When All Else Fails:
Regulating Risky Products through Tort Litigation

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Agency regulation has not only become the preferred approach to protecting public health from risky products and activities, but a number of prominent scholars argue that it should be the only game in town. Derogatorily referred to as "regulation by litigation,"[1] mass litigation against tobacco, breast implant, gun, and a number of drug and other product manufacturers is often considered an illegitimate end-run around the political process rather than an a supplemental institutional mechanism for making products safer. Leading lights like Richard Epstein, Kip Viscusi, Richard Reich, and Peter Schuck[2] argue that, unlike agencies, the courts deciding this regulatory litigation lack technical competence, are equipped with only a limited tool kit of regulatory-like remedies, and, most importantly, lack the democratic legitimacy to resolve inherently political issues about the level and appropriateness of government intervention relating to product safety.[3] Rather than advancing product safety, they argue that the primarily or

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[1] The types of mass litigation discussed here are listed as examples of "regulatory litigation" in a book on "Regulation through Litigation" edited by Kip Viscusi (2002).

[2] Prof. Schuck is more equivocal than some of the other critics and concedes some of the benefits of this litigation. Nevertheless, he tends to understate the role of the litigation in lowering a variety of inflated information costs and the comparative deficiencies of the regulatory process relative to the court in addressing these information costs.

[3] *See, e.g.*, Richard A. Epstein, *Implications for Legal Reform, in* REGULATION THROUGH LITIGATION 325 (W. Kip Viscusi ed. 2002); Peter H. Schuck, *The New Judicial Ideology of Tort Law, in* NEW DIRECTIONS IN LIABILITY LAW 4-17 (Walter Olson ed. 1988); Peter H. Schuck, *Benched: The pros and cons of having judges make the law*, WASHINGTON

perhaps exclusive benefit of this tort litigation is to line the pockets of entrepreneurial plaintiff attorneys.

In this article I argue that these criticisms, as well as the larger body of respected scholarship on public health regulation upon which they are based, suffer from a critical flaw – they ignore debilitating limitations in information that reduce the competence and accountability of agency regulators.[4] In contrast to these wishfulaccounts of the regulatory process, protective regulation is in reality plagued by a variety of important information costs that slow and even halt regulatory progress. By neglecting the limits in the availability and accessibility of policy relevant information, analysts assume away important realities about the regulatory state that are critical to their institutional analysis.

Economists have learned – thanks to the path-breaking work of Nobel laureates Joseph Stiglitz, George Ackerlof, and Michael Spence – that ignoring imperfections and uncertainties in information can lead to ivory tower analyses that diverge in significant ways from reality.[5] As a result of the work of Stiglitz, Ackerlof, and Pence, "much of what economists believed--what they thought to be true on the basis of research and

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MONTHLY, December 2000, at 35, 39; *see generally* Note, Edward T. Schroeder, *A Tort by Any Other Name? In Search of the Distinction Between Regulation Through Litigation and Conventional Tort Law*, 83 TEXAS L. REV. 897, 897-98 (2005) (summarizing the positions of these critics).

[4] When regulatory decisions are made based primarily on the politics of the Executive Branch, the tort system also offers an important mechanism for outsiders to advance their preferred regulatory ends. *See, e.g.*, Editorial, *New Strategy on Clean Air*, New York Times, March 4, 2006, at A26 (describing a nuisance suit by the North Carolina Attorney General seeking injunctive relief against power plants in neighboring states filed as a "'last resort' arising from the administration's weakening of longstanding regulatory tools that had been used to make individual plants clean up their emissions.") This complementary justification for the tort system – to circumvent Executive Branch priorities -- is not considered in this article, however. Most of the "regulation by litigation" of concern does not address regulatory inadequacies that are the result of deliberate political decisions.

[5] *See* http://nobelprize.org/economics/laureates/2001/index.html.

analysis over almost a century—turned out not to be robust to considerations of even slight imperfections [or asymmetries] of information."[6] Legal academics lag quite far behind economists in appreciating how impediments to accessing information can impair the functioning of legal institutions. Legal scholars, for example, rarely acknowledge the problems created by asymmetric information or other limitations in available information in promulgating health and environmental regulations, despite the fact that these information barriers complicate standard setting and licensing and obstruct enforcement.[7]

In some settings, then, the tort system can be more effective than the regulatory system in accessing the various types of information needed to inform regulatory decisions. In consumer and health protection, for example, the tort system provides both more tools and more rewards to enterprising plaintiffs to uncover asymmetric information held by regulated parties regarding their products' risks than the regulatory system. In addition, because the tort system generally involves a less complex process and demands that attorneys provide adequate representation of their clients, the general public can generally gain easier access to information relevant to evaluating the costs and benefits of regulating a risky product as compared with the regulatory process.

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[6] Joseph E. Stiglitz, *The Contributions of the Economics of Information to Twentieth Century Economics*, 115 Q. J. ECON., 1441, 1461 (2000).

[7] Seminal thinkers such as Professors Bruce Ackerman at Yale, Richard Stewart at NYU, and Cass Sunstein at Chicago/Harvard are representative of a top echelon of scholars who insist, often passionately, on the need to implement elaborately information-dependent reforms without considering that this same information might lie in the superior control of regulated parties. *See, e.g.*, BRUCE A. ACKERMAN & WILLIAM T. HASSLER, CLEAN COAL/DIRTY AIR (1981); BRUCE A. ACKERMAN ET AL., THE UNCERTAIN SEARCH FOR ENVIRONMENTAL QUALITY 328–30 (1974); Bruce A. Ackerman & Richard B. Stewart, *Reforming Environmental Law*, 37 STAN. L. REV. 1333, 1335–40 (1985); Richard B. Stewart, *A New Generation of Environmental Regulation?*, 29 CAP. U. L. REV. 21, 151–54 (2001); Cass Sunstein, *Administrative Substance*, 1991 DUKE L.J. 607, 627–42.

Once the information needed to inform regulation is made available through tort litigation, however, the work of the tort system is done. Regulators must then re-enter the process and develop more sophisticated and streamlined approaches to product regulation after the barriers to information have been lowered. In this way, the tort and regulatory system operate in a complementary, rather than mutually exclusive, fashion.

This discussion of the indispensable role of tort litigation in lowering information-related barriers to regulating risky products unfolds in three sections. Part I identifies three factors (or information costs) that impede participation by the public and their representatives in health and environmental regulation and highlights the comparative attributes of the courts, relative to the political process, in lowering the costs of accessing this information. Part II then reviews two of the most controversial mass lawsuits assailed by "regulation through litigation" critics and notices that even in these cases courts manage to lower inflated information costs and improve the availability of regulation-relevant information in valuable ways. Part III concludes by offering several, more general lessons for comparing the institutional performance of the tort and regulatory systems, at least in the arena of public health protection.

I. Information Costs and Institutional Functioning

Contemporary analysts generally take for granted the "fact" that regulatory agencies enjoy far greater access to information regarding product and health risks than the legislative or judicial systems. These analysts assume that since regulators have complicated and extensive legislative grants of authority, they can legally and politically acquire any information they desire.

In the real world of contemporary health regulation, the availability of needed information is limited and can pose insurmountable barriers to participation. Under most environmental and health statutes, regulators have – at best – only limited authority in acquiring basic information about product and activity risks.[8] The public and their official or unofficial representatives face still higher costs in understanding and navigating the regulatory process and often cannot obtain the information made available to regulators without incurring high costs. As a consequence, instead of a system bulging with important health information and characterized by strong public interest representation, quite the opposite situation can exist in the regulatory state: Regulated parties enjoy asymmetries in information relevant to regulation that are not disclosed and can remain tightly held (asymmetrical information); the general public faces high and sometimes insurmountable costs in acquiring this information as well as in participating in the regulatory process itself (process costs); and there is little information available to the diffuse public with regard to how well they are being represented by their nonprofit-agents (agency costs).

While tort litigation is hardly the perfect mechanism for addressing these problems, the tort process does overcome some of the most severe information-related barriers that prevent interested parties from participating in regulatory decisions and, at the same time, creates significant incentives for representatives of the diffuse public – real victims who claim damages – to participate in decisions involving the regulation of

[8] See generally Wendy E. Wagner, *Commons Ignorance: The Failure of Environmental Law to Produce Needed Information on Health and the Environment*, 53 DUKE L. J. 1619, 1670-77 (2004) (detailing the relevant information regarding risky products and polluting activities that regulated parties are not required to provide under existing regulatory programs).

risky products. In his path-breaking work on comparative institutional analysis, Neil Komesar observes that participation is based on the benefits and costs of participation.[9] When the costs of information are lowered and information becomes more accessible, participation increases. Similarly, when the benefits to participation rise – for example through damage awards in tort claims – participation by at least these beneficiaries of the public increases. It is this combined cost-benefit – higher benefits to participation and lower costs – that explains the comparative advantages of the tort system in providing improved access to needed information, at least in settings where the regulatory system is encountering rising information-related barriers to participation.

A. Information Costs

Individuals participate in regulatory decisions when they can access information that allows them to contribute in meaningful ways. The tort system sometimes fares better than the regulatory system at ensuring that this information is available to participants.

1. Asymmetrical Information

When manufacturers conceal information about product risks, they insulate themselves from accountability for the harms they might be causing to society. This privately held information can constitute a costly barrier, sometimes an insurmountable one, to general publicparticipation in decisions about regulating product and related industrial risks. Without key information on the ways in which a product might be risky – evidence that tobacco is addictive, that asbestos is carcinogenic, or that a birth control

[9] *See* NEIL K. KOMESAR, IMPERFECT ALTERNATIVES: CHOOSING INSTITUTIONS IN LAW 8 (1995).

device breeds lethal bacteria to name a few examples – the public cannot participate meaningfully on whether or how to regulate products that cause harms.

While in theory the legislative/executive branch should be able to access a great deal of private information, the political nature of the process imposes real and often quite stark limits on the nature and extent to which this information is actually accessed and made more generally available to the public. Congress' and agencies' vigor in accessing manufacturers' privately held information regarding the risks of products or pollutants reflects a compromise developed with extensive involvement of precisely these same regulated parties.

There are at least three politically-linked restraints on the agencies' access to privately held information in practice. First, private parties are generally not required to volunteer all relevant private information on the risks of their activities or products.[10] For example, even after a chemical is on the market, regulations requiring manufacturers to submit information on "adverse effects" are ambiguous and provide regulated parties with ample legal room to legitimately withhold adverse information on product risks.[11]

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[10] *See supra* note 8.

