Comment on *Using Competition-Based Regulation to Bridge the Toxics Data Gap*

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In *Using Competition-Based Regulation to Bridge the Toxics Data Gap*,[1] Prof. Wendy Wagner offers a useful and provocative proposal intended to address the many shortcomings of current U.S. policy toward industrial chemicals. The proposal derives from a diagnosis of the root causes of these policy failings with which I wholeheartedly concur.[2] The main elements of that critique are the following:

- Despite the fact that the Toxic Substances Control Act (TSCA)[3] states unambiguously that it is U.S. policy that data be developed for all chemicals in commerce adequate to determine their health and environmental effects, and that manufacturers bear the responsibility to develop those data,[4] for the great majority of chemicals, few data are available to the public or to the U.S. Environmental Protection Agency (EPA) to characterize their hazards.
- EPA's authority to require testing of chemicals is highly constrained and hence seldom employed.
- Companies have little or no incentive to develop health and environmental data on their own initiative, not only for chemicals already on the market but also for new chemicals subject to pre-manufacture notification and review by EPA. And because the default in the face of data gaps or uncertainties is no action, industry has an incentive to seek to perpetuate rather than rectify them.
- Even when EPA does manage to obtain evidence of significant risk, its authority to act to control a chemical's production or use is even more constrained than its data gathering authority and is virtually never used.[5]
- EPA's access to information, not to mention its resources, is dwarfed by those of the chemicals industry.

These failings yield a dysfunctional regulatory environment and chemicals market, ill-informed and unable to distinguish, let alone motivate or reward the development of, more benign chemicals and chemical products.[6] It is little wonder, then, that companies have seen little need to innovate toward inherently safer chemical and product design.

Seeking to break up and recast this market dynamic is therefore entirely appropriate, and Wagner's proposal seeks to do just that. In doing so, it also posits a pivotal role for government in the heart of the chemicals market, one that goes well beyond its traditional regulatory role: that of judge and jury in deciding which chemicals and products should succeed in that market and which should fail. Proposing such a role for government raises both major pragmatic questions (many of which Wagner herself anticipates) as to whether and how it might work in the face of government's limited authorities and the enormity of the chemicals economy, and a more fundamental question as to the appropriate role of government in market selection and deselection of chemicals.

Wagner's proposal is not unique in assigning a role to government in identifying and seeking to promote the sub-

1. Wendy Wagner, *Using Competition-Based Regulation to Bridge the Toxics Data Gap*, 39 ELR (Envtl. L. & Pol'y Ann. Rev.) 10789 (Aug. 2009) (a longer version of this Article was originally published at 83 Ind. L.J. 629 (2008)).
2. *See* Richard A. Denison, Not That Innocent: A Comparative Analysis of Canadian, European Union, and United States Policies on Industrial Chemicals (2007), *available at* http://www.edf.org/documents/6149_NotThatInnocent_Fullreport.pdf (last visited June 1, 2009); Richard A. Denison, *Ten Essential Elements in TSCA Reform*, 39 ELR 10020 (Jan. 2009).
3. 15 U.S.C. §§2601-2692, ELR Stat. TSCA §§2-412.
4. TSCA's preamble states: "It is the policy of the United States that . . . adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures." 15 U.S.C. §2601(b)(1), ELR Stat. TSCA §2(b)(1).
5. Since adoption of TSCA in 1976, EPA has succeeded in mandating limited restrictions on the production or use of only five substances. The five substances are: polychlorinated biphenyls (PCBs), by virtue of a mandate from Congress; fully halogenated chlorofluoroalkanes used as aerosol propellants; dioxin in certain wastes; asbestos (limited to products no longer in commerce); and hexavalent chromium used in water treatment chemicals in comfort cooling towers. *See* U.S. Gov't Accountability Office, Chemical Regulation, Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program, (2005) Report No. GAO-05-458, at 58-60, *available at* http://www.gao.gov/new.items/d05458.pdf.
6. *See* Joseph H. Guth et al., *Require Comprehensive Safety Data for All Chemicals*, 17 New Solutions: J. Envtl. & Occupational Health Pol'y 233 (2007), *available at* http://www.louisvillecharter.org/paper.safetydata.shtml (last visited June 1, 2009).

