[This is the questionnaire referenced in Klein, Daniel B. and Jason Briggeman (2010), "305 Economists Called to Answer Questionnaire on the Pre-Market Approval of Drugs and Devices," *Econ Journal Watch* 7(1): 99-106. (link)]

What Do Economists Think About Pre-Market Drug Approval?

Welcome!

We estimate that completing this interview will take about 25 minutes.

The principal investigators of the project are Daniel Klein and Jason Briggeman, a professor and a graduate student in the Department of Economics at George Mason University. We are conducting online interviews of economists who work in fields relevant to pharmaceutical policy. The interview results will be used for scholarly purposes.

In the United States, new pharmaceuticals and medical devices are banned from the market until individually approved by the U.S. Food and Drug Administration. This policy has developed over many decades and is now a complex reality. The immediate goal of the study is to achieve a better understanding of the rationales for the policy. The ultimate goal is improved health and welfare for all those who can or do benefit from pharmaceuticals and medical devices.

We are grateful to you for giving your time and expertise to the project.

A: Our database shows that the link you used to access this survey is assigned to (name). Please make a selection to continue.

Yes, I am (name) and that is the correct spelling. **[skip to B]**
Yes, the link was intended for me, but my name is spelled incorrectly.
No, that is not me; I will need to enter my name and email address to continue.

A2: Please enter your name. **[if A is "Yes, the link was intended for me", skip to B]**

A3: Please enter your email address.

B: As stated in the contact email, your responses will be reported as yours, without anonymity. Please confirm this understanding:

Yes, I understand that my responses will be made public (accurately, completely, and neutrally) and without anonymity.
Sorry, such conditions are unacceptable to me; I decline to participate.

C: Please give your current institutional affiliation and title:

1: The policy that requires pre-market approval of new pharmaceuticals and medical devices may *prevent harm*, and it also may *suppress would-have-been benefits* (by suppressing drug development, causing delays, or increasing costs).

Consider for the moment only the first of these two policy effects, *preventing harm*. Which of the following statements best describes your view of the public discourse about this effect?

In public discourse, the effect of the pre-market approval policy in preventing harm is…

…typically overstated.
…often overstated.
…neither understated nor overstated.
…often understated.
…typically understated.

2: Consider now only the second policy effect, *suppression of would-have-been benefits*. Which of the following statements best describes your view of the public discourse about this effect?

In public discourse, the effect of the pre-market approval policy in suppressing would-have-been benefits is…

…typically overstated.
…often overstated.
…neither understated nor overstated.
…often understated.
…typically understated.

3: Which best describes your attitude toward the U.S. government policy that requires pre-market approval of new pharmaceuticals and devices?

Oppose strongly
Oppose, not strongly
Neutral
Support, not strongly
Support strongly

4: Do you think there is a sound market-failure rationale for the policy that requires pre-market approval?

Yes **[skip to 5b]**
No

[if 3 is "Neutral" or "Support"] 5a: Given that you believe there is no sound market-failure rationale for the policy that requires pre-market approval, please explain why you do not oppose the policy.

6a: Do you believe that consumers or patients systematically err when coping with uncertainties related to health and treatment?

Yes
No **[skip to 8a]**

7a: In what ways does consumer or patient erring manifest itself? (If possible, please cite relevant evidence.)

8a: Do you believe that doctors systematically err when selecting and prescribing therapies?

Yes
No **[skip to 10a]**

9a: In what ways does doctor erring manifest itself? (If possible, please cite relevant evidence.)

10a: Say the policy that requires pre-market approval was eliminated and, in its place, a policy was implemented allowing new pharmaceuticals/devices and initially classifying them as requiring a doctor's prescription (pending a review process to consider dropping the prescription requirement). Do you think such a liberalized system would be superior to the current system?

Yes **[skip to 12a]**
No

11a: Why not?

12a: Do you believe that uncertainty *per se* constitutes a market failure?

Yes
No **[skip to 14a]**

13a: How in your view does uncertainty *per se* constitute a market failure?

14a: Knowledge is often said to have public-goods aspects. Imagine a new pharmaceutical being developed within the current regulatory system and brought all the way through to FDA approval. Do you think the policy that requires pre-market approval induces the generation of more knowledge about the new pharmaceutical than there would have been in the absence of the policy?

Yes
No

15a: As compared to the current system, would you favor making approval of a new drug automatic upon completion of the safety and efficacy testing processes specified by the FDA, regardless of what those testing results turned out to be?

Yes **[skip to 17a]**
No

16a: Why not?

17a: Relative to doctors and consumers, do you believe the government has superior ability to judge the safety and efficacy of pharmaceuticals (assuming, that is, that the government does not have exclusive access to certain research information)?

Yes
No **[skip to 19a]**

18a: How would you describe or explain the government's superior ability to judge safety and efficacy?

19a: As compared to the current system, would you favor a reform so that pharmaceuticals approved by the FDA counterparts in Europe, Japan, Canada, or Australia were automatically approved for the United States?

Yes **[skip to 31]**
No

20a: Why not? **[skip to 31]**

5b: Which of the following describes the nature or source of the market failure that justifies the policy requiring pre-market approval? Please be sure to check any and all that you believe to apply.

