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INTELLECTUAL TYRANNY OF THE STATUS QUO

Colleagues, Where Is the Market Failure? Economists on the FDA

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ABSTRACT

According to the Food and Drug Administration (FDA), some 20 cents of every consumer dollar purchases products that come under the purview of the FDA. It regulates the safety of America's food supply and cosmetics, the safety and effectiveness of pharmaceuticals and medical devices, and the claims that can be made about these and other products.

This article treats three FDA-administered restrictions:

- The permitting of new drugs and devices
- The control of manufacturer speech
- The imposition of prescription requirements.

This article works from a point of view holding that there is no market-failure rationale for these three interventions. The implications of that view are very much at odds with the common and official cultural attitudes about the matter. This article is a cultural analysis of the economic discourse on the issues. It explores how economists approach and discuss an enormous, entrenched apparatus that basic economic reasoning properly condemns as a bane to humanity.

Survey evidence strongly suggests that the modal economist is somewhat supportive of the extant regulations, but this paper focuses on a narrow subset of economists: those who express in print judgments on such matters—a group sometimes referred to here as FDA-expressive economists. This paper works exclusively from such published statements. Many economists have expressed

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judgments concerning the three controls. In almost all cases, they support liberalization, often dramatic. Appendix 1 contains bulky compendia evincing the pro-liberalization judgments. The confounding cases are treated in the text.

The first-order finding—that economists judge very preponderantly for liberalization—is just a preliminary to the main business of the paper. This paper is chiefly concerned with considerations of the second-order. Do economists agree either that economists or that fundamental economic reasoning favor liberalization of the restrictions? In fact, in either variation, they *do not* agree. That is, while the first-order investigation finds that economists' judgments very preponderantly favor liberalization, the second-order investigation finds that some economists deny that liberalization is strongly supported by “economics” —interpreted either as economists' judgment or as economic reasoning as such.

I suggest that taboos surround the issue, particularly taboos against the critical examination of fundamentals. I contend that there is no market-failure rationale for the restrictions. Many FDA-expressive economists exhibit a sort of intellectual schizophrenia. In their heart of hearts, they seem to agree that there is no respectable market-failure rationale. I explore the rhetoric of their writings and the political sociology surrounding such research.

FDA-expressive economists often employ a rhetoric of quantitative cost-benefit analysis. Rhetoric that suggests that a quantitative argument is necessary to arrive at judgment bypasses the question of whether the policies have any respectable market-failure rationale. In bypassing such a fundamental question, the economist effectively presupposes that there is a respectable rationale out there somewhere, and that, therefore, quantitative analysis is necessary to determine whether benefits outweigh costs. I suggest that such bypassing is economic misfeasance.

When market-oriented economists suggest that a quantitative argument is the most serious—or even the only serious—basis for challenging the policies, they are implicitly surrendering the basis that I, for one, consider the most important: Thinking through whether there is any respectable market-failure rationale. I specify several reasons why quantitative argument is very valuable, but I nonetheless maintain that in this case it is not necessary to judge against the observed policies. Because I believe that such scrutiny finds no respectable market-failure rationale, I see fault in economists' insisting that quantitative arguments are necessary.

I then move on to some thoughts on the nature of the quantitative argumentation. I contend that the quantitative argumentation we see on the issue would be best presented as *a fortiori* argumentation, rather than net-benefit calculation. I suggest that *net-benefit calculation* is chimerical. The empirical investigations do not really undertake net-benefit calculations. I suggest that they should not pretend to do so, and that they should not aspire to do so.

I explore why leading experts favorable to liberalization might be reticent

to examine and discuss fundamental presuppositions, or to express their views openly. One point I make is that if an economist confronts fundamentals and lets on that he sees no respectable market-failure rationale, he then implies that any quantitative investigation is merely illustrative, or merely helps in quantifying the net-costs of the policy. That is, any such quantitative investigation is merely illustrating something that is learned from scrutiny of fundamentals: that water runs downhill—and perhaps giving a better idea of how much water, or how fast. But that it runs downhill was—in this case—decided by thinking through fundamentals. I suggest that openly acknowledging such implications might insult the vanity of some of the players and communities involved—both of some of the quantitative researchers and of some officials and others enmeshed in conventional (or establishment) political culture.

ECONOMISTS' JUDGMENTS IN FAVOR OF LIBERALIZATION

“Economist.” I count someone as an economist if he or she has a graduate degree in economics, has been a college-level economics professor, or has had a job with the title “economist.” Qualification details are reported in the Excel file of Appendix 2 ([link](#)). Every person listed in Table 1, 2, and 3 counts as an economist. As this paper is about the judgments of economists only, many non-economists who have published judgments on the issues have simply been passed over.

Judgment Tabulations. Table 1 shows the result of an extensive search for economists’ judgments about FDA permitting of new drugs and medical devices. The search is one I’ve been making for about 12 years, during which time I’ve assiduously collected judgments by economists on the matter. I admit that the search lacks any systematic method. But bias in the search can be exposed and corrected. Below I propose an open-source method for doing so.

Every cell in Table 1 is pro-liberalization. The cells vary by degree of liberalization and definiteness of the judgment. Every economist in Tables 1, 2, or 3 is quoted in Appendix 1 ([link](#)). For each cell, there is a corresponding set of quotations. The compendium strives for sufficiency in economists’ judgments, not in each’s expressions of such. That is, for each listed economist the relevant compendium of quotations in Appendix 1 contains samples that are sufficient to establish his judgment, but does not aim to cover all of his expressions of that judgment.

Table 1 shows 35 economists favoring liberalization. Surely, the table is quite incomplete. But the argument is one of sufficiency. Omissions that would matter would be ones that oppose liberalization. The few confounding judgments that I have found are collected and addressed below.

Table 1: FDA Permitting of New Drugs and/or Devices: Economists' judgments about liberalizing, by definiteness and minimum degree of liberalization advocated.

	Definite	Fairly Definite	Mild
Significant liberalization supported	Gary Becker Noel Campbell Milton Friedman Dale Gieringer David R. Henderson Robert Higgs Randall Holcombe Daniel Klein Sam Peltzman Paul Rubin Russell Sobel Alex Tabarrok Robert Tollison Kip Viscusi Michael Ward Walter Williams	Henry Grabowski Charles Hooper F.M. Scherer John Vernon	
Liberalization supported, but <i>not explicitly significant</i> liberalization	J. Howard Beales Ernst Berndt John Calfee Tomas Philipson Eric Sun Murray Weidenbaum	Ronald Hansen Joseph Harrington David Schwartzman Meir Statman Peter Temin Steven Wiggins	Charles Phelps David Dranove David Meltzer
Total: 35 Economists judge in favor of liberalization in the permitting of new drugs and/or devices.			

Documentation: See quotation compendia of Appendix 1 ([link](#)).

The next two tables follow the same scheme. Table 2 shows the results for FDA permitting of manufacturer speech about their products, in advertising, labeling, packaging, or promotion. It shows 12 economists favoring liberalization.

Table 2: FDA Speech Restrictions: Economists' judgments about liberalizing, by definiteness and minimum degree of liberalization advocated.

