equal status or capacities. To see the shape of this worry consider the possibility that people will use pharmaceuticals to enhance themselves beyond the normal human baseline of functioning. Most pharmaceuticals do not have this feature, so this objection only applies to a small range of enhancement drugs. Still, in light of this possibility liberals have argued in favor of

restrictions on enhancement drugs, including presently existing enhancements like Adderall and steroids.

Say we accept the likely prediction that without prohibitions, people will use pharmaceuticals to cognitively and physically enhance themselves, thereby gaining an edge in competitive situations. If so, that puts pressure on others to use pharmaceuticals as well.

Egalitarians point out that when A does better it can make B worse, even if A didn’t do anything to effect B’s well being or standing. In cases like these, some liberals have argued that A’s rights can be limited for the sake of B. For example, Harry Brighouse and Adam Swift have argued that freedom of association doesn’t protect parent’s right to send their children to private schools.5 Their argument for this claim is that private education undermines egalitarian social justice, even if public schools provide an adequate education, if private schools provide a superior education the students attending public schools will be disadvantaged in society, because educational is a positional good. Positional goods are goods whose value depends on the relative position of others with respect to that good; one’s education is only as good as the value of other’s education in comparison.

Brighouse and Swift also argue that health is a positional good, because health brings many advantages and the value of my healthiness depends on how healthy I am relative to others. Brighouse and Swift then argue that for positional goods like health, liberal egalitarian’s commitment to fair competition gives us reason to favor health-

equality, even if this requires leveling down. And so, the authors suggest that restrictions on access to private health care might be permissible.

Similarly, we can imagine that restrictions on access to pharmaceuticals can be justified for similar reasons. If some people use medicine to become better it might make others worse off even if nothing about the unenhanced changes their position is worse. Michael Sandel flags this as a concern for genetic enhancement, he argues that restrictions are warranted because otherwise parents might feel pressured to enhance their children rather than accepting them as they naturally are, and citizens more generally might become dissatisfied with their natural lot and that we will all lose our appreciation for ‘natural gifts. ⁶ Like this case against genetic enhancement, Sandel makes a similar case against pharmaceutical enhancement, focusing on the example of steroids in sports. Sandel argues that part of the value of sport is that athletes must work within the confines of their genetic gifts, so athletic performances seem to us like an extraordinary achievement. Sandel worries that permitting enhancement will diminish this value and make athletics more like a science experiment than a uniquely human achievement.

My first response to this objection is that competitive pressures are everywhere, and pharmaceuticals aren’t unique in bringing advantage. Further, as Allen Buchanan has pointed out, the presence of pharmaceutical enhancements won’t negate the value of training and hard work because athletes who work harder all things being equal will still retain a comparative edge even if all athletes are enhanced. Some athletes might reject the pressure to use enhancements, but then some might reject the pressure to adopt a healthy diet or quit smoking, not everyone is willing to do all that it takes to gain a competitive

advantage but this is nothing new or unique to pharmaceutical enhancement. In any case, prohibitive policies might make the inequalities caused by enhancing pharmaceuticals even worse because only people with the resources can access them.

Also, when egalitarians like Brighouse and Swift suggest that the exercise of some liberties makes others worse off, so those liberties can be limited to prevent harm to others, liberals should wonder whether those who would be disadvantaged by some people self-medicating are entitled to limit others’ right to self-medication? While I don’t have the space to argue for it here I believe that they are not. People use medicine to improve their health and to enhance their capacities. Limits on self-medication for the sake of equality are a kind of leveling down of one group’s health for the sake of another, because health and capacities are positional goods. While egalitarians might accept leveling down for other positional goods, income or education for example, leveling down of health is generally considered unacceptable. When Brighouse and Swift explained that “in the land of the blind the one eyed man is king” few egalitarians would respond that the one eyed man should be blinded. When Cecile Fabre proposed that the “organ rich” ought to redistribute their kidneys to patients who suffered from kidney failure, even egalitarians agreed that this took the value of equality too far.7 This is because some values, like health and bodily autonomy, are so important and intimately held that they cannot be overshadowed by the inequalities they produce.

Last, enhancing through prescriptions might even the least advantaged people better off on balance. Even if feeling inadequate or facing competitive pressures harms people who abstain from pharmaceutical use, everyone benefits from living in stronger, happier, smarter, more productive society. Most liberals accept these kinds of inequalities even if they reject inequalities in most cases, because if a system of liberties leads to inequalities that make the least advantaged better off than they would have been under a more egalitarian arrangement, then the inegalitarian system is still the most justifiable to those who are least advantaged under it.

To close, I want to flag a related worry about enhancement, that unrestricted access to pharmaceuticals would eventually enable humans to greatly enhance their capacities far above the normal human baseline of capacities. This may cause marked cognitive and physical differences between the enhanced and the un-enhanced in the same way that adults are generally cognitively and physically superior to small children. In light of this possibility, Francis Fukuyama, Leon Kass, and others have predicted that enhancements like these might change the baseline level of capacities that is required for equal moral status, and so enhancement would undermine the human rights of the unenhanced.  

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In response to this prediction, Allen Buchanan has shown persuasively that merely enhancing our existing capacities, increasing strength, IQ, or longevity, would not threaten liberal egalitarian’s commitment to equal moral status for all people anymore than existing asymmetries in strength, intelligence or life expectancy pose a problem for liberalism. Further, even if people used medicine to enhance themselves so radically that a new race of post-humans emerged, while post-humans might require their own special rights and protections, if nothing about humans changed than nothing about human rights would change either. Indeed, Buchanan argues, human rights might become even more relevant in protecting the freedoms of humans in a world of post-humans.

4. Soft Paternalism

To this point I have argued exclusively against hard paternalism, policies that limit the choices of competent, rational, adults. Not everyone in the population is mentally competent, and in these cases soft paternalist limits on self-medication might be warranted. I accept this possibility, but I believe that the cases of permissible soft-paternalism are fewer than we might think, especially because mentally ill patients, children, and addicts are more competent than is generally believed. The foregoing arguments for self-medication point to a theory of competence that can inform our

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9 However, Buchanan does flag the possibility that in the future, unrestricted self-medication and enhancement could conceivably lead to a new race of post-humans, and these post humans might have posthuman rights that differ from the human rights held by all humans. But as Buchanan points out, even if enhancement did have this consequence, it would not undermine the human rights of the un-enhanced, since human rights are a threshold-concept, a person’s status as a bearer of human rights doesn’t depend on her relative capacities, it only depends on whether her capacities exceed a relevant normative baseline. Allen Buchanan, “Moral Status and Human Enhancement,” *Philosophy & Public Affairs* 37, no. 4 (2009): 346–381; Allen Buchanan, “Human Nature and Enhancement,” *Bioethics* 23, no. 3 (2009): 141–150.
judgments about whether paternalism is warranted in cases where we might question a patient’s competence.

Judgments about competence should not vary on the basis of a patient’s specific condition, so if patient A can permissibly use treatment x for condition C then B ought also be permitted to use treatment x even if he doesn’t have an approved medical condition that merits the use of x. Together, these principles tell in favor of the following test:

**Universal Competence:** If A is generally competent to refuse medical treatment then he is competent to self-medicate.

The striking entailment of universal competence is that competent patients are entitled to access any treatment regardless of their condition as long as they meet whatever criteria would trigger informed consent requirements.

Two kinds of incompetence undermine a person’s ability to give medical consent. First, a person can be volitionally impaired, meaning that her intentional capacities are immature or non-existent. Most clearly, unconscious patients are volitionally impaired because they cannot form intentions at all. Second, a person might hold false beliefs. This kind of incompetence has an easy cure in most cases—patient education. However, if a person is delusional or incapable of learning about the risks and benefits of treatment, then medical consent is not required for treatment. This thesis has revisionary implications for the medical treatment of children and mentally ill patients.

First consider children. Clearly, young adults are competent to refuse treatment and very young children are not. For this reason, young adults ought to have the same rights of self-medication that other adults are entitled to but young children obviously
should not. Between these clear cases, teenagers pose an interesting challenge to the idea of medical competence more generally. Regarding pharmaceutical use, I propose that physicians should ask whether a teenager is competent to refuse treatment in order to assess whether she can access treatment. For example, if a teenager is able to refuse chemotherapy then she is competent to consent to take birth control or antidepressants without parental consent as well. This has revisionary implications for the way that teenagers are currently treated in medicine, where some pharmaceuticals are prohibited full-stop for pediatric use, some are selectively prohibited, and teenagers can voluntarily consent to or refuse other treatments.¹⁰

The line between childhood and adulthood is blurry, and I doubt that there’s any definitive age where physicians can draw a line that neatly divides competent teenagers from incompetent teenagers.¹¹ These decisions must be made on a case by case basis, but in cases where a competent teenager is able to make refusal-based decisions, physicians ought to respect her medical autonomy more generally. Even for teenagers who are not sufficiently autonomous to qualify as medically competent, physicians might permissibly cede medical authority to them in order to responsibilize patients into taking responsibility for medical choices, though a failure to do so in these cases would not violate patients’ entitlements.¹²

One worry about my proposal is that certain drugs like antidepressants might affect teenagers differently than adult patients. In these cases, insofar as teenagers are mentally competent to make treatment decisions they ought to be informed of the different risks they face from pharmaceutical use, but these special concerns about the effects of drugs on young patients do not change the fact that some young patients will have the right to choose to self-medicate. Just as some drugs affect people with high cholesterol or liver problems differently, the preexisting condition of youth ought not disqualify a patient from exercising her rights of self-medication.

