



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

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ABSTRACT

By acts of Congress, notably in 1938, 1962, and 1976, all new drugs and medical devices are banned until individually permitted by the U.S. Food and Drug Administration (FDA), a policy known as *pre-market approval*. In reviewing the regulatory history, Peter Temin writes:

The shift from assuming a capable consumer to assuming an incompetent consumer was made within the FDA within six months of the Federal Food, Drug, and Cosmetics Acts' passage [in 1938]. Not only was the shift in assumptions not controversial, the method by which it was accomplished occasioned no comment as well. The decisions of the FDA were ratified by the courts and enacted into statute by the Congress. Neither branch of the government undertook to question the FDA's assumptions. (Temin 1979, 104)

Is it possible that pre-market approval should be seen as an historic mistake, a policy that has never been satisfactorily justified? Is any economist today ready to stand up and stand by a market-failure rationale for the pre-market approval policy? If so, what rationale does he or she have to offer? If no one stands by a market-failure rationale, then we and others who oppose pre-market approval may feel more confidence both in the conclusion that the policy should be liberalized

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and in the implications that such conclusion would hold about the cultural ecology of professional economics and political discourse generally.

Here we call 305 economists to respond online to a questionnaire about the policy. We explain here why the economists summoned may have a moral responsibility to participate, and why any conscientious researcher is entitled to summon them in a manner that makes responding easy and uncompromised. Our questionnaire is straightforward and provides ample opportunity for open-ended responses.

The Economics of Pre-market Approval

Klein and Tabarrok (2009) extensively review the literature, and Klein (2008) specifically addresses whether there is a market-failure rationale to justify pre-market approval. Here we briefly state our doubts about pre-market approval, omitting the elaboration and citations found elsewhere.

Due to pre-market approval, drugmakers face costs, delays, and uncertainties that suppress the development of new therapies. Famous studies of the introduction of beta-blockers showed that many tens of thousands of American deaths could be attributed to the delay between approval in Britain and in the United States. Scores of other drugs have been delayed that plausibly would have saved many other lives. But pointing concretely to delays in the approval of well-known drugs can only illuminate a potentially larger problem: the extra costs and uncertainties imposed by the pre-market approval process may prevent the development of many drugs. Those losses—of not-developed drugs, of would-have-been benefits—are impossible to identify or quantify, but they are no less real.

Might these costs of pre-market approval be redeemed by its benefits? Pre-market approval surely does prevent some baneful products from being developed and marketed. However, the vast majority of economists who address the matter and publish a judgment believe that the costs dominate the benefits, at least at the margins of current policy. Klein (2008) quotes 35 economists who favor some degree of liberalization of pre-market approval. On the other side, Klein finds just three economists who seem to oppose liberalization.

Since Adam Smith, the mainline of economics has worked from a presumption in favor of allowing voluntary action and exchange. We economists may differ in how strongly we hold this presumption, but we all carry such presumption to one degree or another. Restrictions are generally viewed as justified only if some species of market failure plagues the matter and if the restriction is thought to remedy the problem at an acceptable cost. So is there a

market failure in drug development and marketing? Is pre-market approval a wise means to remediate any such market failure that exists?

In illness and therapy, there are great uncertainties, but uncertainty *per se* is not generally seen as a market failure. Consumers no doubt make their share of errors, but is there evidence that they err systematically in a way that pre-market approval would remediate? Doctors, too, make errors, but still they are trusted to prescribe FDA-approved drugs that can be quite dangerous if misused; when doctors err, they face a variety of consequences including the possibility of civil lawsuits.

It seems to us that freeing up approval would give the consumer and her healthcare providers a wider set of options and greater control of the medical decisions they need to make. They are the ones with the greatest knowledge of the particular circumstances that surround the patient, and they are also the ones with the strongest incentives to seek opportune information—which in principle can be made no less available to them than to FDA decisionmakers. Until we have a significant market-failure argument for government intervention, these basic reasons recommend the principle of voluntarism.

Purpose and Ethic

Despite the inability of Klein (2008) to locate in the literature a coherent market-failure argument for pre-market approval, a survey of American Economics Association members revealed broad support for FDA regulation of the pharmaceutical market (Klein and Stern 2007). We seek to explore whether there is any basis for the support.

Here we take an unconventional approach in calling selected economists to answer the questionnaire. Though unconventional, our call may be justified as an ethical summons. In *The Theory of Moral Sentiments*, Adam Smith distinguished types of justice. Commutative justice, “abstaining from what is another’s” (269), clearly places no duty on the summoned economist; one may often fulfill the duties of commutative justice “by sitting still and doing nothing” (82). A duty may spring, however, from distributive justice, which “consists in proper beneficence, in the becoming use of what is our own, and in the applying it to those purposes either of charity or generosity, to which it is most suitable, in our situation, that it should be applied” (270). Smith writes of *proper* beneficence, hence a *duty* of the economist to distribute his social resources—his time, attention, and participation—to the purposes of generosity to which it is most suitable, in his situation, that they should be applied.

