



PRESS RELEASE

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*How much do delays in the
FDA's mandated drug-development and approval process cost patients?*

CLINICAL TRIAL DELAYS COST PATIENTS FAR MORE THAN DRUG COMPANIES

Washington, DC—Drug-development delays resulting from FDA regulations cost patients far more than they cost producers, according to a new report released today. The report, “**Cost of Caution: The Impact on Patients of Delayed Drug Approvals**,” is sponsored by the Manhattan Institute’s Project FDA.

In an effort to ensure drugs are safe and effective, FDA regulations governing the testing of new drugs can add months and years to the time it takes to bring new medicines to patients. While safety and efficacy should be a priority, the current testing process must be balanced with an understanding of the costs of too much caution.

For the first time ever, using a new calculation, authors Tomas Philipson, Ph.D., of the University of Chicago, and Eric Sun, M.D., Ph.D., of Stanford University, assign a price to the unrealized benefits of quicker access to lifesaving medicines—specifically, putting a price tag on the value of longer lives that would have resulted from getting new drugs to patients faster. The authors also offer a list of reforms they would like to see tried in order to accelerate the process.

While traditional cost estimates of drug development have focused on losses to producers, the authors argue that those calculations do not fully capture the costs to patients of shortened life spans. By calculating what patients are willing to pay for earlier drug access and thus longer life, the authors find the most exorbitant costs lie with patients.

The authors looked at three drugs (designed to treat HIV/AIDS, breast cancer, and non-Hodgkin’s lymphoma, respectively) and found that for all three combined, the monetary value that patients assigned to the benefits of access one year earlier would have equaled \$27.3 billion, while increased producer profits would have totaled only \$4.9 billion. The patients’ potential benefits become costs when the benefits remain unrealized.

With the FDA starting hearings and meetings regarding the reauthorization of the Prescription Drug User Fee Act (PDUFA), Congress has a critical opportunity to expand on the legislation’s original goals—in part, streamlining the drug-development process. Armed with this report’s findings, Congress should be able to make more informed decisions and help the FDA grant patients faster access to more innovative drug therapies.

Highlights of the study's findings include:

- To the entire cohort of HIV/AIDS patients, the benefit of just a year's earlier access to the drug HAART would have been worth \$19 billion, while the profits of the firm marketing it would have increased by only \$4 billion.
- To the entire cohort of breast-cancer patients, the benefit of a year's earlier access to the drug trastuzumab would have been \$8 billion, while the profits of the firm marketing it would have increased by only \$730 million.
- To the entire cohort of non-Hodgkin's lymphoma patients, the benefit of a year's earlier access to the drug rituximab would have been \$310 million, while the profits of the firm marketing it would have increased by only \$260 million.

The authors would like to see the following reforms tried in order to streamline the development process:

- *Allowing the payment of stipends to clinical-trial volunteers.* Doing so, after obtaining informed consent, would address the paralyzing shortage of volunteers.
- *Relying on biomarkers.* Biomarkers are by-products of disease processes (such as elevated numbers of CD4 cells in AIDS cases) or indicators of disease risk (such as cholesterol levels). Increasing their use would allow researchers to estimate the likelihood of a treatment's success before completion of full clinical trials.
- *Offering FDA regulators performance incentives.* These could expedite the identification of promising new treatments or the evaluation of new guidelines for clinical trials.
- *Establishing an ombudsman.* Such an official would review the impact of FDA regulations and practices on drug-development times.

The study can be accessed online at http://www.manhattan-institute.org/html/fda_02.htm. To schedule an interview with the authors, please contact Jonathon M. Seidl at (646) 839-3313 or by e-mail at jseidl@manhattan-institute.org.

About the authors:

Tomas J. Philipson is chairman of the Manhattan Institute's Project FDA. A managing director at Precision Health Economics, Philipson is also the Daniel Levin Chair in Public Policy at the Irving B. Harris Graduate School of Public Policy Studies and a member of the Department of Economics at the University of Chicago. In 2003-2004, Philipson served in the U.S. government as senior economic adviser to the commissioner of the Food and Drug Administration (FDA), and from 2004-2005 he was senior economic adviser to the administrator of the Centers for Medicare and Medicaid Services. He is the recipient of several international and national awards, including the Kenneth Arrow Award of the International Health Economics Association in 2000 and 2006 (for best paper in health economics). Philipson earned his undergraduate degree in mathematics at Uppsala University, in Sweden, and his M.A. and Ph.D. in economics from the University of Pennsylvania.

Eric Sun is a resident in the department of anesthesiology at Stanford University and a visiting fellow at the Bing Center for Health Economics at the RAND Corporation. His research has examined the costs and benefits of medical research and development, the role of the FDA and product liability in ensuring drug safety, and the economics of global public health. Sun's work has been published in the *Journal of Health Economics*, the *American Journal of Managed Care*, the *Journal of Public Economics*, *Health Affairs*, *Health Economics*, *Health Services Research*, and *BE Press Forum for Health Economics*. He holds an A.B. in molecular biology from Princeton University, an M.D. from the University of Chicago, and a Ph.D. in business economics, also from Chicago.

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