Turning to mental illness, universal competence holds that if a mentally ill patient is competent to refuse treatment, then he is competent to consent to treatment, including deadly treatments. There are two explanations for this intuitive asymmetry that comport with the model of competence that I sketched above. First, patients with mental illnesses may only be treated as if they can consent to medicine by courtesy, when in fact their mental illness precludes consent. Alternatively, patients with mental illness may be wrongly denied their ability to give consent to some treatments when they are in fact competent.

Whether a particular mental illness precludes consent depends on whether it undermines a patients volitional capacities. Some mental illnesses, like addiction, insofar

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13 see antidepressants teenagers and suicide risks
as it is a mental illness, operate like strong desires. These illnesses do not undermine patients’ beliefs or intentional capacities; rather they change the reasons that patients have for pursuing certain goals, like their drugs of choices.

On the other hand, some mental illnesses and disabilities do compromise patients’ ability to consent. Mentally disabled patients whose intentional capacities are permanently undeveloped (to the extent that they are perpetually like children) do not have rights of self-medication for the same reasons that children are not entitled to self-medicate. Hypochondria and schizophrenia are two kinds of mental illnesses that might justify withholding rights of self-medication because they are reliably associated with false and unjustified beliefs. In contrast, we might imagine another kind of mental disorder, pharmaphilia, which is characterized by a strong desire to use pharmaceuticals (below I will suggest that this is how we should understand addicts). Insofar as a desire for excessive pharmaceutical use is not motivated by false beliefs about the nature of medical treatment or one’s condition, then patients who desire pharmaceuticals ought to be considered competent to give consent.

In other words, some patients with mental health disorders are mentally competent to give medical consent and so they have rights of self-medication, whereas others are not. Assessments of competence to consent will stand and fall with assessments of competence to refuse, but I haven’t taken a stand on whether mental illnesses in general undermine competence to consent or refuse either way. Rights of self-medication for the mentally ill and disabled, like rights of informed consent, ought to be decided on a case by case basis. Whatever determines assessments of competence; assessments of competence cannot be revised once a patient has made a medical decision.
That is, assessments of medical competence should not hang on how a patient does or would decide if she were permitted to. For this reason, it would be a mistake to assume that suicidal patients must be mentally incompetent simply because they chose to use deadly medicines, or to infer from a risky recreational use decision that recreational users are mentally incompetent.  

Institutionally, the behind-the-counter model that I have proposed might combat the possibility that mentally ill and disabled patients will access drugs when they are not competent to make medical decisions for themselves. This possibility is one of the reasons in favor of a behind-the-counter model instead of unrestricted over the counter status for all drugs. Additionally, patients might be asked to give identification before accessing drugs, and incompetent patients might be pre-registered upon diagnosis by their physicians and forbidden from accessing medicines without a prescription.

5. Recreational Users and Addicts

Last, my arguments for self-medication and the above theory of universal competence has revisionary implications for the so-called drug war and for the treatment of recreational drug users. Some of my arguments for self-medication are unconditional, meaning that patients have rights of self-medication regardless of their medical condition.  

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15 As an aside, this theory of competence also has revisionary implications for other areas of medicine which are worth exploring in future research. For example, elective amputation of healthy tissue is currently available for patients with paralyzed limbs. According to the theory I am sketching here, elective amputation ought to also be available for patients with Bodily Identity Integrity Disorder and patients with Gender Identity Disorder ought to have the same access to cosmetic and reconstructive surgery as everyone else. Insofar as mental illness does not compromise one’s general capacity to consent it shouldn’t be a barrier to access. See Tim Bayne and Neil Levy, “Amputees By Choice: Body Integrity Identity Disorder and the Ethics of Amputation,” *Journal of Applied Philosophy* 22, no. 1 (March 24, 2005): 75–86.

16 This is similar to gun control proposals that would prohibit felons from purchasing guns while still permitting gun sales more generally
This means that even recreational drug users are entitled to access pharmaceuticals despite the fact that they don’t have medical conditions. For example, insofar as painkillers, Valium, or medical doses of marijuana, are available to a patient with chronic back pain, then similar drugs ought also be available to patients who intend to make stressful holiday family reunions more enjoyable.

If my argument in Chapter 7 for an unconditional right of self-medication is successful, it protects a right of recreational drug use because even medically inadvisable recreational use may be in a patient’s all things considered best interest, and would fall under the more general right to access medication that I defended earlier. Consider the following two cases. Angel Raich suffered from debilitating pain and the only treatment that effectively managed her pain was medical marijuana. Raich had a prescription for medical marijuana use but could not grow and use marijuana without fear of prosecution.

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17 This might seem like it goes too far, but objections to this proposal seem to hinge on the conception of ‘do no harm’ that I argued against in the previous chapters. There, I argue that there’s no reason to limit access to treatment to the sick or for the sake of health outcomes exclusively because health outcomes are not intrinsically valuable, health is just one among many values a patient might have. Rather, if an addict believes (probably rightly) that his all things considered best option is to take a particular drug, then physicians ought to provide it. Jessica Miller has argued against this move in favor of formal barriers to access for patients who might abuse prescription drugs. She writes “one should not assume that distrust and improving the health of the patient are always at odds. Abuse of opioid analgesics is… increasingly a problem in the US, and some of these abusers do ‘scam’ or ‘con’ physicians to obtain drugs. Misuse or abuse of opioids is often detrimental to health, so reasonable distrust may prevent physicians from making a bad situation worse. In such cases, placing external supports to encourage appropriate, medically indicated use of prescribed opioids can be a way to give patients an opportunity to demonstrate a good faith effort to comply with a treatment plan. Examples I have encountered in clinical bioethics practice include narcotic medication contracts, which specify one provider, one pharmacy, and random drug screens to measure for appropriate levels…of the prescribed drug” see Jessica Miller, “The Other Side of Trust in Health Care: Prescribing Drugs with the Potential for Abuse,” Bioethics 21, no. 1 (December 12, 2006): 51–60.

18 Gonzales v. Raich (previously Ashcroft v. Raich), 545 U.S. 1 (2005)
from federal drug enforcement authorities. Raich sued for the right to grow and use medical marijuana, where she argued on substantive due process grounds that the government did not have the authority to limit her right to grow and use what was medically necessary.

I have argued that medical necessity is only one among many valid reasons to permit self-medication, if a patient had a similarly weighty non-medical interest in using marijuana, states should not privilege medical interests like Raich’s over others. Some notable public figures seemingly do have a similarly weighty non-medical, though personal and professional, interest in marijuana use. For example, Snoop Dogg is a hip hop artist who has developed a public persona where he styles himself as a frequent marijuana user.\(^{19}\) According to Snoop Dogg, he enjoys life substantially more when he’s using marijuana, his work improves, and legal means of recreation are far less enjoyable for Snoop Dogg.\(^{20}\) Based on the arguments from Chapter 7, health care authorities ought not privilege claims like Raich’s over Snoop’s.

An anti-discrimination principle also grounds rights to use recreational drugs. Insofar as sick and disabled patients have rights to treat their medical conditions by using therapeutic drugs it is discriminatory for states to grant access only to some citizens on the basis of their health or ability levels.\(^{21}\) Like my argument in chapter 6 that a principle

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\(^{19}\) Elsewhere I have argued that marijuana plausibly is integral to the develop of Snoop’s moral powers (see “All Liberty is Basic”)

\(^{20}\) Though his affinity for ‘Gin and Juice” is well documented. About marijuana use Snoop raps extensively about the benefits of recreational marijuana use. See for example “Smokin Smokin Weed” by Snoop Dogg feat Nate Dogg, Ray J and Slim Thugg, 2009”

\(^{21}\) Surprisingly, the courts affirmed this principle as well, but not on the side of self-medication. Angel’s appeal was overturned by the US Supreme Court, which found that the government could limit Angel’s right to grow marijuana because even medical use of marijuana would have a substantial impact on the illegal marijuana trade. And so, under
of anti-discrimination tells in favor of expanding access to euthanasia to the healthy, expanding access to other drugs for healthy people also is required insofar as one’s health is normatively extraneous to the decision to use drugs, which I have argued it is.

