
By Prescription Only ... or Occasionally?

Sam Peltzman

THE RETAIL distribution of pharmaceuticals in the United States follows a familiar pattern. The consumer who wants one type of pain killer buys it off the shelf in the front of the drugstore. If something more potent is sought, a doctor's prescription must be obtained and taken to the back of the store to be filled by a pharmacist. Most of us have grown up with this system, and we rarely think about the division of our pharmacopoeia into "over-the-counter" and "by-prescription-only" drugs. To be sure, there are occasional border skirmishes that force the distinction to our attention. Until 1984, for example, the analgesic Ibuprofen was a prescription-only drug. Then, after some regulatory pushing and shoving, it became available over the counter. But I think it is fair to say that the basic system, which erects a well-policed border between the front and the back of the store, is pretty much taken for granted by manufacturers, retailers, and consumers.

The first time I gave this regulatory system more than passing thought was on a trip to Latin America. There, in the thoroughly modern center of Santiago, Chile, every commercial street had its busy "farmacia." These drugstores looked superficially like their American counterparts, but there was one notable difference. Invariably

the window displays were full of the local versions of well-known U.S. prescription drugs. Often these drugs were being promoted as sale-of-the-week items. I puzzled about this to my hosts: Why do your drug stores take up valuable space to promote prescription drugs to consumers alongside aspirin and cosmetics? In Chile almost all well-known drugs were sold like cosmetics or aspirin: no prescription was required in day-to-day practice. I later discovered that Chile was not unique. Most, though not all, of its neighbors have similar systems, as do many countries elsewhere in the world.

The map provides a summary of what I was able to glean about the international pattern of prescription drug regulation from a survey of individuals and organizations familiar with drug retailing in various parts of the world. Most of the countries surveyed have prescription drug requirements, but many do not enforce them. The map shows, as best I was able to determine, what is true of day-to-day enforcement of "prescription-only" laws.

At first glance, the map simply confirms the fact that regulation is what economists call a "normal good": it tends to increase as a society becomes wealthier. Thus it should not be surprising that very poor countries do not, indeed cannot as a practical matter, enforce prescription requirements. It is hardly practical or beneficial to do so when the nearest doctor is 50 miles away. Nor is it surprising that all of the

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wealthiest countries in the world enforce prescription regulations similar to those of the United States.

It is between these extremes that one finds variety in enforcement practices. One not-so-poor country (Argentina, for example) will enforce prescription requirements fairly strictly while its roughly comparable neighbor (Chile) will not. This variety should encourage some reflection on the U.S. system.

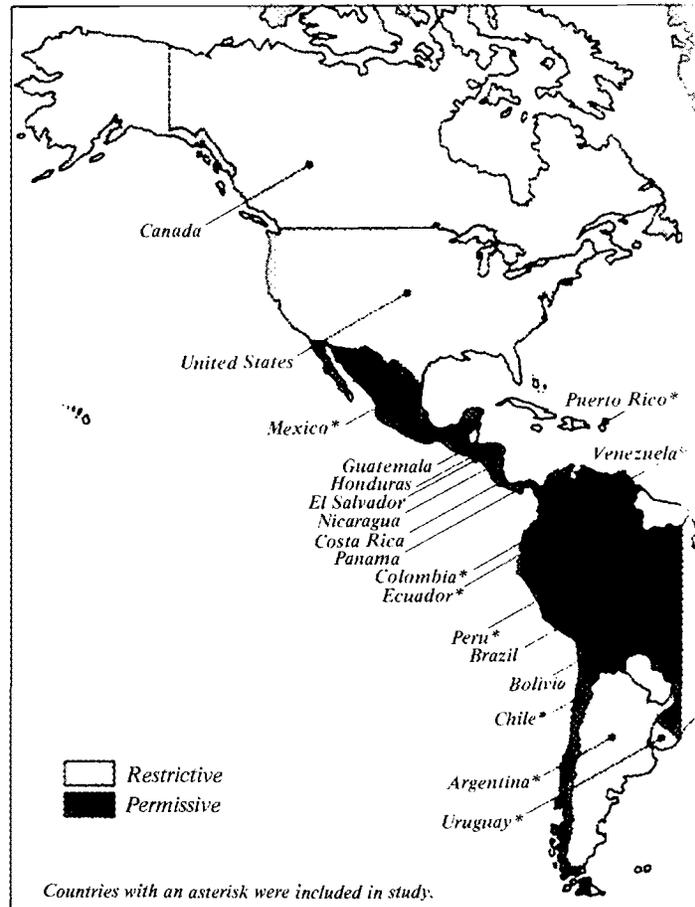
American medical professionals with whom I have spoken often greet this variety in practices with alarm. They are convinced that when consumers, especially relatively unsophisticated consumers in developing countries, have unrestricted access to tranquilizers and antibiotics, they will grossly abuse the former and just as grossly misuse the latter. Some authorities are especially concerned that misuse of antibiotics is fostering the spread of disease-resistant organisms in populations where infectious disease is still a serious public health problem. Undoubtedly they are right to some extent—specific examples of abuse and misuse surely can be found in these countries. But such examples can also be found in countries where prescription regulation is strictly enforced. The harder question that has to be faced by policy makers is whether the degree of drug abuse and misuse is systematically and substantially less when prescription requirements are strictly enforced. The answer suggested by the variety I have alluded to is no. If a country with roughly the same ability as its neighbors to enforce prescription requirements fails to do so, perhaps it does not perceive a very great public health benefit in doing so. This possibility is, I believe, supported by the evidence I have examined.