[11] *See* TSCA, 15 U.S.C. § 2607(c), (e) (2000) (stating that manufacturers and processors must maintain records of "significant adverse reactions to health or the environment . . . alleged to have been caused by the substance or mixture . . . [and must immediately report] information which reasonably supports the conclusion that such substances or mixture presents a substantial risk of injury to health or the environment"); TSCA Section 8(e); Notification of Substantial Risk; Policy Clarification and Reporting Guidance, 68 Fed. Reg. 33129, 33130 (June 3, 2003). The disclosure requirements governing adverse effects from toxic chemicals requires manufacturers only to report what they believe to be "substantial risks" arising from their products. EPA suggests that a "substantial risk" occurs when internal research or evidence "reasonably supports the conclusion that the chemical substance or mixture can produce cancer, mutation, birth defects or toxic effects resulting in death, or serious or prolonged incapacitation." 40 C.F.R. § 159.184. This high, almost causation-like threshold, coupled with the ambiguities in determining when research actually meets the threshold, virtually

Essentially the regulated industry is "in charge of citing what information it would like to disclose and what analyses it would like to do, presenting ample opportunities for industry-funded researchers to keep underlying data and discrepancies confidential and to make strategic decisions as to whether to submit research studies for regulatory consideration."[12] There is also evidence that regulated parties are not in compliance with even these loose and ambiguous information product requirements.[13] As a result, the agency must often affirmatively request the information they believe they need.

Second, despite some generous grants of authority to affirmatively subpoena private information and sometimes even require parties to produce new information, the agencies tend to use these authorities conservatively.[14] The fear of political backlash, the agencies' limited resources, and more invisible political pressures all likely work to temper the agencies' use of these information-production authorities. The best example is the EPA's reluctance to use its power to force parties to produce added testing

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guarantee that compliance with reporting will be done only when it is convenient (financially and legally) for a manufacturer. *Cf.*, Dorothy J. Clarke, *Court Secrecy and the Food and Drug Administration: A Regulatory Alternative to Restricting Secrecy Orders in Product Liability Litigation involving FDA-Regulated Products*, 49 FOOD & DRUG L.J. 109, 131-35 (1994)

[12] Linda Greer & Rena Steinzor, *Bad Science*, ENVIRONMENTAL FORUM, January/February, at 7 (2002).

[13] *Cf.* Agency Watch, *EPA's Voluntary Data*, NAT'L L. J., Nov. 4, 1996, at A10 (reporting that only after the Environmental Protection Agency (EPA) granted substantially reduced penalties for noncompliance with these reporting requirements under the Toxic Substances Control Act did companies volunteer 11,000 studies of their products -- four times the number of studies submitted in the prior 15 years since passage of the statute).

[14] *See, e.g.,* TSCA, 15 U.S.C. § 2604(e); FIFRA, § 136(c)(2)(B). An exception is the EPA's ability to subpoena information under Superfund from potentially responsible parties. 42 U.S.C. § 9604(e). This authority is used relatively extensively by EPA, in part because of private parties' enthusiasm for the authority which provides them with useful information in their private cleanup actions and cross-claims.

information on chemicals, despite its authority to do so.[15] Even though there is a severe shortage of toxicity data available for most chemicals in commerce,[16] EPA uses its authority to require testing only in limited instances and even then tends to employ it through negotiated settlements rather than unilaterally.[17]

Third, when information is provided to an agency like the Environmental Protection Agency (EPA) – either through administrative requirements or through the agency's more aggressive subpoena or inspection authorities – the agency appears often to capitulate to the regulated parties' requests to classify a fair amount of the information as "trade secret" protected and therefore unavailable to the public [18] EPA, for example, generally does not require the regulated party to justify its trade secret claims but accepts

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[15] *See* 15 U.S.C. § 2604(e) (EPA may require testing on chemicals if the data are insufficient to assess the chemical and the EPA has reason to suspect that the new chemical "may present" a risk or hazard).

[16] *See, e.g.,* Office of Pollution Prevention & Toxics, Envtl. Prot. Agency, *What Do We Really Know About the Safety of High Production Volume Chemicals?*, 22 Chem. Reg. Rep. (BNA) 261 (May 1, 1998) (concluding that basic safety information is unavailable for roughly half of the chemicals produced in the highest amounts); *CMA More Optimistic than EDF On Lack of Data for 100 Chemicals*, Daily Env't Rep. (BNA) No. 230, at A-4 (Dec. 1, 1997) (reporting that thirty-three out of one hundred of the Chemical Manufacturer Association's chemical samples had insufficient screening data).

[17] See, e.g., U.S. GEN. ACCT. OFFICE, TOXIC SUBSTANCES CONTROL ACT: LEGISLATIVE CHANGES COULD MAKE THE ACT MORE EFFECTIVE, at 46 (1994) (discussing the lack of testing required of existing chemicals by EPA); Holly E. Pettit, *Shifting the Experiment to the Lab: Does EPA have a Mandatory Duty to Require Chemical Testing for Endocrine Disruption Effects under the Toxic Substances Control Act?*, 30 ENVTL. L. 413, 426–27 (2000) (describing EPA's use of negotiated testing agreements).

[18] *See, e.g.,* EPA, Public Information and Confidentiality Regulations, 59 Fed. Reg. 60446, 60446-60447 (Nov. 23, 1994) ("The [Environmental Protection] Agency collects chemical, process, waste stream, financial, and other data from tens of thousands of facilities in many sectors of American business. Companies frequently consider this information vital to their competitive position, and claim it as confidential business information (CBI)"); GAO, *supra* note 17 at 5:2 (Sept. 26, 1994) (finding that chemical industry does make improper confidentiality claims; HAMPSHIRE RESEARCH ASSOCIATES, INC., INFLUENCE OF CBI REQUIREMENTS ON TSCA IMPLEMENTATION 41 (Mar. 1992) (documenting the extent of industry over-use of trade secret claims to classify data).

them at face value.[19] As a result, trade secret overclaiming is so extensive that some regulated parties have argued that if EPA requires them to justify trade secret claims already in existence, it will constitute a violation of the Regulatory Flexibility Act because of the enormous work burden it will create for small manufacturers.[20] Thus even to the extent that the agency has access to some private information that bears on product risks, the public and even other agency and state officials often cannot access the information.[21]

Relative to their agency counterparts, litigants in tort cases are generally both more eager and more able to access asymmetric information held by manufacturers and industrial polluters. Streamlined document production and discovery tools available in the courts provide litigants with a much broader sweep of privately held information. Rather than relying on manufacturers' self-screened reports of internal information indicating "substantial risk" from their chemicals,[22] for example, litigants can seek out *all* documents and information that has bearing on a product's health risks. The documents and related discovery (i.e., depositions and interrogatories) will provide a more complete

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[19] *See id*. EPA, Public Information, *supra* note 18, at 80395 (Dec. 21, 2000) (observing that "CBI regulations generally do not require a business to submit a substantiation until disclosure becomes an issue").

[20] *See*, *e.g.*, Letter from Warren E. Stickle, President, Chemical Producers and Distributors Association & Bill Balek, President, International Sanitary Supply Association, to EPA, *available at* http://www.cpda.com/Content/regulatory_affairs/archived/regulatory_affairs_archived_material.cfm.

[21] *See*, *e.g.,* James T. O'Reilly, *Seeking a Truce in the Environmental Information Wars: Replacing Obsolete Secrecy Conflicts with New Forms of Sharing,* 30 ENVTL. L. REP. 10203, 10204, 10204 (2000) (observing that "[b]oth EPA employee access and EPA contractor access to formula and process data was sharply curtailed [after the 1976 Polaroid hearing], and the system's cumbersome operation provided frequent *Federal Register* notices when documents were shared with EPA contractors.").

[22] *See* EPA, TSCA Notification, 68 Fed. Reg. 33, 129, 33130 (2003) (defining "substantial risk").

picture of the manufacturers' information on product risks than narrowly drafted self-report requirements. Even to the extent that regulators enjoy residual authority to subpoena a similar range of information, scarce political capital and agency resources may inhibit the use of these document production authorities in many settings.

The court system is also much more aggressive in penalizing unjustified privilege and related claims, like frivolous claims that information is trade secret protected. In the agencies, trade secret protection claims are assumed to be true unless an outside party seeks the information under the Freedom of Information Act.[23] If the agency reviews the claim and discovers that it is wholly without basis, there is no penalty.[24] In such a system, the incentives for over-claiming trade secret protections are strong, evidenced by the large set of information that is classified as confidential business information.[25] In the courts, by contrast, litigants are required to provide the opposing party with enough information to be on notice of the nature of their privilege claims[26] and they understand that challenged privilege claims can be reviewed by the court.[27] Even more important, if the court finds that a privilege claim is unjustified, the party may be sanctioned.[28] While

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[23] *See supra* note 19 and accompanying text.
[24] *See generally* 40 C.F.R. §§ 2.201-2.310. *See also* Christopher J. Lewis, Comment, *When Is a Trade Secret Not So Secret?: The Deficiencies of 40 C.F.R. Part 2, Subpart B*, 30 ENVTL. L. 143, 171-72 (2000) (making this same observation regarding the lack of disincentives for overbroad CBI claims).
[25] *See, e.g.,* United States Environmental Protection Agency, *Confidential Business Information (CBI) Review*, Pesticides: Freedom of Information Act, *at* http://www.epa.gov/pesticides/foia/cbi.htm (listing environment-related information that is commonly claimed as confidential) (last visited June 28, 2003); see also supra notes 18-25 and accompanying text.
[26] *See* Fed. R. Civ. Pro. Rule 26(b)(5).
[27] *See* Fed. R. Civ. Pro. Rule 37(a)(2).
[28] *See* Fed. R. Civ. Pro. Rule 37(a)(4)(7).

over-claiming may still occur in the courts, there are substantially greater disincentives for this behavior.

Finally, in contrast to their regulator analogs, litigants tend to be unencumbered by political considerations in attempting to access critical asymmetrical information. If the litigation is a good investment, a committed attorney who stands to claim a sizable monetary prize has high stakes in locating the suppressed, smoking-gun "needle" in the haystack of file folders. Indeed if the history of several major toxic tort cases are any guide, a litigant's case can rise or fall on discovering suppressed, incriminating information.[29] While some litigants agree to keep damaging private information confidential when the defendant offers bonus payments in a settlement, with this admittedly important exception in some litigation, litigants appear eager to share incriminating information broadly with other parties. [30]

2. Process Costs

Process costs present a second type of information-related cost or barrier that can impede participation and engagement in regulating product risks.[31] To be able to participate meaningfully in a process, one needs information not only on the basic features of the problem, but the information and related costs associated with navigating the rules of the governing institution. It is important to understand how other participants

[29] *See, e.g.*, Bichler v. Eli Lilly & Co., 436 N.E.2d 182, 185 (N.Y. 1982) (describing conduct of manufacturers of DES); PAUL BRODEUR, OUTRAGEOUS MISCONDUCT: THE ASBESTOS INDUSTRY ON TRIAL 118-19 (1985); PHILIP J. HILTS, SMOKESCREEN: THE TRUTH BEHIND THE TOBACCO INDUSTRY COVER-UP 10-11, 20-22, 23-1, 129 (1996); MORTON MINTZ, AT ANY COST: CORPORATE GREED, WOMEN, AND THE DALKON SHIELD 123 (1985); *see also infra* Part II.