stitution of chemicals of concern with safer alternatives. A few examples illustrate a number of possible roles for government. Massachusetts' Toxics Use Reduction Institute (TURI) provides research and technical assistance to the state's businesses in identifying and implementing less toxic alternative materials and processes to specific hazardous chemicals. TURI also conducts formal alternatives assessments of technical and economic as well as the environmental performance of the alternatives.[7]

The European Union's recently adopted Registration, Evaluation, and Authorization of Chemicals (REACH) regulation requires manufacturers seeking a time-limited authorization to use certain so-called "substances of very high concern" themselves to analyze the availability, viability and risks of alternatives. If viable alternatives are identified, a substitution plan and timetable for implementation are required.[8]

The state of Maine adopted in 2008 a law that authorizes (but does not require) the state to ban production and sale of a children's product containing a "priority chemical of high concern" to which children are exposed if the state finds that a safer alternative is available at "comparable cost." The state can also require the manufacturer of a product containing such a chemical to conduct and submit an alternatives assessment, and to pay for an independent assessment if the state finds that the manufacturer's assessment is insufficient.[9]

California recently enacted legislation mandating companies that make or use priority chemicals of concern in consumer products to conduct broad life cycle-based alternatives assessments through a process subject to government oversight, although it leaves to the subsequent regulatory development process critical details as to how the outcome of such assessments will relate to the exercising of the expansive authorities granted the state to regulate such chemicals.[10]

These different approaches to adopting a chemicals policy that seeks to mandate or drive substitution all face a fundamental dilemma. On the one hand, producers or users of a chemical are the ones who know the most about the functionality, performance characteristics and needs and the economics of their chemical and, potentially at least, alternatives to it. On the other hand, they also likely have the highest vested interest in maintaining their ability to continue to produce or use that chemical and are likely to dispute the viability of a claimed substitute. To what extent is it desirable for government to insert itself into such a process—and could it deliver the necessary expertise and objectivity?

Wagner argues that directly pitting against each other the manufacturers of a chemical of concern and of an alternative claimed to be safer—and having EPA to adjudicate the dispute—would both bridge the data gap plaguing chemicals management and foster a robust market for safer alternatives to the most dangerous chemicals. The remainder of this comment addresses the questions: would it work and is it sufficient?

I. Would It Work?

Wagner argues that her proposal could be wholly or largely implemented using EPA's current TSCA authority and would require minimal additional resources.[11] As to authority, she essentially argues that EPA's identification of a safer alternative would be sufficient to meet its burden to find that a chemical "presents or will present an unreasonable risk" in order to regulate it, whether merely to require labeling or to ban it outright. Yet nothing in TSCA suggests the requisite risk finding can be a relative judgment, that is, that no matter how large or small the risk a chemical poses, that risk can be deemed "unreasonable" if an alternative exists that poses less risk.[12] Moreover, beyond the scientific determination of risk, TSCA requires EPA to make several other findings in order to deem a risk unreasonable: it must still find that the economic and social costs of imposing controls on the chemical are outweighed by the benefits, after exhaustively considering the benefits of the chemical, not only the existence but the viability of alternatives, and the impact of regulation on the economy, small businesses and innovation.[13] It must still demonstrate that the proposed control is the least burdensome it could have proposed.[14] And it must still demonstrate that no other statute could address the concern.[15]

There is little question that identifying one or more viable substitutes is a *necessary* part of TSCA's unreasonable risk calculus. It is harder, however, to envision such a finding by itself to be *sufficient* to deem a risk unreasonable under

