

THE LEGAL SANCTUARY FOR HUMAN EXPERIMENTATION

Wendy Wagner

AUTHOR—Richard Dale Endowed Chair, University of Texas School of Law. A big thank you to Professor Marshall Shapo for honoring me with the invitation to contribute to this symposium celebrating his inspirational work. I am also grateful to Samantha Greenky and other members of the *Northwestern University Law Review* for their help in finalizing this Essay.

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INTRODUCTION

Professor Marshall Shapo's prodigious body of work, spanning several distinct fields, provides no shortage of praiseworthy contributions. Ironically, though, it is this same enormity of output that makes it effectively impossible to do justice to it all. So, rather than be thorough or representative, I select only one small subset of his publications in my own field of science and the law to celebrate.

Professor Shapo is the first—and still the only—academic to explain that by allowing untested chemical products onto the market we, as a society, enable companies to experiment on unwitting humans to test drugs, consumer products, workplaces, and environmental exposures. In a series of books beginning in 1979, Professor Shapo placed this phenomenon of human experimentation—what he sometimes calls “mass market experimentation”¹—not only within tort, but also within the scope of regulatory law.² He mapped how legal institutions sometimes “compete” to protect against these types of nonconsensual experiments, how they often conflict,³ and how they sometimes fall short, leading to what he calls “laissez-faire with a vengeance.”⁴ He even drafted an “injury law constitution” that endeavors to extract the very best that this “jagged” body of law has to offer public health and safety,⁵ while also offering some normative principles to guide the law as it continues to develop over time.

In this Essay, I spotlight both how prophetic and how critically important Professor Shapo's four decades of writing on “humans as guinea pigs” have become.⁶ His work is prophetic because he sees a coherent problem that would have otherwise been ignored. His work is of enduring importance because, despite Professor Shapo's painstaking research, the legal response to this experimentation has, if anything, become steadily worse. The need for integrated legal solutions is growing even more urgent,

¹ See, e.g., MARSHALL S. SHAPO, EXPERIMENTING WITH THE CONSUMER: THE MASS TESTING OF RISKY PRODUCTS ON THE AMERICAN PUBLIC 6, 211–14 (2009) (exposing the widespread practice of mass-market experimentation, where consumers are exposed to product risks that have been insufficiently tested, often in deliberate ways, by manufacturers).

² *Id.*; see also MARSHALL S. SHAPO, A NATION OF GUINEA PIGS 5, 7 (1979) [hereinafter SHAPO, A NATION OF GUINEA PIGS] (documenting the harmful effects of a number of prominent products, like DES, and critiquing the legal system's inadequate response to anticipating and preventing these harms); MARSHALL S. SHAPO, THE EXPERIMENTAL SOCIETY, at xi (2016) [hereinafter SHAPO, THE EXPERIMENTAL SOCIETY] (tracing society's varied responses to experimenting on humans which occurs through exposure of persons to untested risks of new technologies without their permission).

³ MARSHALL S. SHAPO, AN INJURY LAW CONSTITUTION 92–93, 264 (2012); SHAPO, THE EXPERIMENTAL SOCIETY, *supra* note 2, at 314.

⁴ SHAPO, *supra* note 3, at 169.

⁵ *Id.* at 193.

⁶ See *supra* note 2.

and his contributions on this subject will play a central role in locating solutions.

In the first two parts of this Essay, I survey several foundational pieces of Professor Shapo's framing of the human experimentation problem. This includes both the legal, normative principles that should guide technological innovation, discussed in Part I, as well as practical evidence that these principles are being violated, particularly in the production and use of chemical-based products, explained in Part II. The third Part then explores how the law seems to be absent from overseeing this human experimentation, particularly for chemical-based products. Instead of deterring nonconsensual human experimentation, existing laws actually reinforce these practices, creating legally tolerated sanctuaries of human experimentation. The final Part of this Essay applies Professor Shapo's legal methods of inter-institutional analysis to locate better legal approaches to counteract unreasonable human experimentation.

