The Medical Profession and Prescription Drugs

By Trent McBride
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Any claim that paternalism is an artifact of medicine's past is simply wrong. Even though the culture has improved recently, it still lives with us today and it has no appearances of going away anytime soon. In other industries, service models revolve around a customer who hires someone to serve her needs. In medicine, doctors, with an assist from the federal government, have a dominant position with regard to the patient and have a unique amount of control over their paying customers. Many people may disagree with this characterization, but I fail to see anything different in spite of recent efforts to change this relationship. Patient autonomy does not exist in any way like it should.

In no area is this more apparent than in the prescription-only status of most medicines. It always amazes me that this fact is never called into question, especially among my medical school colleagues. There is no shortage of debate in and about medicine on just about any other topic, but we accept this culture of the gatekeeper almost without question. You would think just once you would here somebody say, "Doesn't anybody find it odd that it is illegal for this patient to by this drug unless I write it down on a little piece of paper and then sign it." Maybe I lack imagination, but I can't think of another aspect of the human experience where one set of people, not members of the government, wield that amount of power over others.

But so it goes, consuming up some of the doctors' and patients' days, scribbling on a pad and turning crime into commerce. Should it be this way? And is there an alternative? Before we answer those questions, we should consider how we got here in the first place.

Economists Alex Tabarrok and Daniel Klein have a wonderful website FDAReview.org where they have a detailed history of the laws passed by Congress and their effects on the FDA's power. In it they write:

> Prior to 1938, consumers could buy any non-narcotic drug without first obtaining a doctor's prescription. Consumers often obtained prescriptions or at least sought the advice of physicians before self-medicating, but were under no legal compulsion to do so.[1]

But in 1938, Congress passed the Food, Drug, and Cosmetic Act which gave Congress broad new powers to regulate drugs through the FDA. A lesser provision of the act stated that some must be labeled "Caution: To be used only by or on the prescription of a physician." Before this, pharmaceutical companies decided whether to sell drugs over-the-counter or by prescription when they began marketing a drug. However, if the FDA later deemed that an OTC drug should have had the previous label, under the FDC Act they could rule the drug "mislabeled" and the company was liable for any harm that stemmed from its use. Now that the FDA had this power, drug companies would have been foolish to sell anything but the most harmless drugs OTC.

Very quickly, the market for medicines changed drastically and drugs were restricted, even though lawmakers claimed that was something they were trying to avoid. The House committee at the time stated, "This bill 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.[1]" Regardless of their stated or real intentions, the obvious effect was to restrict the market for OTC drugs.

This power was further magnified by the Durham-Humphrey Amendment of 1951, which "drew a clearer legal distinction between prescription-only and OTC drugs, and authorized the FDA to classify drugs accordingly,[1]" write Tabarrok and Klein. The previous legislation just gave drug companies an incentive to adopt a de facto prescription requirement. The D-H Amendment codified it into law.

And so it has existed for 50+ years since then that a new class of illegal drugs (with an asterisk) was created. There must be some sound arguments for this practice, otherwise it would not have been adopted and would not have persisted. So what were they? The three most common that come to mind:

- The most obvious is safety. This, of course, is the proposed justification for most legislation, especially in the realm of health care. The assumption is that unknowing consumers must be protected from harmful drugs that, if taken without physician guidance and permission, would lead to adverse outcomes.

- In addition, with the war on drugs that is currently being waged, nobody would dare suggest that certain classes of prescription drugs should be available over the counter. Benzodiazepines, narcotics, barbiturates, etc. would be cheaper to obtain and would have much greater potential for abuse.

- With antibiotic resistance becoming a greater problem, OTC antibiotics would be used for non-bacterial illnesses and would quickly become less efficacious.

As a matter of fact, the prescription-only status for drugs is a prescription of our liberty. The idea that physicians and lawmakers can tell citizens what they can't put into their bodies violates the spirit of human freedom and the moral fact that we as individuals own our own bodies. Indeed, the federal government has gained this power only through a very broad interpretation of constitutional powers. I really don't think anybody would dispute these statements. The dispute arises on whether the arguments stated above justify restricting human liberty with regard to medicine. I will try to show that there is no justification.

