EJW
A JOURNAL OF THE AMERICAN INSTITUTE FOR ECONOMIC RESEARCH

Econ Journal Watch
Volume 7, Number 2
May 2010, pp 162-173

44 Economists Answer Questionnaire on the Pre-Market Approval of Drugs and Devices

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ABSTRACT

In the January 2010 issue of this journal, we asked 305 economists to complete an online questionnaire on the pre-market approval of drugs and medical devices. You may access the questionnaire **here** (interactive html) or **here** (pdf showing questionnaire architecture). The 305 individuals called to the questionnaire were selected because they were on the editorial board of a leading health-economics journal, because they had been identified as having published a judgment on the issue, or because of a secondary reason (detailed at Klein and Briggeman 2010, 105). In fact, all but one (Kenneth Arrow) of the 44 respondents who have since completed all or part of the questionnaire fall into at least one of the two categories just mentioned.

While our questionnaire speaks of pre-market approval in terms of United States government policy administered by the Food and Drug Administration (FDA), we invited economists across the world to address the matter. The 44 respondents come from 12 countries. Most of them hold academic positions but some are in government, industry, the non-profit health sector, and independent research/consultancy firms. We have not established that every one of the 44

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Acknowledgments: We are grateful to the 44 individuals, identified in the present article, who answered our call. Also, we thank Joel Friedman and SurveyWriter, Inc. for their help in hosting the survey, and Mike Watkins for help with outputting the data to manageable forms.

respondents is an "economist," whether by degree, title, or publication record, but clearly most are, and all are working on matters included under the rubric of health economics. Hence we refer to them as economists.

We promised to "collate the responses of the summoned economists and write up a summary report to publish alongside the individual transcripts. As with a similar non-anonymous questionnaire on the minimum wage (Klein and Dompe 2007), the follow-up report to appear in this journal will not criticize or challenge the responses" (Klein and Briggeman 2010, 105).[4] The present article is the promised report. In addition to this brief report, a compendium of complete transcripts is included as an appendix in both PDF (**link**) and Excel (**link**) formats. The appendix consists of nothing more than 44 transcripts that can be read naturally as conversations, and, indeed, it makes for better reading than does this report.

Here is a list of the 44 individuals who kindly took our questionnaire. Our deep appreciation goes out to each of them:

Kenneth Arrow
Pedro Pita Barros
Marc L. Berger
Cornelis Boersma
John E. Brazier
James F. Burgess Jr.
Noel D. Campbell
J. Jaime Caro
William S. Comanor
Anthony John Culyer
Thomas DeLeire
David Dranove
Randall P. Ellis
Denis Getsios
Dale H. Gieringer
Paul Greenberg
Paul Grootendorst
Michael Grossman
László Gulácsi
David R. Henderson
Randall Holcombe
Charles L. Hooper
John Hornberger
Don Husereau
John Hutton
Naoki Ikegami
Michael Iskedjian
Jonathan Karnon
Gordon G. Liu
Nikos Maniadakis
Karl A. Matuszewski
C. Daniel Mullins
Sam Peltzman
Charles E. Phelps
Gérard de Pouvourville
José Luís Pinto Prades
Paul H. Rubin
F. M. Scherer
David A. Sclar
Robert M. Sigmond
Shirley Svorny
Robert Tollison
Michael R. Ward
Albert I. Wertheimer

Results

Here is the list of respondents grouped by answer to the question, "Which best describes your attitude toward the U.S. government policy that requires premarket approval of new pharmaceuticals and devices?"

4. Readers might be interested in a methodologically similar study by Klein and Tabarrok (2008), based on virtual conversations regarding off-label practices and efficacy requirements for both on- and off-label uses. That investigation differed from ours in three ways: (1) the respondents were physicians, not economists; (2) the respondents were anonymous; (3) the authors provided their evaluations of the responses.

Oppose strongly (11): Campbell, DeLeire, Gieringer, Henderson, Holcombe, Hooper, Peltzman, Rubin, Svorny, Tollison, Ward.

Oppose, not strongly (4): Burgess, Caro, Dranove, Grootendorst.

Neutral (6): Greenberg, Grossman, Gulácsi, Hornberger, Iskedjian, Phelps.

Support, not strongly (7): Barros, Boersma, Ellis, Husereau, Hutton, Liu, Sclar.

