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Project FDA Report

Medical Innovation Hampered By Conflict-of-Interest Rules

New York, NY: While some level of regulation is necessary to protect the general health and welfare of the public, growing conflict-of-interest rules in medical industries are proving wrong the old adage "better safe than sorry." A new report by Manhattan Institute visiting scholar Richard Epstein and published by the Manhattan Institute's Project FDA, "How Conflict-of-Interest Rules Endanger Medical Progress & Cures," details the impact of growing conflict-of-interest mandates on the development of potentially lifesaving drugs and technologies.

Government agencies and research institutions oversee the research, production, and marketing of new drugs and medical technologies. However, recent conflict-of-interest regulations go far beyond the prevention of real conflicts to chase ever more "potential" or "apparent" conflicts. Rare cases of corruption among scientists and drug companies are leading a public overreaction that is generating broad conflict-of-interest rules to limit the collaboration of physicians, scientists, and universities with drug and medical technology companies.

In his report, Epstein explores the unintended consequences of these conflict-of-interest regulations and offers pragmatic solutions.

Conflict-of-Interest Rules Consequences:

- **The FDA** requires the public disclosure of the financial ties and payments of potential experts for its drug approval committees. The result: Nearly one-third of all drug approval committees remain unfilled.
- **The National Institutes of Health (NIH)** forbids any communication between its scientists and scientists working in the private sector. The result: Premier experts in both sectors are denied the free exchange of ideas essential to medical innovation.
- **Prominent medical societies** restrict their physician members from accepting fees from pharmaceutical companies for participation in presentations marketing new drugs. The result: Experts in the field are unable to help new drugs come to market, even though studies and reports are presented to knowledgeable and skeptical audiences.
- **Two Harvard-affiliated hospitals** now monitor the *per diem* compensation their physicians receive for service on corporate boards. The result: Physicians devote less time to their hospital duties.
- **Massachusetts** enacted legislation that prohibits all physician gifts from pharmaceutical companies and medical device companies, including training sessions. The result: The Pharmaceutical and Medical Device Manufacturer Conduct Act forces valuable training and other vocational activities out of the state.

Epstein's Solutions:

- **Release all experimental data** and disclose funding of services prior to the production of new drugs and devices.
- **The FDA should grant more waivers** to experts on their oversight committees, so experts do not have to disclose personal financial information.
- **The NIH must develop a conflict-of-commitment policy** that brings scientists from government and universities to work together on joint projects. One day a week should be available for collaborative consulting.

"The current conflict rules that are ordered by such key organizations as the NIH, the FDA, and various medical schools and medical societies have passed the point of good sense and have entered an area where we can predict serious difficulties." – Richard Epstein

Richard A. Epstein is a Manhattan Institute visiting scholar. He is also the Laurence A. Tisch Professor of Law at New York University School of Law, the Peter and Kirsten Bedford Senior Fellow at the Hoover Institution, and the James Parker Hall Professor at the University of Chicago. His writings span a broad array of fields, including common law subjects of property, contracts, and torts. Professor Epstein is one of the three most cited law professors in the United States and the most cited professor writing largely in

private law. Among his books are Mortal Peril: Our Inalienable Right to Health Care? (Perseus, 1997), and Overdose: How Excessive Government Regulation Stifles Pharmaceutical Innovation (Yale 2006).

The Manhattan Institute's **Project FDA** is a committee of physician-scientists, economists, medical ethicists, and policy experts that conducts research and holds forums to streamline and accelerate medical innovation.

The report is available at http://www.manhattan-institute.org/html/fda_03.htm. If you would like to schedule an interview with Richard Epstein, please contact Bridget C. Carroll at 646-839-3313 or bcarroll@manhattan-institute.org.

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