	Definite	Fairly Definite	Mild
Significant liberalization supported	John Calfee Milton Friedman David R. Henderson Alison Keith Daniel Klein Keith Leffler Paul Rubin Russell Sobel Alex Tabarrok		
Liberalization supported, but <i>not explicitly significant</i> liberalization			Ernst Berndt Davina Ling Margaret Kyle
Total: 12 Economists judge in favor of liberalization in manufacturer speech.			

Documentation: See quotation compendia of Appendix 1 ([link](#)).

Suppose a drug has been permitted by the FDA. Prescription requirements say that retailers cannot sell the drug without the buyer presenting a doctor's prescription. The FDA decides whether the drug will be prescription-only or "over the counter." Table 3 shows the results about FDA imposition of prescription requirements. It shows 8 economists favoring liberalization.

Table 3: FDA Prescription Requirements: Economists’ judgments about liberalizing, by definiteness and minimum degree of liberalization advocated.

	Definite	Fairly Definite	Mild
Significant liberalization supported	Milton Friedman Daniel Klein Russell Sobel Alex Tabarrok	F.M. Scherer	
Liberalization supported, but <i>not explicitly significant</i> liberalization	Kathleen Johnson Shirley Svorny	Sam Peltzman	
Total: 8 Economists judge in favor of liberalization in prescription requirements.			

Documentation: See quotation compendia of Appendix 1 ([link](#)).

APPARENT ANTI-LIBERALIZATION JUDGMENTS

I have assiduously searched for and collected scholarly judgments suggesting an anti-liberalization view. Here we examine cases of economists.

Paul Krugman. In a *New York Times* column of March 22, 2000, Krugman wrote about genetically modified foods and favored liberalization on that matter. But he set up the point with remarks on the dietary supplements industry. He said dietary supplements “are known to pose big health risks—but nobody knows how big, because lobbying by the industry has blocked effective regulation, testing and even reporting. . . . There is extensive evidence that dietary supplements can, if misused, be quite dangerous. [Omitted here is a brief alarmist quotation from a *Washington Post* survey.] But a 1994 law specifically exempts supplements from almost all federal regulation, including the need to report adverse effects.”

That's it. Krugman seems to be favoring FDA regulation of dietary supplements, but doesn't say whether "effective regulation" would look like traditional FDA controls. Again, Krugman was setting up his objections to illiberal attitudes and policies on genetically modified foods, which is the main point of the column.

A second item comes from Krugman, again in the *New York Times* (May 21, 2007). It is about food safety, not drugs, but it contains three sentences that refer to FDA drug controls:

Who's responsible for the new fear of eating? Some blame globalization; some blame food-producing corporations; some blame the Bush administration. But I blame Milton Friedman. ...

The economic case for having the government enforce rules on food safety seems overwhelming. Consumers have no way of knowing whether the food they eat is contaminated, and in this case what you don't know can hurt or even kill you. But there are some people who refuse to accept that case, because it's ideologically inconvenient.

That's why I blame the food safety crisis on Milton Friedman, who called for the abolition of both the food and the drug sides of the F.D.A. What would protect the public from dangerous or ineffective drugs? 'It's in the self-interest of pharmaceutical companies not to have these bad things,' he insisted in a 1999 interview. He would presumably have applied the same logic to food safety (as he did to airline safety): regardless of circumstances, you can always trust the private sector to police itself.

O.K., I'm not saying that Mr. Friedman directly caused tainted spinach and poisonous peanut butter. But he did help to make our food less safe, by legitimizing what the historian Rick Perlstein calls 'E. coli conservatives': ideologues who won't accept even the most compelling case for government regulation. (Krugman 2007)

Jerome Rothenberg. In 1993, Rothenberg published a review essay of Aaron Wildavsky's highly libertarian book, *Searching for Safety* (1988). The review essay is a broad discussion of safety issues; it is not specifically on the FDA. In the article (180) he describes himself as "considerably less optimistic" than Wildavsky and clearly expresses judgments in support of restrictions:

Perceptibly safer versions of a commodity, or commodities that can protect users against predictable hazards, will be profitable and hence

likely to be produced through competitive pressures. Even some forms of precautionary information—for example, safety ratings on consumer goods—will be generated by the market. But these will be inadequate where product performance is hard to monitor by users, where hazards are not widely or accurately perceived, or where people do not realize that they are uninformed. (Rothenberg 1993, 166)

Market processes do provide a partial corrective to consumer ignorance where hazard identification is relatively straightforward. When consumers suspect they are dangerously uninformed about private commodities, they may be willing to purchase product information as though it were a private commodity itself. Entrepreneurs may then profit from selling such information, their success depending on the perceived relevance and accuracy of the information they provide. *Consumer Reports* and *The Medical Letter* are notable examples of such success. But such instances are in fact rare. The more likely sources of such precautionary information are governmental product safety programs, scientific studies, and journalistic exposés. (171-72)

The market's myriad decentralized actions do not themselves ensure adequate safety. Centralized controls of various sorts are needed. These have been instituted in the form of regulations, constraints, information programs, licensing and certification. (172)

But if one does not know how to recognize 'beneficial' new drugs dependably without screening, and if the purpose of screening, with all its delays, is to point the way to devising new drugs that are *more* beneficial, then introducing 'beneficial' new drugs without screening has a possibly serious indirect opportunity cost—namely, the delayed development and introduction of even more beneficial drugs—in addition to the direct cost of unnecessarily high side effects.

The net weight of both sets of direct and indirect costs is not easy to gauge empirically, so Wildavsky makes his case with examples rather than solid quantitative evidence. How pervasive are well-publicized cases of apparently unwarranted delay? We certainly do not have quantitative estimates of the damage that has been directly prevented by screening, and indirectly by the incentives screening creates. More extensive, tightly analyzed data are required before we can make a trustworthy judgment about the issue. Wildavsky's anecdotal evidence is insufficient. (175-76)

Rothenberg never identifies a market-failure rationale for the interventions. Citing only works by Peter Temin and Victor Fuchs, he demonstrates little acquaintance with economic research on the FDA. He shows no acquaintance with the myriad ways that private practices and institutions certify and assure medical products, such as a doctors' prescription, nor that off-label medicine functions in a realm of efficacy assurances largely disconnected from FDA efficacy certifications. He never mentions that most drugs are prescription-only. Also, the essay does not note that voluntary practices—which of course include “scientific studies” and “journalistic exposés”—will be distorted by the banned-till-permitted system with a monopoly permitter.