Support strongly (16): Arrow, Berger, Brazier, Comanor, Culyer, Getsios, Ikegami, Karnon, Maniadakis, Matuszewski, Mullins, Pouvourville, Prades, Scherer, Sigmond, Wertheimer.

While we did not aim at obtaining a sample representative of any particular population of economists, that a majority of our respondents support pre-market approval comports with research showing broad support among American Economics Association members for FDA regulation of the pharmaceutical market (Klein and Stern 2006, 334).

As stated in the January article, our impetus for this project was to "explore whether there is any basis for the support" given by economists to the pre-market approval policy; specifically, we wondered, "Is any economist today ready to stand up and stand by a market-failure rationale for the pre-market approval policy?" In the questionnaire, we asked whether each respondent thought there was a "sound" market-failure rationale for the policy. Thirty of the 43 who replied to that question said yes; not surprisingly, belief that such a rationale exists was well correlated with support for the policy, as illustrated in the following table.

4. Do you think there is a sound market-failure rationale for the policy that requires pre-market approval?	**Oppose pre-market approval**	**Neutral**	**Support pre-market approval**
Yes	3	4	23
No	12	1	0

Those who said there is a sound market-failure rationale then were asked the closed-end question "Which of the following describes the nature or source of the market failure that justifies the policy requiring pre-market approval?" We offered four answer choices: "Imperfect information," "Public-goods aspects of knowledge," "Government has superior ability to assure safety and efficacy," and "Other." Respondents were able to select any or all of the choices, and were asked to elaborate on a response of "Other." Of the 29 respondents answering this question, 24 selected "Imperfect information," 17 selected "Public-goods aspects

of knowledge," eight selected "Government has superior ability to assure safety and efficacy," and nine described an "Other" market failure. All 29 selected at least one of the provided choices, i.e., no one selected "Other" only. Here are the respondents grouped by combination of provided choices selected:

> 5b. Which of the following describes the nature or source of the market failure that justifies the policy requiring pre-market approval?
>
> - Imperfect information [II]
> - Public-goods aspects of knowledge [KPG]
> - Government has superior ability to assure safety and efficacy [Gov]

Respondents by response-combination:

II, KPG, and Gov: (5) Boersma, Ikegami, Maniadakis, Matuszewski, Sigmond.

II and KPG: (7) Arrow, Barros, Brazier, Dranove, Hutton, Scherer, Sclar.

II and Gov: (3) Getsios, Husereau, Prades.

KPG and Gov: (0).

II only: (9) Berger, Culyer, Ellis, Gulácsi, Karnon, Mullins, Pouvourville, Ward, Wertheimer.

KPG only: (5) Comanor, Grootendorst, Grossman, Liu, Phelps.

Gov only: (0).

Irrespective of whether the respondent thought there was a market-failure rationale, he or she was asked questions related to common notions of market failure. While we are not attempting to summarize in this report the responses to the several open-end questions (see appendix for these), the frequencies of responses to the closed-end questions are reported in the following tables:

1. In public discourse, the effect of the pre-market approval policy in preventing harm is…	**Oppose pre-market approval**	**Neutral**	**Support pre-market approval**
…typically overstated.	7	0	1
…often overstated.	7	0	5
…neither understated nor overstated.	1	5	11
…often understated.	0	1	3
…typically understated.	0	0	1

2. In public discourse, the effect of the pre-market approval policy in suppressing would-have-been benefits is…	**Oppose pre-market approval**	**Neutral**	**Support pre-market approval**
…typically overstated.	0	0	2
…often overstated.	0	2	8
…neither understated nor overstated.	1	2	3
…often understated.	3	1	2
…typically understated.	11	1	5

7b/6a. Do you believe that consumers or patients systematically err when coping with uncertainties related to health and treatment?	**Those who believe there is a sound market-failure rationale**	**Those who do not**
Yes	18	7
No	10	6

9b/8a. Do you believe that doctors systematically err when selecting and prescribing therapies?	**Those who believe there is a sound market-failure rationale**	**Those who do not**
Yes	11	5
No	17	8

11b/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?	**Those who believe there is a sound market-failure rationale**	**Those who do not**
Yes	3	10
No	25	3

13b/12a. Do you believe that uncertainty per se constitutes a market failure?	**Those who believe there is a sound market-failure rationale**	**Those who do not**
Yes	5	0
No	23	13

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?	**Those who believe there is a sound market-failure rationale, but *not* from public-goods aspects of knowledge**
Yes	6
No	5