One worry about this proposal then is that a non-prohibitive prescription system will lead to widespread drug abuse and addiction. The sale of black market painkillers has received increasing media attention and pharmaceutical addiction has ruined patients’ lives in the same way that addictive recreational drugs have ruined lives. Yet as with the recreational use of non-therapeutic drugs, evidence does not support the hypothesis that patients are better off all-things-considered as a result of prohibitive policies. Just as many policy experts and ethicists like Douglas Husak favor decriminalization of recreational drugs because the cost of drug wars are unacceptably high given the effects of drug use, so too should they favor the decriminalization of prescription drugs. Yet the case for decriminalization of pharmaceuticals is even stronger than the case for the decriminalization of recreational drugs because many illegal users of pharmaceuticals

the commerce clause, the US government was empowered to regulate Angel Raich’s fully self-regarding medical choices. This ruling had substantial implications for other liberties as well, insofar as states sought to protect liberties that the federal government did not. See “Gonzales v. Raich; Federalism as a Casualty of the War on Drugs;” by Somin, Ilya, 15 Cornell J.L. & Pub. Pol'y 507 (2005-2006) In a similar case, the Oakland Cannabis Buyers Cooperative argued before the US Supreme Court that they could permissibly grow and distribute medical marijuana because the controlled substances act, which gave the US government the authority to prohibit the sale and use of drugs, exempted those drugs that were sold for ‘medical necessity’. The Supreme Court rejected this defense, and held instead that there is no medical necessity exemption to the controlled substances act. United States v. Oakland Cannabis Buyers’ Cooperative, 532 U.S. 483 (2001)

22 I do not mean to discount these costs, which I think are significant impediments to the public health. That said, I am skeptical that prohibitive policies mitigate the harms of painkiller abuse. As I mentioned in an earlier, Vicodin is the most prescribed pharmaceutical, even subject to rationing by the DEA.

access the drugs for legitimate medical purposes, not because they are addicts using the drugs recreationally. For example, in the United States it is common for elderly patients who cannot afford US prescription drug prices to illegally purchase cholesterol and blood pressure medication from Canadian pharmacies. These patients are also subject to criminal sanction for illegal pharmaceutical use, despite the fact that they are treating a medical condition.

Still, some prescription drugs are addictive and addicts might be better off without unrestricted access to prescription drugs. However, recent philosophical and empirical investigations into addiction by Richard Holton, Bennett Foddy and Julian Savulescu have reviewed psychological studies of addiction, which reveal that drug addiction does not undermine an addict’s capacity act autonomously or to consent to their drug of choice because most addicts will refuse their drugs of choice given strong enough incentives. Since addicts are autonomous and able to give informed consent for treatment, including for their drug of choice, they ought to be granted similar authority to access treatment, including accessing their drug of choice.

Sometimes recreational drug users are more likely to do other immoral things, like neglecting their families or driving while intoxicated. These activities ought to be prohibited by the state, but the fact that people who use drugs recreationally reliably do other immoral things doesn’t mean that using drugs recreationally is wrong—it is not. Further, even if recreational drug use were wrong, it doesn’t follow that prohibitive

25 Husak, “Recreational Drugs and Paternalism.”
policies are warranted because prohibitions also carry substantial cost and encourage other acts of wrongdoing like black market sales and underground, unmonitored drugs.

One way to mitigate the potential harm of addictive pharmaceuticals would be to designate some addictive drugs as behind the counter and enable addicts who do not wish to use addictive pharmaceuticals to pre commit to not using by enrolling in a voluntary prohibition registry. Casinos have used this strategy to help gambling addicts without withholding access to casinos from customers who endorse their desire to gamble.\textsuperscript{26}

6. Conclusion

Like other rights, even important rights, the right of self-medication is not absolute. When exercising the right of self-medication is directly harmful to others it can rightly be limited. In cases where self-medication is indirectly harmful institutions ought to treat the bad effects of self-medication instead of prohibiting self-medication itself.

Not everyone has the right of self-medication. Some people are not competent to make medical decisions for themselves, either because they are unconscious, autonomously impaired, or mentally ill. Some mental illnesses do not undermine volitional capacities.

\textsuperscript{26} Husak, “Paternalism and Consent.”
Conclusion

Some of my arguments for a right of self-medication are qualified, and some are more extreme. I believe that citizens have unconditional rights to access almost any medication without authorization from their physicians or government regulators. Pharmaceutical markets, including markets in experimental, deadly, and recreational drugs, ought to be as open as markets in other consumer goods. This proposal will strike many readers as implausible and infeasible, but more moderate reforms could also promote public health and respect patients’ rights, short of unrestricted open markets but more open than the current system.

Institutional rights of self-medication are possible. In the nineteenth century, self-medication was considered a basic right. Relatively unregulated drug markets and caveat emptor standards of product liability empowered consumers to make risky medical decisions without state or physician interference. Further, the current system of pharmaceutical regulation has staggering costs, including drug loss, drug lag, higher drug prices, and limited access to lifesaving medicine. In light of this evidence, I have suggested that the current system of drug regulation is too prohibitive. Libertarians and liberals ought to agree that indirect governmental strategies for promoting citizens’ welfare are worth promoting, and in the case of self-medication, that pharmaceutical deregulation is compatible with universal health care.1 Based on the evidence alone,

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1 One thing that I have not discussed is the provision medication. Resource limitations may also set limits on self-medication even if no one is prohibited from using pharmaceuticals. The consumer model that I proposed in Chapter 10 suggested that many drugs ought to be treated like other consumer goods and available on an open market. On this model some medicines may be unaffordable even if they are formally available, or manufacturers might choose to discontinue drugs that don’t sell. Yet the consumer model
fellow liberals should agree that some forms of pharmaceutical deregulation deserve our attention; reform is necessary.

Even liberals who are paternalists ought to endorse some regulatory reforms because in many cases using prescription drugs is not dangerous and it might even enhance citizens’ autonomous capacities. This argument is qualified; sometimes respecting rights of self-medication will advance citizens’ overall interests, in these cases liberal states ought to respect self-medication even from a paternalist perspective. Patients have particularly weighty rights to some potentially dangerous experimental medications. Even if a drug is dangerous, if a patient’s illness puts her below a crucial baseline level of human functioning, or if she is terminally ill, she has a basic right to use dangerous medicine if it could potentially benefit her or save her life. Patients also have rights to use deadly medicines because everyone has the right to die.

Together, these arguments support qualified rights of self-medication. They tell in favor of wider access to drugs in those cases where unrestricted access would on balance promote patients’ capacities, where access could treat debilitating and terminal illnesses, and where access is required to respect patients’ rights to die, and shorter approval times. These arguments do not cover all potential drug users.

Readers who are convinced by these qualified arguments ought to endorse the abolition of prohibitive premarket efficacy testing, behind the counter status for drugs that bring substantial benefits with low risks, the legalization of physician assisted suicide does not preclude public subsidies for drugs that treat or prevent certain conditions. A right of self-medication is only a right against interference and penalties for pharmaceutical choices. A positive right to health care might tell in favor of providing or subsidizing some drugs, though self-medication on its own does not.
drugs, and unrestricted access to some experimental and unapproved drugs for very sick patients.

I have also argued that an unconditional right of self-medication, even rights to use dangerous and deadly drugs and to use pharmaceuticals recreationally, is supported by the same considerations that justify the doctrine of informed consent. This argument extends rights of self-medication to all potential drug users, and will therefore strike some readers as implausible, even the premises are sound and the inference is valid. My aim was to show that everyone has the right to make self-regarding decisions for themselves, even if those decisions have substantial medical risks.

There are two intuitive justifications for pharmaceutical regulations like the current system. First, one might think that pharmaceutical regulation prevents wrongful death, so even if it causes more deaths on balance it is justified in order to prevent poisonings. I argued that pharmaceutical regulation actually causes wrongful deaths, and that deaths that are caused by dangerous drugs are not cases of wrongful death as long as patients were informed about the risks of the drugs and consented to use them. Another intuitive justification for drug regulation is the idea that agencies like the FDA provide a public good. I argued that the FDA does not provide a public good because it is subject to indirect democratic oversight and therefore it entrenches the public biases and cannot promote public health. If the FDA were insulated from public influence it would be well placed to provide epistemic public goods, but consumer drug prohibitions are not a public good in the first place so public goods arguments do not justify prohibitions.

A non-prohibitive vision of pharmaceutical policy would include the abolition of premarket safety and efficacy testing requirements, an end to the prescription drug
system, and a culture shift in medicine. Still, there are some limits to self-medication. Mentally incompetent patients do not have rights of self-medication, and the right of self-medication does not justify using medicines that are directly harmful to others.

Pharmaceutical prohibition is a kind of everyday injustice that causes thousands of deaths and needless suffering but is generally overlooked because its victims seemingly die from their diseases. Despite all the political rhetoric about fighting illness and disease, we are strangely complacent when people suffer or die from natural causes. One of my goals in this dissertation is to shake the reader from this complacency. Death and suffering from natural causes is made worse by government interventions, and that these interventions also violate our most fundamental rights. Countless lives can be saved and improved if government officials and physicians played an epistemic role and respected our rights to make our own medical choices.

