

# Gingrich: Why we need a 21st century Food and Drug Administration

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Today, we are on the cusp of an explosion of new science that will create new opportunities in health, agriculture, energy, and materials technology.

Breakthroughs in brain science, in particular, will open up enormous opportunities for cures and treatments for Alzheimer's, Parkinson's, autism, mental illness and learning disabilities.

Agriculture will continue its two-century-long march to greater productivity and greater capability.

This knowledge will present us a historic opportunity to save lives, lower health costs and create millions of high-paying American jobs.

In order to take advantage of this new knowledge, however, we need a new 21st century Food and Drug Administration. The current obsolete, adversarial, inefficient, and obstructive FDA is a dangerous obstacle to life-saving innovations and dynamic American job creation.

The reach of the FDA cannot be underestimated: Nearly a quarter of all

products Americans consume are regulated by the FDA. Every drug and medical device we use, as well as nearly 80 percent of our food supply must pass FDA muster before heading to the market.

Americans deserve a fair and competent regulatory regime that emphasizes both consumer safety and ensures that life-saving breakthrough products get from our labs to our pharmacies and homes as efficiently as possible. Unfortunately, the FDA falls well short of this expectation, and its stagnant bureaucracy has only gotten worse in recent years.

According to the National Center of Education and the Economy, clinical trials now take 21 percent longer and require two to three times as many participants as they did in the late 1990s.

The Cato Institute estimates that it now takes up to 15 years to complete the FDA's development, testing and review requirements to get new lifesaving drugs to patients.

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Every extra day of delay allowed some patients to die and others to get sicker. Every extra day of delay raised the cost of drug development and reduced the number of companies that could afford to develop a breakthrough.

The brilliant entrepreneur who used to create new jobs and new products that made America the world's leader in scientific innovation cannot get the financing to survive a 10- to 15-year government bureaucratic process.

Josh Makower, a Stanford University professor and founder of six medical device companies, told a House committee in February that because of the regulatory environment at the FDA, "...investment is drying up, companies are moving overseas or closing their doors and U.S. patients are being denied timely access to safe and effective new medical products."

The goal of a new 21st century FDA must be to ensure that in America knowledge moves to market so rapidly that no other country in the world can compete with us in developing and marketing new solutions for health, food, energy, and materials technology. It should be designed so individual entrepreneurs and small teams have as much ease of access and opportunity to succeed as giant companies.

As the world becomes more prosperous people everywhere will want better health, better diets, more energy and better materials technology. If the United States modernizes its FDA and shifts its tax policy to encourage innovation we will create tens

of millions of new, high-paying, wealth-producing jobs as the world leader in translating biology into better living.

That is why we need a 21st century FDA now.

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