I. IDENTIFYING THE UNDERLYING NORMATIVE FRAMEWORK GOVERNING HUMAN EXPERIMENTATION

In *An Injury Law Constitution*, Professor Shapo employs his mastery of product liability law to inductively locate constitution-like principles that generally represent the thrust of the common law's normative goals for public health and welfare.⁷ There are two principles from Professor Shapo's *An Injury Law Constitution* that are particularly instructive to understanding the phenomenon of human experimentation. The first is the critical role of law in encouraging socially beneficial innovation.⁸ The second is the need for those engaged in risky activities (and innovations) to take responsibility for anticipating and preventing unreasonable harm in settings where they are better suited to assess long-term safety.⁹

When these two principles are combined, their "balancing" leads to a relatively clear goal: that in the innovation and manufacture of complex products, manufacturers should share some responsibility for the safety of those products.¹⁰ Beneficial innovation, in other words, involves a reasonable anticipation and prevention of unnecessary health and environmental harms from new technologies. By factoring safety considerations into firms' research and development (R&D) activities, the law thus helps guide innovation in a positive, public-benefitting direction.¹¹

⁷ SHAPO, *supra* note 3, at 268–72.

⁸ *Id.* at 169; SHAPO, A NATION OF GUINEA PIGS, *supra* note 2, at 254.

⁹ SHAPO, *supra* note 3, at 215, 269.

¹⁰ *See, e.g., id.* at 197.

¹¹ *See, e.g.,* SHAPO, A NATION OF GUINEA PIGS, *supra* note 2, at xv, 53, 259.

This “injury constitution” also underscores the importance of living in a world with these kinds of legal directives in place. If consumers were responsible for testing and ensuring product safety in complex markets, then not only would the consumers regularly encounter risks they cannot reasonably understand or avoid, but manufacturers would be allowed to innovate in ways that are largely blind to public safety.¹² Rather than conducting reasonable anticipatory research on safety, humans would unwittingly become the experimental subjects.¹³

Instead, we expect the law to channel manufacturers towards socially beneficial innovation. This could be done—among other ways—by placing the burden on manufacturers to engage in reasonable research and development of safer products and sanctioning them with tort liability and regulatory penalties when they miss the opportunity to do so.¹⁴ Once the law points innovative behavior in the right direction, it will also be easier for consumers to evaluate competitor products and services with respect to safety.

II. PRACTICAL EVIDENCE OF HUMAN EXPERIMENTATION WITHOUT CONSENT

Despite enshrining these principles in an “injury constitution,” Professor Shapo recognizes, and meticulously traces out, the vast, real-world slippage occurring in practice, particularly with respect to chemical-based products and activities that cause long-term harms.¹⁵ In a series of books spanning more than three decades, Professor Shapo documents rampant experimentation on humans—without their consent—that appears to be both unreasonable and preventable through responsible premarket testing and analysis.¹⁶ A small sampling of this much larger body of work includes the following illustrations.

Chemical Manufacture. The area of chemical manufacture has long been plagued by what seems to be rather stark evidence of underinvestment

¹² See SHAPO, *supra* note 3, at 269–72.

¹³ *Id.* at 268–70.

¹⁴ See, e.g., SHAPO, *supra* note 1, at 8, 129.

¹⁵ Other areas of this problematic experimentation that Professor Shapo documents, not spotlighted in the text, include innovation on HIV/AIDS drugs, breast implants, Viagra, Estrogens, vaping, PFAS chemicals, the birth control pill, the use of food and color additives, DES, asbestos, and gene technologies. See generally SHAPO, A NATION OF GUINEA PIGS, *supra* note 2 (tracing harms caused by human experimentation in the marketing of the birth control pill, nitrites, DES, asbestos, and recombinant DNA); SHAPO, THE EXPERIMENTAL SOCIETY, *supra* note 2 (examining human experimentation using a wide range of products and activities that include prescription drugs, BPA, and hydrofracking).