[30] *See infra* note 60 and accompanying text.

[31] *See* Komesar, Imperfect Alternatives, *supra* note 9, at 8 (referring to the "formal barriers to access associated with institutional rules and procedures").

weigh in on those issues and the radius of their influence, the types of alternatives that are acceptable, the impediments to reform, and the points in time that participation can take place. These process costs vary according to the institutional setting and can be so high as to effectively preclude participation. Would-be participants simply may not have the expertise or resources to master existing rules, power structures, legal constraints, and participatory procedures.

Again in contrast to its common law counterpart, the political process appears overwhelmed with unduly high process-related costs, some of which may in fact be constructed in part to protect agencies and even regulated parties from vigorous oversight by outsiders, including the courts and Congress. Over the last few decades, the growing complexity of the regulatory state – especially with regard to health and environmental regulation – has become a concern to commentators.[32] Juridification, complexity, and chaos theory have been summoned to explain the growing incoherence of public health regulation, even to those who are full-time experts in the field.[33] When a great deal of regulatory requirements are mired in technical reports, agency guidances, and agency preambles, opportunities for participation become limited to short windows of time on

[32] See, e.g., Eric W. Orts, *Reflexive Environmental Law*, 89 Nw. U. L. Rev. 1227, 1240-41 (1995) (collecting a mix of scholarly commentary lamenting unwieldy "mounds" of environmental laws that escape understanding); Oliver A. Houck, *Of Bats, Birds, and B-A-T: The Convergent Evolution of Environmental Law,* 63 MISS L.J.403, 403 (1994) ("Today, eyeing the tangle of statutes, regulations and court decisions [in environmental law] ... the question arises: why is there so much of this stuff and why is it so hard?").
[33] *See, e.g.,* Orts, *supra* note 32, at 1239-40 (discussing the problem of juridification); Peter H. Schuck, *Legal Complexity: Some Causes, Consequences, and Cures,* 42 DUKE L.J. 1 (1992) (providing a theory for why law can become inordinately complex); Donald T. Hornstein, *Complexity Theory, Adaptation, and Administrative Law*, 54 DUKE L.J. 913 (2005) (discussing the role of complexity theory in administrative law).

narrow legal issues.[34] As a result, attentive publics and interest group representatives may find themselves unable to participate due to the sheer costs of processing the relevant information and identifying a useful entry point into the political process.[35]

Relative to the courts, the political branch may also be inherently more susceptible to needless legal complexity. Sophisticated rent-seekers and even agency officials or Congress may find it beneficial to construct a regulatory program so complex that it defies understanding by attentive participants.[36] Complex programs alienate participants and increase agency or political power. A sizable body of public choice literature theorizes that political officials benefit by making regulatory systems complex in order to provide personalized benefits to their constituents.[37] By contrast, although there are some incentives for legal complexity in the courts, the counter-pressure for clear communication makes courts significantly less inclined towards needlessly complex rules

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[34] Mark B. Seidenfeld, *A Table of Requirements for Federal Administrative Rulemaking*, 27 FLORIDA STATE UNIVERSITY LAW REVIEW 533 (2000); see also Nina A. Mendelson, "Regulatory Beneficiaries and Informal Agency Policymaking" (draft 2006 available on SSRN) (arguing that the diffuse public is generally not included as participants in agency guidances that set policy and enforceable requirements).

[35] *See, e.g.,* Wendy E. Wagner, *Restoring Polluted Waters with Public Values*, 25 WILLIAM & MARY ENVIRONMENTAL LAW AND POLICY REVIEW 429 (2000). Effective participation, particularly at the political or legislative level, also requires participants to understand the political landscape, including stakeholder responses to the problem and the history and fate of reform efforts in the policy-making process over time (informal legal costs). While particularly savvy or resourceful participants may locate an attorney or interest group well-versed in this information, locating these uniquely suited experts within the political process can involve high search and oversight costs. (These costs are discussed more fully below at section I.C.).

[36] *See, e.g.*, Schuck, *supra* note 33, at 26 (observing that the beneficiaries of complex laws include "groups that are relatively well equipped to cope with complexity and for whom complexity can create a competitive advantage").

[37] *See, e.g.*, Morris Fiorina & Roger G. Noll, *Voters, Bureaucrats and Legislators: A Rational Choice Perspective on the Growth of Bureaucracy*, 9 J. PUB. ECON. 239 (1978); Morris P. Fiorina & Roger G. Noll, *Voters, Legislators and Bureaucracy: Institutional Design in the Public Sector*, 68 AM. ECON. ASS'N PROC. 256 (1978).

and processes. Advocates generally benefit by simplifying their cases for juries and judges.[38] The nature of the litigation process also forces a judge to render a decision; judges, or at least life tenured judges, also face incentives to write clear and coherent opinions that can serve as a guide for interested parties and future litigants.

Process costs also impede the ability of more attentive participants to catalyze fellow sympathizers since catalyzing participants generally requires low cost, accessible messages.[39] The higher the costs needed to understand the regulatoryissues, the larger the challenge to catalyze others to partake in the institutional process.[40] Because regulatory processes involve maze-like rules with equivalent maze-like problems, communicating these problems and strategies may be difficult. Without concrete harms, moreover, it is difficult to spark the diffuse public's interest. Indeed, in the past when the dormant majority has been successfully catalyzed to demand reform of existing regulatory programs, catastrophes or near-catastrophes served as the focal point to generate interest.[41] Short of an Exxon Valdez spill or a Love Canal, however, these adverse consequences seem most likely to present themselves in civil litigation.

Civil litigation can serve a vital catalytic role in lowering the process costs to onlookers-participants to understand the relevant information and evaluate their stakes in ways that are not possible in the political process. First, civil litigation, with its discrete

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[38] *See, e.g.*, ROGER HAYDOCK AND JOHN SONSTENG, ADVOCACY – PLANNING TO WIN: EFFECTIVE PREPARATION 10-11 (1994) (advocating "understandable language" and "simple explanations" as winning strategies).

[39] *Cf.* Timur Kuran & Cass R. Sunstein, *Availability Cascades and Risk Regulation*, 51 STAN. L. REV. 683, 707 (1999).

[40] *Id.*

[41] *See, e.g.*, Comment, James Kimmel, Jr., *Disclosing the Environmental Impact of Human Activities: How a Federal Pollution Control Program based on Individual Decisionmaking and Consumer Demand Might Accomplish the Environmental Goals of the 1970s in the 1990s*, 138 U. PA. L. REV. 505, 511-12 (1989).

claims of concrete harms, helps to lower process costs that overwhelm the political branches by focusing participants on the underlying health benefits to greater regulation. Civil litigation can also spotlight regulatory exceptions and gaps that permit, for example, harmful products to remain on the marketplace without adequate regulatory oversight despite laws that appear to govern these risks. Civil litigation can even bypass enforcement slippage that undercuts regulatory programs due to limited government resources and complex and effectively unenforceable legal rules.[42] Courts, in other words, have the capability of educating lower stakes participants about complex social issues when the political process has become inaccessible to them.[43]

3. The Costs of Monitoring Agents

The third information cost is the cost the diffuse public incurs in overseeing nonprofit agents in a setting where facts are incomplete and the process for making decisions is nearly impenetrable. Because of high information costs arising from asymmetric and complex information in the regulatory system, the diffuse public grows more dependant on interest groups to lead, educate, and lobby for public-serving ends. But these same informational impediments make it difficult for the members to hold their public interest agents accountable.[44]

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[42] *Cf.* Daniel A. Farber, *Taking Slippage Seriously: Noncompliance and Creative Compliance in Environmental Law*, 23 HARV. ENVTL. L. REV. 297, 315-16 (1999).
[43] *See, e.g.*, Schuck, Benched, *supra* note 3, at 40 (conceding this attribute of some "impact" litigation).
[44] *See, e.g.*, Enrico Colombatto & Jonathan Macey, Information and Transaction Costs as the Determinants of Tolerable Growth Levels, 155 JOURNAL OF INSTITUTIONAL AND THEORETICAL ECONOMICS 617, 623 – 624 (1999) (arguing that "information and transaction costs prevent the public from grasping the implications of most of the bargains reached among narrow interest groups and ruling political coalitions.")

Courts again are often superior in lowering the costs of overseeing agents relative to regulatory processes. Because of their commitment to adequate representation, the courts dedicate some, albeit incomplete effort to insisting on a nexus between attorney and client through a series of ethical and court-made rules.[45] By ruling on the merits of arguments and insisting they be supported by some evidence, the courts also serve as gatekeepers on the quality of the positions taken by attorney-agents.[46] Even the rules governing class actions regulate attorneys through a series of imperfect, but nevertheless relatively specific requirements.[47] Finally, the public record of all filings provides ready information for clients and others interested in an attorney's arguments and positions.

By contrast, the political process makes no effort to lower the costs of monitoring interest groups that purport to speak for a broader constellation of members and passive participants. There are no ethical or legal rules governing representation in the political process; instead interest group representatives operate free of constraints, except for reputation-related considerations, in determining how to represent and educate members on relevant issues. This lack of oversight is especially problematic because of interest groups' need to generate support for their cause, which may cause them to overstate the adverse consequences and formulate positions based at least as much on generating membership as educating the diffuse public on key issues of interest to them.[48] Also in

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[45] *See, e.g.*, Model Rules of Prof'l Conduct, Rules 1.4, 1.7, 3.2.
[46] *See, e.g.*, Fed. R. Civ. P. 11, 12(b)(6); Model Rules of Prof'l Conduct R. 3-1.
[47] *See, e.g.*, Fed. R. Civ. P. 23. For an argument that these rules could be improved see Linda S. Mullenix, *Taking Adequacy Seriously: The Inadequate Assessment of Adequacy in Litigation and Settlement Classes*, 57 VANDERBILT L. REV. 1687 (2004).
[48] In fact, on more than one occasion, the information provided by an organization revealed a conflict of interest between their own mission (and effort to retain members) and their neutrality on the issue of concern. *See, e.g.*, David E. Seidemann, *Insufficient Accountability: Case Study of the Recycling Plan of a Public Interest Research Group*, 3

contrast to the courts, there is no "neutral" arbiter in the political process to verify the strength of the evidence and legal arguments or to oversee the credibility of interest group positions. The primary constraint on the plausibility of interest group claims is oversight by its members. But the members of interest groups may be unaware of the positions their agent/interest groups are taking in the political process and often have no way, other than accompanying them to meetings, to learn about these positions.[49] Although these problems also plague some class actions, the political process is devoid of any mechanisms of oversight or exit for those who are purportedly represented by a lobbyist or other self-appointed spokesperson.

