305 Economists Called to Answer Questionnaire on Pre-Market Approval of Drugs and Medical Devices

Daniel B. Klein and Jason Briggeman*
George Mason University

*and Kevin Rollins

Pre-Market Approval of Pharmaceuticals

- New drugs and medical devices are banned in the United States until they are individually permitted by the Food and Drug Administration (FDA).
- Since Adam Smith, the mainline of economics has worked from a presumption for the market, with restrictions justified only when they promise to remedy a market failure at acceptable cost.

Pre-Market Approval of Pharmaceuticals

- Is there a market failure in drug development and marketing?
- If so, is pre-market approval a wise means to remediate that market failure?

Costs and Benefits

- Pre-market approval is costly and creates uncertainties for drug developers. Useful drugs have been delayed or suppressed, at a heavy cost to patients.
- Pre-market approval prevents some baneful products from being developed and marketed.

What Economists Say

- The vast majority of economists who have published a judgment on pre-market approval of drugs believe its costs dominate its benefits. No coherent market-failure rationale for the policy appears to exist in the literature. (Klein 2008)
- AEA members broadly support FDA regulation of the pharmaceutical market. (Klein and Stern 2007)

Our Project

- We have summoned selected economists to answer questions related to market failure and pre-market approval of pharmaceuticals.
- We have asked them to answer on the record (i.e., not anonymously), for publication in a future issue of *EJW*.

Why Should Anyone Respond?

- This is an important matter.
- Those summoned are experts.
- The preponderance of scholarship indicates current policy is misguided.
- Participation is easy.
- Fair, transparent questioning is consonant with academic ideals, e.g., the open exchange of learning.

Central Questions

- "Which best describes your attitude toward the U.S. government policy that requires pre-market approval of new pharmaceuticals and devices?”
- “Do you think there is a sound market-failure rationale for the policy that requires pre-market approval?” “Which of the following describes the nature or source of the market failure that justifies the policy requiring pre-market approval?”

Preliminary Results

- Our respondents are split about evenly in their views on pre-market approval (13 oppose, 5 neutral, 16 in favor).
- Two in three think there is a sound market-failure rationale for the policy.
- Most of these say imperfect information (n=17) or public-goods aspects of knowledge (n=12) are a source of failure.

Sample Responses

"Most consumers lack the information needed to evaluate the drugs they take; indeed, many don't even read the FDA-required label indications. […Physicians] err randomly, and frequently, in large measure because they are simply so busy that they don't have time to consider indications and contra-indications. Also, there are informational economies of scale in having an agency like the FDA consider in detail, however imperfectly, all the evidence available on indications and contra-indications." –F.M. Scherer (Harvard University)

Sample Responses

"Behavior economics and studies of risk aversion show that consumers have a hard time making intelligent decisions when confronted with risky prospects or decisions over time. […] Doctors err in prescribing in the same way that the entire medical system does because of the effects of insurance. The cost of pharmaceuticals is largely irrelevant to their decisions, only whether there is a positive benefit. Direct to consumer advertising of pharmaceuticals is also not particularly informative." –Randall Ellis (Boston University)

Sample Responses

"I am much less concerned about asymmetric information than I am about the public good nature of research. Systematic clinical trials will facilitate learning by physicians. It is not at all obvious whether a manufacturer will wish to promote learning in a way that maximizes social welfare."
–David Dranove (Northwestern University)

To Learn More…

- You can find the article introducing our project in the January 2010 issue of *EJW*.
- Full results should appear in the May 2010 issue.