In one sense this proposal seems revisionary, but in practice things might stay the same. Patients could still consult with their physicians and defer to government certifications when making pharmaceutical choices, but some patients’ lives would improve if physicians and regulators respected rights of self-medication. More generally, everyone would benefit from having rights of self-medication, even if it were rarely used, because a right of self-medication would free us from the dominating influence of medical experts who have claimed the authority to make medical decisions for us even in cases where we disagree. Self-medication is a principle of patient authority and respect that medical and civic institutions ought to adopt. Paternalism in medicine has terrible consequences, it violates our rights, it is offensive to the dignity or persons, and is a
fundamentally disrespectful way to treat patients and citizens. Rights of self-medication are the cure for the systematic injustices that persist in medicine and government.

Over time, the world has become freer on balance—not only are more people free but also more freedoms are protected. This expanding circle of liberty represents an incredible moral triumph from the perspective of any moral framework. Yet states remain morally deficient insofar as they enforce pharmaceutical regulations that violate important personal liberties like self-defense or bodily autonomy. It is easy to overlook these violations, since the patients who suffer and die of their diseases have little recourse against popular pharmaceutical regulators and their suffering too-often goes unnoticed. The foregoing arguments are intended to acknowledge this unseen tragedy. More importantly, this is a small step towards a cure for deadly and unjust regulations.

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2This idea comes from Peter Singer, who once wrote that moral progress is possible, and that ethics could be understood as an expanding circle of moral concern, where humans gradually have extended their moral consideration to include people outside their families, states, races, nations, (and eventually perhaps, species.) As Singer writes, the idea of the expanding circle originates with WH Lecky. P. Singer, “The Drowning Child and the Expanding Circle,” New Internationalist 289 (1997): 28–30.
Appendix: Medical Experts and Institutional Failure

In Chapter 9, I argued that agencies like the FDA institutionally constrained in ways that make it difficult for medical experts to set policies in ways that promote public health. Specifically, I suggested that democratic and electoral oversight undermines agency independence. In this appendix I will develop this point in more detail, and I will sketch a formal model that illustrates how democratic preferences can become entrenched in a seemingly independent institution like the FDA.¹

1- A Model of FDA Independence

I begin with several uncontroversial assumptions about the policy preferences of elected and agency officials. Even if medical experts who are employed by agencies like the FDA sincerely wish to make the most medically advisable policies, elected officials who are responsive to their constituents may indirectly influence expert’s behavior. The purpose of this model is to show how institutional actors affect agency decision-making and to provide a framework for understanding why FDA officials sometimes appear to behave independently (as in the case of Avastin approval) and other times they are politically strategic. The model shows that the institutional context determines the extent to which officials can behave independently, or the extent to which they must be strategic.

1.1 Policy Space

¹ This model is based on a model of institutional constraint and judicial independence that I developed in an earlier essay. That model was helpfully improved by comments from Chuck Cameron and Lee Epstein.
To illustrate this institutional environment I will develop a decision model that explains how officials might decide to approve drugs. The dependent variable of this model is FDA policy like drug approval, approval status, or approval time relative to the elected official’s most preferred approval times. This variable depends on the FDA’s judgment about which approval plan will have the best public health outcomes and agency constraints. Ultimately, an understanding of variability in the levels of constraints on FDA officials will contribute to an understanding of the outcomes of new drug approvals.

1.2 Signaling Models

The game is a signaling model where elected officials observe their own override distance, signal that to the FDA, and the FDA in turn sets a policy that may or may not be motivated by that signal. The game consists of two stages. The first stage determines expectations. In the second stage FDA officials set policy in light of a) their medical judgment and b) institutional constraint. 

Several equilibria emerge from the model, all of which explain Agency-Electoral interactions and policy outcomes, some of which may also be predictive of FDA decision-making. I conclude that agency approval is sometimes influenced by electoral oversight, and that the public can indirectly constrain the FDA through elected officials. I discuss several kinds of signaling equilibrium that may help to explain approval decisions.

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2 This model also has predictive power in forecasting approval behavior, and it makes a methodological contribution to traditional separation of powers models by developing a way to establish the public as a direct constraint on electoral institutions, and therefore as an indirect constraint on the FDA.

3 The game will focus on decisive agency officials, but it can be generalized to any member of the agency. Also, drug approval will be the subject of agency decision-making, though this model applies to other agency decisions as well. Additionally, analysis is based on several simplifying assumptions about the players and the nature of the constraints.
in various cases. I then discuss the normative implications of this model. Insofar as the FDA’s function is to provide an epistemic public good that compensates for the public’s inability to make medically advisable decisions, the political climate compromises the FDA’s ability to do so. The FDA should therefore not have prohibitive power over the minority of citizens whose judgments depart from elected officials’, the public’s, and so the FDA’s judgment.

1.3 The Players

The first set of assumptions refers to the players in the game. As was described above, several players could have been included in the model. The House, Senate, President, Public Opinion, and the courts have all been identified as constraining actors on the FDA.

Elected officials are modeled as a range of ideal points that could have been the outcome of bargaining between the two houses and the President. Thus, on a unidimensional policy space Congress and the President can be treated as a policy interval that came about through partisan bargaining between the two. This is similar to the approach taken by Gely and Spiller in their separation of powers model.4 I assume that both the president and Congress are rational and have complete information about their own ideal points as well as those of the other institution, public opinion and interest groups. Further, I assume that there exists a bargaining outcome in the policy range that is pareto efficient. The pareto efficient policy position that emerges from the bargaining

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4 There the authors show that which shows that the outcome of such a bargaining process will lead to a set of ideal points on the contract curve of both institutions, which is better than the status quo. P. T Spiller and R. Gely, Strategic Judicial Decision Making (National Bureau of Economic Research, 2007).
process between president and Congress represents the preferred regulation of elected officials (C).

This model treats the Public as exogenous to the process and the policy preferences of the Public are not included for several reasons. First, the public only becomes involved in the game when Congress or the President (gatekeepers) seeks to overrule administrative policy. The public is a directly constraining force on Congress and the President, and is only an indirect constraint on the FDA insofar as the institutional restraint effects how much the FDA policy can drift from the public’s preferences. Thus, public opinion determines the extent to which Congress or the President can respond to FDA decisions. When public opinion is in favor of institutional action, the signal of elected officials is strong, and when it is unclear or opposed the signal is weak.⁵ In this way, the public ideal point is not incorporated into the model, because the public does not have any direct institutional authority to override a FDA decision.⁶

Therefore, I combine the public and the media and interest groups, as well as other constraining factors on Congress and the President as one variable, (r). This

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⁵ Again, an analogy to judicial decision making is instructive here. As Ignagni and Meernik show, when a majority of public opinion is either opposed to a decision of the Court or in favor of a Congressional response, Congress is significantly more likely to respond to the Court. Joseph Ignagni and James Meernik, “Explaining Congressional Attempts to Reverse Supreme Court Decisions,” *Political Research Quarterly* 47, no. 2 (June 1, 1994): 353–371; James Meernik and Joseph Ignagni, “Congressional Attacks on Supreme Court Rulings Involving Unconstitutional State Laws,” *Political Research Quarterly* 48, no. 1 (March 1, 1995): 43–59.

⁶ Public opinion also plays a direct role in influencing the Court, because the Court must anticipate long term legitimacy but the effect of these direct constraints will be the same as their indirect effect through Congress, they will either make the Court act in a more or less constrained way given Congressional preferences. Willmann G. et al., “Invitations to Override: Congressional Reversals of Supreme Court Decisions,” *International Review of Law and Economics* 16, no. 4 (1996): 503–521.
variable represents issue salience, interest group participation, and overall public opinion. All of these factors exogenously determine the level of FDA policy deviation from elected officials’ ideal point that the officials will allow.\(^7\)

The final component of this model is the FDA. While the FDA approval process involves many actors, this analysis assumes that the process of policymaking by the FDA is such that the policy that emerges from the FDA is that of a particular decision maker on an issue. Intuitively, this assumption is justified, especially given the substantive assumptions of the model. Given that each member of the FDA wants to advance what they think is the medically advisable policy, consistent with maintaining their own authority, each decision maker in some way represents the interests of the agency. Therefore, the ideal policy of the FDA is represented as a single ideal point \((x_m)\) of the medical decision maker.

1.4 Preferences

Rather, than utilizing the most general (and most commonly used) concave or strictly quadratic utility function \(- (x-x_0)^2\) to explain the utility to elected officials of a certain policy, this model introduces an external constraining influence on congress, \((r)\) such that \(-r(x-x_0)^2\) that causes the width of the quadratic utility function of elected officials to vary.\(^8\) This combined with an exogenous utility threshold constrains the

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\(^7\) Because \(r\) is simply a magnitude which affects congressional utility, it may simply consist of a sum of various measures of the above uncorrelated independent variables such as public opinion+ Presidential alignment+ Interest Groups.

\(^8\) The relevant nature of the utility functions remains the same and similar results emerge if the utility function of each player is a non quadratic but still concave or quasi concave utility function. However, quadratic functions are computationally more flexible and they introduce an element of risk aversion that may motivate further research into how institutional actors make decisions.
policy space of outcomes that elected officials will not override around the electoral ideal point.  