Patricia Danzon and **Eric Keuffel**. Danzon is one of the most prolific economic researchers of the pharmaceutical industry, focusing especially on issues of pricing, price controls, liability, insurance, and drug development. In work with a doctoral student in Health Care Systems Eric Keuffel, she has recently expressed views that must be counted as opposing significant liberalization of the issues examined here:

Thus in our view, the case remains strong for a regulatory agency such as the FDA to establish minimum standards of safety, efficacy and quality as a condition of market access. However, the optimal integration of post-launch data with the prelaunch [randomized controlled trials] data remains an important issue to be resolved. (Danzon and Keuffel 2007, 28)

There is a strong argument that structuring and interpreting such data analysis is a public good that is best delivered by an expert regulatory agency. The existence of regulatory systems to perform these functions and control market access in all industrialized and most developing countries is strong evidence for consensus opinion on this basic proposition. (82)

OPEN-SOURCE SCHOLARSHIP: TEST THE FOREGOING ANALYSIS

Again, the only apparent anti-liberalization statements that I have found are those of Krugman, Rothenberg, and Danzon and Keuffel. Perhaps I have been biased in my search or presentation. The present journal invites communications that provide other apparently anti-liberalization statements by economists, as well as communications that contend that any of the judgments tabulated in Tables 1, 2, and 3 and compiled in Appendix 1 have been taken out of context, misrepre-

sented, or wrongly categorized. All such communications will be gathered up and shared in a future issue of the journal. As for additional pro-liberalization statements by economists, those are welcome as well.²

DENIALS OF CONCLUSION

John Calfee (2000, 25-31) has explained that if a firm develops a good new drug and it gets permitted, the potential benefits will go unrealized if patients and doctors never recognize it. Calfee further points out that confidence in future recognition is crucial, in the first instance, to creating the new drug.

Similarly, if an economist develops a good piece of economic discourse, the potential benefits will go unrealized if others never recognize it. If the cultural ecology of economics fails to recognize good economic discourse, benefits will go unrealized and, in the first instance, the development of good discourse will be discouraged. One factor inhibiting the realization of potential benefits is silence. Another is denial.

The first-order question has been: Do economists' judgments constitute a consensus on reforming the FDA? That question, I maintain, is answered quite decisively in the affirmative, and the consensus is for liberalization.

Now we turn to two related second-order questions:

Second-order question A: Do economists agree that economists reach a conclusion in favor liberalization of the restrictions in question?

Second-order question B: Do economists agree that there are no respectable market-failure rationales for the restrictions?

If all FDA-expressive economists agreed that there is no respectable market-failure rationale, then they would presumably agree that economists favor liberalization.³ Hence, the two questions are related. Both A and B are worthy of investigation, and they could be investigated separately. I find that at the second-order, in either version of the question, economists do not agree. As I think that some economists are getting it wrong in either version, my treatment tends to combine the two questions, rather than take pains to keep them separate.

Some economists seem to suggest that economists do reach a conclusion on FDA policy. For example, in their well-known textbook, *Economics of Regulation*

² Send communications to dklein@gmu.edu. Please provide full quotations, complete citation information, and information about the economist qualifications of the quoted authors.

³ I must write "presumably" because, even if all FDA-expressive economists agreed that there is no respectable market-failure rationale, they might not all agree that such economists favor liberalization, either because some of those economists falsify their views on the matter, or because some of them either misread or misrepresent the record of expressed views.

and *Antitrust*, Viscusi, Harrington, and Vernon (2005) write: “Although a few critics have charged that the FDA has been too lax, the consensus in the economics literature is that the FDA has placed too great an emphasis on ‘Type II errors’” (795). In other words, the consensus favors liberalization.

Others, however, deny that economists reach a conclusion. Here we present statements by economists suggesting that economic research has not arrived at any definite judgment in favor of liberalization. Some of the economists treated here are ones who have expressed judgments in favor of liberalization and are listed in Tables 1, 2, and/or 3—to wit, Ernst Berndt, David Dranove, David Meltzer, Tomas Philipson, and Eric Sun. There is no inconsistency in saying (a) liberalization is desirable, and (b) economic reasoning and research does not decisively favor liberalization. I think (b) is wrong, but it is not contradicted by (a).

An economist may maintain that income taxes should be lower and that economic analysis does not decisively support that conclusion. Analogously, Adam Smith (1790, 175, 327) distinguished between grammar-like rules, that are “precise and accurate,” and aesthetic-type judgments, that are inherently “loose, vague, and indeterminate.” In judging a matter of the latter type, for example, in ranking movies by quality, we might all put *Back to the Future* over *Bride of Chucky*, but not insist that our judgment rides a force of grammar—which flatly declares that “He goes” is proper and “He go” is not.

Perhaps it would be useful to extend Smith’s distinction to anticipate some of what follows in the present article. We have seen that most FDA-expressive economists favor liberalization. But I will criticize those who suggest that there is no strong grammar behind that conclusion. I will suggest, first, that there is a “grammatical” force behind the conclusion, and, second, that to treat the matter as looser than it really is, or to overstate the role of empirical artfulness in judging the policy issue, is to fail to apply political-economy grammar when it ought to be applied,⁴ and hence to fail to strengthen the norm within economics of following such grammar when it applies.⁵

4 The political-economy grammar that I invoke is a liberal grammar in the sense that it puts aside certain aspects of welfare, in particular, the gratification of wants that would favor the restrictions for reasons that one might frame as identity or cultural externalities. In fact, many people favor the restrictions because, as they might say, the regulations affirm community or social responsibility, restrain greed, or restrain or subvert capitalistic or neoliberal culture. Such aspects play a subterranean role in the setting and subtext of some of the discourse about FDA policy, but, at least among economists, such aspects are never explicitly recognized as helping to justify the restrictions. Until those aspects are put squarely onto the table I think it is appropriate to invoke a political-economy grammar that puts them aside. When they are put openly onto the table, the conversation becomes less grammar-like and more art-like.

5 By the way, the “political-economy grammar” to which I allude would be Quinean (and, I would argue, Smithian and Coasean) in the worldly nature of its presumptive authority, the warrant residing neither in “deduction” nor “induction” (Quine 1961). In particular, I do not see the presumptive authority of the grammar as deriving from axioms or “first principles”

William S. Comanor. The AEA's outreach and review organs, the *Journal of Economic Literature* and the *Journal of Economic Perspectives* are crucial nodes in the ecology of economic culture, and hence of the political culture at large. On the FDA topic, the record of those two journals has been disturbing. Only two pieces on the topic have ever appeared. The first was in *Journal of Economic Literature* in 1986, entitled "The Political Economy of the Pharmaceutical Industry," by William S. Comanor. He addresses the then extant work on the suppression effect, delays, the international drug lag, and drug promotion. He makes some loosely pro-liberalization remarks, such as: "There is wide acceptance of the general depressing effects of regulation—in the political arena as well as among economists. And studies of pharmaceutical regulation have, for the most part, followed that trend" (Comanor 1986, 1210-11). His review suggests, however, that the suppression effects have been overstated. He concludes his piece with the following sentences:

Although the existing economic literature on the pharmaceutical industry has provided a wealth of detail regarding its structure and performance, it has not supplied the research findings needed to permit accurate judgments on the critical issues for public policy. Perhaps this is due to the ways in which this literature has interacted with the continued political debates. There remain important tasks to be done. (Comanor 1986, 1214-15)

David Dranove and David Meltzer. These authors provide useful evidence that more important drugs are developed and approved more quickly. At the conclusion of their study they say: "Of course delays in approval also have their costs, and appropriate policies must weigh the costs and benefits of accelerated testing and approval on a case-by-case basis depending on the drug's specific risks, benefits, and difficulty of testing" (Dranove and Meltzer 1994, 422), seemingly rejecting—or at least failing to affirm—the idea that economists should have a strong presumption against the withholding of permission, regardless of a drug's risks, benefits, and difficulty of testing.