Is it suitable that the summoned economist's time, attention, and expertise be applied to completing this questionnaire? The issue at hand is one of great importance; the vast preponderance of scholarly judgment indicates that something is amiss with current policy; participation in the study is easy and uncompromised; those invited are fitted to address the issue. It seems to us that, within the summoned economist's present situation, it is suitable that his social resources be applied to completing the questionnaire. To abstain, while no infraction of commutative justice, would be unbecoming, a blot on distributive justice.

Similarly, we believe that any conscientious researcher is entitled to issue a summons such as this one. Scholarship aspires to be an open exchange of learning. If questioning is fair, convenient, and transparent to all, then anyone should feel entitled to summon anyone. Such an attitude enhances the accountability of scholarly discourse. Furthermore, scholarship ought to inform politics, certainly in a democratic society. Greater accountability improves political discourse. Openness and dialogue have always been ideals of political democracy. Democratic values would seem to favor participation in efforts such as ours.

Study Logistics

Each economist listed in Table 1 here has been sent **an email** containing a unique link to a gated version of the questionnaire. Each completed questionnaire will yield a transcript of the virtual conversation. A future issue of this journal will publish the transcripts of summoned economists, each with the respondent identified—i.e., those who complete the questionnaire at the gated site *will* be identified; that is, gated responses will *not* be anonymous.

Table 1: 305 Economists Summoned to Answer the Questionnaire.