This alteration to the traditional separation of powers model of institutional preferences increases the explanatory and predictive power of the model in several ways. First, the utility to Congress or the President of any given policy now incorporates a proxy for issue salience, (operationalized through \((r)\)) which explains a single ideal point distribution can lead to different outcomes in different cases. This means, for example, that electorally controversial decisions like over the counter approval for PlanB contraceptives or approval for the use of Avastin in breast cancer are more likely to motivate elected officials to take an interest in the FDA’s decisions, in contrast to most decisions. In other words, not all drug approval decisions are equally salient to elected officials.

Second, the \(r\) variable represents the nature of the influence of the public and other politically relevant actors on Congress and the President, which in turn constrains the FDA. These actors do not constrain independent administrative agencies directly but they do exert some influence. A modeling approach like this is more consistent with the structure of political institutions. Congressional and presidential preferences directly constrain the FDA because Congress and the President can override approval decisions and limit the FDA’s power. While the public has no such ability to constrain the FDA directly, the media and the public do have the ability to constrain Congress and the President though, through electoral mechanisms and campaign donations. This modeling approach reflects the FDA’s decision environment more than traditional separation of

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\(^9\) In this way, this model also contributes methodologically to studies of separation of powers and agency independence.
powers approaches in that it includes the influence of the media and public opinion as a constraint on institutional actor’s preferences, not as a constraint on the FDA.

1.5 Constraints

The above analysis showed that Congress and the President serve as a constraint on the policy-making ability of the FDA. However, these elected officials are themselves constrained by exogenous factors such as the media, public opinion, issue salience, and interest group participation in the issue.

Members of the FDA have only partial information about the actions of elected officials. Although it is possible to identify the pareto optimal result of a bargaining process between Congress and the President, other factors such as campaign contributions, interest groups, and simple error in the bargaining process makes it so that the interval of acceptable policy space in which elected officials will not overturn a decision is not known to the FDA.

Further, elected officials do not overrule FDA decisions because the policy made by the FDA is not their favorite policy, they only overrule when the decisions fall beyond a range of acceptable policy positions. Members of the FDA must therefore interpret the signal of Congress or the President (or their bargaining range) as an interval, and anticipate institutional actions.

This model is similar one of strategic information transmission, like Crawford and Sobel’s analysis of separation of powers, because Congress can signal a size of an interval, and signals only what interval their true preferences are in.\(^\text{10}\) However, in this case, the sender and receiver’s preferences are more closely aligned, but that perfect communication is unlikely. However, this model differs from the Crawford and Sobel

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\(^\text{10}\) The result of the strategic information model is that more communication occurs if the sender and receiver’s preferences are more closely aligned, but that perfect communication is unlikely. However, this model differs from the Crawford and Sobel
model information is signaled to the receiver about the range of acceptable outcomes to Congress, so the information is about the preferences of Congress itself (and how much Congress will deviate from those preferences.) In this way, the signal is more like the discretion ranges set for agencies by Congress, as specified by Craig Volden.\(^{11}\)

Depending on the FDA’s alignment with electoral institutions, the FDA is either constrained or unconstrained. The FDA receives a noisy signal from electoral institutions. Electoral institutions maintain policy preferences, but the range of the policy signal varies. The FDA must therefore take into account these factors in determining a specific drug policy. Therefore, uncertainty exists about the extent to which the FDA is aligned with electoral institutions, even though ideal points are known.

1.6 The Game

The following model unfolds from the theory above. Interest group’s preferences and public opinion are an indirect and not a direct effect on the actions of the FDA.\(^{12}\) These preferences do not constrain the FDA’s strategy function but they constrain Congress and the President, and these constraints have an effect on the strategies of the FDA.

The players include elected officials \(c_i\) whose ideal point is represented as the pareto point of the bargaining space between the President and the Congress \(x_c\), and the decisive agency official \(m\) with ideal point \(x_m\). Other, indirect players include the

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\(^{12}\) Figure 1 provides an illustration of this model that is helpful throughout the analysis.
media, public opinion, interest groups, and other actors who affect issue salience. These actors play a role in the game as well, and are modeled as a constraint on Congress (r.)\(^{13}\)

First, a level of Institutional constraint (d\(^*\)) is exogenously determined. It is a function of public opinion and of the media, interest groups (r) and a level of utility (-\(\bar{U}_c\)) beyond which elected officials will not accept policy but will override the policy set by the FDA and reassert their own ideal point. Thus the first move in the game is made by nature, d\(^*\)((-\(\bar{U}_c\)),r) which represents a new drug application from a pharmaceutical manufacturer.

Elected officials knows their own level of constraint, d\(^*\), and send a signal to the FDA about their own override level (d) which may or may not reflect the true override level d\(^*\). Elected officials have an incentive to set a lower level of d than d\(^*\), such that (d< d\(^*\)) if it will move policy closer to the electoral institution’s ideal point \(x_c\). The FDA observes the signal. Next, the agency official chooses an approval outcome. Then, elected officials override the policy outcome of the FDA if it is outside of their constraint level.

1.7 Strategies

Players develop strategies within this sequence of play based on the informational asymmetry between elected institutions and the FDA modeled within this game. Strategies also develop based on the utility functions of both players. Players are assumed to have quadratic utility functions, building on Spiller and Tiller’s (1996) assumption of concavity of preferences. Therefore the utilities of each players are derived from their ideal points such that \(U_c=-r(y-x_c)^2\) and \(U_m=(y-x_m)^2\) The elected official’s message strategy is one in which elected institutions signal a level of constraint. This signal is a function of

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\(^{13}\) Below is a list of notation that will be helpful throughout the following three models.
the state of the world r, which also determines d*. So, the Congressional message strategy is d(r).

The FDA’s strategy is based on what policy the FDA will assert after elected institutions have sent a signal about their override point. The FDA does not know how constrained electoral actors are, (they do not know the true value of d* or r,) which substantively makes sense. Congress and the President have far more mechanisms of knowing their own electoral constraints both because they have access to more resources to discern those constraints and because the constraints affect them directly, by determining electoral success. Therefore the policy outcome set by the FDA, $y_m$, will be affected exclusively by the signal sent by elected officials, and the FDA’s knowledge of that signal, and the FDA’s ideal point. The FDA’s strategy is $y_m(d)$ because it depends on the signal d, which is set by elected officials. However, d is only affects payoffs insofar as it is representative of d*. In this way, the game is similar to cheap talk models such as Farrell and Rabin, yet it is not a cheap talk model because the signal sent by elected officials does affect the official’s payoffs.\(^{14}\)

If the FDA’s strategy yields a policy outcome that is outside of the true override range of elected officials, elected officials will overturn the policy set by the FDA because the utility of overriding will be greater than the utility of accepting the policy set by the FDA, even though overriding is costly. In other words, elected officials will override if $x_c - v > r[y(d)]^2$.

All of the above strategies are derived from the payoffs. The payoff to elected officials to announce at a certain level of policy space (d) given the state of the world, (r), is $U_c(d|r)$, which is equivalent to the utility that they will get from the deciding official in the FDA proposing a certain approval decision given that signal, $U(y(d)|r)$, which given our assumptions of quadratic preferences and the strategy of the FDA, will be $-r(y(d))^2$, which is baseline utility of elected officials $U_c$, which is a function of r, at the policy position set by the FDA. In other words, $U_c(d|R)= U(y(d)|r) = -r(y(d))^2$.

There is also a cost to sending a false message. There is an exogenously imposed cost (L) to elected officials when they send a false signal and are caught doing so. For example, when elected officials send the message that they will override and then do not overturn a policy or when the signal is that elected officials will not overrule and then they do, elected officials lose credibility and authority with the FDA as well as the exogenous actors when false signals are made and are not enforced.\textsuperscript{15}

Once elected officials have signaled a level of override distance, d, the FDA makes a decision that may or may not be influenced by the signal. The utility of the FDA is influenced by the payoff of asserting their ideal point ($x_m$), and the payoff of asserting another policy position between their own and elected official’s ideal point $-(y-x_m)^2$, and the probability of a elected official’s overriding their policy ($p_v$). Therefore, the utility to the FDA of asserting a policy y is dependent on the elected official’s override distance, $d^\ast$. $U_m(d)=p_v(-x_c- x_m)^2+(1-p_v)(y_m-x_m)^2$. The FDA seeks to maximize their own utility.

\textsuperscript{15} Other costs may exist as well. For example, elected officials may have an exogenous cost (s) to signaling that it is less constrained than it is because public opinion, interest groups, and the media will view punish elected officials for diluting the influence of r in its signal. Elected officials thus have a general incentive not to under-represent their level of constraint. Such an additional would not have an effect on this model and would not facilitate equilibrium.
by ensuring that the policy advanced y is as close to their ideal point, m, as possible. However, the policy that they advance is too far from the elected official’s ideal point c it may exceed the true distance \( d^* \) and be overridden.

If the utility of overriding is greater than the utility that is gained by accepting the FDA position, elected officials will override the position of the FDA. The utility of overriding the position of the FDA, \( -\bar{U}_c \), includes the payoff that elected officials get from asserting their own policy position, and the cost of overriding (which can be understood both as a cost in terms of resources as well as the potential public opinion/institutional risk involved in overturning an FDA decision.) Thus, the utility of overriding \( -\bar{U}_c = x_c - v \), where \( x_c \) represents the utility to elected officials of the outcome of the game being their ideal point, and \( v \) is the cost of overriding a decision of the FDA.