¹⁶ See, e.g., SHAPO, *supra* note 1, at 6–7 (cataloging different types of experimentation).

in R&D on long-term safety.¹⁷ In the U.S., more than 40,000 chemicals are sold that serve as ingredients for numerous consumer, industrial, and medical products.¹⁸ Yet the toxicological understanding of this large universe of chemicals and products is quite limited. According to a series of reports, nearly two-thirds of all chemicals in commerce are insufficiently assessed based on existing toxicological standards, and the remaining 10,000-plus chemicals are supported by almost no safety data.¹⁹ Indeed, for thousands of chemicals, independent researchers cannot even learn the name, much less the chemical identity, of the chemical, due to overly generous trade secret claims.²⁰ Untested and unanalyzed chemicals thus flood the market, and their potentially adverse effects on humans and the environment remain largely unstudied.²¹

Nanotechnology. Despite the potential for health and environmental harms stemming from nanotechnology, in which products are comprised of man-made micro particles at the atomic scale, there is scant testing for their potential latent hazards either pre- or post-market.²² As one former government scientist summarized: “‘We have no information about chronic exposure, or whether or not those materials have a delay of 10 or 15 years,’ like asbestos.”²³ To remedy the regulatory agencies’ own ignorance on these pivotal issues, the EPA requested that the industry voluntarily provide safety data, but little information was produced.²⁴ Instead, it appears that industry

¹⁷ See, e.g., SHAPO, THE EXPERIMENTAL SOCIETY, *supra* note 2, at xv–xvii.

¹⁸ See *TSCA Chemical Substance Inventory: How to Access the TSCA Inventory*, EPA (2020), <https://www.epa.gov/tsca-inventory/how-access-tsca-inventory> [<https://perma.cc/D5S4-7FAT>].

¹⁹ See, e.g., STEERING COMM. ON IDENTIFICATION OF TOXIC AND POTENTIALLY TOXIC CHEMS. FOR CONSIDERATION BY THE NAT’L TOXICOLOGY PROGRAM & NAT’L RSCH. COUNCIL, TOXICITY TESTING: STRATEGIES TO DETERMINE NEEDS AND PRIORITIES 118 fig.2, 119 (1984); Richard Judson, Ann Richard, David J. Dix, Keith Houck, Matthew Martin, Robert Kavlock, Vicki Dellarco, Tala Henry, Todd Holderman, Philip Sayre, Shirlee Tan, Thomas Carpenter & Edwin Smith, *The Toxicity Data Landscape for Environmental Chemicals*, 117 ENV’T HEALTH PERSP. 685, 685 (2009).

²⁰ Rob Coleman, Melanie Benesh & David Andrews, *Off the Books II: More Secret Chemicals*, EWG (May 9, 2016), <https://www.ewg.org/research/off-the-books-ii-more-secret-chemicals> [<https://perma.cc/6XGZ-G5A8>].

²¹ See, e.g., U.S. GOV’T ACCOUNTABILITY OFF., GAO-12-696T, CHEMICAL REGULATION: OBSERVATIONS ON THE TOXIC SUBSTANCES CONTROL ACT AND EPA IMPLEMENTATION 13–14 (2013); U.S. CONG. OFFICE OF TECH. ASSESSMENT, OTA-BP-ENV-166, SCREENING AND TESTING CHEMICALS IN COMMERCE 11 (1995).

²² See SHAPO, *supra* note 3, at 168–69; SHAPO, *supra* note 1, at 188–210; see also *Health Risks of Nanotechnology: How Nanoparticles Can Cause Lung Damage, And How the Damage Can Be Blocked*, SCIENCE DAILY (June 11, 2009), <https://www.sciencedaily.com/releases/2009/06/090610192431.htm> [<https://perma.cc/N4KQ-F9EM>].

²³ Sheila Kaplan, *Nanotechnology: Harmful or Benign?*, FLA. BULLDOG (July 24, 2013), <https://www.floridabulldog.org/2013/07/nanotechnology-harmful-or-benign/> [<https://perma.cc/TCR9-DX2F>].

²⁴ *Id.*

investments in nanotechnology innovation prioritize the marketable benefits of the technology rather than its safety. Moreover, since human exposures are diffuse and almost impossible to track, the primary data we are able to collect from human experimentation comes from highly exposed workers,²⁵ which is largely produced by academics and government researchers rather than by nanotech manufacturers.²⁶

Fracking. Fracking, a technique used to tap difficult-to-reach natural gas reserves, utilizes chemicals to facilitate the extraction processes. Existing research on the long-term risks and harms associated with fracking in general and fracking fluids in particular is slim and, again, is largely produced by government and academic scientists outside of industry.²⁷ At most, the fracking industry has complied with the regulatory agencies' requests to provide data on spills and similar events during fracking processes, with the government conducting the resulting health and safety research.²⁸ Additionally, at least some of the chemicals used for extraction are trade secret protected, making it difficult for third parties to evaluate the safety of the chemicals with respect to the short and long-term risks, including those risks associated with worker exposures and water contamination.²⁹ As a result, if fracking imposes risks to human health, we will likely learn of these unwelcome effects from exposed populations after the fact.