Akerlof, George (5)	Culyer, Anthony John (1)	Gottschalk, Adrian H. B. (2)	Kyle, Margaret K. (2)
Akerman, Mary Kay (3)	Currie, Janet M. (1)	Grabowski, Henry G. (2)	Langley, Paul C. (1)
Anis, Aslam H. (1)	Cutler, David M. (1)	Green, Colin (1)	Lapuerta, Pablo (1)
Antoñanzas, Fernando (1)	Danzon, Patricia M. (1,2)	Greenberg, Paul (1)	Lawrence, Robert Z. (4)
Arrow, Kenneth (5)	Darling, Helen (1)	Greiner, Wolfgang (1)	Lazear, Edward P. (4)
Askildsen, Jan Erik (1)	de Pourville, Gérard (1)	Grootendorst, Paul (1)	Le Pen, Claude (1)
Auerbach, Alan J. (3)	DeLeire, Thomas (1)	Grossman, Michael (1)	Leffler, Keith B. (2)
Autor, David (3)	DeLong, J. Bradford (3)	Gruber, Jonathan (1)	Levinsohn, James (3)
Badia, Xavier (1)	Destache, Chris (1)	Guest, Julian F. (1)	Levitt, Steven D. (6)
Baicker, Katherine (1,4)	Donaldson, Cam (1)	Gulácsi, László (1)	Levy, Adrian (1)
Baily, Martin N. (4)	Dong, Hengjin (1)	Hadley, Jack (1)	Lindeboom, Maarten (1)
Barro, Robert (6)	Doran, Chris (1)	Hall, Jane (1)	Ling, Davina C. (2)
Barros, Pedro Pita (1)	Dranove, David (1,2)	Hamilton, James D. (6)	Liu, Gordon G. (1)
Basu, Anirban (1)	Drummond, Michael F. (1)	Hansen, Ronald W. (2)	Lucioni, Carlo (1)
Beales, J. Howard III (2)	Ekwurzel, Druilla (3)	Harrington, Joseph E. Jr. (2)	Luft, Harold S. (1)
Beard, Stephen M. (1)	Elliott, Rachel (1)	Haycox, Alan (1)	Manca, Andrea (1)
Becker, Gary S. (2)	Ellis, Randall P. (1)	Hellinger, Fred J. (1)	Maniadakis, Nikos (1)
Berger, Marc L. (1)	Escarce, José J. (1)	Henderson, David R. (2)	Mankiw, N. Gregory (4)
Bernanke, Ben S. (4)	Ettner, Susan (1)	Hester, James A. (1)	Manning, Willard G. (1)
Berndt, Ernst R. (2)	Evans, Robert G. (1)	Higgs, Robert (2)	Marquis, M. Susan (1)
Bingefors, Chris (1)	Feder, Judith (1)	Hill, Suzanne (1)	Marron, Donald B. (4)
Birnbaum, Howard (1)	Feenstra, Talitha L. (1)	Hines, James R. Jr. (3)	Marx, Steven E. (1)
Bishai, David (1)	Fehnel, Sheri (1)	Holahan, John (1)	Matuszewski, Karl A. (1)
Blank, Rebecca M. (4)	Feldman, Roger (1)	Holcombe, Randall (2)	Mauskopf, Josephine (1)
Bleichrodt, Han (1)	Fenwick, Elisabeth (1)	Hollenbeak, C.S. (1)	Maynard, Alan (1)
Blinder, Alan S. (4)	Field, Alexander J. (3)	Hooper, Charles L. (2)	McClellan, Mark B. (4)
Boersma, Cornelis (1)	Fiscella, Richard (1)	Hornberger, John (1)	McGhan, William F. (1)
Bootman, J. Lyle (1)	Forbes, Kristin J. (4)	Hubbard, R. Glenn (4)	McGuire, Thomas G. (1)
Boskin, Michael J. (4)	Frank, Richard G. (1)	Hughes, Dyfrig (1)	Meek, Patrick (1)
Bradford, W. David (1)	Frank, Robert H. (6)	Husereau, Don (1)	Meltzer, David O. (2)
Brazier, John E. (1)	Frankel, Jeffrey A. (4)	Hutton, John (1)	Milne, Richard J. (1)
Brennan, Alan (1)	Freemantle, Nick (1)	Iezzoni, Lisa I. (1)	Moon, Marilyn (1)
Brennan, Troyen A. (1)	Freund, Deborah A. (1)	Ikegami, Naoki (1)	Morris, Louis A. (1)
Bridges, John F. P. (1)	Fullerton, Pete (1)	Iskedjian, Michael (1)	Mullahy, John (1)
Briggs, Andrew (1)	Gagnon, Jean Paul (1)	Iversen, Tor (1)	Mullins, C. Daniel (1)
Brouwer, Werner (1)	Gandjour, Afschin (1)	Johannesson, Magnus (1)	Mullner, Ross (1)
Bryan, Stirling (1)	Garattini, Livio (1)	Johnson, Kathleen A. (2)	Munnell, Alicia H. (4)
Buchmueller, Thomas (1)	Garattini, Silvio (1)	Jones, Andrew M. (1)	Nash, David B. (1)
Bungay, Kathleen M. (1)	Garber, Alan M. (1)	Jones, Charles I. (3)	Naughton, Michelle (1)
Burgess, James F. Jr. (1)	Garrison, Lou (1)	Jönsson, Bengt (1)	Neumann, Peter J. (1)
Buxton, Martin (1)	Gaynor, Martin S. (1)	Karnon, Jonathan (1)	Newhouse, Joseph P. (1)
Calfee, John E. (2)	Geisler, Benjamin (1)	Keith, Alison (2)	Niederman, Michael S. (1)
Campbell, Noel D. (2)	Geoffard, Pierre-Yves (1)	Kenkel, Donald (1)	Norton, Edward C. (1)
Cantor, Joel C. (1)	Getsios, Denis (1)	Keuffel, Eric L. (2)	Nuijten, Mark (1)
Caro, J. Jaime (1)	Getzen, Thomas E. (1)	Kifmann, Mathias (1)	O'Donnell, Owen A. (1)
Carswell, Christopher I. (1)	Gieringer, Dale H. (2)	Kind, Paul (1)	Olivella, Pau (1)
Claxton, Karl (1)	Glazer, Jacob (1)	Klein, David H. (1)	Onukwugha, Ebere (1)
Coast, Joanna (1)	Glick, Henry (1)	Knickman, James (1)	Paladino, Joseph A. (1)
Cohen, Alan B. (1)	Glied, Sherry A. (1)	Kroszner, Randall S. (4)	Palmer, Stephen J. (1)
Comanor, William S. (2)	Goolsbee, Austan (4)	Krueger, Alan B. (3)	Pashos, Chris L. (1)
Cowen, Tyler (6)	Gordon, Roger (3)	Krugman, Paul (2)	