Berndt, Ernst R., Adrian H. B. Gottschalk, Tomas Philipson and Matthew W. Strobeck. These authors write:

A central tradeoff facing the FDA involves balancing its two goals—protecting public health by assuring the safety and efficacy of new drugs, and advancing the public health by helping to secure and speed access to new innovations. Although little quantitative evidence has been produced on this central tradeoff, some observ-

(just as English grammar does not find its presumptive authority from first principles).

ers have argued that the FDA is not taking enough time evaluating new drugs and biologics, while others have argued that the agency is taking too long in doing so. Little empirical evidence has been put forward to make the case that the FDA is too slow or too fast in its drug approval process, *partly due to significant difficulties in measuring the costs and benefits of greater speed*. (Berndt et al 2005, 1; italics added).

Elsewhere, the same authors say:

[S]urprisingly, very little quantitative empirical evidence has been put forward to evaluate the degree to which the speed and safety tradeoff facing the FDA is being resolved efficiently. More generally, *there seems to be no suggested quantitative methodology or framework for assessing the economic efficiency of the central speed-safety tradeoff of the agency*. (Philipson et al 2005, 3; italics added)

Philipson and **Eric Sun** writing in the *Journal of Economic Perspectives* say that speed of new product approval was underprovided prior to the reform of 1992 and add: “although more analysis would be needed to see *whether additional gains in speed at the expense of drug safety might be worthwhile*” (Philipson and Sun 2008b, 99; italics added).

Patricia Danzon and **Eric Keuffel** (2007) write that “the only significant attempt to weigh both the benefits and costs of the 1962 Amendments is Peltzman’s (1973) study” (22).

Regarding direct-to-consumer advertising (DTCA), they write:

[D]rawing welfare conclusions from the empirical evidence is particularly problematic. The economic/marketing literature generally views advertising that expands aggregate category sales as more likely to be informative, and hence welfare-enhancing, whereas advertising that simply changes market shares without affecting aggregate use is more likely to be wasteful ... However, in the case of heavily insured pharmaceuticals, for which consumers pay only a small fraction of the cost out-of-pocket, it is possible that even category-expanding effects could reflect unnecessary use (and/or unnecessarily costly use), even though such purchases are well-informed and rational for individual consumers, given their insurance coverage. (Danzon and Keuffel, 2007, 76)⁶

⁶ I don’t think the subsidization rationale for restrictions on direct-to-consumer advertising withstand scrutiny, but I refrain from digressing on the matter.

The existing evidence on effects of DTCA is mixed, with quite strong evidence for category expansion and weaker evidence for improved compliance and product specific benefits. *Effects on patient outcomes and on competition and overall costs have not been measured. Thus several of the components of a full welfare analysis remain to be developed.* (Danzon and Keuffel 2007, 86; italics added)

Anonymous *Journal of Economic Literature* referee. In late 2001, I submitted to the *Journal of Economic Literature* a proposal to write a literature review on the FDA that would organize the studies and evidence by natural-experiment comparisons and would suggest that the various analyses point to liberalization. In using this material here, I am probably uncollegial, but it is important to see the reasons actually given at the crucial moments at the crucial nodes of the economic culture, and unseemliness would seem to be the only way to bring the evidence to light.

One of the two referees wrote:

I do, however, have a number of problems with the outline, some serious, I believe. The most fundamental is the one of *measuring welfare or consumer surplus in this context. In particular, I think most of us would agree that standard measures, like integrating under demand curves, are problematic here, due to the informational asymmetries and the agency issues.* Furthermore, there are obvious econometric problems with looking for changes in morbidity and mortality arising from changes in regulation regime. This paper is mainly a literature review, so you might think it's unreasonable for me to suggest that you tackle this question. However, *your thesis rests entirely on it and most of the literature you review is agnostic on the question of welfare* (for the reasons I mentioned above). How, for instance, would a finding that some regulation had decreased the rate of drug innovation or reduced use of a drug be interpreted to support your thesis of 'overregulation' without a discussion of welfare? (Anonymous *JEL* referee 2002; italics added)

The referee seems to be saying that to arrive any firm judgment about the restrictions we need a net-benefit calculation, and we haven't yet figured out how to measure welfare. It seems that the then-editor of the *JEL* John McMillan reasoned along similar lines. In his cover letter rejecting the proposal he wrote:

Both [referees] say they are predisposed to agree with your position on the FDA (one says this in the report, the other in a cover letter

to me). But both say the evidence, as it currently exists, doesn't stand up to scrutiny. Both say, also, that there are methodological problems that will have to be addressed before the literature gets to be something more than advocacy. That being the case, it is premature to consider running a *JEL* article on this topic. (McMillan 2002)

Jerome Rothenberg. Above I quoted from Rothenberg to show that he seems to oppose liberalization. The material quoted also contains remarks to the effect that “anecdotal evidence is insufficient” and that policy judgment must await “solid quantitative evidence” (Rothenberg 1993, 176).

THE THERE IS NO MARKET-FAILURE RATIONALE

I contend that the longstanding banned-till-permitted policies⁷ have no market-failure rationale. If that contention is correct, the implications are intriguing and far reaching, particularly as regards the economic literature on the FDA. Now I offer a brief case for the contention.

Uncertainty engulfs us especially in matters of health and treatment. Some might say that such uncertainty makes us child-like. But the “child” metaphor holds water only if there is a “parent” counterpart. A rationale for the observed restrictions would need to assert, at least somewhat plausibly, that what amounts to FDA veto power somehow corrects systematic erring in the face of such grave uncertainty. But no grounds are ever offered for any such systematic erring, much less for the corrective effect of FDA veto power.

Litigation weighs heavily on product safety and medical treatment. More importantly, people have demands for ex ante assurance of quality and safety, and those demands give rise to supplies.⁸ Reputation is but one form of assurance, and it suffers by product recalls (Jarrell and Peltzman 1985). Assurance and litigation do not work perfectly. But there is no theory contending that they err systematically AND that the longstanding policies constitute any plausible correction to such erring. A defense of government intervention must open with a rationale and proceed to a reasonably well-rounded case—a case that recognizes important costs and the imperfections of the alternative arrangement. As regards the longstanding policies, we do not find even a coherent opening rationale, much less a well-rounded case.

Consider some of the articulations of market-failure rationales found in the literature. Danzon and Keuffel (2007, 11) articulate the arguments for proof-of-efficacy:

⁷ I use this phrasing because Congress, not the FDA, imposed the bans. The FDA decides whether to give or withhold permissions. To be sure, it can give permissions more freely, but it can not repeal the bans.

⁸ On the demand and supply of assurance see Klein (2002).

The presumption underlying the requirement for proof of efficacy was that imperfect and possibly asymmetric information prevented physicians and consumers from making accurate evaluations, leading to wasted expenditures on ineffective drugs and excessive product differentiation that undermined price competition.