7. *See* TURI—Toxics Use Reduction Institute, www.turi.org.
8. *See* The European Parliament and the Council of the European Union, Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), Regulation (EC), No. 1907/2006, OJ L 396/1 (Dec. 30, 2006), art. 62, *available at* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:396:0001:0849:EN:PDF (last visited June1, 2009). Some observers have argued that such companies will have little incentive to identify alternatives to the very chemical they seek authorization to use. Others, however, see significant advantage in compelling a search for alternatives by the party that possesses the most precise knowledge of the technical and economic performance requirements and arguably has the most to gain from an orderly transition to alternatives for a chemical under such intense scrutiny. *See also* Denison, Not That Innocent, *supra* note 2, at VI-4-5 box 5.
9. 38 Me. Rev. Stat. Ann. tit. 38, §§1691-1699 (2008).
10. *See* Cal. Health & Safety Code §25252 (2009).
11. Wagner also sees competition-based regulation as a means to facilitate subsequent TSCA reform by driving wedges between companies now forming a united front that has and will otherwise continue to succeed in blocking such reform. While industry unity has indeed been an obstacle to reform, it is difficult to see why this proposal alone would drive challenger companies to embrace broad-based reform complete with expanded data requirements and regulatory authority. In practice, might it not have the opposite effect of relieving political pressure for such reform?
12. One key conceptual advantage of the proposal is that it could foster the application of risk assessment methodologies in a comparative rather than absolute manner, as a means to determine preferability among options rather than seek to derive an absolute measure of risk of a single option. A recent report of the National Academies identifies this comparative use of risk assessment as a much-needed enhancement of existing risk assessment methodologies, *see* National Research Council, Science and Decisions: Advancing Risk Assessment 4 (2008), *available at* http://www.nap.edu/catalog.php?record_id=12209.
13. It is difficult to imagine this burden could be met merely by identifying a safer alternative. And while the adjudicants might deliver some information useful to EPA in meeting its evidentiary burdens, EPA would still need to produce its own risk, cost-benefit, alternatives and regulatory impact assessments. *See* 15 U.S.C. §2606(c)(1), ELR Stat. TSCA §6(c)(1).
14. *See* 15 U.S.C. §2606(a), ELR Stat. TSCA, §6(a).
15. *See* 15 U.S.C. §§2606(c), 2609, ELR Stat. TSCA §§6(c), 9.

TSCA. Nor do I see a basis in TSCA to presume that EPA has authority to require a product to be labeled as inferior to another, as opposed to bearing warnings as to its hazard or instructions for safe use or disposal.[16]

Beyond whether or not EPA has the requisite authority under TSCA, the proposal raises questions of feasibility, given the scale of the chemicals market. With tens of thousands of chemicals in commerce for which safety information is needed and to which safer alternatives may exist or emerge, two questions must be asked of Wagner's proposal. First, could EPA manage the workload? Second, could chemical-by-chemical adjudications in practice yield sufficient and reliable information to "bridge the toxics data gap" for such large numbers of chemicals? These questions are intimately related and directly trade off against each other, of course: the fewer in number the adjudications that companies seek or that EPA can handle, the fewer chemicals for which data would be developed.

Wagner projects that requests for adjudications would be small in number, somehow limited only to "places in the market where dramatic improvements in the safety of chemicals are possible."[17] But assuming they see advantage in winning such a contest, why would competitors so restrain themselves? Competition in relation to other product attributes is certainly not so limited; brands constantly churn out new products like rabbits, look-alike products abound and marketers seek to exploit even the slightest perceived advantage. In anticipating this problem might arise, Wagner suggests that EPA could solve it by requiring "an unambiguous showing of superiority" to qualify for adjudication.[18] But this puts the cart before the horse: while EPA could set in advance clear criteria defining what constitutes both a chemical of concern and a legitimate claim of superiority, how could it judge whether the evidence of superiority was unambiguous before agreeing to adjudicate a dispute, when that is the purpose of the adjudication in the first place? To the extent companies see market value in prevailing in EPA's decisions, there is every reason to expect EPA would be swamped with requests to adjudicate claims (however spurious) of superiority (however small).[19]