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Peltzman, Sam (2)	Runge, Claus (1)	Singer, Mendel E. (1)	Tyson, Laura D'Andrea (4)
Pencavel, John (3)	Rutten, Frans (1)	Skjoldborg, Ulla S. (1)	van Doorslaer, Eddy (1)
Phelps, Charles E. (2)	Schelling, Thomas (5)	Slaughter, Matthew J. (4)	Vernon, John A. (1)
Philipson, Tomas J. (1,2)	Scherer, F.M. (2)	Smith, Richard (1)	Vernon, John M. (2)
Polsky, Daniel E. (1)	Schmalensee, Richard L. (4)	Smith, Vernon (5)	Vestal, Robert E. (1)
Prades, José Luis Pinto (1)	Schmier, Jordana (1)	Sobel, Joel (3)	Viscusi, W. Kip (2)
Priori, Stephen (1)	Schulman, Kevin A. (1)	Sobel, Russell S. (2)	von der Schulenburg, J. (1)
Propper, Carol (1)	Schumock, Glen T. (1)	Statman, Meir (2)	Wagner, Anita K. (1)
Prosser, Lisa A. (1)	Schwartzman, David (2)	Stearns, Sally C. (1)	Wagstaff, Adam (1)
Ramsey, Scott (1)	Sclar, David A. (1)	Stein, Jeremy C. (3)	Waldman, Michael (3)
Redekop, Ken (1)	Scott, Anthony (1)	Stiglitz, Joseph E. (3,4)	Ward, Michael R. (2)
Revicki, Dennis (1)	Scuffham, Paul (1)	Stoddart, Greg L. (1)	Wasserfallen, J.-B. (1)
Rice, Nigel (1)	Sculpher, Mark (1)	Street, Andrew D. (1)	Weidenbaum, Murray (2)
Richardson, Jeff (1)	Seibert, Uwe (1)	Strobeck, Matthew W. (2)	Weinstein, Milton C. (1)
Rizzo, Mario (6)	Severens, Johan L. (1)	Sullivan, Sean D. (1)	Wertheimer, Albert I. (1)
Roberts, Jennifer (1)	Shanahan, Marian (1)	Sun, Eric (2)	Whitty, Jennifer (1)
Robinson, James C. (1)	Shapiro, Carl (3)	Sutton, Matthew (1)	Wiggins, Steven N. (2)
Rodrik, Dani (6)	Shaw, Kathryn L. (4)	Svorny, Shirley (2)	Williams, Walter E. (2)
Rogowski, Jeannette (1)	Shields, Michael (1)	Szucs, Thomas D. (1)	Williamson, Oliver E. (5)
Romer, Christina (4)	Shih, Ya-Chen Tina (1)	Tabarrok, Alexander (2)	Wolak, Frank A. (3)
Rosen, Harvey S. (4)	Shleifer, Andrei (3)	Taylor, John B. (4)	Wonnacott, Paul (4)
Rothenberg, Jerome (2)	Siciliani, Luigi (1)	Taylor, Timothy (3)	Yellen, Janet L. (4)
Rouse, Cecilia E. (4)	Sigmond, Robert M. (1)	Temin, Peter (2)	Yip, Winnie (1)
Rovira, Joan (1)	Simoens, Steven (1)	Thoma, Mark (6)	Zuckerman, Howard S. (1)
Rowland, Diane (1)	Simon, Kosali (1)	Tollison, Robert (2)	
Rubin, Paul H. (2)	Sindeljar, Jody L. (1)	Torrance, George W. (1)	

Numerals in parentheses indicate group(s) (as given on next page) to which each economist belongs. A linked Excel sheet gives the breakdown of the general list by the various sub-groups specified below.

We have also created an ungated site where anyone can answer the questionnaire. We will not store or use any data from this ungated site; all users have direct access and should feel free to explore it. The ungated site provides the user with a transcript of his or her virtual conversation. We encourage readers to take the questionnaire. We believe they will find it convenient, fair, clear, and valuable.

Also, a PDF document containing the questions and sequencing can be found here: ([link](#)). It affords a bird's eye view of the questionnaire, but for one who wishes simply to engage the questionnaire as natural conversation it will be less useful, as it requires one to follow the sequencing instructions.

We also encourage the summoned economists to practice either with the PDF or at the ungated site, exploring the questionnaire there before completing it at the gated site. Again, none of the responses given at the ungated site will be stored or used in any way.

In deciding whom to summon, we aimed at those with expertise and leadership in health economics, research publications on the FDA, leadership in the cultural ecology of professional economics, and eminence in topics of information, uncertainty, and regulation. The 305 economists listed in Table 1 belong to at least one of these groups (details shown in worksheet ([link](#))):

1. Members of the editorial boards of seven leading health-economics journals: *Health Economics*; the *Journal of Health Economics*; *Inquiry: The Journal of Health Care Organization, Provision, and Financing*; the *European Journal of Health Economics*; *Applied Health Economics and Health Policy*; *Pharmacoeconomics*; and *Value in Health*.
2. Economists writing on the FDA cited in Klein (2008).
3. Current and former (post-1990) editors, associate or co-editors, and managing editors of the *Journal of Economic Literature* and the *Journal of Economic Perspectives*.
4. Current and former (post-1990) members of the President's Council of Economic Advisers.
5. Selected luminaries in the fields of information and/or health economics not otherwise included.
6. Selected prominent generalists and public intellectuals not otherwise included.

We will 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.

Meanwhile, we encourage all readers to examine the questionnaire or to complete it themselves. Again, a PDF document containing the questions is available here: [\(link\)](#). To complete (or practice, for those summoned) the questionnaire online, please visit the ungated site here: [\(link\)](#).

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