More generally, they write:

The rationale for heavy regulation of pharmaceuticals is not intrinsic natural monopoly, since any market power enjoyed by individual products derives ultimately from government-granted patents. Rather, regulation of market access, manufacturing and promotion arise because product efficacy and safety can be critical to patient health but are not immediately observable. Evaluating safety and efficacy as a condition of market access and monitoring manufacturing quality and promotion accuracy over the product life-cycle are public goods that can in theory be efficiently provided by an expert agency such as the Food and Drug Administration (FDA) (Danzon and Keuffel 2007, 3; see also 5-6, 11).

Thus, Danzon and Keuffel say that that knowledge has certain public goods properties. But the public-goods point in no way justifies the restrictions we see; it could only justify government subsidization of knowledge production.

As for uncertainty and the hazard of medical mistreatment, these in themselves provide no market-failure rationale. Danzon and Keuffel provide no mention of systematic erring in the face of such uncertainty. Without an even superficially plausible case of systematic erring that is somehow corrected by the policies, there is nothing here making for justification. Surely the restrictions do prevent some medical mistreatments. But a ban on driving automobiles would prevent some injuries. Market failure can be adduced in the first case no more than it can be adduced in the second. Market failure can be adduced from the presence of risk and uncertainty no more than from the presence of scarcity. Stigler (1961) showed us how to see information as costly, and Demsetz (1969) justly argued that such scarcity in and of itself does not imply failure.

A market-failure rationale requires a plausible story about how government, with its special abilities, might improve matters. It is not legitimate to look at the situation, notice risk, ignorance, and uncertainty, and declare “failure.” That ignorance, risk, and uncertainty, as well as folly and presumptuous, plague political and governmental affairs leads us into other epistemic arguments against government intervention, per Smith and Hayek. If “failure” has any meaning at all, it is as an idea in comparative institutions.

Furthermore, in assessing permitting and promotion restrictions, Danzon and Keuffel scarcely acknowledge that most sensitive drugs are prescription-only, and hence uncertainty arguments for pre-market approval and speech restrictions implicitly declare that doctors' access to wisdom discerned by FDA officials is so poor that that deficiency is not redeemed by their obviously far superior knowledge of the local situation. Not only is the FDA assumed to have some special ability in evaluating safety and efficacy (and speech by manufactures), it is assumed that the wisdom discerned by those officials cannot be imparted and entrusted to the medical professionals who actually know something about the patient. Thus, presuppositions of FDA specialness are implicit throughout, but scarcely ever explicit.

Maybe FDA evaluation is a public good, but that would not justify the observed restrictions. The government is special, notably in its exclusive power of institutionalized coercion. That specialness makes for a coherent rationale for taxpayer subsidization of basic research and other public goods. But the policies under discussion are not of such nature.

Danzon and Keuffel also suggest (pp. 28, 82) that a voluntary and competitive field in the assuring of quality and safety and the creation of associated standards would perform less well than a situation in which a governmental agency had privileges and powers over such matters. But they give no grounds for such a view. A very good case can be made for the opposite conclusion, that is, that quality and safety assurances develop best within processes that are voluntary and competitive. Not only does a monopoly government certifier run the risk of producing bad, simplistic, or too few standards, the awesome power inherent in the current system damages integrity throughout the scientific and certification process. In the face of awesome power, people are especially reluctant to be candid about doubts and weaknesses. If, instead, the market were free and the processes were voluntary, the fears associated with candor would be much reduced—the certifier might withhold its seal of approval, but it could not withhold freedom.

Another summary of arguments for banned-till-permitted policy for new drugs is provided by Ronald Hansen:

The principal benefit claimed is the elimination of unsafe and ineffective drugs thereby reducing the harmful effects no patients either directly from unsafe drugs or indirectly from delaying proper therapy as the result of using an ineffective drug. Control over the claims that companies could make for their products would reduce the need for physicians to verify independently the claims made for products that they prescribed, thus reducing information costs. To the extent that the administration of the regulations discouraged me-too research, research would be directed to more innovative projects. (Hansen 2000, 274)

Hansen's presentation leads us to believe that he himself does not think much of the arguments. Clearly, they in no way suggest that the observed policies correct systematic erring.

If we go down a checklist of market-failure rationales— adverse selection, externalities, natural monopoly, equity, etc.—we do not find one that can be invoked for the policies. Robert Higgs (1994; 1995a, 7-9) examines the official rationales and finds them empty.⁹ Likewise, Russell Sobel (2002, 464-65) challenges the presupposition of market failure.

Consider the following from F.M. Scherer, an economist not known to be a free-market stalwart:

An information market failure may need correction. But why doesn't the regulator merely require appropriate testing and disclosure of test data, letting physicians decide from the data whether the drug is safe and efficacious? If there is an argument for regulation of *whether* new drugs may be marketed, it must lie in a further information market failure—e.g., from the possibility that most physicians are too busy to make well-informed independent decisions. (Scherer 2000, 1315)

Most sensitive drugs would normally be prescription-only. Opposing liberalization in permitting and speech must see comparative failure, not only in voluntary assurance and litigation, but in the profession that writes prescriptions.¹⁰

If uncertainty sometimes makes us child-like in the face of illness and choice of treatment, who is the parent? The presuppositions surrounding the FDA might stem from an unexamined precept that there must be some kind of parent out there, a yearning for some kind of validator, as well as from the cultural convention of finding the validator in government (Buchanan 2005). If so, it is the responsibility of economists to explain that government is no less child-like than the patient's medical professionals, and that arrangements that effectively give veto power to child-like officials devoid of local knowledge only make a bad situation worse.

Meanwhile, if phantom validation and the like are the actual impetus of the observed policies, then such facets ought be brought out onto the table, presu-

⁹ I do not agree with the following by Higgs: "By simply denying me the option to consume X, you have definitely made me worse off, because you have removed my most preferred object of choice from the set of alternatives open to me" (1994, 6). But I think the point—and similar "Austrian" claims in his argument—can be suitably altered or omitted, such that the basic contention of no market-failure rationale holds.

¹⁰ Incidentally, Philipson and Sun (2008b) discuss the inefficiency of duplication by liability and FDA approval, but, oddly, they make no mention of the yet third layer of control in prescription requirements.

ably as some kind of cultural public good, and defended as such. Until such time, I will regard them as off the table, as is customary in economics, and persist in invoking the political-economy grammar that then applies.

**THE INTELLECTUAL TYRANNY OF THE STATUS QUO:
THE POLITICAL SOCIOLOGY OF ECONOMIC DISCOURSE ABOUT THE FDA**

Peter Temin—again, no free-market stalwart—examined the history of political attitudes surrounding these issues. He writes of new presuppositions spearheaded by officials and then adopted as public doctrine, a shift that lacked critical thought:

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)

The public doctrine tacitly attributes specialness not merely to government, but to *American* government. Counterparts to the FDA function in other countries. The FDA could adopt a standing policy that drugs permitted in Europe, Canada, Japan, Australia, etc. automatically become permitted in the US. Why doesn't the FDA adopt such a policy? Is it because a drug that is safe and effective in Australia, Canada, or France may not be safe and effective in the United States? Of course not. The presupposed specialness is not, in fact, special to the American government. Most players of the economic cultural elite—such as the AEA editors and officers, the most prestigious health economists, etc.—do not welcome candid discussion of this point. They observe the standard public doctrine. They observe the taboos of officialdom, academia, and “the policy community.” Were the elites to defy the taboos, we would see clearly that the presupposed specialness is, not only not special to American government, but altogether baseless. There is no helpful specialness in this matter—there is no market-failure rationale. The public doctrine is public superstition.