1.8 Equilibrium

Equilibrium emerges from this game only under certain conditions. Two types of pure strategy equilibrium can emerge from the game as it is specified above; a separating and a pooling equilibrium. A separating equilibrium is one where each type of the sender chooses a different signal to send, and upon observing the senders signal, the receiver knows the senders type.

In this case, a separating equilibrium will exist when the sender (elected officials) signals the true value of \( d, d^* \), and the FDA sets policy at that point or within that range. The FDA will always set policy \( y_m \) at \( d^* \) if its ideal point \( x_m \) is outside of the range, because setting policy at its ideal point would lead to an override and the FDA would receive \( -(x_c - x_m)^2 \) which is less than the utility that it gets from its ideal point. If the FDA
sets policy $y_m$ at $d^*$, then it receives a payoff of $-(y_m-x_m)^2$ and elected officials receive a payoff of $-(y_m-x_c)^2$. If the FDA is within the range $[x_c, d^*]$ then it will be free to set policy at its ideal point $x_m$, which maximizes its utility. If the FDA is within the range $[x_c, d^*]$ and sets policy at its ideal point $x_m$, then elected officials receive a payoff of $(x_m-x_c)^2$.

A pooling equilibrium exists when all types of senders choose the same signal to send so the signal gives the receiver no idea as to the true type of sender. A pooling equilibrium would exist if elected officials always set the value of $d$ at their ideal point for example, saying that they would override any policy that was not their most preferred policy position. If this were the case the FDA wouldn’t know if the true nature of electoral institutions was that they actually had a level of override distance such that $d^* = c$ or if the true $d^*$ was further from $c$. The signal would be completely uninformative. Alternatively, such a scenario could emerge if elected officials made no comment on their override range.

When signals are uninformative, equilibrium can still emerge when the FDA advances a policy that exists at a weighted average of the two possible policy outcomes from setting any policy, the outcome of $y_m$ if the policy is not overridden and $x_c$ if the policy is overridden and elected officials reasserts their ideal policy. Therefore, in order to find such an equilibrium policy $y_m$, when the FDA does not know $d^*$, the FDA must make certain assumptions about the distribution of $y$ within the range $[x_c, x_m]$.

Assume that $F(y_m)$ (the cumulative density function of the policy space) is uniformly distributed as $y_m$, and that the range $[x_c, x_m]$ is distributed from 0 to 1. Given these assumptions, the expected utility of a certain policy is maximized when the policy that emerges is maximized when the policy advanced by the FDA on the range $[0,1]$ is
equal to $\sqrt{(2/3)}$, or .8165. This shows that the FDA can maximize the utility of advancing any given policy position, given the potential of being overridden when the policy advanced is between the ideal points of the FDA and elected officials. Further, because this example set the range from $[x_c, x_m]$ as $[0,1]$, the results are intuitively generalizable as well. When the FDA policy exists at a point on between the FDA’s and elected officials’ ideal points such that it is $1/5^{th}$ of the distribution from the $x_m$ and $4/5^{th}$ of the distribution from $x_c$, then the FDA can maximize its expected utility given that there is still a possibility of an override. This result is true regardless of what the true value of $d^*$ is, because in a pooling equilibrium, the FDA does not have any information about the true value of $d^*$.\(^{16}\)

However, these are not the only equilibrium that could emerge. As Figure 1 shows, elected officials can also signal levels of override distance at $d$ not equal to $d^*$. Because the sender has more than 2 ‘types’, but rather a range of types $d \in [x_c, d^*]$, mixed strategy equilibrium may exist as well as mixtures of the above pure strategy equilibrium. For example, the continuum of types may be partitioned into smaller subsections, and in each subsection all types in that subsection act the same and different from types in other subsections. If the actions in each subsection maintain certain incentive compatibility constraints, such as if the cost of overriding is always coincides such that at $d^*$ elected officials are indifferent between overriding and not overriding, mixed strategies may emerge as well. This would require the FDA to assign a probability distribution to magnitude of $(d-d^*)$ which would enable them to predict being overridden given a signal $d$ not equal to $d^*$ and a policy $y$ between $c$ and $m$. The FDA may also mix

\(^{16}\) For a further explanation of this equilibrium, see proof 1
by choosing a point in an interval, signaled by elected officials, that makes the FA indifferent given that the true $d^*$ exists in that interval. This approach is similar to the one taken by Crawford and Sobel where the receiver chooses to assume that the true state within the interval existed at the midpoint, and thus in each interval maintained possibility of being wrong about the true range, even though the interval signal was partially informative. Examples of these types of mixed strategy equilibrium are developed further in the following discrete model. 1.9 Discussion

Substantively, one of the implications of this study is that the level to which an agency official is constrained or unconstrained by electoral actors determines how she can behave (that is, how closely an official can simply assert her most preferred policy based on her interpretation of medical data). In many cases issue salience is very low, new drug approvals often do not gain a forceful public constituency either way. In these cases FDA officials are free to decide purely based on their own preferred outcome because their most preferred policy exists within the override range of elected officials.

FDA officials may also behave freely if their ideal point is very close to the ideal point of elected officials, and so even if elected officials are very constrained, the ideal policy of the FDA still won’t be overridden. According to Carpenter’s analysis, citizens seem to know what pharmaceutical regulators do, and they seem relatively more aware of the costs and benefits of drug regulation than of other kinds of regulation. One explanation for this support is that citizens realize that they are unable to make medical decisions, in light of cognitive biases or for whatever reason, so they collectively self

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17 Crawford and Sobel, “Strategic Information Transmission.”
bind to create a regulatory agency that will compensate for this deficit, and they look to regulators to provide medical expertise as a public good.

Still this model also illustrates that when the most preferred policy of the FDA is outside the override range of elected institutions, FDA officials must behave more strategically and try to assert a policy that is at the indifference point of electoral actors between the most preferred policy of the FDA and the most preferred policy of Congress or the President. This means that in cases where the public cannot recognize its own inabilitys in medical decision making, the FDA remains constrained by electoral institutions nevertheless.

If the FDA does not know where the indifference points of elected institutions are, an equilibrium still emerges given certain assumptions about the strategies of the actors, as described in the continuous case. From this mixed strategy the FDA will propose a policy that maximizes the expected medical gain given the possibility that they will be overridden and their authority will be limited. This proposed policy will also be a compromise policy position between the medically preferable policy of the FDA and elected actors’ most preferred policy.

These considerations indicate that FDA policy, even in the absence of congressional and presidential oversight, might nevertheless respond to the indirect influence of a biased public and the direct oversight of institutions that work on the public’s behalf.
2. The Discrete Model

The above model illustrated the process of signaling between elected officials and the FDA about override models in the general form. This section illustrates a simple example as an alternative to the abstractness of the continuous model, and finds more distinct equilibrium outcomes, such as partially informative equilibria.

2.1 Simplifying Assumptions

In order to model the discrete case I will introduce several simplifying assumptions. First, assume rather than the media and public opinion being continuous constraining factors on elected officials, that the influence of these actors on elected officials is either large or small. In other words, assume r is either big, which would lead to a small override range \((x_c-d^*)\), or that r is small, which causes a large override range \((x_c-d^*)\). Also assume that elected officials can send 2 signals, a signal that their override range is small or that the range is big. These assumptions change the nature of elected officials’ and the FDA’s constraints and signals from continuous to discrete.

Following these assumptions, elected officials can either be constrained or unconstrained, depending on the location of \(d^*(r)\) where r is either big or small. The states of the world are thus \(d^*_1\) or \(d^*_2\). Elected officials can also signal a location of \(d(r)\), which is either big \((d_1)\) or small \((d_2)\). For simplicity, assume that the location of \(d^*_1 = d_1\) and \(d^*_2 = d_2\). Once nature determines \(d^*\) and elected officials signal \(d\), the FDA can decide to choose a policy far or close to its ideal point, \(m\). If the FDA chooses a policy \((y_n)\) near its ideal point it will choose a policy that is within the range of \(d^*\) but outside of the override range of \(d^*_b\). If the FDA chooses a policy \((y_f)\) far from its ideal point and closer to elected

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18 Figure 2 provides an illustration of this model that is helpful throughout the analysis.
officials’ ideal point $x_c$, then the FA will not be overridden by elected officials. Because the FDA would like to move policy closer to its ideal point $x_m$, $u(y_f) < u(y_n)$.

The assumptions of the discrete case described above can be described in the following ideal point diagram.

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Based on the above preference and policy distribution, the continuous case can be reduced to a simple signaling model with eight possible outcomes. The above diagram shows the utility to both actors of each possible outcome.