International Evidence on Health

Though necessarily crude and tentative, the evidence I have compiled suggests that drug abuse and misuse are *not* systematically and substantially reduced where prescription requirements are enforced. Internationally comparable health data are rather sketchy, and, practically, we are limited to examining only gross vital statistics in which are buried the extreme cases—deaths caused by abuse or deaths not prevented due to misuse. In addition, there are factors other than regulation, such as income and medical infrastructure, that might have independent effects

on health. These caveats understood, what do the data show?

Consider first infectious disease mortality (other than from viral diseases). In wealthy countries this form of mortality has been reduced to the vanishing point by antibiotics. In much of the rest of the world, however, infectious disease mortality continues to be substantial. To ferret out the role of prescription regulation I studied differences in infectious disease mortality among middle-income countries where prescription regulation varies. Specifically, for the period 1970 to 1980, I compared a group of such countries that do enforce the regulation (Argentina, Uruguay, Ireland, Israel, Italy, Portugal, Spain, and Japan, also including Puerto Rico) with a group of countries that do not enforce it (Chile, Colombia, Ecuador, Mexico, Peru, Venezuela, Greece, Yugoslavia, Egypt, Hong Kong, Philippines, Singapore, and Thailand). The latter group tends to be poorer than the former and, among middle-income countries, income differences and mortality are



This finding may seem paradoxical, but there is a plausible explanation in drug consumption patterns. If one looks at total drug consumption across countries, there are no discernible differences that are attributable to the degree of enforcement of prescription regulation. But the share of ethical drugs consumed—those that are sold only by prescription in the United States—is considerably higher where prescription regulation is enforced. The available data imply that, all else being the same, enforcement of prescription requirements raises per capita ethical drug consumption by over half. On average, ethical drugs are more potent than over-the-counter drugs. This means they have more potential benefit *and* more potential risk; it is apparently the latter that is reflected in the poisoning mortality differential.

Choices and Risks

This last finding is worth pondering when thinking about the lessons that can be drawn for public policy in the United States. For one thing, it illustrates how subtle and even unexpected are the effects of a seemingly straightforward regulation. The framers of the regulation certainly did not intend for it to stimulate sales of strong drugs. Indeed, the history of U.S. prescription regulation suggests the opposite intent. And from simple first principles, the opposite should have occurred. After all, the regulation is something like a tax on ethical drug sales in that it requires an added expenditure (of time and doctors' fees) over and above the retail price of the drug. That

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tax, standing by itself, should shift sales away from ethical drugs, not toward them. The missing subtlety is that consumers frequently are unsure about the appropriate drug to take. They simply want to "get better" and, before any drugs are purchased, must choose between two general approaches: attempting self-treatment or seeking professional advice. Prescription regulation, by narrowing the range of drugs available

for those who choose self-treatment, tilts the choice toward seeking professional advice.

Consider someone who would, in the absence of the regulation, opt for self-treatment. This, in essence, is a choice to save some time and some money on doctors' fees in return for less information about how to use some drugs—information which is especially important for the most potent drugs. Having made such a choice, the self-treater would tend to shy away from very potent drugs. If the advent of prescription regulation induced this same individual to visit a doctor, the knowledge-based deterrent to consuming potent drugs would be reduced. This is at least one way to understand why enforcement of prescription regulation ends up stimulating sales of more potent drugs. It is not logically inevitable—but neither is it unexpected—that this should also lead to higher poisoning mortality. The doctor's advice reduces the risk involved in consuming potent drugs compared to what it would be without such advice. But it does not necessarily make potent drugs less risky than the drugs that would be consumed if the doctor's advice had not been sought in the first place.

The Origin of Prescriptions

It is always difficult to be precise about the true intent of the framers of any regulation. But it seems fairly clear that the prescription system in the United States did not come into being to stimulate sales of powerful drugs. Quite the opposite; the regulation was shaped by a concern for drug safety. Indeed, it emerged in the aftermath of an episode in the mid-1930s in which an improperly manufactured drug was implicated in several deaths.