Latent Harms in Consumer Products Such as Dietary Supplements, Cosmetics, Fragrances, and Children's Toys. There is similarly little evidence of significant industry investment in R&D of the long-term safety of consumer products that contain toxic substances with potential latent hazards.³⁰ As just one example, widespread public concerns about the latent

²⁵ See, e.g., Thomas A.J. Kuhlbusch, Susan W.P. Wijnhoven & Andrea Haase, *Nanomaterial Exposures for Worker, Consumer and the General Public*, 10 NANOIMPACT 11, 11 (2018).

²⁶ See, e.g., Ira Bennett & Daniel Sarewitz, *Too Little, Too Late? Research Policies on the Societal Implications of Nanotechnology in the United States*, 15 SCI. AS CULTURE 309, 309–10 (2006).

²⁷ See generally SHAPO, THE EXPERIMENTAL SOCIETY, *supra* note 2, at 33–40 (discussing governmental and academic research conducted into fracking and the ways in which it conflicts with industry research and rhetoric to form an uncertain understanding of surrounding risks).

²⁸ The EPA, for example, has published several reports on the effects of fracking on drinking water. See, e.g., EPA, EPA-600-R-16-236ES, HYDRAULIC FRACTURING FOR OIL AND GAS: IMPACTS FROM THE HYDRAULIC FRACTURING WATER CYCLE ON DRINKING WATER RESOURCES IN THE UNITED STATES (2016).

²⁹ Neela Banerjee, *Fracking Companies Keep 10% of Chemicals Secret, EPA Says*, INSIDE CLIMATE NEWS (Mar. 31, 2015), <https://insideclimatenews.org/news/31032015/fracking-companies-keep-10-chemicals-secret-epa-says> [<https://perma.cc/CG4D-TZ59>].

³⁰ See SHAPO, THE EXPERIMENTAL SOCIETY, *supra* note 2, at 115–31 (documenting misleading representations and other unethical behavior by some product manufacturers regarding the risks of their products); see, e.g., NANCY UDING & ERIKA SCHREDER, CHEMICALS REVEALED: OVER 5000 KIDS' PRODUCTS CONTAIN TOXIC CHEMICALS 1 (2013), <http://toxicfreefuture.org/wp->

risks of bisphenol A (BPA), an industrial chemical used to make plastics, led to considerable regulatory pressure (primarily from individual states) and market pressure on manufacturers who, in turn, found it necessary to invest in research and innovation on alternative plasticizers.³¹ Ironically, though, these alternative plasticizers are largely untested and may lead to adverse health effects as well.³² This same story can be retold for the substitute products used in place of other known hazards, such as the PFAS-laden, nonstick coatings used widely in cookware and a variety of other household products.³³

III. WHY IS THIS HUMAN EXPERIMENTATION OCCURRING?

Combining Professor Shapo's normative principles in *An Injury Law Constitution* with the disturbing evidence of mass market human experimentation leads naturally to the diagnostic question: How is this happening?

Professor Shapo's analytical methods—which insist on examining the legal system writ-large, rather than just one area, such as tort law, at a time—point to at least one contributing explanation.³⁴ The cumulative law, as currently applied to latent chemical hazards, not only tolerates human experimentation as the primary way to learn about chemical hazards, but may actually be tacitly encouraging this approach. Indeed, even after a chemical-based product or activity is sold in commerce, there are no incentives—and potentially high costs in terms of financial liability and regulatory consequences—for the creators of the technologies to collect post-market data to learn about hazards or ways to improve the product. The law, in

content/uploads/2016/09/Chemicals_Revealed_Report.pdf [https://perma.cc/KQE8-RTHM]; Maureen Rice, *Revealed . . . The 515 Chemicals Women Put on Their Bodies Every Day*, DAILY MAIL (Nov. 20, 2009, 9:59 PM), <http://www.dailymail.co.uk/femail/beauty/article-1229275/Revealed--515-chemicals-women-bodies-day.html> [https://perma.cc/55CT-DQZT].