2.2 Discrete Case Equilibrium

There exists a pure strategy separating equilibrium when players have compatible incentives to follow their signals. For instance, when the true state is $d^*_1$ and elected officials must have an incentive to signal $d_1$ and the FDA must have an incentive to choose a policy at $y_f$, which is within the override range set by $d^*_1$. Similarly, if a separating equilibrium can be found, when $d^*_2$ is the true state of the world and $d_2$ is signaled by elected officials the FDA chooses policy at $y_n$ because it is within the override range of the elected officials and it is closer to the FDA ideal point $x_m$ than $y_f$ is. If costs of signaling were not included in this model, a separating equilibrium would not exist because there would be no incentive for elected officials to choose to honestly signal $d_2$ given $d^*_2$, the FDA would actually have an incentive to send a false signal.

However, as specified the model does include costly signaling to elected officials. It is costly for elected officials to lie when a the true state of the world is $d^*_1$ because by
signaling $d_2$ elected officials bear a cost for sending a false signal because it looses legitimacy with the FDA and the constraining actors (L).

For a separating equilibrium to exist the FDA must prefer far policies $y_f$ when $d_1^*$ and near policies when $d_2^*$. This implies that:

$$d_1^* : -(y_f-x_m)^2 > -(x_c-x_m)^2$$

and

$$d_2^* : -(y_n-x_m)^2 > -(y_f-x_m)^2.$$ 

As the diagram above indicates, both of these implications are true by the nature of the constraints ($U_m(x_c)<U_m(y_f)<U_m(y_n)$)

Also, elected officials must prefer to signal $d_1$ when $d_1^*$ and $d_2$ if $d_2^*$ given the FDA’s preferences above. This is also the case. Elected officials prefer to signal honestly because:

$$d_1^* : -r(y_f-x_c)^2 > -r(y_f-x_c)^2 - v - L$$

and

$$d_2^* : -r(y_n-x_c)^2 > -r(y_n-x_c)^2 - L.$$ 

$L$ is positive

This separating equilibrium exists as long as the legitimacy cost when a false signal is made and elected officials are ‘caught’ is positive. Therefore, if elected officials have a disincentive to lie about their signal (because the FDA will believe the false signal and elected officials will be caught sending it) then elected officials will always send a true signal, the FDA will always follow it, and a pure strategy separating equilibrium will emerge.
A pooling equilibrium also exists in this discrete model. Consider the pooling equilibrium where the elected officials always signal that they are very constrained $d_1$ and the FDA always chooses a policy that is far from their ideal point. Bayes’ rule indicates that the FDA believes $P(d^*_2 \mid d_1) = \rho$. Bayes’ rule is uninformative however about $P(d^*_2 \mid d_2)$ in this case. Assume however the case where $P(d^*_2 \mid d_2) = 0$. The FDA will set a far policy $y_f$ when it is better than setting a near policy given the probability of being wrong. In other words, a pooling equilibrium exists when the FDA has an incentive to play it safe. This occurs if:

$$\rho(-(y_f-x_m)^2) + (1-\rho)(-(y_f-x_m)^2) > \rho(-(y_n-x_m)^2) + (1-\rho)(-x_c-x_m)^2$$

or

$$\rho(-(y_f-x_m)^2) > \rho(-(y_n-x_m)^2) + (1-\rho)(x_c-x_m)^2$$

which implies,

$$(1-(x_c-x_m)^2) ((-(y_f-x_m)^2)/(-(y_n-x_m)^2)) > \rho$$

or more simply,

$$((U_m(y_f)-U_m(x_c))/U_m(y_n)-U_m(x_c)) > \rho$$

When $\rho$ is less than the utility relationship stated above, meaning that the probability of an incorrect signal given that the true level of constraint is $d_2^*$, This pooling equilibrium introduces an opportunity for some informative comparative statics, which will be further explored in a numerical example. Namely, the probability threshold in which the signal becomes uninformative is dependent on a ratio of the difference in utilities between a far policy and the elected officials’ ideal point to a near policy outcome and the elected officials’ ideal point. Thus, as the near policy outcome drifts from the elected officials’ ideal point, the probability that elected officials will send a false signal decreases. Also,
as the far policy outcome drifts from the elected officials’ ideal point, the probability that elected officials will send a false signal increases.

However, more equilibrium can exist in this game. Although these equilibrium could not be identified in the continuous case without imposing an arbitrary partitioning schema on the continuum of \([x_c, d^*]\), in the discrete case the partitions defined have intuitive and substantive meaning. This natural partition in the discrete model generates identifiable mixed strategy partially informative equilibria in addition to the pooling and separating equilibrium identified above.\(^{19}\)

Solving for partially informative equilibria requires that several assumptions about the actor’s strategies. Assume that if elected officials signal \(d_1\) that the FDA plays a mixed strategy between \(y_f\) and \(y_n\) and if elected officials signal \(d_2\) that the FDA responds by proposing the policy near its ideal point \(y_n\). This assumption makes substantive sense, because it states that if elected officials signal that they are highly constrained, the FDA plays a mixed strategy due to the fact that elected officials have an incentive to lie if it will potentially move the policy proposed by the FDA \(y_m\) closer to the electoral ideal point. If elected officials signal that they are not constrained then the FDA advances a policy closer to their own judgment because elected officials have a disincentive to lie and say that they are unconstrained because they would rather move policy proposed by the FDA \(y_m\) closer to \(x_c\).

Assume also that if elected officials observe \(d_1^*\) they will signal \(d_1\) and if they observes \(d_2^*\) they will play a mixed strategy between signaling \(d_1\) and \(d_2\). This assumption states that if elected officials are constrained, they do not have an incentive to lie and

\(^{19}\) See below for the complete proof (2) of a partially informative mixed strategy equilibrium

19 See below for the complete proof (2) of a partially informative mixed strategy equilibrium
signal that they are unconstrained, because it will only encourage the FDA to choose a policy outside of its override range, which will result in an institutional override wherein Congress or the President receives the utility of asserting the electoral ideal point, but pays the cost of overriding v and a legitimacy cost. If elected officials observe that they are unconstrained, they may still want to signal that they are constrained because if the FDA believes that they are constrained then FDA policy $y_m$ will move closer to $x_c$.

In other words, these assumptions state that actors behave strategically given institutional constraints, even if agency officials at the FDA are altruistic medical experts. If agency officials are unconstrained then they can advance medically advisable policies more reliably than if they are constrained. These assumptions follow directly from the utility functions specified by in the model, which are theoretically motivated.

If there does not exist a legitimacy cost $L$, or if that legitimacy cost is negative (sending false signals is beneficial rather than costly) then a mixed strategy partially informative equilibrium will not emerge, because there is no disincentive for elected officials to send a false signal even if they get caught. Therefore, elected officials will always signal that they are constrained, $(d_1)$ even if they are not, to encourage the FDA to propose $y_f$. If elected officials are indifferent between sending false and true signals, the equilibrium becomes a babbling equilibrium because signals are entirely uninformative.\(^\text{20}\)

When sending a false signal is costly ($L$ is positive) a partially informative mixed strategy equilibrium can emerge from the discrete model. When the FDA asserts a policy far from its ideal point with probability $q = (L/(U_c(y_f) - U_c(y_n)))$ Elected officials and the FDA are both indifferent between near and far policies when electoral institutions signal

\(^{20}\) See below for a proof (3) of the babbling equilibrium
that they are constrained (and the FDA still always asserts near policies when elected
officials say they are unconstrained, which they always are when they signals that they
are.) When the FDA asserts policy far from its ideal point with this probability, elected
officials are indifferent between signaling that it is constrained (d₁) and unconstrained
(d₂).

This result creates an opportunity to study the relationships between the utility of
asserting a policy and the probability of doing so, through comparative statics approach.
Holding constant the cost to elected officials of a false signal L, this equation shows that
as the difference in \( U_c(y_f) \) and \( U_c(y_n) \) increases, the probability \( q \) of the FDA choosing a
policy that is far from its ideal point \( y_f \) must decrease in order for elected officials to
remain indifferent between signaling \( d_1 \) and \( d_2 \). In other words if the FDA policy
becomes more divergent, the FDA policy becomes more likely to move towards \( x_c \).

The discrete model shows therefore that there are discernable equilibrium results
that follow from the continuous model, above. This can be better illustrated with an
example that applies real numbers to the utilities of policy outcome to each player.