While Wagner's observation that EPA's "cops" are greatly outnumbered by both companies and chemicals is sound, EPA's "judges" under her proposal could be even more outnumbered by the potentially endless numbers and combinations of potential adjudicants. And because any given adjudication would necessarily apply only to that case, even slight variations on it (an additional use of a chemical, a new claimed alternative or alternative to an alternative) would compel a *de novo* adjudication. EPA's workload would be further compounded by its likely having to provide an appeals process for its decisions, given that they would be adjudicated "through adversarial hearings in formal rulemaking fashion."[20]

The proposal's premise that it would be easier and less work for EPA to digest, judge and challenge two competing companies' claims and counterclaims than to conduct and defend its own assessment is far from a given. While the competitors might to some extent police each other (as Wagner puts it, "do the dirty work"), what is to guard against companies generating or bringing forth only selective information biased in favor of their chemicals? And the more "open-ended" the scope of analysis as to what constitutes a "safer" alternative—while clearly desirable in order to avoid so-called "regrettable substitutions" that replace one set of hazards with another—the greater the complexity, the opportunity for conflicting data and claims and for risk-risk trade offs, and the demand for EPA expertise, time and resources.[21]

Finally, because it would be making a decision intended to directly influence the market, EPA would necessarily have to judge, and hence become expert in assessing not only environmental superiority, but also whether an alternative is economically and functionally equivalent to the incumbent chemical or product. And in most if not all cases, the competitions would have to be waged and EPA's judgments rendered use-by-use, since cost and performance, and sometimes environmental preferability, are necessarily specific to a given application.

II. Is It Sufficient?

Wagner's proposal could be made more manageable by strictly limiting the number and nature of adjudications in some fashion, imposing such limits would also curtail the proposal's primary objective to "bridge the toxics data gap," because information would only be developed for the relatively small number of chemicals subject to adjudications.

Even if larger numbers of adjudications were feasible for EPA to conduct, it is difficult to see how this approach would yield reliable safety data for most of the tens of thousands of chemicals in commerce—in my view a key objective of chemicals policy reform, essential to identify both "bad actors" and a broad range of potential safer substitutes. Data would be developed only for those chemicals challenged by, plus the limited alternatives made by, companies able and willing to engage in adjudications. This would limit the scope and applicability of any alternatives assessment and make it unlikely that data sufficient to identify the best among the full range of possible substitutes for a chemical of concern would be developed.

Finally, given TSCA's overly generous allowances for companies to claim submitted information confidential, it

16. TSCA §6(a)(3) provides EPA with authority only to require a substance, or any article containing the substance, to be labeled or accompanied by warnings and instructions for use, distribution or disposal. 15 U.S.C. § 2606(a)(3), ELR Stat. TSCA §6(a)(3).
17. Wagner, *supra* note 1, at 10793.
18. *Id.* at 10794.
19. Wagner anticipates this same problem. *See id.* at 10794.
20. *Id.* at 10792.
21. Here again, Wagner has raised a similar concern with the proposal; *see id.* at 10792-94. However, seeking to make EPA's workload more manageable by "quickly dispens[ing] of cases that involve apples-oranges comparisons," could well increase the likelihood of regrettable substitutions, thereby frustrating the proposal's objective of facilitating the migration to truly safer alternatives. *Id.* at 10794.

must be asked whether this proposal would, without broader reform of TSCA's information policies, actually lead to an increase in publicly available information about chemicals of concern and their alternatives.