B. The Benefits to Participation

Since participation is predicted not only by assessing the costs or barriers to participation but each participant's benefits in participating, a comparison of institutional capabilities is not complete without considering the benefit side of the participatory equation.[50] With respect to health and environmental protection, the courts are able to transform at least some of the public's diffuse interest in protective regulation into high stakes damages packages.[51] In this role, the courts provide a counterforce to a political system that gradually overwhelms the interests of the diffuse public through rising information costs. As long as a particular product or related health or environmental

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BUFF. ENVTL. L.J. 221 (1995) (detailing inaccuracy of NYPIRG study on recycling as the answer to NYC's solid waste problem). A similar allegation was made with respect to the NDRC's handling of the Alar controversy. *See, e.g.*, Leslie Roberts, *Pesticides and Kids*, 243 SCIENCE 1280, 1280-81 (1989) (discussing NRDC report); Joseph D. Rosen, *Much Ado About Alar*, ISSUES IN SCI. & TECH., Fall 1990, at 85, 87-88 (1990) (identifying weaknesses in NRDC's risk assessment, which include using arguable math, arguable food consumption data, and arguable potency factor).

[49] *See infra* Part II.B.

[50] *See* Komesar, Imperfect Alternatives, *supra* note 9, at 8.

[51] *Id*. at 171-77.

concern can be repackaged into a tort claim, with exposed and harmed plaintiffs, then at least some of these diffuse, low stakes issues can be reprocessed as high stakes issues for a subgroup of the dormant majority. If many individual damage claims can be consolidated into a class action, then the stakes for the attorney-agents can be higher still, giving them the incentive to dig for secreted information in ways that political actors or even public interest groups filing run-of-the-mill enforcement or qui tam sorts of actions lack.

In the political arena, the diffuse public generally faces very low benefits to participate in environment and health regulatory decisions.[52] The asymmetries in information regarding the risks of individual products and activities combined with the other informational impediments arising from process and agency costs, only further alienate them from understanding the underlying issues at stake or mustering the resources necessary to participate in them. Even the public's nonprofit agents are handicapped in transforming unknowns regarding product safety into salient political issues regarding "credible risks."[53] Regulated parties, on the other hand, are acutely aware of the costs that could flow from divulging their internal information and face potentially very high stakes in avoiding legal rules that require them to share this information with others. Industries' aggressive efforts to lobby against legislation

[52] *See, e.g.,* KOMESAR, IMPERFECT ALTERNATIVES, *supra* note 9, at 167-68, 192 (noting that in product safety where potential for injuries is small, but harm to individuals is serious, "[t]he skewed distribution can lead and, in this context, appears to have led to overrepresentation of the position of the potential injurer group" in the political process).
[53] *See, e.g.,* Constance A. Nathanson, *Social Movements as Catalysts for Policy Change: The Case of Smoking and Guns*, 24 J. HEALTH POL. POL'Y & LAW 421, 422 (1999).

requiring even minimal information disclosures,[54] coupled with their efforts to expand mechanisms for shielding the information that is disclosed from the public using trade secret and related legal privileges,[55] reinforces a common sense judgment that avoiding the disclosure of potential risks of their activities is an important issue to industry. As long as the stakes of the general public remain diffuse, and the nonprofits are unable to overcome rising information costs, regulated parties can effectively "capture" the decision-making process by keeping damaging information secret and the applicable legal rules complex, or at least complex enough so that less sophisticated parties lack the resources to invest in understanding them.

By contrast, in "regulation through litigation" cases, the lucrative damage awards for at least a subset of the diffuse public and their attorney-agents create circumstances under which the courts can excel relative to regulatory processes with respect to counteracting the problem of inflated information costs.[56] In order for this shift in stakes to occur, there must at least be sufficient time for victims to be exposed to a risk and develop harm. If these conditions have materialized and there is some research linking

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[54] *See, e.g.,* David Roe, *Toxic Chemical Control Policy: Three Unabsorbed Facts*, 32 Envtl. L. Rep. (Envtl. L. Inst.) 10,232, 10,234 (2002) (discussing industries' consistent opposition to Proposition 65 (a California law requiring additional toxicity labeling on products)); Sidney M. Wolf, *Fear and Loathing About the Public Right to Know: The Surprising Success of the Emergency Planning and Community Right-to-Know Act*, 11 J. LAND USE & ENVTL. L. 217, 220 (1996) (discussing strong industry opposition to passage of Environmental Planning and Community Right-to-Know Act (EPCRA)).

[55] For example, industry argues that even more trade-secret protections are needed given the "mosaic" effect–the ability of competitors to piece together information about their operations from bits of publicly available data. *See*, *e.g*., 59 Fed. Reg. at 80396 (discussing how the regulated community "has made the argument that multiple pieces of data which may not qualify individually to be treated as CBI and are made publicly available can be pieced together to reveal a trade secret."); Letter Stickle & Balek, *supra* note 20, at 5 (same).

[56] *See* KOMESAR, IMPERFECT ALTERNATIVES, *supra* note 9, at Cht. 5 (discussing these issues in the context of tort reform).

the harms to exposure to a defendant, the stage is set for a subgroup of the diffuse public to become extremely interested in the safety of a particular product or waste in a way not present in the political process. Perhaps still more significant, it is not only the victims but their attorney-agents who enjoy large awards in the courts; indeed in personal injury class actions, the attorneys' stakes are likely higher than the individual claimants because of the possibility of aggregated awards. Thus, in contrast to nonprofits who face an uphill battle to catalyze the dormant majority around such esoteric problems as unspecified product risks, with no fiscal remuneration for their efforts, attorneys handling litigation involving injurious products face potentially high payoffs for their efforts, enabling them to dedicate far more resources and energy to overcoming information costs, particularly those posed by asymmetrical information. Moreover, some of these cases also involve corporate misconduct, such as the suppression of damaging information about a product or industrial activity, adding the prospect of lottery-sized punitive damages to the attorneys' already high stakes equation.[57]

The ability of the courts to transform some diffuse, low stakes issues into high stakes issues may not apply for all types litigation, however. Instead, the transformation seems most likely when the litigation promises high compensation awards. Enforcement cases, injunctive awards, or related suits challenging agency regulations do not produce high financial returns; as a result, the lawyers can be expected to be less tenacious in dislodging privately held information or even pursuing the litigation at all, perhaps in part

[57] *See, e.g.*, Thomas Koenig & Michael Rustad, *His and Her Tort Reform: Gender Injustice in Disguise*, 70 WASH. L. REV. 1, 39-46 (1995) (providing survey of punitive damage awards in Dalkon Shield, Copper-7 Intrauterine Device, super-absorbent tampons, and silicone and saline breast implants, based in part on the fact that manufacturers concealed adverse information or avoided testing product in face of mounting evidence of hazard).

because of a lack of resources rather than the absence of will or interest.[58] The precise tipping point– in terms of the size and probability of large awards needed to make the litigation successful in lowering information costs – is unclear, although in regulation through litigation cases, successful litigation generally involved high individual awards that were consolidated into class actions.

Although courts can lower information costs due, in part, to the higher stakes and tenacity of victims and their attorney-agents, these litigants may not always represent the public interest in their cases. In some class actions, the attorney-agents can have stakes that are even higher than their individual clients. This can lead to behaviors that deviate from those that the public or even the client-victims would accept, such as blackmailing or extorting defendants with weak class action claims or settling mass claims quickly in order to avoid a trial.[59] Litigation may also not serve the general public interest if the ultimate results of a case are concealed. For example, if the litigants agree to seal any damaging documents that might be divulged as a condition to settlement, then the courts can do little to dislodge this stubborn, privately held information.[60]

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[58] Although it is an issue that cannot be taken up here, it seems likely that in measuring the "stakes" of participants, financial resources to support strong interest in issues must be taken into account. Single mothers in poverty, for example, certainly have exceedingly high "stakes" in their children's welfare. Yet without time or resources, they cannot engage in the political process in the way that less-interested but much more wealthy participants (i.e., high wage earners who are opposed to taxation) can. Thus, stakes much include an economic component in order to be realistic about the out-of-pocket costs of citizen engagement.

[59] *See, e.g.*, In re Rhone-Poulenc Rorer Inc., 51 F.3d 1293, 1298 (7th Cir. 1995) (Posner, J.).

[60] *See, e.g.,* Jack B. Weinstein & Catherine Wimberly, *Secrecy in Law and Science*, 23 CARDOZO L. REV. 1, 18–30 (2001) (discussing the problem of secrecy agreements in mass tort cases and how they may in fact conflict with the protection of public safety); Keith Schneider, *Court Rejects U.S. Effort to Keep Exxon Valdez Settlement Agreement Secret*, N.Y. TIMES, Mar. 9, 1991, at A9. Although it is less likely, it is also the case that

C. Summary

A variety of information-related costs can significantly impair the ability of the attentive public to participate meaningfully in the regulation of risky products. These information costs exacerbate the already low benefits that typically accrue to most of the diffuse public in participating in regulatory decisions.[61] Affected industries, by contrast, have high stakes and often set significant resources aside for continuous participation in these issues. These high stakes participants put their adversaries at a significant disadvantage, especially if some of the asymmetries and legal complexity can be protected and perpetuated by these higher stakeholders.

The courts are able to penetrate the rising information costs that can fog in the regulatory system by transforming low stakes issues regarding general public safety into high stakes damages claims, at least for a subset of issues. Lucrative damage awards give victims and their attorneys the needed incentives to dislodge secreted information and translate their findings to the public at large, thus lowering all information costs at once. As a result, when courts are summoned to engage in these issues, their involvement can reduce inflated information costs and lead to broader participation across all institutions.

The courts generally serve only a preliminary role in resolving environmental or public health issues, however. The critics of regulation through litigation are likely correct that the courts fare badly, relative to their political counterparts, in reaching a full resolution of these complex social problems and are institutionally poorly suited to this

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if the media fails to cover the litigation, the results will not be publicized in a way that can lead to important public pressure on the political processes.

[61] *See, e.g.,* Komesar, Imperfect Alternatives, *supra* note 9, at 171-77.

task.[62] Even if this is so, litigation is essential – at least in some cases of public and environmental protection – to make the political process work. In these settings, the deficiencies that afflict the court system are dwarfed by much more serious problems that paralyze the regulatory process. The litigation thus serves a vital role in dropping inflated information costs, thus sparking public understanding and debate more broadly in the market and political process.

II. UNPOPULAR REGULATORY LITIGATION AND ITS SUCCESS IN REDUCING INFORMATION COSTS

The courts' superior abilities to lower information costs are supported not only by theory, but practice. This section reviews some of the allegedly worst examples of regulatory litigation – the litigation over breast implants and the municipal gun litigation – and concludes that even this litigation succeeds in lowering one or more of the inflated information costs and provides public access to otherwise unavailable information, often in permanent ways. The resulting, more level participatory playing field then serves to jumpstart other institutional responses to ensuring the safety of these products.