Some know better but play it strategically. Partly, the problem is a Catch-22 embedded in a cultural prisoner's dilemma: If a “player” were to defy the taboos, he might disqualify himself from “playerhood,” possibly to the detriment of social welfare. He may engage in noble lying so as not to make the best the enemy of the good.

But the words people publish spell paradox. There are good reasons for us to expect that some, if not most, of the power players—and hence some, if not

most, of the experts—will tend to believe in the goodness of bad policies.¹¹ If the counterparts in 15 other countries could also permit for use in the US, the FDA would have to compete in drug review and would lose prestige, power, influence, and funding. The whole structure would unravel. Politicians would have to face up to a colossal mistake, and explain it somehow to voters. Other sacrosanct institutions share the same lack of rationale. Grand superstitions would be challenged and taboos shattered. The great powers—including the two parties who vie for power and pander to voters who systematically under-appreciate liberalism—could scarcely tolerate such implications. They participate in open communication only with those who take care to avoid any such talk. Timur Kuran (1995) explains how the unsaid becomes the unthought and then the unthinkable. The economics profession is supposed to stand up against the collective foolishness of officialdom and society at large. Instead, it has stooped so low that some of its liberal grammar has become unspeakable, even unthinkable.

The presupposition of FDA specialness is political superstition buffeted by power structures. It has given rise to taboos that gull most of the ordinary citizens and cow the regulatees—the pharmaceutical industry—and many of the researchers who interact with the central players. The researchers often depend on the FDA for data access, institutional expertise, visibility, and prestige. Also, the researchers often depend on the regulatees again for data access, institutional expertise, visibility, and funding, if only indirectly. For example, industry provides most of the funding for the Tufts Center for the Study of Drug Development and significant funding for the American Enterprise Institute and the George Stigler Center for the Study of the State and the Economy at the University of Chicago. All told, it is very plausible that we have a polite social network that tends to cut out those who would scrutinize “progressive” presuppositions ensconced long ago and subsequently made ever more permanent and politically sacrosanct. Even an economist in the network who personally doubted the establishment presuppositions would likely suppress such thoughts because of his interdependencies with others who would either take offense or simply doubt whether he can be relied upon as an effective and respectable ally.

I have often pondered whether “big pharma” would make less profit if permitting restrictions were significantly relaxed.¹² There are arguments pointing in both directions. However, one should not assume that all of the people inside big pharma would favor company profits, which might be diminished by liberalization, over social well-being, which would be enhanced by liberalization. They are part of medicine and humanity, and hence consuls of the impartial spectator, and they must see as clearly as anyone the tremendous social downside of restrictions.

11 I have offered a general treatment of why power players will tend to believe in the goodness of the bad policies that they administer or are expert in; see Klein (1998).

12 As for the speech and prescription restrictions, it seems fairly clear that relaxation would enhance their profits.

But even if inclined toward significant liberalization of any of the restrictions, they would still be extremely constrained in voicing such views or bringing their expertise to bear in the policy debate. The diffidence would stem not only from prudence—slaves are never wise to criticize the whipping-master—but from the realization that anything they say is likely to be scandalized as pure greed, particularly by journalists, leftist pundits, opposition politicians, and so-called consumer advocates. Big pharma is a big player in the funding of social research on the FDA, and in the provision of data and institutional expertise, but there is little reason to think that they would fund, openly assist, or themselves voice challenges to the basic presuppositions challenged here.

The important questions are cultural, and the answers must be sociological and psychological. I am not suggesting that economists have been bought off by the drug industry. On the contrary, I am pointing to an explanation of how the problem can persist without conspiracy or venality. At one level, the problem might be sheer status-quo bias, as would exist within any society, even a freer society. But why can't status-quo bias in our present context be more substantially overcome by the power of enlightenment? At that deeper level, I suggest that the problem is a symptom of—and cause of—undue cultural statism—among the electorate, among the power players, among the experts, and among academics. Unenlightenment may feed unenlightenment, particularly when institutionalized coercion enters the contest, as it does here in a big way. Getting it right on the FDA is but part of a much larger set of views.

Our sociology must also delve into the psyche of the researcher. Now we return to the words of the expert economists, especially those who tepidly favor liberalization but preach a kind of agnosticism. Consider this: If there is a market-failure rationale for the observed policies, then we need researchers to explore whether they are warranted and, if so, how they might be fine tuned. But if the observed policies lack a market-failure rationale, then we know—do we not?—that their costs are not fully redeemed. The quantitative research comes to look like complicated demonstrations that water runs downhill. Such awareness might threaten the researcher's selfhood. It is good that scholars demonstrate that the accelerations following 1992 improved welfare, etc., but in a sense they are simply showing evidence on an issue that was settled as soon as we saw that there was no market failure. Thus, many of the leading figures, though favorable to liberalization, might be quite antipathetic to any critical examination of basic presuppositions.

MUST QUANTIFICATION PRECEDE ECONOMIC JUDGMENT?

Quantitative empirical work on the effects of the observed restrictions is extremely valuable. It is good to confirm basic tenets with responsible empirics.

Second, the basic message is made more convincing. Third, in quantifying effects we delve into and learn about institutional and practical affairs; we learn to refine the tenets, their application, and our understanding of their applicability. Fourth, empirics improve our sense of the magnitude of the effects. And other reasons exist for admiring and rewarding good quantitative empirical research.

But some economists' rhetoric concerning quantitative research gives me pause. I see two problems. The first, treated in this section, is that some of the rhetoric tends to surrender, slight and undermine the power of non-quantitative argumentation on the issue.

I quoted economists who deny that FDA-expressive economists come to a conclusion. Some of those authors seem to suggest that economics cannot come to a conclusion without quantitative analysis of the effects of the policy. Philipson, Berndt, and their coauthors show little regard for the theoretical arguments for liberalization, and proceed as though the only relevant discourse is quantitative evidence. They claim that "[l]ittle empirical evidence has been put forward to make the case that the FDA is too slow," and that "there seems to be no suggested quantitative methodology or framework for assessing the economic efficiency of the central speed-safety tradeoff." With such remarks they have slighted and dismissed many economic studies rooted in a theoretical argument for liberalization. Philipson and Sun (2008b) suggest we need further empirical analysis to judge "whether additional gains in speed at the expense of drug safety might be worthwhile" (99). Danzon and Keuffel (2007, 86) write: "Effects on patient outcomes and on competition and overall costs have not been measured. Thus several of the components of a full welfare analysis remain to be developed."