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?	**Those who believe there is a sound market-failure rationale, based at least in part on public-goods aspects of knowledge**
Yes	7
No	9

20b/14a. 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?	**Those who believe there is a sound market-failure rationale**	**Those who do not**
Yes	24	5
No	3	8

22b/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?	**Those who believe there is a sound market-failure rationale**	**Those who do not**
Yes	3	6
No	23	7

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)?	**Those who do not believe there is a sound market-failure rationale**
Yes	4
No	9

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?	**Those who believe there is a sound market-failure rationale, based at least in part on government's superior ability to assure safety and efficacy**
Yes	5
No	1

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?	**Those who believe there is a sound market-failure rationale, based at least in part on government's superior ability to assure safety and efficacy**
Yes	6
No	0

29b/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?	**Those who believe there is a sound market-failure rationale**	**Those who do not**
Yes	11	9
No	15	4

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?	**Those who believe there is a sound market-failure rationale**	**Those who do not**
Yes	2	9
No	24	4

32. Efficacy requirements were introduced in 1962. Do you believe that the pre-1962 record shows systematic failure in assuring efficacy?	**Those who believe there is a sound market-failure rationale and who oppose dropping efficacy requirements**	**Those who do not believe there is a sound market-failure rationale and who oppose dropping efficacy requirements**
Yes	15	1
No	9	3

Conducting the Survey

We were able to find at least one email address for 304 of the 305 listed individuals, though some of these initial addresses turned out to be invalid. By paying careful attention to bounced emails and then doing additional web research to find second and third email addresses, we were eventually able—we think—to find valid or current email addresses for 302 of the 305. [5] A first round of emails (to the initial 304 email addresses) was sent out January 21-26. A round of reminder emails was sent February 15-17 to those who did not acknowledge the initial emails. We then searched for telephone numbers for those who had not completed the survey or refused, and placed a round of calls in the evenings and on weekends

5. Of the 305 economists, there is only one (John M. Vernon) whom we are sure we failed entirely to contact. Two others (David H. Klein and Ben S. Bernanke) could only have been reached with the postcard sent toward the end of the data-collection period.

March 9-28, leaving voicemails with instructions for accessing the survey. To those who could not be contacted by phone, a postcard was mailed on April 16. Finally, a last round of emails was sent April 15-19.

In addition to the 44 individuals who completed all or part of the survey, another 28 contacted us in some way; that leaves 230 individuals whom we believe we contacted via email but from which we received no personal communication.[6] Several of those who contacted us but declined to participate indicated that they did not feel well suited to address the subject matter of the questionnaire. A few mentioned our ideological orientation as a concern; for example, one refusal read in part: "This does not look to me like social science but like pure policy advocacy, albeit advocacy driven by a specific economic point of view." While in the January piece (which was cited and offered by link in the personalized invitations) we were open about our being decidedly pro-liberalization, some of those who were invited likely did not read the January article. In hindsight, we might have done better explicitly to have reiterated our decidedly pro-liberalization position in the introduction to the survey itself. Doing so would have made it clear that the voice of the survey itself was coming from such a position.

If we were to conduct the survey again, we might consider replacing some of the yes-no questions with Likert questionnaire items, i.e., allowing for variation in intensity of agreement or disagreement as well as for neutral responses. Several respondents expressed frustration with the "forced choices" between yes and no. When we designed the survey, we opted for the yes-no questions because the primary purpose of such questions was not statistical but rather the elicitation of interventionist rationales. We believed that open-end questions would be more naturally posed and understood if they were to follow "no" responses than if they were to follow responses of (for instance) "disagree somewhat."

Concluding Remark

We feel that the 44 conversations provide a rich set of discourse that should help anyone think through the matter and decide for him- or herself: *Is there a sound market-failure rationale for the banned-till-permitted policy for drugs and devices?* We hope that researchers, students, policymakers, and citizens make use of this unique set of material.

6. The 230 figure includes those from whose email accounts we received only automated replies (e.g., "out of office").

Appendix:

Compendium of complete transcripts of all 44 conversations. Links (**PDF**, **Excel**).

References

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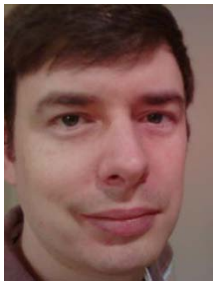
About the Authors



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