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The Vital Mission of the U.S. Food and Drug Administration

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Regulating pharmaceutical drugs and tobacco products is one of the most important and widely appreciated activities of the U.S. government. The budget of the Food and Drug Administration may be relatively small. But this agency, typically dubbed "the FDA," has a much greater impact than other parts of the federal government that spend much more each year. For Americans and people across the globe, lives and physical and mental health are at stake – and so are the operations and profits of major industries. U.S. regulations work well, but they could be undermined by surprising trends in today's federal courts.

The Authority to Keep Food and Drugs Safe

America's internationally influential system of pharmaceutical regulation was shaped by three milestone laws. Each was enacted by Congress at the urging of social movements and professional experts (including, in the case of later laws, experts employed at the FDA):

- The **Pure Food and Drug Act of 1906** gave the federal government clear authority over the safety of foods and drugs sold in interstate commerce, and authorized the agency that later became the FDA to prevent the distribution of "adulterated" foods and drugs.

- The **Food, Drug, and Cosmetic Act of 1938** required any new drug to be reviewed and approved by the FDA *before* being marketed.

- The **Kefauver-Harris Drug Amendments of 1962** added the requirement that drugs be effective, laying the foundation for the modern system of clinical trials for new drugs.

How Pharmaceutical Regulation Works

Over the years, the FDA has developed a reputation for effective regulation by honing and deploying three kinds of powers:

- **Directive** powers are exercised when the FDA issues commands backed by the force of law to private parties such as manufacturers.

- **Gatekeeping** powers come into play when the FDA vetoes the marketing of a proposed new commodity. This power has led companies to try to anticipate which products will be accepted, or not, and adjust their commercial development strategies accordingly. The effects are therefore felt even when the agency takes no new steps.

- **Conceptual** powers refer to the FDA's influence on scientific ideas and technical methods. When the FDA stipulates that only a certain form of clinical trial or statistical test will suffice to prove that a new drug is safe and efficacious, drug companies, medical schools, and research hospitals take note. They invest in the approved kinds of trials, and their experts learn to work with the appropriate scientific methods.

What are the effects of these measures to regulate drugs? Most obviously, FDA regulations ensure that drugs on the market are safe – and that they do what they are supposed to do to save lives and promote health. Hazardous drugs can, and have, cost tens of millions of lives.

Even more importantly, U.S. pharmaceutical regulation has created a market where producers and purchasers can operate with confidence. Government regulations are often portrayed as "interfering" with market forces, but in many ways the opposite is true. Modern economic markets depend on public regulations to establish a basis for stable expectations about product safety and quality, about fair play, and even about reasonable pricing.

The pay-offs from well-regulated markets can be huge. One of my research teams is currently developing a statistical estimate of the effects of FDA decisions in the 1970s to remove hundreds of drugs from the market on the grounds that they did not deliver the health benefits they promised. Our preliminary results suggest that tens of thousands of lives may have been saved. And companies and researchers were encouraged to put their efforts into useful innovations.

Regulating Tobacco Too

Recent policy changes have bolstered the FDA's authority to regulate tobacco. Enacted in 2009, the Family Smoking Prevention and Tobacco Control Act was the fulfillment of decades of efforts by tobacco control advocates and public health officials. One the most comprehensive tobacco-control policies launched by any nation, this law authorizes the FDA to restrict tobacco sales and advertising near schools and other places where children are located, and it authorizes graphic health warning labels to be placed on each cigarette pack. Tobacco companies must secure the approval of the FDA before they market new tobacco products; and the FDA is developing new forms of risk analysis for tobacco products.

Will Activist Judges Undermine Regulation?

The Food and Drug Administration faces surprising threats from rulings in the U.S. federal courts. Since the late 1970s, some activist judges have ruled that America's constitutional protections for free speech apply to commercial advertising – in essence, that companies can advertise claims even when they misrepresent the safety or efficacy of their products. Some judges have struck down the FDA's requirement of graphic warning labels on cigarette packages on the grounds that they impose an unconstitutional restriction of speech; and one appeals court ruled that a man convicted for marketing a medicine for uses not tested or approved by the FDA should not have been prosecuted, because of his constitutional right to commercial free speech.

This judicial movement is quite radical. Over the first two centuries of the American republic, no court ever held that the First Amendment prevented government regulation of commerce. Even before the federal government became strongly involved, state and local governments regulated advertising without any worry that commercial parties enjoyed the same speech rights as individual citizens. The recent judicial moves to

treat companies like individuals could, over time, eviscerate the health and safety regulations so carefully built up over many decades by Congress and the Food and Drug Administration. Ironically, judicial steps taken in the name of promoting free markets could have the effect of undermining the delicate web of trust and mutual expectations that actually function to make U.S markets work quite well.