It is also interesting to ask—though more difficult to answer—whether or to what extent EPA's decisions would, in the absence of regulatory prohibitions on a chemical of concern, drive a sufficiently broad shift in the market to justify the effort. Even if EPA had the authority to require losers of adjudications to label their products as "inferior" to the winners', would the market respond to such labels? Other attempts by government or third parties to identify greener products, through, for example, eco-labeling and preferential procurement policies, have achieved only limited boosts in the market for alternatives.[22]

Finally, in the absence of broader reform that substantially lessens EPA's burdens of proof under TSCA to regulate a chemical, I worry that the current proposal's linking of a chemical of concern with alternatives to it runs the risk of exacerbating rather than alleviating one of the core flaws of TSCA: making EPA's ability to ban a chemical of concern contingent on the identification of viable alternatives for each use of the chemical.[23]

III. Concluding Remarks

Wagner's creative proposal for competition-based regulation is motivated by the clear need to increase both chemical information in the market and incentives and rewards for the development of safer alternatives. A role for government in promoting the market's transition to safer chemicals and products is clearly needed and appropriate. But I question whether EPA is either able or best suited to serve as exclusive judge and jury as to what constitutes a safer and viable alternative to a chemical of concern—especially given the complexity and pitfalls inherent in seeking to assess (often in advance of commercialization) the detailed economic and technical performance characteristics of each use of a chemical and its potential substitutes.[24] Might not those questions be better left to the market itself to decide, with EPA's role focused on setting data and disclosure requirements, test protocols and ground rules for judging health and environmental safety, and banning or restricting chemicals that cannot be shown to be safe?

If applied in a limited fashion, competition-based regulation may contribute to accelerating a shift in current markets away from reliance on particular chemicals of high concern. But given the sheer scale of the chemicals market, I believe that only broader reform of policies will be sufficient to drive the needed changes. Paramount among these reforms is to require development of and broad public access to comprehensive and reliable safety and use information on chemicals already in and entering commerce. Only in this manner can we enlist and empower the many thousands of market participants—who make decisions on a daily basis that determine which chemicals are produced and how they are used—who must act in order to drive our chemicals economy toward safer chemicals and products. Additionally, policy reforms must shift the burden of proof from government to show harm to industry to show safety of its chemicals, and must provide government with broad authority to regulate chemicals that can harm human health or the environment.[25] These reforms, in my view, are essential to fostering a truly innovative and competitive chemicals economy.

Wagner's proposal can be viewed as offering a creative means to expand on the ways in which EPA might act within its current limited authorities. When offered in 2007, it was in the face of what seemed to be insurmountable odds against achieving the needed broader reforms of TSCA. Happily, that situation has begun to change, with a remarkably diverse range of actors recognizing the need for just such reforms, encompassing environmental and consumer advocates, academic research scientists, organized labor, groups representing health professionals and health-affected individuals, and companies that both produce and use or sell chemicals and chemical products. Wagner's proposal is still useful in helping to discern a place in that broader reform for market competition as a means to accelerate the development of safer alternatives to chemicals of concern.

22. *See*, *e.g.*, Jamie A. Grodsky, *Certified Green: The Law and the Future of Environmental Labeling*, 10 Yale J. Reg. 147 (1993); Lisette Ibanez & Gilles Grolleau, *Can Ecolabeling Schemes Preserve the Environment?*, 30 Envtl. Resource Econ. 233 (2008) 40:233–:249; and Misty L. Archambault, *Making the Brand: Using Brand Management to Encourage Market Acceptance of Forestry Certifications*, 81 N.Y.U. L. Rev. 1400 (2006).
23. TSCA §6(c)(1) requires EPA to assess " the benefits of such substance or mixture [it seeks to ban or restrict] for various uses and the availability of substitutes for such uses." 15 U.S.C. §2606(c)(1), ELR Stat. TSCA §6(c)(1). Wagner herself suggests that, under her proposal, "regulatory restrictions would fall only on those products that are completely out-competed with regard to all uses relative to the certified superior substitute." Wendy E. Wagner, *Using Competition-Based Regulation to Bridge the Toxics Data Gap*, 83 Ind. L.J. 629, 643 (2008).
24. One intriguing but unexplored question raised by Wagner's proposal is: What would be the legal consequences if EPA's "safer" alternative later proves unsafe?
25. *See* Denison, *Ten Essential Elements in TSCA Reform*, 39 ELR 10020 (Jan. 2009).