³¹ See Mark J. Andreini, Charles H. Moellenberg, Jr. & Paul M. Pohl, *BPA, Phthalates, and the Law*, JONES DAY: INSIGHTS (Mar. 2010), http://www.jonesday.com/bpa_phthalates/ [https://perma.cc/4QW6-2E38].

³² LOWELL CTR. FOR SUSTAINABLE PROD., *PHthalates and Their Alternatives: Health and Environmental Concerns* 8 (2011), <http://www.sustainableproduction.org/downloads/PhthalateAlternatives-January2011.pdf> [https://perma.cc/AYN3-AZGV].

³³ See, e.g., Linda S. Birnbaum & Philippe Grandjean, *Alternatives to PFASs: Perspectives on the Science*, 123 ENV'T HEALTH PERSP. A104, A104 (May 2015), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4421778/> [https://perma.cc/K7EU-3KZT]; Laura Castañón, *What You Need to Know About the 'Forever Chemicals' in Your Food, Water, and Air*, NEWS@NE. (Oct. 23, 2019), <https://news.northeastern.edu/2019/10/23/heres-what-you-need-to-know-about-pfas-the-forever-chemicals-in-your-food-water-and-air/> [https://perma.cc/RP2V-ZVVV].

³⁴ See, e.g., SHAPO, *A NATION OF GUINEA PIGS*, *supra* note 2, at xiii; SHAPO, *supra* note 3, at 92–93; SHAPO, *THE EXPERIMENTAL SOCIETY*, *supra* note 2, at xiv, xvi–xvii, 288; Marshall S. Shapo, *Changing Frontiers in Torts: Vistas for the 70's*, 22 STAN. L. REV. 330, 338–40 (1970).

effect, creates a legal “sanctuary” for unconstrained human experimentation.³⁵

Before examining how the law may create these aggregate incentives, the next Section provides a quick refresher as to why manufacturer-innovators are generally best situated to factor long-term safety considerations into their R&D but might not be inclined to do so without external legal pressure.

A. Is the Law Even Needed to Discourage Human Experimentation?

There are several practical reasons, beyond the normative principle that Professor Shapo identifies, why it makes sense to place responsibility on manufacturer-innovators to invest in reasonable research on the long-term safety of their chemical-based products. First, and perhaps most important, since manufacturer-innovators are engaged in the development of products, incorporating safety considerations into the early stages of R&D is most efficient. Certainly product development and marketing expenses can be saved by creating safer products at this stage, before the product is prepared for the market. Manufacturers are also uniquely suited to do this testing because they can pass the costs of testing along to the final cost of their products. And as the creators of new products, manufacturers also enjoy superior access to understanding the potential risks and most useful types of toxicological research. Finally, even post-market, manufacturers serve as the central clearinghouse for consumer complaints, worker exposures, and other chemical-related information and are thus best able to analyze and act on emergent information on chemical hazards.

Yet, without legal intervention, market pressures and associated reputational considerations are unlikely to adequately compensate manufacturers for conducting research on the latent harms of their chemical products.³⁶ Conducting in-house research to identify long-term health hazards can be costly, and, even after the investment, the research may still be inconclusive.³⁷ This research can also take time, which further delays marketing and profits. And chemical manufacturer-innovators have few to no market benefits to offset these costs; even if the manufacturer does rigorous five-star safety assessments as part of its R&D, consumers will likely discount this extra effort as “green-washing” because consumers have

³⁵ See generally SHAPO, THE EXPERIMENTAL SOCIETY, *supra* note 2 (documenting this unconstrained human experimentation by manufacturers and other industrial risk-creators in a number of illustrative areas of market activity).

³⁶ See WENDY WAGNER, INCOMPREHENSIBLE! 135–36 (2019).

³⁷ See, e.g., Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 CORNELL L. REV. 773, 784–85, 788–89 (1997).

no way to validate the quality and rigor of the manufacturer's assessments.³⁸ Finally, market intermediaries, like lenders and insurers, also face high costs in validating manufacturers' self-assessments and comparing this information against competitor products.³⁹ Without market rewards for these assessments, the least expensive (and perhaps the most risky) products will fare the best, leading to a classic market for lemons.⁴⁰

B. *The Legal Sanctuary for Human Experimentation*

Based on these general market features with respect to latent hazards, it seems clear that the law is needed to counteract the rational incentives of manufacturer-innovators to neglect, or even ignore, long-term safety considerations in the course of technological innovation.⁴¹

So how is the law abdicating its role and failing to place primary responsibility on manufacturers for considering safety in chemical innovation? Tort and regulatory law are considered in turn.