3. A Numerical Example

Consider the discrete model above, but eliminating the abstraction of the model
even further. 21 The intuitive implications of this equilibrium will emerge when we assign
numerical values to the player’s payoffs. 22

<table>
<thead>
<tr>
<th>( d^*_1 )</th>
<th>( d^*_2 )</th>
</tr>
</thead>
</table>

|-------|-----------|-----------|-----------|

21 Figure 3 in this Appendix provides an illustration of this model that is helpful
throughout the analysis.
22 Although it is an arbitrary exercise to assign ordinal preferences to a continuum of
policy outcomes without any relational restrictions, doing so provides a useful illustration
of how the assumptions of the model affect the ultimate strategies and payoffs.
In this case we can imagine that the policy space for a new drug approval yields the above payoffs. Recall that a separating equilibrium exists when the FDA prefers to follow the signals of the elected officials such that:

\[-(y_f - x_m)^2 > -(x_c - x_m)^2 \quad \therefore \quad -(1-5)^2 > -(0-5)^2 \quad \therefore \quad -16 > -25\]

and

\[-(y_n - x_m)^2 > -(y_f - x_m)^2 \quad \therefore \quad -(1-3)^2 > -(1-5)^2 \quad \therefore \quad -4 > -16\]

and elected officials must prefer to signal $d_1$ when $d^*_1$ and $d_2$ if $d^*_2$ given the FDA’s preferences above. This is also the case. Elected officials prefer to signal honestly because:

\[-r(y_f - x_c)^2 > -r(y_f - x_c)^2 - v - L \quad \therefore \quad (-r(4-5)^2) > -r(4-5)^2 - s \quad \therefore \quad -1r > -1r - v - L\]

and

\[-r(y_n - x_c)^2 > -r(y_n - x_c)^2 - L \quad \therefore \quad (-r(3-5)^2) > -r(3-5)^2 - L \quad \therefore \quad -4r > -4r - L\]

*v and L are positive

These equilibrium exist therefore as long as the costs L and v are positive, as was stated above. This game is also a pure strategy equilibrium because it does not require that the players assign probabilities to signals or actions.

The pooling equilibrium also benefits from a numerical representation. Recall that the pooling equilibrium that existed and its application to this example:

\[\rho(-(y_f - x_m)^2)^2 + (1-p)(-(y_f - x_m)^2)^2 > \rho(-(y_n - x_m)^2)^2 + (1-p)(-(x_c - x_m)^2)^2\]

or
\((-y_f-x_m)^2 > \rho (-y_n-x_m)^2 + (1-\rho) -(x_c-x_m)^2\)

which implies,

\((1-(-(x_c-x_m)^2)) \left((-y_f-x_m)^2/(-y_n-x_m)^2\right) > \rho\)

or more simply,

\(\left(\frac{U_m(y_f)-U_m(x_c)}{U_m(y_n)-U_m(x_c)}\right) > \rho\)

\[\therefore \quad -16r+25r/-4r+25r > \rho\]

\[\therefore \quad 9/21r > \rho\]

Therefore, when the probability that the signal is false is less than \(\frac{3}{7}\), a pooling equilibrium exists.

Finally, the partially informative mixed strategy equilibrium can emerge under the conditions stated above if \(q=(L/(U_c(y_f)-U_c(y_n)))\), where \(q\) is the probability that the FDA will select a policy that is far from their ideal point. Elected officials will be indifferent between signaling \(d_1\) and \(d_2\) if the FDA is mixing with a probability \(q\) of choosing \(y_f\) such that:

\[q=(L/(-1+9))\]

\[q=(L/8)\]

This implies that as the cost of sending a false signal and getting caught increases, so too does the probability that the FDA will choose a policy that is farther from their ideal point, because it is more likely that elected officials will be more sincere in asserting policy positions.
4. Notation

Players

\[ M = \text{Medical Experts (FDA)} \]
\[ C = \text{Congress (and the President)} \]
\[ R = \text{(Public opinion, Media, Interest Groups)} \]

\[ \rightarrow \text{Actors that constrain elected officials} \]

Ideal Points = \( x \)

\[ x_m = \text{Medical Expert Ideal Point} \]
\[ x_c = \text{Elected officials Ideal Point} \]

Policy Proposals = \( y \)

\[ y_m = \text{A policy proposed by the FDA} \]
\[ y_n = \text{A policy proposed by the FDA that is close to their ideal point} \]
\[ y_f = \text{A policy proposed by the FDA median that is far their ideal} \]

Override ranges/Distances (Congressional constraint)

\[ d^* = \text{True level of electoral constraint } d^*(r) \]
\[ d_1^* = \text{True level of electoral constraint } d^*(r=\text{big}) \]
\[ d_2^* = \text{True level of electoral constraint } d^*(r=\text{small}) \]

Signals

\[ d = \text{Signal of electoral constraint } d^*(r) \]
\[ d_1 = \text{Signal of electoral constraint } d^*(r=\text{big}) \]
\[ d_2 = \text{Signal of electoral constraint } d^*(r=\text{small}) \]

Signaling Costs

\[ L = \text{Legitimacy cost when a false signal is made and elected officials are ‘caught’} \]
Institutional Costs

\[ v = \text{Cost of overriding an FDA decision} \]
5. Figures
Fig. 1- The Continuous Case

\[ U_c(y) = -r(y - x_c)^2 \]
\[ U_m(y) = -(y - x_m)^2 \]

*The grey lines represent what the FDA’s utility would look like if their ideal point \( x_m \) were at various intervals.
Fig. 1 - The Discrete Case

\[-(x_c-x_m)^2,\quad -(y_f-x_m)^2,\quad -(y_n-x_m)^2,\quad -(y_f-x_c)^2,\]
\[-r(x_c-x_c)^2-v,\quad -r(y_f-x_c)^2,\quad -r(y_n-x_c)^2-L,\quad -r(y_f-x_c)^2\]
Fig. 3- A Numerical Example

<table>
<thead>
<tr>
<th></th>
<th>(d_1^*)</th>
<th>(d_2^*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>C</td>
<td>y₀</td>
<td>d₁</td>
</tr>
<tr>
<td>y₁</td>
<td>yₙ</td>
<td>d₂</td>
</tr>
<tr>
<td>d₂</td>
<td>M</td>
<td></td>
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<tr>
<td>M</td>
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</tr>
</tbody>
</table>

\[U_c= 1 \ 4 \ 3 \ 2 \ 1 \ 0\]
\[U_m= 0 \ 1 \ 2 \ 3 \ 4 \ 5\]

FDA: \[-25 \ -16 \ -(y_n-x_m)^2, \ -(y_f-x_m)^2,\]
EO’s: \[0 \ -r \ -16r-L \ -r\]

FDAs: \[-25 \ -16 \ -(y_n-x_m)^2, \ -(y_f-x_m)^2,\]
EO’s: \[-v-L \ -r \ -16r \ -r\]
6. Proofs

Proof 1:

Equilibrium will emerge when policy exists at a weighted average between \(-y(xm)^2\) and \(-(xc - xm)^2\), because the median voter doesn’t know what the true value \(d^*\) is and signals are uninformative. The policy that yields the maximum expected utility will be the equilibrium policy outcome.

1) \(F(y)\) represents the CDF of policy \(y\)

2) Assume that \(F(y)\) is uniformly distributed as \(y\): \(Fy\) from \([0,1]\)

3) Therefore, \(f(y)=1\)

4) \(EU(y) = F(y)(-(xc-xm)^2+(1+Fy)(-y-xm)^2)\)

5) \(\max(EU(y)) = f(y)(-(xc-xm)^2+(1+Fy)(-2(y-xm))+f(y)(-y-xm)^2)=0\)

6) \(\max(EU(y)) = 1(-(xc-xm)^2+(1+y)(-2(y-xm))+1(-y-xm)^2)=0\)

7) Here it was useful to substitute in values for policy utility

\[1+(1+y)(-2)(1-y)-(1-y)^2=0\]

8) \[1-2(1-y^2)-(1-y)^2=0\]

9) \[1-3(1-y^2)=0\]

10) \[3y^2-2=0\]

11) \(y=\sqrt{2/3}\)

Proof 2:

1) The expected utility to the Congress of mixing by the FDA given the assumptions made in the appendix will be a function of the probability that the FDA will choose a near or far policy. This utility emerges when Congress then is indifferent between outcomes and is forced to mix strategies given \(d^*_2\).
2) \(q(-(y_n-x_c)^2-L)+(1-q)(y_f-x_c)^2)=(y_n-x_c)^2\) This is based on the assumption that if Congress signals \(d_2\) the Agency will always choose \(y_n\), but that the FDA will mix if congress choose \(d_1\). This restriction makes Congress indifferent between the two.

3) Simplify by substituting in expected utilities of a given value of \(y\):

\[(1-q)(U_n)-L+q(U_f)=U_n\]
\[U_n-qU_n-L+qU_f=U_n\]
\[q=L/(U_f-U_n)\]

**Proof 3:**

Assume \(L=0\)

\[EU_c(n)=(y_n|d_1)=\mu-y_f-x_m^2+(1-\mu)(-(y_n-x_m)^2)\]
\[EU_c(f)=(y_f|d_1)=-(y_f-x_m)^2\]
\[EU_c(n)=EU_c(f)\]
\[\mu-y_f-x_m^2+(1-\mu)(-(y_n-x_m)^2)=-(y_f-x_m)^2\]
\[\mu=(\pi/(\pi+(1-\pi)p)\]
\[(\pi/(\pi+(1-\pi)p)-y_f-x_m^2+(1-(\pi/(\pi+(1-\pi)p))(-(y_n-x_m)^2)=-(y_f-x_m)^2\]

Substituting Bayes law for \(\mu\) and solving for \(p\), without any cost, when \(L=0\), this condition only holds if \(p=1\), and consequently the signal \(p\) is entirely uninformative and talk becomes meaningless. This is a babbling equilibrium because the receiver (agency) can still mix, but the signals are not a meaningful part of the strategy because they in no way vary to reflect true states.
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