Imperfect information
Public-goods aspects of knowledge
Government has superior ability to assure safety and efficacy
Other

[if 5b answers include "Other"] 6b: Please describe the 'other' source of market failure that justifies the policy requiring pre-market approval.

7b: Do you believe that consumers or patients systematically err when coping with uncertainties related to health and treatment?

Yes
No **[skip to 9b]**

8b: In what ways does consumer or patient erring manifest itself? (If possible, please cite relevant evidence.)

9b: Do you believe that doctors systematically err when selecting and prescribing therapies?

Yes
No **[skip to 11b]**

10b: In what ways does doctor erring manifest itself? (If possible, please cite relevant evidence.)

11b: Say the policy that requires pre-market approval was eliminated and, in its place, a policy was implemented allowing new pharmaceuticals/devices and initially classifying them as requiring a doctor's prescription (pending a review process to consider dropping the prescription requirement). Do you think such a liberalized system would be superior to the current system?

Yes **[skip to 13b]**
No

12b: Why not?

13b: Do you believe that uncertainty *per se* constitutes a market failure?

Yes
No **[skip to 15b]**

14b: How in your view does uncertainty *per se* constitute a market failure?

[if 5b answers include "Imperfect information" and if "No" to 7b, 9b, and 13b]
15b: If neither consumers nor doctors err systematically in these matters and uncertainty *per se* does not constitute a market failure, then in what sense do you believe that imperfect information is a source of the market failure that justifies the policy requiring pre-market approval?

[if 5b answers include "Imperfect information" and if "Yes" to any of 7b, 9b, and 13b] 16b: In addition to systematic error on the part of consumers/doctors and/or uncertainty *per se*, is there any other sense in which you believe imperfect information to be a source of the market failure that justifies the policy requiring pre-market approval? If so, please explain.

[if 5b answers do not include "Public-goods aspects of knowledge"] 17b: You indicated that public-goods aspects of knowledge do not justify the policy requiring pre-market approval. Is that because you think such aspects are better addressed by subsidizing the generation of knowledge, *e.g.*, via the National Institutes for Health?

Yes **[skip to 20b]**
No **[skip to 20b]**

[if 5b answers include "Public-goods aspects of knowledge"] 18b: You indicated that public-goods aspects of knowledge are a source of the market failure that justifies the policy requiring pre-market approval. Do you think that this source of market failure would be better addressed with a policy that subsidizes the generation of knowledge, *e.g.*, via the National Institutes for Health?

Yes **[skip to 20b]**
No

19b: Why not?

20b: Imagine a new pharmaceutical being developed within the current regulatory system and brought all the way through to FDA approval. Do you think the policy that requires pre-market approval induces the generation of more knowledge about the new pharmaceutical than there would have been in the absence of the policy?

Yes **[skip to 22b]**
No

[if 5b answers include "Public-goods aspects of knowledge"] 21b: How is it, then, that the public-goods aspect of knowledge provides a rationale for the current system?

22b: As compared to the current system, would you favor making approval of a new drug automatic upon completion of the safety and efficacy testing processes specified by the FDA, regardless of what those testing results turned out to be?

Yes **[skip to 24b]**
No

23b: Why not?

[if 5b answers include "Government has superior ability to assure safety and efficacy"] 24b: You indicated that a superior ability of government to assure the safety and efficacy of pharmaceuticals justifies the policy requiring pre-market approval. Does that superiority stem from the FDA having special expertise in evaluating safety and efficacy?

Yes
No **[skip to 26b]**

[if 5b answers include "Government has superior ability to assure safety and efficacy"] 25b: Why is it that doctors and consumers have inferior judgment in evaluating safety and efficacy?

[if 5b answers include "Government has superior ability to assure safety and efficacy"] 26b: Would you say that impartiality or commitment to the public good are sources of the government's superior ability to assure safety and efficacy?

Yes
No **[skip to 28b]**

[if 5b answers include "Government has superior ability to assure safety and efficacy"] 27b: In what ways does the FDA's impartiality or commitment to the public good render it superior to doctors and patients in judging safety and efficacy?

[if 5b answers include "Government has superior ability to assure safety and efficacy" and if 24b and 26b are both "No"] 28b: What is the basis of government's superior ability to assure safety and efficacy, if not the FDA's special expertise, impartiality, or commitment to public good?

29b: As compared to the current system, would you favor a reform so that pharmaceuticals approved by the FDA counterparts in Europe, Japan, Canada, or Australia were automatically approved for the United States?

Yes **[skip to 31]**
No

30b: Why not?

31: Prior to 1962, the FDA did not consider efficacy when making drug approval decisions. Doctors today are at liberty to prescribe drugs for "off-label" use—that is, for use where there has been no FDA evaluation of the drug's efficacy. However, as part of the current pre-market approval process, the FDA requires proof of efficacy in the drug's "on-label" use(s). Would you favor dropping efficacy requirements from the pre-market approval process?

Yes **[skip to 34]**
No

32: Efficacy requirements were introduced in 1962. Do you believe that the pre-1962 record shows systematic failure in assuring efficacy?

Yes
No **[skip to 34]**

33: What evidence can you cite for systematic failure in assuring efficacy prior to 1962?

34: Do you have any general comments about this questionnaire or further thoughts about the matters treated?