A. Breast implant litigation

The breast implant litigation is generally regarded as exemplifying all that is wrong with "regulation through litigation."[63] Critics argue that the litigation was not only an end-run around existing regulatory processes, but that it illustrates the hazards of empanelling juries to decide technical issues like causation.

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[62] *See, e.g.,* Schuck, Benched, *supra* note 3, at 40.

[63] *See generally* MARCIA ANGELL, SCIENCE ON TRIAL: THE CLASH OF MEDICAL EVIDENCE AND THE LAW IN THE BREAST IMPLANT CASE (1996); David E. Bernstein, *The Breast Implant Fiasco*, 87 CAL. L. REV. 457, (1999).

The breast implant litigation targeted several manufacturers – particularly Dow Corning – that manufactured implants made with silicone gel. Because little was known about the effects of silica in the body and there was evidence, at least to Dow Corning, that some of the silicone leaked from the implants, women who suffered from various connective-tissue disorders after receiving their implants argued that their diseases were attributable to the implants.[64]

Initially, plaintiffs enjoyed jury verdicts based in large part on their arguments that implants were to blame for their injuries and that the manufacturers were negligent for failing to warn or conduct follow-up testing. Late in the life cycle of litigation, however, new scientific research revealed that the verdicts in favor of plaintiffs were likely in error with respect to causation since implants did not appear to cause a statistically significant increase in connective tissue and autoimmune diseases.[65] This scientific revelation that the early juries were wrong in finding causation, critics claim, is striking evidence that the judicial branch lacks the competence to decide highly technical issues that routinely arise in health and environmental litigation.

These criticisms, however, miss the value of the litigation set amidst the larger landscape of institutional failure. The litigation not only overcame information asymmetries that allowed manufacturers to conceal incriminating information regarding implant safety, but it provided the sanctions and public pressure to force manufacturers and public institutions to conduct research to determine whether implants were causing serious harms.

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[64] *See, e.g.*, ANGELL, *supra* note 63, at 101-08.
[65] *See id.*

1. *Cutting through the Asymmetrical Information and Process Costs that Plagued Regulation*

There is no disagreement that the breast implant litigation was uniquely successful in divulging important, asymmetric information about the risks of implants held by implant manufacturers. Because plaintiffs uncovered "smoking gun" evidence of manufacturers' preliminary knowledge that silicone was leaking into the patients' bodies, the litigation succeeded in establishing risks to the implants that at least warranted further scientific research. Indeed, through the course of this early litigation, industry documents were discovered that revealed one of the implant manufacturers, Dow Corning, not only knew that implants were gradually leaking (in addition to their potential for rupture), but it suppressed internal research on the few animal studies it had conducted on rats.[66]

Disagreement about the value of the litigation instead focuses on whether early jury verdicts based on this smoking gun evidence of possible harm reflect juror incompetence or instead rough justice. In terms of the scientific basic for the early verdicts, critics are correct thatthe verdicts were likely more the result of outrage at the manufacturers' indifference to health risks than on definitive scientific evidence of causation.[67] But this does not by itself suggest juror incompetence. In fact, internal documents of manufacturer recognition that the devices were leaking once surgically implanted, when paired with the defendant-Dow Corning's resistance to conduct follow-

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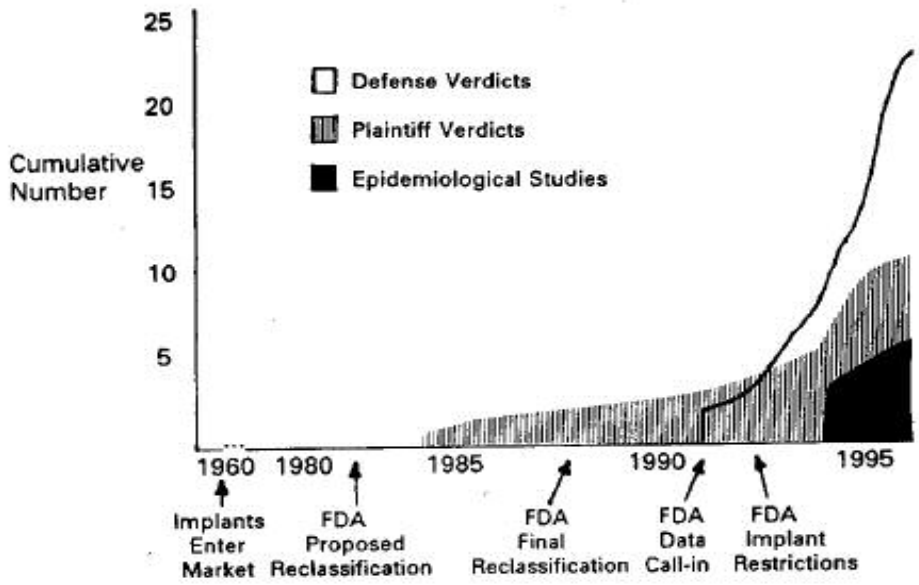
[66] *See, e.g.,* ANGELL, SCIENCE ON TRIAL, *supra* note 63, at 57-61; *see also Human Resources and Intergovernmental Relations Subcomm., Comm. On Gov't Operations, 102d Cong., The FDA's Regulation of Silicone Breast Implants* 29-31, 34-37 (Comm. Print 1993).

[67] *See, e.g*., Fredric L. Ellis & Ernest Hornsby, *Dow Chemical Hid Truth on Breast Implants*, N.Y. TIMES, Nov. 8, 1995, at A24 (letter from attorneys in one breast implant case citing jury's unanimous finding that "Dow Chemical committed fraud and exhibited a conscious disregard for the health and safety of the women receiving silicone gel breast implants.").

up testing, apparently outraged the jury sufficiently to cause them to not only award damages to the plaintiff, but also a sizable punitive damage award.[68] And when more comprehensive research was ultimately available years after the litigation had begun that effectively exonerated the manufacturers as a significant cause of connective tissue and autoimmune diseases, plaintiff verdicts dropped and defense verdicts rose. See Figure 1.[69] In short, had the manufacturers conducted research into the safety of implants prior to marketing and made thatinformation available to juries, jury verdicts would likely have been favorable to them. Instead, the very fact that they took advantage their asymmetric access to information and withheld information from patients contributed to juries awarding significant judgments against them.

[68] *See id.* at 52. Although the incriminating documents were sealed in an eventual settlement of the litigation, they were used in subsequent litigation by the same attorney and eventually leaked to the media and the press. *See* Bernstein, *supra* note 63, at 473-74.
[69] Figure 1 is copied from Rebecca Dresser, et al., *Breast Implants Revisited: Beyond Science on Trial*, 1997 WISC. L. REV. 705, 744.

Figure 1: Timeline of Breast Implant Science, Litigation, and FDA Regulation



From this life cycle of the litigation, it appears that juries entering early plaintiff verdicts were not scientifically illiterate, but instead enjoyed a broader view of the regulation of implants as a result of presiding over these high stakes cases. This more comprehensive legal perspective allowed them to cut through processand related complexity costs that overwhelm the regulatory system and find a way to place basic responsibility back on manufacturers for ensuring the safety of their products before marketing. In short, these juries appear to have considered the reason for incomplete evidence on causation – the manufacturers' staunch refusal to conduct the needed research – in weighing all of the evidence having a bearing on causation.[70] Their more

[70] It has been argued that these juror embellishments on the evidence and liability rules in the breast implant cases actually constitute juror nullification. Yet, even granting that the jurors did nullify the liability rule in these cases – a complicated technical and legal argument -- this concern must also be put in comparative institutional context. If jurors rightly perceive that the political process failed them, based both on evidence of the

holistic approach to weighing incomplete evidence does not necessarily smack of jury illiteracy as much as the development of more sophisticated evidentiary presumptions when evidence is incomplete. To the extent that some of the missing evidence was due to defendants' misconduct, the jurors may have reasoned, then there is a presumption that this evidence would be incriminating unless evidence is produced rebutting that presumption – much like the evidentiary presumptions governing spoliation of the evidence.[71] A defense verdict would be both a reward and tacit encouragement for

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manufacturers' recalcitrance in meeting their testing responsibilities and FDA's laxity in enforcing the laws, then nullifying or "adjusting" common law rules in ways that reinforce other statutory requirements might be the most democratically responsive reaction among the alternatives. *See, e.g.*, E. Donald Elliott, *The Future of Toxic Torts: Of Chemophobia, Risk as a Compensable Injury and Hybrid Compensation Systems*, 25 HOUS. L. REV. 781, 787 (jury verdicts in toxic torts may reflect "our society's prevailing sense of justice in cases where innocent people have been involuntarily exposed to substances that are potentially dangerous to their health" rather than a jury's misunderstanding of the scientific mechanisms underlying causation). Legal scholars have in fact argued for reform of causation rules that would place the scientific burden on defendant to *dis*prove causation when preliminary testing is the responsibility of the defendant manufacturer or polluter and they have shirked their responsibility. *See, e.g.*, Margaret A. Berger, *Eliminating General Causation: Notes Towards a New Theory of Justice and Toxic Torts*, 97 COLUM. L. REV. 2117 (1997). Indeed, perhaps even tort causation rules have been beset by legal complexity of sorts that jurors attempt to correct through their nullified verdicts. In any event, when the political process has failed to accomplish its promise of requiring manufacturers of drugs and invasive medical devices to engage in safety testing, is it so clear that jurors are acting "unaccountably" or "incompetently" by attempting to accomplish *sub rosa* what the legal system promised it would do in existing legislation? In a comparative institutional sense, critics need to provide at least some support for other institutional routes to this same end; namely other institutional mechanisms for forcing manufacturers to conduct and publicly disseminate high quality research on the safety of their products.

[71] *See, e.g.,* Sweet v. Sisters of Providence, 895 P.2d 484, 491-92 (Alaska 1995) (holding that missing medical records that result from negligence or intentional acts of defendant and that impair the ability of plaintiff to prove a prima facie case create a rebuttable presumption shifting the burden of proof for negligence and cause to defendant); *see also id.* at 491 (citing cases creating similar presumptions).

defendants who stonewall testing requirements on their risky products.[72] As Professor Dreyfuss observes: "In other words, [in the breast implant litigation] we may be seeing something of a new liability rule rather than a mistake of fact-finding."[73]

2. *The Information-Generating Consequences of the Litigation*

It also appears clear from the life cycle of the breast implant litigation that the surge of research on implant safety resulted largely from the pressures created by the litigation; without the litigation there may have been little additional research.[74] In the wake of the early plaintiff verdicts, the manufacturers moved from vigorously resisting conducting research on the safety of implants and selectively concealing the research that was produced, to investing tens of millions of dollars into implant safety research. As one scientist concludes with regard to the litigation and regulatory aftermath:

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[72] *See, e.g.*, Fredric L. Ellis & Ernest Hornsby, *Dow Chemical Hid Truth on Breast Implants*, N.Y. TIMES, Nov. 8, 1995, at A24 (letter from attorneys in one breast implant case citing jury's unanimous finding that "Dow Chemical committee fraud and exhibited a conscious disregard for the health and safety of the women receiving silicone gel breast implants").