I. *Tort Law*

At first glance, we would expect tort law to create strong incentives for manufacturers to ensure the reasonable safety of their products. Tort doctrine imposes liability for negligent activities, which would seem to encompass deliberate, nonconsensual experimentation on humans. In fact, scores of successful plaintiffs have demonstrated the strength of tort law in product cases, holding manufacturers liable for a range of dangerous chemical products that involve acute hazards.⁴² Liability has also been periodically imposed on manufacturers for some long-term chemical-based harms. For example, consider the bankrupting effects of tort liability on asbestos manufacturers and the costly waves of litigation against the manufacturers of DES, lead paint, tobacco, and others.⁴³

³⁸ Leyla Acaroglu, *What is Greenwashing? How to Spot It and Stop It*, MEDIUM (July 8, 2019), <https://medium.com/disruptive-design/what-is-greenwashing-how-to-spot-it-and-stop-it-c44f3d130d5> [<https://perma.cc/XJ4B-LWB8>]; Mary L. Lyndon, *Information Economics and Chemical Toxicity: Designing Laws to Produce and Use Data*, 87 MICH. L. REV. 1795, 1814 (1989) (“Buyers’ inability to screen products removes any incentive for manufacturers to differentiate between toxic and nontoxic products and to screen before production . . . [and so] as long as the information market remains undeveloped, ignorance of toxicity may be an advantage to a product.”).

³⁹ See, e.g., WAGNER, *supra* note 36, at 137–38.

⁴⁰ See, e.g., Lyndon, *supra* note 38, at 1814 n.72.

⁴¹ See, e.g., SHAPO, *A NATION OF GUINEA PIGS*, *supra* note 2, at 244. There is a general sense, in other words, that for these long-term risks, “uncertainties should be resolved against the creators of potential danger” and at a minimum, “those who experiment on consumers . . . must let the consumers know that they are experimental animals.” *Id.* at 250, 251.

⁴² See, e.g., Keith Cunningham-Parmeter, *A Poisoned Field: Farmworkers, Pesticide Exposure, and Tort Recovery in an Era of Regulatory Failure*, 28 N.Y.U. REV. L. & SOC. CHANGE 431, 470–82 (2004).

⁴³ See, e.g., Wagner, *supra* note 37, at 821–25.

Yet, as several scholars have noted, to file a case, the victim–plaintiff must also produce some scientific evidence that the product actually caused his or her harm. It is therefore the plaintiff who bears the burden of introducing sufficient expert evidence to prove that the defendant’s product or action was more probably than not a cause of the plaintiff’s injuries.⁴⁴

This basic pleading requirement creates a catch-22 in latent injury litigation. To press forward, the plaintiff must present credible evidence that the product was capable of doing the long-term harm they are alleging. But that burden undermines the safety incentives on manufacturers; the less testing conducted by the manufacturer-defendant, the more likely that defendant will be spared liability, at least without an independent body of incriminating third-party research.

Indeed, over the last few decades, rather than becoming more forgiving with regard to this problematic burden of causation, some courts have become increasingly demanding in requiring rigorous scientific evidence supporting plaintiffs’ allegations before proceeding to trial.⁴⁵ An evidentiary screening step—a *Daubert* hearing—presents perhaps the most significant impediment to latent harm cases.⁴⁶ Under *Daubert*, defendants can file motions *in limine*, which seek to exclude some or all of plaintiffs’ expert testimony on causation, arguing that it is not scientifically reliable. These motions are especially successful in cases where there is no conclusive epidemiological research and plaintiff experts must inductively synthesize different bodies of evidence (e.g., case studies, pharmacological evidence, and animal studies) to support a potential causal link.⁴⁷ Indeed, in a few jurisdictions, some district courts have attempted to go even further and actually insist on human evidence as a necessary predicate to a showing of causation in tort.⁴⁸

Mass litigation in asbestos, lead paint, DES, Dalkon Shield, Agent Orange, and C8 (used in Teflon), to name a few, uniformly showcases how the evidence needed to support private tort cases typically comes from experimentation on unconsenting humans.⁴⁹ In Professor Shapo’s terms, this

⁴⁴ See Joseph Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 HASTINGS L.J. 301, 331 (1992); *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 587 (1993).