Suppose an economist is asked: Which policy is better, import quotas on sugar or freedom to import sugar? In judging the matter, does the economist require quantitative evidence specific to the policy? Does a competent econometrician need to do a quantitative study before we can come to judgment? Certainly not. Quantitative material of such nature is not necessary to arrive at a judgment on the sugar program. Political-economy judgment is complex, but it has been developed—within, by the way, a broad enterprise that *does* depend on empirics of wide array—so as to make part of it is rather simple (or grammar-like), and that part suffices here: *If the situation apparently involves no significant, systemic market imperfection, we side in favor of allowing voluntary action.*

Many of the works cited in the first cells of the Tables 1, 2, and 3, and quoted in Appendix 1, question the presupposition of market failure. For example, in his empirical study of speech restrictions, Leffler (1981) writes, "restrictions on pharmaceutical promotion appear to risk large losses in consumer welfare *for the promise of unproven and perhaps nonexistent gains*" (74; italics added). That is, he establishes the broken eggs and implicitly asks, *Where are the omelets?* Again, Higgs (1994; 1995a, 7-9) and Sobel (2002, 464-65) directly dispute the market-failure presupposition. But many of the establishment authors quietly elide

this fundamental argumentation. Most neither assert the existence of a market-failure rationale, nor do they assent that none exists.¹³ But isn't that where the conversation should start?

Consider research on the lessons of off-label practices. Building on suggestions by Beales (1996) and others, Alexander Tabarrok (2000) developed an analysis that asked: What can we learn about the need for efficacy requirements from the pervasive experience of off-label medicine, which has no FDA efficacy certification? The thrust of Tabarrok's argument is that off-label seems to work quite well and so why not drop efficacy requirements entirely? The voluntary assurances for off-label treatment, such as listing in professional medical compendia, are illustrated with evidence of various kinds. To explore the matter further, Tabarrok and I (Klein and Tabarrok 2008) searched for justifications by interviewing those in the trenches. We constructed an online questionnaire that asked doctors about off-label issues. The findings showed that virtually all doctors opposed the idea of imposing efficacy requirements on off-label uses. The survey challenged doctors on the matter of consistency: If one opposes efficacy requirements on off-label uses, shouldn't he also oppose them on initial (on-label) uses? In effect, the doctors were asked: What is the market-failure argument that is decisive for initial uses but not for off-label uses? We collated the responses, breaking them down into a number of arguments. Those arguments were then critically examined. Although we uncovered limitations to the consistency argument, we found nothing resembling a respectable market-failure rationale for initial efficacy requirements.

Such research suggests that off-label practices speak to efficacy requirements. But the learning is not a net-benefit calculation. It is about presuppositions. Such is how much of the critical literature has worked—what do real experiences in other times, other places, other industries, and other realms of medicine tell us? The suggestion, very often, is either that there is no real market imperfection to correct, or that any market imperfection that might exist would call—if it called for any government action at all—for corrections different than the established policies.

The establishment authors sustain faulty presumptions, and correspondingly, they have a faulty idea of where the burden of proof lies and what it entails (Lewin 2007). It is useful to distinguish two vying attitudes:

1. **The liberal attitude** starts with the presumption that free markets work tolerably well, and places the burden of proof on intervention, beginning with a market-failure rationale.
2. **The establishment attitude** starts with the presumption that the

¹³ As we've seen, there is an exception in Danzon and Keuffel (2007).

status quo reflects some kind of collective wisdom, and hence places the burden of proof on those who would change it. That burden often takes the form of a demand for a quantitative, empirical demonstration that the change will improve social welfare.

Alas, the latter has largely displaced the former. Had the establishment attitude prevailed in previous centuries, Adam Smith would have been obliged to remain professionally reticent on mercantilism, Jeremy Bentham on usury, and John Stuart Mill on slavery and women's rights. None of them pretended to resolve the issue by recourse to quantification of the effects of the debated policies. Rhetoric that suggests that such quantification is necessary to arrive at judgment bypasses the question of whether the policies lack any respectable market-failure rationale. Of course, there were individuals who offered rationales for slavery, coverture, and usury restrictions.¹⁴ But the perniciousness of such policies must be understood in terms of general principles, and must be defeated in such terms. When an economist bypasses the fundamental questions, he effectively presupposes that there is a respectable rationale out there somewhere. The presupposition becomes conventional behavior and conventional thought.

THE CHIMERA OF NET-BENEFIT CALCULATION

Now, the second problem: Some of the remarks surveyed earlier insist not merely on quantitative evidence about effects, but more specifically on a complete, if rough, calculation of net benefits (benefits minus costs). They suggest that policy judgments are mere "advocacy" until we have a net-benefit calculation. Moreover, some pretend to or aspire to net-benefit calculation.

Philipson et al (2005) study the review-time acceleration following 1992. The authors tout their study as the real thing. The gist is that, because the acceleration expedited permission of mutually advantageous exchanges, the acceleration was beneficial. Even under extreme assumptions, any health losses resulting from the reckless permitting of unsafe drugs weren't nearly enough to offset the gains.

To fit things into a net-benefit calculation, they do things like multiplying a life-year by a supposed value of life. Again, I appreciate the merits of being quantitative. At the same time, the drive to fit the matter into an encompassing calculation can lead to the omission of factors that are difficult to quantify. For example, without ever acknowledging it, Philipson et al (2005) left out entirely the effect that faster review times have on drug development! The authors have also left out the all moral, ethical, cultural, and political consequences. These

¹⁴ Here we should acknowledge that, paradoxically enough, Smith offered and endorsed rationales for the usury laws that were the status quo in his times.

effects pertain to the sources of moral approval set out by Adam Smith in *The Theory of Moral Sentiments* (1790, 326-27). The first three of those sources have to do with the character of social affairs, in particular how norms of propriety affect how sentiments interact. Some of us would be willing to pay for a more liberal culture in these matters, apart from any effects on health and wealth more narrowly construed. Surely many suffering patients are willing to pay simply for the feeling of not being denied the liberty to decide their own affairs.

But besides getting the net-benefit calculation wrong, there is a more fundamental problem: The rhetoric of net-benefit calculation is phony, and that phoniness can be highly damaging. In reading Philipson et al 2005—whose approach and basic results are recapitulated by Philipson and Sun (2008b) in the *Journal of Economic Perspectives*—we are struck by the many ways in which the authors have simplified the problem.¹⁵ Most of the simplifications tilt the calculation—sometimes sharply and implausibly—*against* finding net benefits from the acceleration. What the authors are really doing is mounting an argument *a fortiori* in favor of the acceleration. An *a fortiori* argument endeavors to make a claim persuasive by making an even stronger claim persuasive—I will show that I can lift 50 pounds by showing that I can lift this bench here which weighs *at least* 50 pounds. That is, Philipson et al are tacitly arguing that the accelerations were beneficial on net in the following manner: *Even when we tip the calculation heavily against the acceleration, we still find that it was beneficial on net.*

In making an empirical argument, trying to quantify all significant effects is usually vain. Instead, we construct the stronger claim by simplifications that make that claim easier to represent and to judge. In *The Rhetoric of Economics* (1985, 115-30), Deirdre McCloskey explains how Robert Fogel argued that the impact of the railroads in the development of the U.S. economy was much smaller than commonly supposed. Fogel estimated not the social savings of railroads but upper bounds on the savings, showed the bounds were small, and concluded that the social savings were small.