[73] Rochelle Cooper Dreyfuss, *Galileo's Tribute: Using Medical Evidence in Court*, 95 MICH. L. REV. 2055, 2070 (1997). Social science research on the Bendectin litigation reveals a similar sort of juror nullification phenomenon when plaintiff's evidence is weakly suggestive of harm and reveals corporate misconduct in failing to produce safety testing in the first place. See, e.g., Joseph Sanders, *From Science to Evidence: The Testimony on Causation in the Bendectin Cases*, 46 STAN. L. REV. 1, 53-54 (1993).

[74] *See, e.g.*, David A. Kessler, *The Basis of the FDA's Decision on Breast Implants*, 326 NEW ENG. J. MED. 1713, 1715 (1992) (observing the likelihood that "[h]ad the FDA failed to intervene, the uncontrolled and widespread available of breast implants would probably have continued for another 30 years—without producing any meaningful clinical data about their safety and effectiveness. Such a situation is obviously unacceptable."). Even Angell, a critic of FDA and the litigation, concedes that these legal interventions led to much needed scientific research on implants. *See, e.g.,* Marcia Angell, *Shattuck Lecture—Evaluating the Health Risks of Breast Implants: The Interplay of Medical Science, the Law, and Public Opinion*, 334 NEW ENG. J. MED. 1513, 1515 (1996) ("After the [FDA] ban, under Kessler's prodding, the breast-implant manufacturers began to do what they should have done years earlier: they began to fund serious studies of the safety of breast implants.").

> It is possible that the research being driven by this controversy will result in a greater understanding of the immunologic implications of xenobiotics, of the importance of nonbiased observations, of the need for ready access to valid data sets, and of the opportunity for valid scientific information to guide legal decisions.[75]

Rather than a sign of weakness, it is a testament to the success of the litigation that we now have a considerable body of scientific research against which to evaluate early jury verdicts. Indeed, if the results of the later research had instead confirmed what appeared possible early in the litigation – namely that implants did lead to a statistically significant increase in chronic harms – then some of the critics would be forced, by the underlying logic of their criticisms, to concede that the litigation made a positive contribution to implant safety.[76]

The motivational force of the litigation is even more impressive when set against the failure of regulators to force manufacturers to conduct this same research. Although existing regulatory structures were in place at the time of the litigation to require or force manufacturers to produce information on implant safety, FDA's regulatory demand that these manufacturers test the safety of their implants dragged on for more than a decade

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[75] Ralph R. Cook et al., *The Breast Implant Controversy*, 37 ARTHRITIS & RHEUMATISM 153 (1994).

[76] For example, Bernstein's critique of the litigation, *supra* note 63, turns on the fact that the research ultimately exonerated implants. Bernstein does not attempt to argue that this causal conclusion was preordained or that the preliminary evidence of leaking implants should have been dismissed as a scientific matter. Presumably, if the research instead had followed the path of the asbestos, DES, ultra-absorbent tampon and Dalkon Shield litigation, Bernstein would be forced to concede that the litigation served as a positive force in creating incentives for safe products.

without consequence.[77] Throughout this period of regulatory inaction, there was an overwhelming consensus among the scientific community that more research was needed to be assured that implants were safe and were not causing a host of problems. A representative of the American Medical Association, for example, concluded that "[s]ilicone gel breast implants could have benefited from better regulation, quality control in manufacturing, preclinical toxicity testing, product development, clinical trials, clinical use, informed consent, and less inappropriate patient demand for augmentation by those associated with each of these functions."[78] One of FDA's own scientific advisory groups concluded in 1991 that the manufacturers' clinical studies were "'so weak that they cannot provide a reasonable assurance of the safety and effectiveness of these devices.'"[79]

Over this period of time, nonprofits and others concerned about FDA's policies were hamstrung in forcing the agency to take action, and were resigned to a more peripheral role that involved regulatory challenges under the Freedom of Information Act

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[77] *See Human Resources and Intergovernmental Relations Subcomm., Comm. On Gov't Operations, 102d Cong., The FDA's Regulation of Silicone Breast Implants* 10, 13-37, 49 (Comm. Print 1993). Bernstein criticizes the FDA for its partial ban of implants when there was insufficient evidence to establish they caused harms. Bernstein misunderstands the legal requirements, however, which place the burden on the manufacturer to provide "reasonable assurance of the safety . . . of the device." 21 U.S.C. § 360c(a)(1)(C). FDA was required to ensure that the manufacturers provided this demonstration of safety, and Bernstein acknowledges that the manufacturers failed in this effort. Bernstein, *supra* note 63, at 470-71. Contrary to his suggestion, then, the FDA's ultimate decision to impose a partial ban on implants under this provision was neither a "grand display" of addled or political logic, but instead a half-hearted effort to enforce requirements that had been unenforced for over ten years. *Id.* at 476.

[78] *See* Council on Scientific Affairs, *American Medical Association, Silicone Gel Breast Implants*, 270 JAMA 2602, 2606 (1993).

[79] House Report, *supra* note 77, at 22 (quoting FDA Task Force memorandum).

and pressuring Congress to hold oversight hearings to embarrass the agency into action.[80] Other than suing the agency for not taking more vigorous action under a mandate that granted the agency broad discretion, these advocates had little recourse beyond lobbying Congress for additional legislation that reaffirmed what FDA seemed unable to demand – testing as a prerequisite to implant use and marketing.

Set against this regulatory inaction, the litigation acted as a catalyst for heightened public awareness and accompanying regulatory oversight and accountability. The FDA ultimately instituted a ban on the implants, but this was implemented nearly a decade into the litigation and thirty years after implants first went on the market.[81] In fact, Administrator Kessler reportedly decided to institute the moratorium on implants shortly after reading the incriminating documents produced through the breast implant litigation. The FDA action then appears likely to be at least as much a reaction to the litigation and its products as to the peripheral pressures from within the regulatory system.[82]

Because the litigation accomplished precisely what the regulatory system was supposed to do and failed, it seems mistaken to simply write the courts off as inappropriate institutional players in the regulation of implants. Rightly one can question whether mass litigation is the most cost-effective way to force the production of valued information on the safety of medical devices. But the litigation appeared to be necessary

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[80] *See, e.g.*, Teich v. FDA, 751 F. Supp. 243 (D.D.C. 1990); *Is the FDA Protecting Patients from the Dangers of Silicone Breast Implants?" Hearing Before the Human Resources and Intergovernmental Relations Subcomm. Of the House Comm. On Government Operations, 101st Cong. 2d Sess.* (1990).

[81] *Hearing Before the Subcomm. On Human Resources and Intergovernmental Relations of the House Comm. On Gov't Reform and Oversight* (Aug. 1, 1995), Statement by David A. Kessler, Commissioner, Food and Drug Administration, at 8

[82] *See* Bernstein, *supra* note 63, at 474 (discussing the controverted role of the documents in prompting the FDA moratorium on implants).

to create the needed incentives to conduct research on implant safety. The inadequacy of the political process relative to the courts to force the production of this information in fact makes sense when one accounts for the very low stakes of the diffuse public. When the only rallying call is the deficiency of safety information in light of some evidence of harm, it is difficult to catalyze others to participate in the political process, especially, as in the case of implants, when existing legislation already promises to require the research. The damages claim in the class actions shifted the stakes from a diffuse public interest in product safety to lucrative, high stakes awards to implant victims and their attorneys.

The breast implant litigation also underscores how manufacturers who are in a superior position to research their products can deplete the catalyzing capabilities of public health advocates by enshrouding the riskiness of their products in mystery. The absence of information about product risks can effectively shut down the political/regulatory process, at least in terms of providing issues needed to catalyze the dormant majority. By contrast, the roulette of juries deciding causation when faced with stark evidence of industry indifference to the health of patients is a motivating force for manufacturers to produce information if it holds out at least a chance of exonerating them. While some might argue the litigation goes too far in producing these incentives to conduct safety research, the dearth of safety testing on chemicals in general suggests that it probably doesn't go far enough.[83] Whatever the case, without an institutional "check" on preexisting regulatory commitments to force the production of this information,

[83] STEERING COMM. ON IDENTIFICATION OF TOXIC AND POTENTIALLY TOXIC CHEMICALS FOR CONSIDERATION BY THE NAT'L TOXICOLOGY PROGRAM, NAT'L RESEARCH COUNCIL, TOXICITY TESTING: STRATEGIES TO DETERMINE NEEDS AND PRIORITIES (1984); ENVIRONMENTAL DEFENSE FUND, TOXIC IGNORANCE (1997).

regulators themselves may be more lax in insisting on the information, especially given the vigorous participation of regulated industry in agency decision-making.

B. Municipal gun litigation

The gun litigation, more than any of the other examples of regulation through litigation, is said to test the outer limits of the courts' competency and legitimacy.[84] The gun litigation includes a number of disparate suits. After small pockets of successful litigation by victims who were injured by guns that were poorly designed, other litigation followed that sought broader social goals of safer gun design and distribution.[85] Most controversial is the gun litigation brought by municipalities to recover health care costs associated with gun crimes. The plaintiff-municipalities typically sue distributors and manufacturers for design and sales that are unsafe, arguing in essence that the industry neglected to take simple measures that would make guns both less available and less lethal, especially in criminal settings.[86] According to critics, not only are these municipal plaintiffs using tort claims to accomplish regulatory ends, but they are doing so with unaccountable litigants and judges, thus undercutting existing democratic processes.

1. Overcoming Information Asymmetries and the Process Costs that Obscure Regulatory Failure

Like breast implants, critics who charge that the gun litigation is socially without merit again neglect to factor into their analyses the extraordinary barriers to information that can impede broader participation in gun control policymaking. Although the litigation has made less progress than hoped because of the early dismissal of most of the

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[84] *See, e.g.,* Peter Schuck, *Why Regulating Guns through Litigation Won't Work, in* SUING THE GUN INDUSTRY 225 (Timothy D. Lytton ed. 2005).
[85] Timothy D. Lytton, *An Overview of the Lawsuits against the Gun Industry, in* SUING THE GUN INDUSTRY, *supra* note 84.
[86] *Id.*

suits, some of this litigation has exposed the gun manufacturers' and distributors' superior information regarding safe gun design and safe distribution and their longstanding reluctance to invest in research or practices that could lead to fewer gun accidents and crimes. At least one smoking gun memo divulged through the litigation, for example, reveals Colt's efforts to delay public release of the "smart gun," partly in the hopes of receiving federal funding and partly in order to stave off law suits.[87] Other discovery from the litigation reveals how, "'until faced with a serious threat of civil liability for past conduct, leaders in the [gun] industry have consistently resisted taking constructive voluntary action to prevent firearms from ending up in the illegal gun market and have sought to silence others within the industry who have advocated reform.'"[88] In the lengthy opinion resolving the NAACP's nuisance suit against gun manufacturers and distributors in New York City, Judge Weinstein concluded that "the manufacturers and distributors . . . [are peculiarly situated], through the use of handgun traces and other sources of information, [to] substantially reduce the number of firearms leaking into the illegal secondary market and ultimately in to the hands of criminals in New York."[89] His 136 page district court opinion lists a variety of ways that the manufacturers and distributors currently are in a superior position to discourage dealerships from allowing straw purchases and illegal sales. More generally the litigation has underscored the perverse incentives that gun manufactures and distributors face with regard to gun safety:

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[87] *See* Memorandum from Steven M. Silwa, CEO and President, Colt to Zilkha Captial Partners et al., June 28, 1999, "iColt Offering Memorandum Draft", at 27, available at http://www.gunlawsuits.org/pdf/docket/041803.pdf.