⁴⁵ See, e.g., *Daubert*, 509 U.S. at 597–98.

⁴⁶ See SHAPO, THE EXPERIMENTAL SOCIETY, *supra* note 2, 209–15; Allan Kanner & M. Ryan Casey, *Daubert and the Disappearing Jury Trial*, 69 U. PITT. L. REV. 281, 314–16 (2007).

⁴⁷ See, e.g., *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1201–02 (11th Cir. 2002) (rejecting plaintiffs’ evidence as speculative where it extrapolated from studies of similar drugs and animal studies).

⁴⁸ See, e.g., Arthur H. Bryant & Alexander Reinert, *Epidemiology in the Legal Arena and the Search for Truth*, 154 AM. J. EPIDEMIOLOGY S27, S29 (2001).

⁴⁹ See, e.g., Wagner, *supra* note 37, at 818–19. See generally ROBERT BILOTT, EXPOSURE (2019) (discussing the human evidence underlying our understanding of C8).

means that the courts are sometimes requiring nonconsensual human experimentation as a condition to tort liability.

The benefits of ignorance regarding latent hazards are even more evident in cases where the plaintiffs' claim survives dismissal and the plaintiffs can access the industry's internal files during discovery. During this discovery, plaintiffs often learn of what Professor Shapo calls "red flag" evidence, which reveals that a manufacturer-defendant was alerted to potential long-term risks but chose to ignore these red flags while simultaneously suppressing them from public view.⁵⁰ This internal evidence often plays a central role in explaining plaintiff verdicts, especially in cases with weak causation evidence, because it underscores the defendant's unreasonable behavior.⁵¹

On the other hand, from the manufacturers' point of view, these red flags also inculcate the wisdom of an "ignorance is bliss" approach to testing and tracking latent product hazards. From these cases, manufacturers learn that resisting any testing and innovation insulates them from tort liability, but partial testing and presumably well-intended efforts to identify safer substitutes can trigger a barrage of legal vulnerabilities that can ultimately lead to bankrupting litigation. Professor Sanders observes that in these settings, the ability of firms to conduct research after litigation becomes a "lose-lose proposition" because "[i]f they showed an effect, the studies would be used against the company," and if they did not, "[a]ny slight technical flaw in the design or execution of the experiment would be exploited by plaintiffs to undermine [the defendant's] findings."⁵²

By contrast, a manufacturer that knows nothing and learns nothing about its product faces lower risks of liability. Of course, this makes human experimentation still more problematic since it means that not only are unwitting humans exposed to under-tested hazards, but their injuries are not even monitored to allow society to learn about the human hazards caused by new technologies.

2. *Regulatory Law*

But, as Professor Shapo reminds us, there is a larger institutional setting within which tort law operates.⁵³ One might assume that the reams of laws

⁵⁰ SHAPO, *THE EXPERIMENTAL SOCIETY*, *supra* note 2, at 69, 127-29.

⁵¹ *See, e.g.*, MICHAEL D. GREEN, *BENDECTIN AND BIRTH DEFECTS: THE CHALLENGES OF MASS TOXIC SUBSTANCES LITIGATION* 263, 289 (1996); Joseph Sanders, *From Science to Evidence: The Testimony on Causation in the Bendectin Cases*, 46 *STAN. L. REV.* 1, 53-56 (1993); Fredric L. Ellis & Ernest Hornsby, Letter to the Editor, *Dow Chemical Hid Truth on Breast Implants*, *N.Y. TIMES*, Nov. 8, 1995, at A24.

⁵² Sanders, *supra* note 44, at 337.

⁵³ *See, e.g.*, Shapo, *supra* note 34, at 340.

and regulations governing chemical-based hazards fill in these legal gaps and encourage manufacturers to conduct rigorous premarket testing and institute rigorous post-market tracking and analyses. Accordingly, tort law would serve primarily a prophylactic role, providing compensation in cases where there is fraud or other particularly egregious conduct by the manufacturers.

