MANHATTAN INSTITUTE FOR POLICY RESEARCH

Press Release

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New Report
The Digital Future of Molecular Medicine:
Rethinking FDA Regulation

New York, NY: Rapid advances in the science of personalized medicine are being slowed by an outdated regulatory system that relies on 50-year-old statistical models to evaluate new medicines, according to a new Manhattan Institute report, **The Digital Future of Molecular Medicine: Rethinking FDA Regulation.** Senior fellow Peter Huber presented his new report at a Manhattan Institute conference featuring influential stakeholders in the debate over biomedical innovation and FDA regulation.

"This has been an insider issue for far too long. We have the technology, innovation, and investor support, now we need the FDA to modernize." –Lawrence Mone, President

"During my tenure as commissioner of the U.S. Food and Drug Administration…it became increasingly clear to me that a revolution in biomedical science augured the need for significant changes to assure the future success of the agency." -Dr. Andrew von Eschenbach, Former FDA Commissioner (From Foreword)

Because the FDA has not found a way to fully incorporate cutting-edge discoveries from fields like genomics into new clinical-trial designs, countless patients may not get the drugs they need. Huber argues that combining the information-technology revolution with advances in molecular biology will unleash unprecedented advances for the treatment of complex diseases like cancer—but this transformation requires fundamental reform of FDA policies that base new drug approvals on how the "average" patient fares in large clinical trials.

Report Summary

- **Part One: The Biomedical Revolution**
  - Patients are kept from life-saving drugs they need not because of a lack of innovation, technology, or money, but because FDA protocols have not kept pace with medical advancements. Biochemists have the tools to design a drug that can inhibit almost any molecular target. Led by a rapidly growing group of companies as diverse as IBM, Myriad Genetics, and 23andMe, the digital community has grasped—far ahead of the FDA and much of the medical community—how fast molecular medicine can advance by taking full advantage of the recent convergence of astonishingly powerful molecular and digital technologies.

- **Part Two: A Path Forward For the FDA and Congress**
    - The FDA is using antiquated, randomized, "double-blind," placebo-controlled trials to evaluate new medicines. This mismatch between science and regulation has critical implications for patient health.
    - The FDA should fully embrace the latest advances in molecular biology, using adaptive clinical trials and powerful new statistical tools that will allow companies to safely match promising new drugs with the patients most likely to benefit from them and least likely to suffer serious adverse effects.
    - The FDA's one-size-fits-all regulatory pathway has become breathtakingly expensive and time-consuming: it takes well over $1 billion and a decade to develop a single FDA-approved medicine, according to recent estimates. These enormous sunk costs mean that some diseases will never be cured, because it costs too much to develop drugs for them.
    - The FDA recognizes its system is outdated and has already taken initial steps to implement several of these tools, particularly for some cancers, HIV/AIDS, and some rare diseases. But the agency needs Congress to mandate additional reforms before it can fully embrace these new protocols.

Peter Huber is a senior fellow at the Manhattan Institute specializing in the issues of drug development, energy, technology, and the law. Previously, Huber served as an assistant and later associate professor at MIT for six years. He clerked on the D.C. Circuit Court of Appeals for Ruth Bader Ginsburg, and then on the U.S. Supreme Court for Sandra Day O'Connor. Huber also is a partner at the Washington, D.C. law firm of Kellogg, Huber, Hansen and Todd. He is the author of *The Bottomless Well* (2005), co-authored with Mark P. Mills, and the forthcoming book, *The Cure in the Code: How 20th Century Law Is Undermining 21st Century Medicine* (Basic Books, November 2013). Huber earned a law degree from Harvard University and a doctorate in Mechanical Engineering from MIT.

Project FDA *is a Manhattan Institute initiative that aims to reform the FDA to meet 21st century challenges. Under the leadership of former FDA commissioner Dr. Andrew von Eschenbach, Project FDA promotes reforms that can enable the FDA to offer a more predictable, transparent, and efficient pathway for bringing safe and effective new products to patients.*

The report is available at www.manhattan-institute.org/html/fda_06.htm. **If you would like to schedule an interview with Peter Huber, please contact Laura L. Eyi at 646-839-3313 or** leyi@manhattan-institute.org.

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