I suspect that Philipson and his various economist coauthors, in their heart of hearts, believe that the FDA is much too restrictive—I suspect that, if cornered, they would be inclined to agree that there is no market-failure rationale, and that they would admit the profound implications of that. Between the lines, they argue *a fortiori*. In that respect their work is really like the many other works that cite less technical or merely exemplary evidence of costs and argue that, *since there is no market failure*, the costs of the restrictions are not fully redeemed.

That form of argument would be fine, but it ought to be presented as such. If, instead, an *a fortiori* argument is presented as a net-benefit calculation,

15 Some of the simplifications are summarized at Philipson et al 2005, 31-33; and at Philipson and Sun 2008b, 99.

as though judgment hinges on whether they come up with a positive or negative answer, then the research might mislead.

First, readers might take the calculation at face value and say, “Oh look, FDA restrictions are not that big a deal, our leaders have more important problems to worry about.” In fact, the range of net-benefits that Philipson et al come up with for the accelerations following the 1992 reform are unimpressive. Political attention and political will are scarce. One might well react to the finding by saying we have larger fish to fry. The problem would be avoided if Philipson et al made plain that they were not estimating the net benefits of the accelerations but a lower bound, and aiming to show merely that it was smaller “than the true but unmeasurable amount” (McCloskey 1985, 115).

More importantly, when an *a fortiori* argument is presented as a net-benefit calculation, it will quite possibly legitimize wrongheaded notions.

Suppose I am recovering from an injury and my doctors decide that I will need an additional invasive procedure unless I can lift 50 pounds. The only object readily available for lifting is a bench. We sense that the bench weighs at least 50 pounds. I struggle and just manage to lift the bench, so the assurance is provided, *a fortiori*. Now, if someone were to say, “OK, let’s say the bench weighs 50 pounds; Dan struggled to lift it, so clearly Dan can only lift about 50 pounds.” The danger here is that perhaps the bench weighs much more than 50 pounds, perhaps 100 pounds. Say that, upon my lifting the bench, the doctors record my ability to lift as 50 pounds. Were the cutpoint for the invasive procedure subsequently raised to 70 pounds and my records reviewed in light of that change, I would then be called in to undergo the procedure—erroneously.

It is not plausible that my doctors and I would be so dysfunctional, but the political process is highly dysfunctional. Accordingly, with Philipson et al’s calculation, some major parts of the calculation will necessarily be vague and speculative. Opponents can take most of the calculation at face value—after all, its authors have presented it as a complete calculation of costs and benefits. But opponents can then contest certain parts, particularly vague and speculative parts, revise them, and then proclaim that the sign of the calculation reverses. Thus, claiming to do a net-benefit calculation when one is really doing an *a fortiori* argument sets oneself up for refutation.

In general, calls to police government policy with net-benefit calculations—such as Hahn and Tetlock (2008, 73)—can backfire, because very often a net-benefit calculation is beyond the constraints of time, costs, and credibility. Rather, as Ronald Coase (1982) writes in “How Should Economists Choose?,” positions, very often, are arrived at by economic reasoning “based on assumptions about human nature so basic that they are difficult to question” (24, 25), and then argumentation deploys “measurements of an effect” (25)—not *all* effects—in an *a fortiori* manner. Empirical measurements of effects are valuable, but the pretense of doing a net-benefit calculation is often chimerical.

Whether they admit it or not, economists typically do not withhold judgment prior to calculation. I noted that the great economists who criticized mercantilism, usury restrictions, slavery, and the subjection of women did not pretend to resolve the issue by recourse to quantification. Even less did they pretend to do a net-benefit calculation. The two problems we have visited—the abandonment of market-failure framing and the pretense of basing judgment on net-benefit calculation—stem from professional norms against critically challenging established policy, norms against acknowledging the viability of condemning many major established interventions on the basis of the grammar of liberal economics.

WE CAN DO BETTER

This article has taken the economic literature on the three FDA-administered interventions as a case study in how statist political culture degrades academic economic discourse. While this article's middle and later parts have been critical of the economic culture, the first part showed that—save Paul Krugman and a few others—the degradations have not gone so far as to embolden economists to judge against liberalization. Rather, much good economic sense survives the degradations. The first part of the paper showed that FDA-expressive economists preponderantly favor liberalization of the three restrictions.

How far should liberalization go? Proposals include international reciprocity, creating a competitive field of certifiers certified by the FDA (Miller 2000), dropping efficacy requirements, “split-label” reforms and such for speech, dropping prescription requirements, —all the way to abolition. The idea is to move some distance from banned-till-permitted to allowed-till-forbidden. For example, the FDA allows dietary supplements, but, after a concern about a product in the store arises, decides whether to forbid it. Much of food control works similarly, as does the Consumer Products Safety Commission. In *Searching for Safety*, Aaron Wildavsky (1988) called it “resilience,” and favored it over restrictive “anticipation.” Pure resilience would be just the court system. My view tends towards pure resilience (and a better court system), because I see large costs to restrictive “anticipation” and believe that the heavy lifting in assurance is done, and will be done, by voluntary practices and institutions. The voluntary processes are self-correcting, while restrictive systems do not exhibit that virtue with anything like the same agility, diversity, and sensitiveness—and humaneness, decency, and equity. Hence the great costs that many studies have substantiated.

The matter is urgent, the stakes very high. A leading figure, Sam Peltzman, speaking in 2005 of the proof-of-efficacy requirement imposed in 1962, said:

I concluded that the proof-of-efficacy requirement was a public health disaster, promoting much more sickness and death than it prevented. Nothing I have seen since has moved me to change that conclusion—the disaster is ongoing.

He goes on to say that because of biases, “The carnage from this regulation, I regret to assure you, will continue for a long time” (Peltzman, 2005, 15-16).

Such pessimism is hard to escape. A 2003 survey showed that most economists are *supportive* of FDA controls.¹⁶ If we are to escape Peltzman’s pessimistic forecast, it must be by way of better, bolder, braver leadership at the crucial nodes in the ecology of economic culture. Economists ought to know that vital economists reach a conclusion on the FDA, and, further, that there is not and never was a market-failure rationale. Economists must face up to economics, even if sacred cows must be slaughtered. Our central calling is to correct attitudes that are gravely mistaken. We can do much better. What’s needed is fuller embrace of the by-and-large Smithian verities that sustain liberal presumptions and a corresponding readiness to oppose established policies and the establishment-mindedness that surrounds them.

APPENDICES

Appendix 1: Compendia of judgments to substantiate the listings of economists in Tables 1, 2, and 3. [Link](#).

Appendix 2: Substantiation that the individuals listed in Tables 1, 2, and 3 or treated in the “Apparent Anti-Liberalization” section meet at least one of the criteria required to be counted as an “economist.” [Link](#).

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NOTE: A large portion of these items are cited only in Appendix 1.

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