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Columns: A World Without the FDA

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Back in 1980 I had the good fortune to spend a summer in Santiago, Chile. My woeful high-school French produced an even more woeful Spanish, but I was able to travel about that beautiful country with wonderful people.

In the middle of my stay I developed a fearful cold and wandered into what looked like a drugstore in search of comfort for my ailing throat, nose, and head. I picked up a bottle of this, a bottle of that, and tried to puzzle out their purposes. I quickly realized that my command of Spanish, while adequate for getting around on the bus or in the grocery, was a major handicap when trying to figure out the ingredients and expected impact of any of the products lining the shelves.

As I stood there peering at labels, it occurred to me that there probably was not a Chilean equivalent of the Food and Drug Administration. I remembered the time my father had surgery overseas. His post-operative condition was an emotional roller coaster: he found out later that he had been given cocaine as an anesthetic.

My problem went beyond my language deficiency: I was about to take on more risk than I was accustomed to in the United States. After years in the risk-free world of the American pharmacy, I was uneducated and unprepared for the choices on the shelves before me. I decided to endure my ailments drug-free.

My ignorance was the rational result of growing up in a world where the drugs that have any impact are only available by prescription and the ones available over the counter are about as dangerous as the candy in the next aisle. But if there were no FDA and if any drug were available over the counter, my incentives to become educated would change.

Voluntary Testing

The world would change in all kinds of interesting ways. Let's try to imagine what that world might look like. No FDA. No prescriptions. Any drug could be sold over the counter. And for simplicity, when I speak of drugs I mean purely medicinal drugs, even though my father's experience might make that a tough line to draw in practice.

Would drug companies test their drugs if tests were voluntary? I don't think drug companies' profits would be enhanced if their customers died from using their products. They would test their drugs. Would they test them as thoroughly as they are required to do now by the FDA? I doubt it.

Drugs would be riskier. Is that good or bad? We tend to think of drugs as safe or unsafe. But no drug is completely safe. The only way to avoid the side effects of drugs is not to take them. And most of us understand that as long as the risk is small enough and the benefits large enough, putting foreign substances into our bodies is a good idea.

What is more difficult to accept is the possibility that a drug can be "too safe." Under current drug regulations, it takes years of testing to get FDA approval. There is no free lunch: making drugs as safe as the FDA requires has costs.

Some worthwhile drugs for uncommon diseases never make it to market because the costs of proving their safety and effectiveness aren't worth it. Other drugs are worth it, but while waiting for FDA approval, people are dying or suffering. Finally, there are risky drugs the FDA rejects but that a patient might be willing to take a chance on. Without the FDA, there would be a lot more choice in the marketplace.

And with choice comes a lot more risk. That increase in risk would encourage consumers to become more educated. You could insulate yourself from that risk by using your doctor as you do now: as the gatekeeper to the dangerous world of drugs. But we would have the freedom to have a different relationship with our doctors. Many of us would take greater responsibility for our decisions by using a doctor as a resource rather than as a surrogate parent.

Most of us will not want to master the effects of drugs, even with a doctor's help, so we will also have a demand for other sources of good information. With the government out of the business of risk control, there will be a large profit opportunity to provide reliable information on drugs and how they work. The Internet is one way to provide that information.

Perhaps a private nongovernmental version of the FDA would come into existence akin to Underwriters Laboratory or *Consumer Reports*, certifying drugs as having a particular effect on an ailment or not having particular side effects. Such testing would be expensive, but drug manufacturers and consumers might be willing to pay a premium for drugs that had been extensively tested and certified independently. There might be different organizations with different standards of effectiveness or safety certifying the effects of drugs.

All of the above is mere speculation, an attempt to fathom how the market might respond to the intense demand for information in a riskier world. I can only begin to guess how the market might solve that problem.

All I know for certain is that a world without the FDA and without prescriptions would have more personal responsibility and more choice.

I also know for certain that there would be tragic outcomes as well. Without the protection of the government, some people would be taken advantage of by unscrupulous drug manufacturers and deceptive marketing. Some people would hurt themselves taking the wrong drugs or neglecting various drug interactions.

But others would be saved by the wider and earlier availability of life-saving drugs.

Would a world without an FDA and prescriptions be a better world? The answer depends on how many lives would be lost from mistakes and how many lives would be saved by the wider and earlier availability of drugs. It would also depend on the value you place on putting responsibility in our own hands rather than having the government take responsibility for us.

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