It's considered a forgone conclusion that medicines in the hands of unsupervised patients are definitely harmful. During the recent debate to switch Claritin to OTC status, a letter to *The New York Times* read:

> Your May 7 editorial praising the switch of Claritin from prescription to over-the-counter status does not mention the effects such switches have on patients seeking medical attention for serious illnesses.
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> Americans have a tendency to self-medicate rather than seek expert advice if possible. Allergies are serious illnesses, and, especially coupled with asthma, they can kill. Moreover, many individuals benefit from therapies other than antihistamines, but only doctors can properly advise them.
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> The current debate about whether to allow emergency contraception over the counter also illustrates the fact that Americans would choose not to go to a doctor if they could receive medications without one -- a testament to the inability of Americans to see doctors quickly and affordably, and a serious deficiency in our health care system.[2]

But is this necessarily so? It's sure sounds true, but let's be skeptical. Fortunately, there are economists who study the effects of gatekeeping regulation. University of Chicago's Sam Peltzman is one of the preeminent researchers in the effects of regulation. In a 1987 paper entitled "The Health Effects of Mandatory Prescriptions," he investigated this very issue. While acknowledging that by its very nature government regulation is difficult to study in a controlled fashion, he tried to answer the following questions: how has compulsory prescription regulation affected health outcomes across countries with different laws? How have mortality rates from accidental poisonings changed in the US over the 1900's? And what has been the "rate of decrease in infectious disease mortality since 1950[3]" in different countries?

His results were striking. First, he found that the rate of accidental poisoning/overdoses and mortality from poisoning fell steadily from 1900 to 1940 only to begin rising again after 1940 – precisely the time that prescription-only regulation was being introduced to keep such things from occurring. He concluded that such regulation yielded to the common problem of moral hazard – the phenomenon that "drug consumption in these (regulated) countries switches to more potent drugs." "The regulation may lower the risk-cost per-pill, but this shifts consumption toward riskier pills.[3]" Now the rise in drug discovery during this same period could explain some of the rise in accidental mortality, but this just supports Peltzman's conclusion that consumers are willing to take a given level of risk for drug rewards. And regulation has either no or negative effect on those risks while not increasing the reward.

In addition he found "no additional favorable effect" on infectious disease mortality rates "from enforcement of compulsory prescription regulation – that is, no evidence that consumers with a given income and access to doctors were better informed about the life-saving potential of drugs in countries where prescription is required for purchase of antibiotics." He concluded that "consumers are able to understand the value of a doctor's advice even if they are not required to seek it.[3]" This should alleviate fears that switching drugs to OTC would lead to increased mortality from self-diagnosis. I, as does Peltzman, concede that there is great limitation to this study. However, it does not support the idea that gatekeeping improves safety. And more importantly, there is no similar study to find such support.

But there is intuitive evidence that has not been addressed to support the idea that prescription-only regulation actually has other harmful effects. By creating this large barrier to obtaining necessary drugs, patients are put at risk for not having drugs they need for periods of time. Countless times have I seen patients in clinic who come after running out of medications and needing only new prescriptions. Now some would say that this has little effect, and others might reply that patients can just call in for prescription renewals. But just because they could call in, does not mean that they do call in. This does have to be considered when trying to justify this regulation. And any argument over the magnitude of this phenomenon ignores the fact that effect, if it exists, is negative.

A specific argument that definitely falls into the category of "negative" is the prescription status of birth control pills. It's no mystery that this fact causes a lot of people who **need** birth control to not obtain it. I don't have the data, but until shown otherwise, I will assume that the risks of underage (or any) pregnancy are greater than the small risks of thrombosis, malignant hypertension, or cancer. Actually, the University of Washington is conducting a study to experimentally allow OTC birth control pills. However, unfortunately this study simply transfers the gatekeeper status from physician to pharmacist, which still has its own problems. This is a small step in the right direction, but still far from optimal.

More importantly, these regulations increase the cost of all drugs by requiring the patient to expend time in the office, money for the visit, and value of missed work and transportation. Indeed, MIT's Peter Temin, another expert in this field, found that switching drugs from prescription to OTC (with regard to many cold medications) yielded a consumer surplus in the billions of dollars. He did state that this might not apply to all drugs, and every class needed to be looked at individually[4]. But we should operate under the assumption that this regulation imposes costs to all drugs, and then be forced to prove that regulation is necessary. Literally, this regulation is costing consumers an outrageous amount of money, and there is no measured benefit in the form of safety. Where is this money going? (More on that later.)

Moving on to the argument dealing with controlled substances, I must first state that one does not have to be opposed to the War on Drugs (even though I am) to still see the logic of the previous arguments. However, there still is a deficiency in the current system with regard to controlled substances and their prescription status. It drives a wedge between the physician-patient relationship like no other. Patients who are in pain or have anxiety are at the mercy of the doctor, who must decipher whether the patient is being honest. Patients in pain sometimes suffer because they are under-treated due to the current atmosphere of government scrutiny. Patients who are drug-seeking take up physician time and health care resources better spent on real health problems. I will tackle drug prohibition (and especially its effect on health care and paternalism) later in this series.