[88] Deposition of Robert Riker, gun executive, in Brady Center to Prevent Gun Violence, *Smoking Guns: Exposing the Gun Industry's Complicity in the Illegal Gun Market* 18 (quoting Riker deposition).

[89] NAACP v. AcuSport, Inc., 271 F. Supp.2d 435, 449-50 (E.D.N.Y. 2003).

Since manufacturers and dealers generally profit from gun violence because it lead to still more gun sales, at least in the short term, most of their market incentives are oriented towards making guns more lethal.[90]

The gun litigation also circumvents the complex process and rules thatoverwhelm the regulatory system by spotlighting the political concessions that gun manufacturers and distributors, as well as National Rifle Association (NRA) executives, have extracted from the political process. Other than a few limited requirements governing gun sales and distribution, such as background checks, there is effectively no regulation of gun manufacturers and only scant regulation and enforcement of gun distributors.[91] Guns in fact may be one of the few products in the United States whose design is not overseen by federal regulators, despite the fact that that firearms are second only to motor vehicles as the major cause of product-related deaths in the U.S.[92] These legislative exemptions are not easily located, however; they are spread through a half a dozen statutes and guarded closely by the gun industry and affiliated interest groups. As a result, the mechanisms for reforming the current legislative and regulatory maze of exemptions are opaque to most attentive participants. The recent legislation that attempts to immunize gun manufacturers from civil liability only exacerbates the manufacturers' lack of

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[90] *See generally* TOM DIAZ, MAKING A KILLING: THE BUSINESS OF GUNS IN AMERICA (1999).
[91] *See, e.g.,* David Hemenway, *Editorial: Regulation of Firearms*, 339 NEW ENG. J. MED. 843 (1998).
[92] *See, e.g.,* S.P. BAKER, B. O'NEILL, M.J. GINSBURG AND G LI, THE INJURY FACT BOOK (New York: Oxford Univ. Press, 1992).

accountability for the safe design of guns and further underscores its strong influence within the existing political-regulatory system.[93]

2. *Lowering Agency Costs and Providing Better Public Education on Safe Gun Design and Distribution*

The gun litigation also counteracts the unaccountability of interest groups to the people they purport to represent -- and the high costs associated with monitoring them -- that operate in the political process. The gun litigation may even suggest that in settings when information costs are unusually high, the courts may serve the diffuse public (nonlitigants) more effectively than the political process, both because there is little adequate public representation going on in the political process and because the litigation helps educate the broader public to the basic issues -- such as minimal regulation of the design and sale of firearms -- that have become obscured by political wrangling and legal complexity.

The possibility that litigation, filed by a subset of more "extreme" (albeit government) advocates might be more responsive to stakeholders and the public than the political process seems, at first blush, preposterous. Indeed, this is one of the primary criticisms of the litigation; namely that unaccountable litigants and courts are left to resolve social issues without input from the broader public through the democratic process.[94] Yet as detailed below, the political process leaves much to be desired in providing these democratic services when information costs are excessive.

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[93] *See* Protection of Lawful Commerce in Arms Act (PLCAA), Public Law 109-92, 199 *U.S. Statutes at Large* 2095 (2005); Lytton, *Afterword: Federal Gun Industry Immunity Legislation, in* GUN LITIGATION (Mich U. Press forthcoming 2006).

[94] *See* Schuck, *Why Regulating Guns Won't Work, supra* note 84, at 236-38, 244-47.

The effective failure of the political process arises in large part from the combination of deficient empirical information and the historic presence of vigorous interest groups at both ends of the debate. The issue of gun control, perhaps more than other public health issues, is unusually devoid of helpful empirical information. Research on firearms violence prevention is so deficient that the National Academy of Science committee and a Harvard research center are dedicating substantial resources to identifying these research gaps and structuring programs to fill them.[95]

Social issues that lack reliable information to answer pressing policy questions provide interest groups carte blanche to frame social issues to their liking. To the extent these groups are interested in attracting members or media attention, they may prefer to portray the problems in the most extreme and catastrophic way. When there are competing public positions on an issue and little credible information to constrain the positions, as in the case of gun control, the groups tend to become polarized, emphasizing the constellation of facts at the tails of the bell curve of possibilities. This seems to be precisely the way the gun control debate has played out in the political process. Over the past few decades, some gun control groups have advocated complete gun bans as the preferred reform and portray gun violence as a disease that needs to be eradicated.[96] The

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[95] *See, e.g.,* The Harvard Injury Control Research Center, at http://www.hsph.harvard.edu/hicrc/nviss/; DIVISION OF BEHAVIORAL AND SOCIAL SCIENCES AND EDUCATION, NATIONAL RESEARCH COUNCIL, NATIONAL ACADEMY OF SCIENCE, FIREARMS AND VIOLENCE: A CRITICAL REVIEW 2 (Washington: National Academy Press 2004) (committee found that "answers to some of the most pressing questions cannot be addressed with existing data and research methods, however well-designed").

[96] *See, e.g.,* Nathanson, *supra* note53, at 465-66, 474.

NRA and its affiliates, by contrast, frame any gun control effort as a direct infringement on the "right to bear arms."[97]

Beyond the absence of credible information against which to evaluate interest group positions, there are other impediments thatthe diffuse public encounters in monitoring their interest-group agents' performance in the political process. Interest groups engaged in lobbying or other forms of political activity are not required to record their positions or communicate them to members. Meetings, letters, congressional briefings, and a large variety of disparate contacts can involve positions that might not even be in accord with member preferences. For example, a survey of 607 gun owners by Harvard researchers revealed that most NRA members supported types of gun control, like registration and waiting periods, that the NRA leaders actively lobbied against.[98] This same survey also revealed that members were not fully aware of the leadership's opposition to all forms of gun control. For example, 90% of the NRA members said they "agree[d] with the positions of the NRA", yet their preferences for gun control diverged to a significant extent from the NRA's on virtually every gun control issue.[99] In a study of environmental nonprofits, survey research similarly revealed incomplete, and in some cases very limited communication of an environmental organization's policy positions to

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[97] *See, e.g.,* Douglas S. Weil and David Hemenway, *I Am the NRA: An Analysis of a National Random Sample of Gun Owners,* 8 VIOLENCE AND VICTIMS 353, 361 (1993).
[98] *Id.*
[99] Douglas S. Weil and David Hemenway, *Reply to Commentary: A Response to Kleck*, 8 VIOLENCE AND VICTIMS 377, 378, 382 (1993) (compare Table 1 and 2). The researchers conclude from their survey that "the leadership positions of the NRA do not represent the views of either the typical NRA member or nonmember gun owners with respect to important gun control policies." Weil and Hemenway, I Am the NRA, *supra* note 99, at 363.

its members, at least for the five major nonprofits in the study.[100] In some settings, moreover, the limited communications between interest group and members may not be wholly accidental. Incomplete communication, especially when positions are expected to be controversial within the membership, assists interest groups in avoiding alienating members who provide needed financial support.[101]

Even more perversely, interest groups often serve as the primary source of information to members and even the broader public. Research on nonprofits reveals that access to information and education is one of the primary reasons people join nonprofit groups.[102] Yet, this educational service provides the interest group with still more latitude to take extreme positions when available information is limited, particularly when crises are likely to generate greater amounts of member dollars. Distorted or incomplete education of members, especially when that education helps keep members from leaving the organization, may be a recurring problem with nonprofit representation more generally in information-deficient arenas.[103] And this deficiency is again magnified

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[100] In the case of the National Wildlife Federation, for example, Shaiko reports that its membership appears completely split on the issue of opposition to nuclear power. Despite this fact, "[t]he leadership of NWF does take a position on nuclear power (antinuclear), but one would have a hard time finding evidence of the position in the leaders' communications to their members." RONALD G. SHAIKO, VOICES AND ECHOES FOR THE ENVIRONMENT: PUBLIC INTEREST REPRESENTATION IN THE 1990S AND BEYOND 161 (1999).

[101] *See, e.g.*, Seidemann, *supra* note 48, at 224-25 ("While [environmental groups] may serve the public as watchdogs, it should be remembered that they have interests (e.g., their financial well-being) which do not coincide with those of the public."); Mark Seidenfeld, *Empowering Stakeholders: Limits on Collaboration as the Basis for Flexible Regulation,* 41 WM. & MARY L. REV. 411, 463 (2000) (detailing how nonprofit leaders may sue some polluters and not others based on issues that affect the sustainability of the organization rather than reflect member preferences).

[102] *See, e.g.,* SHAIKO, *supra* note 100, at 150.

[103] *See, e.g,. id.* at 152, 161, 165, 173.

in the political process where these agents face few, if any, institutional constraints in how they choose to educate and represent their members.[104]

The cumulative deficiencies in interest group representation in the regulatory process significantly erode one's confidence in the democratic supremacy of the regulatory process relative to the judiciary in settings when information is badly lacking. At least in the case of gun control, these interest group problems appear to be largely to blame for political inaction regarding gun control reform, even though a vast majority of the public, including a majority of NRA members, support gun control reforms.[105] At least part of this discrepancy between public preferences and political outcomes can be attributed to the high information costs that attend monitoring these agents in the political process and the general public's low stakes in engaging in the issues more directly.

The representational problems that arise in litigation may ultimately be less debilitating as compared with the political branches, at least once one accounts for the courts' and litigants' corresponding ability to dislodge closely-held information relevant to gun design from the manufacturers and distributors. More importantly, because these claimants' positions are largely transparent and go "on record", they are much easier for the broader public (and media) to understand and react to – forming essentially the equivalent of a lightning rod for broader social discussion.

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[104] In the courts, there are at least requirements that all factual allegations be made in good faith, sanctions against frivolous arguments, and mandatory ethical rules governing client representation. *See supra* notes 45-47 and accompanying text.

