



HEALTH OPTIONS FORECLOSED How the FDA Denies Americans the Benefits of Medical Research

The desire to live longer, healthier lives has been a driving force throughout human history. New technology in this century offers the potential for many people to achieve both parts of this desire—by detecting diseases before symptoms begin, being treated or cured by individually targeted drugs, and using 3-D-printed medical devices such as hands and organs. But major medical innovations hit major roadblocks when they reach the Food and Drug Administration (FDA) for premarket approval, where institutional risk aversion is impeding the availability of new treatments and procedures.

A new study for the Mercatus Center at George Mason University explains how the FDA's inability to keep up deprives Americans of health options that could result in longer lives and greater quality of life. The study urges policymakers to reform the FDA in favor of more innovation, allowing market forces to monitor risks and minimize harm.

To read the study in its entirety and learn more about its authors, Richard Williams, director of the Mercatus Center's Regulatory Studies Program, Marc Joffe of Public Sector Credit Solutions, and Mercatus MA Fellow Ariel Slonim, see "[Health Options Foreclosed: How the FDA Denies Americans the Benefits of Medical Research.](#)"

KEY FINDINGS

The FDA's static structure is not aligned with dynamic changes in research and technology, and is not designed to confront current and future public health challenges. In fact, the FDA owes much of its power to reactions following significant events in the market. For instance, hype related to Upton Sinclair's *The Jungle*, a nightmarish exposé of the meatpacking industry, contributed to the passage of the 1906 Food and Drug Act. This law required truth in labeling and laid the foundations for the FDA.

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The FDA has kept tremendous scientific breakthroughs from being used to treat US patients by denying or holding up premarket approval for new technologies. This has led some medical manufacturers to set up shop overseas and has encouraged medical tourism among patients.

- *Cellular therapy.* Cultured stem cell therapies offer nonsurgical treatment options for orthopedic conditions and provide the potential to treat neurodegenerative conditions such as ALS (amyotrophic lateral sclerosis), multiple sclerosis, and Parkinson's disease. But the FDA has not approved a single one of these treatments in 15 years.
- *Big data and the Internet.* The company 23andMe used to offer \$99 genetic testing kits that analyzed 600,000 genetic markers for ancestry, drug responsiveness, and predispositions to more than 90 medical conditions. The FDA intervened in 2013 amid fears consumers would respond to results by requesting unnecessary medical tests and life-changing procedures. Though the FDA has approved a limited set of 23andMe's services, the company is still barred from providing many of the tests it used to offer, ruining an opportunity to gather more genetic data for research.
- *Synthetic biology.* Treating US patients for diabetic foot ulcers costs \$9 billion to \$13 billion each year. Yet a treatment developed in Cuba, which has shown great promise for 165,000 patients in 26 countries, is not allowed in the United States because of the Cuba trade embargo and the costly FDA trial process. Similarly, antiaging therapies that may reverse organ system degeneration and effectively treat Alzheimer's disease face expenses of \$1 billion or more in the FDA clinical trial process.

The FDA's focus has shifted from ensuring that the public has complete and accurate information about drugs to exercising strict regulatory oversight of their manufacture and use. At the same time, the world itself has changed while the FDA has failed to keep up: science is poised to make rapid improvements to both human health and human longevity that were not possible in the 20th century. More data is now available to patients, physicians, and insurers than ever before, which means that unsafe or ineffective products and their makers face the rigor of market rejection and judicial remedies.

Legislative efforts that make only small changes to the regulatory system, while granting the FDA new authority, will not solve the problems with the FDA. This approach continues to reinforce the old model that puts the FDA at the center of medical product innovation.

Costs of missed opportunities are ignored. The FDA's restrictive regulatory policy itself is not risk free. Real harm can result from severely limiting patients' access to innovative treatments and hindering medical discovery.

CONCLUSION AND POLICY IMPLICATIONS

The FDA's multiple and expensive requirements prevent Americans from accessing the best possible treatments—cultured stem cell therapies, diabetic ulcer medications, genetic tests, and antiaging drugs, to name a few. Americans should not be denied the potential to improve their life expectancy and quality of life. We need new ways to get new treatments to market while

protecting patients from dangerous treatments. The medical treatment approval system should rely on premarket middlemen—private approval bodies similar to Underwriters Laboratories and Good Housekeeping in other industries; postmarket consumer monitoring by patients, physicians, and insurers; and the tort system—to enable lifesaving treatments to reach Americans more quickly.