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[COMMENTARY](#)

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In the Spotlight

An Information Prescription for Drug Regulation

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Americans reading about the sorry state of drug regulation in China—an unhappy mixture of ineptitude and corruption—can be forgiven their sense of superiority. Flawed though it may be, the FDA has managed to keep antifreeze out of our medicines for the last 70 years and none of its administrators now awaits the death penalty. Still, we are not entitled to complacency. It's clear that some dangerous and ineffective drugs have garnered FDA approval. Less well known, yet perhaps more costly overall, is that in the name of promoting safety, some potentially beneficial drugs have been denied access to the market as well.

Relaxing the standards for allowing a drug to enter the market while simultaneously elevating the standards for remaining in it may help solve both of these problems. Maximal disclosure of information to the public is the key.

Congress, in its 1962 amendments to Section 505 of the Food, Drug, and Cosmetic Act, dictated that a drug cannot be sold until its seller demonstrated that the drug is both safe and effective. The 1962 amendments passed Congress in a unanimous vote, with no resistance from industry, and today "safe and effective" drugs remain one of the most popular achievements of American regulation. Yet close scrutiny reveals that Congress handed the FDA an impossible task. "Safe and effective" are variable standards—criteria based inherently on personal preferences, individual values and unique tolerances for risk. Nonetheless, the FDA was asked to apply them as absolutes.

No drug can be absolutely safe. Indeed, all drugs are poisons. They are taken in small doses in hopes of poisoning a specific biological process—inflammation, or bacterial growth, say—without poisoning the host. Drugs vary in their margins of safety, but none are without dangerous side effects. (Even over the counter drugs, which are generally considered very safe, come with extensive warning labels.) Likewise, no drug is perfectly effective. As Dr. Nortin Hadler wrote, even with the best possible drugs, death rates will remain the same: one per person.

Because the standards are subjective, bureaucrats can no more determine whether a drug is safe and effective than they can determine that your light beer is less filling and tastes great.

Another problem vexing the drug approval process is that the law simply has not kept up with the times. In 1906, when snake oil salesmen overran the drug market, we needed the Pure Food and Drug Act and a strong sheriff to enforce it. In 1938, when prescription drugs were not yet even a formal legal category, the Food, Drug, and Cosmetic Act sent an important message about safety. In 1962, when doctors were dominant, patients were docile, and Al Gore was a sophomore at St Albans not even contemplating the Internet, informational asymmetries might have justified an arbitrary application of the safety and effectiveness standard. But we are living in different times.

In 2005, the FDA issued its first race-based drug approval, the antihypertensive drug BiDil, for prescription to African-American patients. Over the next decade, it's not too hard to imagine, the secrets of the human genome will be unraveled to the point that one might predict whether a given drug is going to be helpful (i.e., safe and effective) not just for a given racial group, but for a given individual. In that setting, rigid standards for safety and effectiveness will be a Procrustean Bed that harms patients.

American consumers need access to all drugs which meet a minimum threshold for safety and effectiveness (we don't want to revert to the snake oil days) and, beyond that, the information with which they can determine whether a particular drug is valuable or useful *for them*.

We therefore propose a new standard: A drug should not be introduced until its seller demonstrates that it has collected and shared enough information for the public to make informed choices about safety and effectiveness; and the drug should not be allowed to remain on the market unless its seller continues to collect and share such information. The primary role for the FDA, thus, is to determine what studies must be done, validate the results of these studies and ensure that all needed data are readily available to the public.

In this model, the FDA becomes more like the SEC. The Securities and Exchange Commission correctly recognizes that it can't certify a stock as a "safe investment" or, for that matter, an effective one. What the SEC tells investors is that the information shared by firms is reliable. The SEC has stated "only through the steady flow of timely, comprehensive, and accurate information can people make sound investment decisions." Likewise, a steady flow of timely, comprehensive, and accurate information on a drug's safety and effectiveness allows patients and their doctors to make sound ongoing decisions regarding the consumption of a drug.

The current FDA drug approval system is binary when it should be nuanced; it commands when it should inform. Applying generic utility values to an indeterminate statutory mandate, as the FDA does today, is fundamentally disdainful of consumers' preferences and contemptuous of their autonomy. What Americans really want is not a bureaucrat's blessing for a given drug but information to make their own decisions. The people who choose drugs should be empowered to go intelligently after what they want and abide by the consequences.

Because patients and their physicians cannot make wise choices without data in hand, gathering, validating and disseminating information lies at the heart of the FDA's "safe and effective" regulatory mission.

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