[105] *See, e.g.,* Stephen P.Teret, et al., *Support for New Policies to Regulate Firearms: Results of Two National Surveys*, 339 NEW ENG. J. MED. 813 - 814 (1998).

3. *Evidence of the Gun Litigation's Success in Lowering Information Costs*

The most instructive feature of the gun litigation from the standpoint of the comparative attributes of the courts, however, is its ability to lower all of the information costs at once, overcoming participatory barriers that have slowly paralyzed the political process and made it unresponsive to the underlying preferences and views of the broader public. First, by breaking through some of the manufacturers' asymmetrical information, the public and their representatives became more educated about the ways guns could be made safer. Privately held industry information disclosed in municipal litigation in California, for example, not only led to a settlement between the municipality and gun dealers, but was followed by some modest state legislation regulating gun distributors.[106] This progress in gun control is offset in part by an NRA-designed backlash to the litigation that resulted in state laws that insulate the industry from the litigation.[107] Nevertheless, evidence that the litigation might lead to gun regulation in some states could be a sign of heightened public awareness of the lack of industry accountability stemming from the gun litigation.

Second and perhaps more surprising, increased information on the manufacturers' and distributors' historic disinterest in gun safety has led to a number of voluntary changes within the industry that may be the result of greater public accountability. As a

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[106] *See, e.g.*, Jim Wasserman, *Assembly passes requiring gun design changes*, CONTRACOSTA TIMES, Sept. 5, 2003, at http://www.bayarea.com/mld/cctimes/news/6697952.htm.

[107] *See generally* Lytton, *supra* note 85.

result of the litigation, the gun manufacturers focused more attention on safer designs[108] and dealers voluntarily instituted efforts to make distribution less susceptible to criminal trafficking as a result of the litigation.[109] After the litigation was filed, for example, Colt discontinued its most dangerous and inexpensive models[110] and other manufacturers began for the first time to equip their guns with external locks.[111] Distributors have also begun to focus on ways that dealers can prevent straw purchases to criminals.[112] Although it seems counterintuitive that manufacturers and dealers might change their behavior in response to the largely unsuccessful litigation, this increased attention to safety may simply be a rational reaction to economic realities. Prior to the litigation, manufacturers faced no probability of sanctions for careless distribution or design practices. After the litigation was filed, the manufacturers faced a public that had greater access to information regarding their practices and could now hold them accountable in the marketplace, political process, and courts. At least in rational choice terms, the change in accountability could lead manufacturers to make some investments in safety if they believed they could limit or stave off further lawsuits, regulatory requirements, and adverse consumer reactions by doing so. There may be other reinforcing reasons for this changed behavior, including the possibility that the industry itself was unaware of the gap between its practices and the public interest. Most explanations, though, are tied to the

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[108] *See, e.g.,* Rachana Bhowmik, *Aiming for Accountability: How city Lawsuits Can Help Reform an Irresponsible Gun Industry*, 11 J.L. & POL'Y 67, 127 - 34; Jim Lietzel, *Comment*, in REGULATION THROUGH LITIGATION, *supra* note 3, at 98.
[109] *See, e.g., id.*, 95-96.
[110] *See, e.g.,* Barbara Vobejda, *Colt to Discontinue Cheaper Handguns*, WASHINGTON POST, EI, Oct. 12, 1999.
[111] *See, e.g.,* Brady Center, *Smoking Guns*, *supra* note 88, at 15.
[112] The National Associations of Firearms Retailers now posts on their home page the BATFE's training video for ways that retailers can prevent straw purchasers. *See* http://www.nafr.org/DontLie/index.html.

fact that by lowering at least some of the information costs for all participants, the litigation caused the industry to engage in internal self-evaluation. Others have observed similar voluntary industry changes as a result of regulatory disclosure requirements, which can bring about improvements in industry practice through greater internal and external accountability.[113]

C. Summary

These two case studies confirm the importance of taking information-related barriers to participation into account in comparing the courts against the regulatory process. When relevant information is asymmetrically held or is deficient in ways that allow parties to shirk responsibility, as it was in the manufacture of breast implants, then participation will be tilted against those who lack access to the information. In such cases, the institution best able to lower information costs will have a comparative advantage over the others. Process costs and the costs of monitoring interest-group-agents can also be higher in the political process relative to the courts. The gun litigation reveals how advocates that purport to represent broader constellations of interests in the political process can operate with limited accountability and might even manipulate issues in ways designed to enroll more members. The courts' ability to lower these monitoring costs, as well as to provide stronger incentives for dealers and manufacturers to become concerned with how they can counter gun violence prevention, deserves credit in assessing the merits of common law litigation relative to regulation in protecting public health.

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[113] *See, e.g.,* William M. Sage, *Regulating through Information: Disclosure Laws and American Health Care,* 99 COLUM. L. REV. 1701 (1999); Bradley Karkkainen, *Information as Environmental Regulation: TRI and Performance Benchmarking, Precursor to a New Paradigm?* 89 GEO. L. J. 257 (2001).

III. GENERAL LESSONS FOR THE REGULATION OF RISKY PRODUCTS

The analysis here suggests that tort litigation is indispensable in ensuring the safety and accountability of product manufacturers and industrial polluters. While regulation may sometimes or even frequently prove adequate to access and act on information on health and environmental risks, the case studies and general analysis suggest that this will not always be the case. These findings have significant practical import and also suggest refinements to existing theories about comparative institutional analysis.

The most immediate and practical lesson is that tort reform and related legislation that bars tort litigation against industrial subgroups may eviscerate a vital institutional tool for regulating risky products and activities. Over the last decade, there have been a variety of legislative attempts to preclude or reduce incentives for tort litigation, most obviously the recent federal law protecting gun manufacturers from some civil litigation.[114] The analysis in this paper suggests that we risk losing important regulatory tools when we foreclose the courts and litigants from participating in these regulatory decisions. If information is stubbornly withheld by product manufacturers or polluters and if regulatory powers are invisibly constrained through political compromises, the courts may be the only institution able to overcome the various barriers to regulation that encumber risky products. At a minimum, those who seek to bar litigation should

[114] *See supra* note 93 and accompanying text; *see also* Terry Carter, *Piecemeal Tort Reform*, ABA J., Dec. 2001, at 51 (reporting on tort reform bills that provide immunity to specific narrow sets of industries).

establish that the regulatory system is fully engaged in regulating the risky products or activities at issue.

The errors that "regulatory litigation" critics have made also provide a platform for learning more general lessons about comparative institutional analysis. First, the critics' critical mistake in ignoring limits in information underscores the importance of considering information costs in comparing relative institutional capabilities. If a great deal of the relevant information regarding product risks remains unavailable to all but a few participants – either due to asymmetries or high legal complexity – then an institution is needed that will overcome these information barriers. This is especially important since the availability of information affects participation, both in terms of understanding the issues in need of input and appreciating whether one has stakes in an issue at all.

A second and perhaps larger lesson for institutional reformists is the need to combine institutions in a way that maximizes their respective capabilities to correct or compensate for underlying participatory imbalances. Rather than a horse race that seeks out a single institutional winner with respect to resolving a social problem, the best institutional response may be a mix of institutions that enter the decision-making process at different points in the life cycle of an issue or offer different services to overcome different types of participation deficiencies.[115] Since the cost of information is not static, the cost-lowering qualities of the various institutions may differ over time on a given issue.[116]

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[115] NEIL K. KOMESAR, LAW'S LIMITS: THE RULE OF LAW AND THE SUPPLY AND DEMAND OF RIGHTS 164 (2001) (observing the limited role for the courts in some settings).

[116] Access/production costs related to information may need to be separated from transaction/processing costs in comparing institutional competence, for example.

Third and finally, in terms of institutional choice, finding an institution able to dramatically lower information costs can be an end unto itself. In a setting where information costs have become inflated by asymmetrical information, legal complexity, and unrepresentative interest groups, an institution that can enter and reduce these information costs can make a significant difference to public participation across all institutions. Even the cycling between institutions that has been observed in contemporary social regulation[117] may begin to take care of itself, or at least reduce its purposeless passing between institutions, by gaining traction and resultant progress on an issue through enhancingpublic participation across all institutions. The case studies lend support to the value of conducting comparative institutional analysis that has as its endpoint identifying the institution best able to lower information costs, rather than simply the institution best able to resolve a problem completely.

The case studies detailed above suggest that for the regulation of potentially dangerous products, the courts may be the first and best institution to force information costs downward, at least once the regulatory system has become mired in asymmetric information and convoluted rules and exceptions. Excessive information costs, coupled with the already low stakes of most diffuse public, can raise an insuperably high barrier for meaningful participation by the passive majority in the political/regulatory process. After litigation by a subset of this majority, the information costs can be lowered significantly, making more meaningful participation possible. Plunging information costs can even cause regulated parties to voluntarily alter their practices in order to stave off the liability or regulation that inevitably follows heightened public accountability.

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[117] *See, e.g.*, KOMESAR, LAW'S LIMITS, *supra* note 115, at 163 (discussing the cycling phenomenon).

The defense of the courts in lowering information costs does not put an end to all debates over regulation through litigation, however. Doctrinal and jurisprudential concerns remain with respect to some of these suits, and the extent to which preexisting doctrine and traditional institutional roles should constrain institutional choice is a debate that involves considerations largely separate from comparative institutional analysis.[118] It is perhaps this battleground that critics are better prepared and more interested in defending. But in these discussions, critics should acknowledge the comparative institutional capability of the courts in lowering information costs in ways that can lead to improvements in the functioning of all institutions.

IV. CONCLUSION

Contrary to scholarly commentary and contemporary tort reform legislation, tort litigation does play a vital and indispensable role in ensuring the safety and accountability of product manufacturers and industrial polluters. Information regarding the safety of products and polluting activities is a key ingredient to public health and environmental regulation. Yet regulators do not always enjoy comparative advantages in accessing this vital information. Instead the courts sometimes serve as the only institution able to penetrate and lower information costs that can obscure and preclude important public deliberations about health and environmental risks.

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[118] For example, some of the criticisms of regulatory litigation raise doctrinal concerns, such as arguments that individual lawsuits are legally frivolous or in violation of constitutional requirements. *See, e.g.*, Margaret A. Little, *A Most Dangerous Indiscretion: The Legal, Economic, and Political Legacy of the Governments' Tobacco Litigation*, 33 CONN. L. REV. 1143 (2001); Walter Olson, *Big Guns*, REASON, Oct. 1999, at 60. These very different doctrinal concerns are not addressed in this article.

The fact that the courts are sometimes best suited to lower information costs relative to political institutions does not mean that they are capable of resolving these policy problems completely. The courts' information cost-lowering capabilities do suggest, however, that the courts may be the best, first institution capable of penetrating social problems characterized by badly asymmetrical information and a high level of complexity. After the courts lower information costs, other institutions that require more accessible, low cost information to operate smoothly will be able to engage in problem-solving and develop more sophisticated political or market responses.