Economic historian Peter Temin has ably documented the history of prescription regulation in the United States, and only the briefest summary is necessary here. The 1938 Food, Drug and Cosmetic Act required that every drug bear a label adequately instructing the consumer in the safe use of the product. It said nothing about prescriptions. However, the Food and Drug Administration quickly ruled that some drugs were inherently so unsafe that no adequate label could be written. Such drugs could still be sold, the FDA ruled, but only if the consumer first secured a doctor's prescription. The modern dichotomy between prescription-only and over-the-counter drugs dates from this 1938 ruling. Thus a law

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Temin was struck by the seeming lack of contemporary discussion of the factual basis for such an interpretation. When we examine the

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facts available to policy makers of that day, that lacuna becomes even more striking. In the pre-antibiotics era most drugs were palliatives and contained their share of dangerous ingredients. For example, the active ingredient in the contemporary drug-of-choice for syphilis was mercury. While the vital statistics for that period are not as detailed as those today, it would have been reasonable for policy makers to infer that many accidental poisoning deaths—indeed, a majority of those involving ingestion of non-food substances—were drug related. These mainly drug-related deaths numbered perhaps 1,000 per year, or something under 10-per-million people, when the 1938 act was passed. However, it was also clear that considerable progress had already been made in improving drug safety. The accidental poisoning rate had declined fairly steadily, even dramatically—by about two-thirds over the preceding four decades. This occurred in the face of gradually increasing drug consumption. It was also known that many consumers were seeking physician guidance in their drug purchases even though they were not legally required to do so. About one-third of drug purchases were being made under a doctor's prescription at the time the 1938 act was passed. That share did not increase substantially until the advent of antibiotics a decade later. Thus the unregulated markets for drugs and for information about them had already substantially shrunk the problem that mandatory prescriptions were designed to deal with.

The subsequent history is not without some irony. The 10-per-million accidental poisoning rate of the late 1930s proved to be close to an historical nadir. Within a decade the accidental poisoning rate began to climb, reaching a peak in the mid-1970s at more than twice the 1938

rate. The most plausible reason for this dramatic reversal of the preceding downward trend, according to my analysis of the data, is the marked acceleration of drug consumption engendered by the post-war pharmacological revolution—another reminder that great benefits are not costless. This lesson has to be kept in mind when one tries to link the current experience of less developed countries with U.S. history. The fact that prescription requirements in developing countries engender both higher sales of ethical drugs and higher poisoning mortality is not peculiar to those countries. The post-war experience in the United States reveals the same concomitant increase in the sale of powerful new drugs and in poisoning deaths.

Thinking the Unthinkable

What lessons are there in the American and foreign experiences? First, I believe the intellectual basis of prescription drug regulation needs to be reexamined. Let us, for a moment, think the unthinkable and suppose that we did away entirely with the regulation. What would happen? Most likely, given the evidence I have reviewed here, the number of deaths from drug abuse would *decrease*. This is not because consumers are receiving inadequate advice from their doctors. Instead, it is because of the apparent conservatism of many consumers: if given the option of not seeking a doctor's advice first, the evidence suggests that consumers are likely to shift from consuming more potent ethical drugs toward consuming generally less potent over-the-counter remedies. Now one might decry such a shift as

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ill-informed or worse. But to do so would acknowledge a new rationale for prescription requirements, one based on some need to embolden consumers to seek more medical advice. Even if such a need exists, we should understand the consequences of fostering it through prescription requirements. Prescription drug

requirements do not promote safety; they promote a particular pattern of drug consumption in which immediate safety is sacrificed in order to obtain more prospective benefit.

We should not expect those benefits to include any perceptible reduction in deaths from treatable illness. The foreign experience implies that, at least in the case of infectious disease, life-threatening illness is treated in about the same way whether or not there is a prescription requirement. Again, that finding should not be misinterpreted to imply that professional treatment is useless. Recall that prescriptions were common in this country before they were required. They are also common today in countries that do not require them. The lack of any connection between prescription requirements and infectious disease mortality appears to reflect similar treatment patterns for life-threatening infections among patients with similar incomes and access to medical advice. In cases of extreme risk to life, the prescription requirement is superfluous. It is in the more subtle cases involving tradeoffs between the benefits of reduced discomfort and disability, on the one hand, and the costs of more drug safety risk, on the other, that prescription requirements appear to tip the treatment patterns toward more risk.

Of course, to jettison the prescription drug requirement is unthinkable in the U.S. context. Here the relevant policy issue is whether to move particular drugs from the back to the front of the drug store. But thinking about the unthinkable should provide a useful perspective on that issue. It should remind us that increasing the spectrum of risks *available* to the consumer does not necessarily increase the *actual* risk consumers choose to take. Relatively unsophisticated drug consumers in other countries tend to choose less risk when they can buy most anything over the counter. This may not be true in this country for every drug that might be moved to the front of the store. But U.S. law and practice has for almost 50 years simply assumed the contrary. For this there was no factual basis in 1938, and there is none today. □

Selected Readings

Peltzman, Sam. "Health Effects of Mandatory Prescription Regulation," *The Journal of Law and Economics* (October 1987).
 Temin, Peter. *Taking Your Medicine*. Cambridge: MIT Press, 1980.
 ———. "The Origins of Compulsory Drug Prescriptions," *The Journal of Law and Economics* (April 1979).



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