With regard to antibiotics and the specter of resistance, here lies the one and only one justification I see for any drugs to be available by prescription only. This issue has gained importance over the last few decades as medicine has witnessed the rise of new drug-resistant bacteria that were previously easily handled by antibiotics. The reasons for this are too

numerous to mention here, but one cause is the wide availability and improper use of antibiotics in poorer foreign countries. As Stuart Levy writes in The Antibiotic Paradox:

> …antibiotics are available through the pharmacy without a prescription or they can be bought through the black market. To some extent, the ease of procuring antibiotics relieves some of the problems created by the paucity of medical personnel for these people. Still, a safe balance between the health needs of the people and the efficacy of antibiotics must somehow be realized.
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> While over-the counter sales have been one solution to the problem of too few doctors, the situation has created menacing results. The easy availability has contributed to the emergence and spread of resistant strains so that readily accessible drugs no longer cure common infections. Yet antibiotics continue to be used. Consequently, rather than kill off the disease-causing agent, they enable them to thrive in the patient and spread easily to others.[5]

To switch gears, let's look at two recent examples of drugs that switched to OTC status to much fanfare. In 2003, the heartburn medication Prilosec was granted OTC status. Their price quickly fell from $4 to $1 per pill. In 2002 the allergy medication Claritin underwent the same transformation with a similar fall in price. It amazes me that I have actually heard some physicians say they didn't understand why. When the gatekeeper was removed, supply was no longer artificially restricted and the price was bound to fall. (Claritin was complicated by the fact its patent was set to expire. However, its price fell independent of its patent expiration.)

(Sidebar: As an example of the perverse incentives of health insurance, while the price of the medicines fell, the price the patients had to pay out-of-pocket actually *increased* because OTC meds are not covered by health insurance plans or Medicare. So patients had the incentive to buy the more expensive medicines, increasing the costs for everyone.)

But it important to realize that the increased price due to prescription-only status does not entail the entire increase cost of this regulation. As discussed before, this issue burdens patients with other financial and non-financial costs that they should not have to pay.

Gatekeeping increases the cost of health care, perpetuates paternalistic medicine and infringes on patient autonomy, drives a wedge between the patient-physician relationship, and violates the human moral of self-ownership. In exchange for this, there has been no measurable increase in safety and evidence exists that it is harmful to patient health. I don't know, Monte, I'd like to see what's behind door number three.

That's a pretty raw deal. But if patients lose, who gains? The benefits have to accrue somewhere. And they accrue right into the lap of physicians. Under the pretenses of patient safety, we have supported a system that restricts access to drugs so that patients will be more reliant on our care. By placing ourselves at the top of the drug information hierarchy, with the

government's blessing, we have created a system that artificially increases demand for our services (thus increasing fees) and stresses the service capability of the health care system.

The government sees gain in this system, too. They gain power by being able to mandate the circumstances under which patients can purchases certain products. And it further increases their control over certain substances they deem "harmful" (i.e. narcotics) in an attempt to regulate human behavior. The unspoken truth of the War on Drugs and compulsory prescription status is that neither can exist with out the other, as they have similar justification. If one loses its justification, the other has a very tenuous hold on that same justification.

As Tabarrok and Klein write:

> Licensed doctors, therefore, became deputies and spoilsmen in the growing system of controls. Consumers had to pay for the drug and a visit to the doctor. These new privileges for doctors were the bounty of the government's regimentation of the drug industry and assault on consumers' freedom to self-medicate. Dependence on doctors was further institutionalized and legitimated by making it difficult for consumers to gain information, in particular by the labeling and advertising controls that prohibited information or mandated unintelligibility. Thus, licensed doctors gained wealth and relative status by stripping others of freedom and by dumbing down consumers.[1]

My purpose in writing this is to get health care personnel, especially medical students, to think about this. It is not something that is ever discussed, but it no doubt should be. We must come to terms that this is a violation of liberty, and then ask ourselves two questions. Is this violation justified? And can we look ourselves in the mirror if it is not?

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1. http://www.FDAReview.org
2. Basu, Nina. 2002. Letter to the editor. *New York Times*. May 12, 2003.
3. Peltzman, Sam. 1987. The Health Effects of Mandatory Prescription. *Journal of Law and Economics* 30, no. 2: 207–38.
4. Temin, Peter. 1992. Realized Benefits from Switching Drugs. *Journal of Law and Economics*. vol. 35: 351–69.
5. Levy, Stuart. 2002. The Antibiotics Paradox. pp 286-7.

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