Unfortunately, despite more than one hundred pages of statutory text that seems to suggest otherwise,⁵⁴ chemical regulatory oversight in the United States barely engages in the regulation of chemicals or chemical-based consumer products (except drugs and, to some extent, pesticides).⁵⁵ Under these regulatory programs, there are few to no requirements on manufacturers for pre- and post-market testing and data analysis. And this limited government oversight remains fully in place despite a widely acclaimed legislative overhaul of the chemical regulatory program in 2016.⁵⁶

Specifically, as a matter of U.S. law, manufacturers of chemicals bear no burden for affirmatively analyzing or testing the safety of their chemicals, except when they are given explicit testing orders by the EPA (a process which manufacturers can oppose in court).⁵⁷ Manufacturers *are* required by law to submit case reports of adverse effects they are aware of that occur post-market (e.g., red flag evidence).⁵⁸ However, even with these mandated notifications, manufacturers are not required to evaluate the adverse effects or even submit the information to the regulators in a way that makes it easy for regulators to analyze.⁵⁹

Thus, rather than place responsibility for anticipatorily testing or assessing the long-term safety of chemicals on manufacturers, the responsibility is left to regulators.⁶⁰ Without data to analyze, regulators essentially must guesstimate which of the 40,000 largely untested and

⁵⁴ See, e.g., Toxic Substances Control Act (TSCA), 15 U.S.C. § 2601 (2012) (chemical substances); Federal Hazardous Substances Act, 15 U.S.C. § 1261 (2012); Consumer Product Safety Act (CPSA), 15 U.S.C. § 2082 (2012) (consumer products).

⁵⁵ See, e.g., WAGNER, *supra* note 36, at 138–39.

⁵⁶ Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114-182, 130 Stat. 448 (2016).

⁵⁷ See, e.g., 40 C.F.R. §§ 720.45(a), 720.50(a)–(b) (2019) (listing the information required for new chemicals, which includes only “known” information about hazards); *Chem. Mfrs. Ass’n v. EPA*, 859 F.2d 977, 984 (D.C. Cir. 1988).

⁵⁸ 15 U.S.C. § 2607(e) (2012).

⁵⁹ In response to this requirement, manufacturers in fact sometimes send all raw data—even data having no bearing on hazards—to understaffed regulators. See Wendy Wagner & David Michaels, *Equal Treatment for Regulatory Science: Extending the Controls Governing the Quality of Public Research to Private Research*, 30 AM. J.L. & MED. 119, 146 (2004).

⁶⁰ See, e.g., WAGNER, *supra* note 36, at 130–49.

unanalyzed chemicals sold in commerce are likely to be dangerous.⁶¹ And it is up to regulators to assemble risk assessments for each worrisome chemical selected out of the larger list. This means that for each suspect chemical, regulators—rather than the chemical manufacturers—must evaluate the scientific literature, order manufacturers to do specific toxicity tests on a case-by-case basis, and conduct regulatory evaluations to assess whether the combined exposure and toxicity of a worrisome chemical presents an unreasonable risk.⁶² The manufacturers' primary role, by contrast, is limited to submitting comments critiquing the regulators' efforts and ultimately challenging a regulatory assessment in court if a manufacturer finds an assessment or restriction to be unsatisfactory.⁶³

Moreover, even in the rare case that an individual chemical is ultimately identified as potentially hazardous and restricted in some way,⁶⁴ manufacturers may simply substitute other untested chemicals in its place.⁶⁵ The cycle then begins anew. It is once again up to the regulators to learn about whether these new chemical substitutes are hazardous and, if the information is lacking, to order additional testing. No wonder we see worrisome substitutions occurring for hazardous chemicals like BPA and PFAS in the chemical market.⁶⁶

With the aggregate burden on regulators for assessing latent chemical hazards, the incentives for factoring long-term safety considerations into manufacturing practices are set in reverse.⁶⁷ Much like the incentives created by tort law, rational manufacturers will find that the most expedient and least expensive way to navigate the regulatory requirements is to forgo safety testing, internal risk assessments, and active post-marketing tracking of long-term risks. Internal due diligence by manufacturers again creates a lose-lose proposition that triggers greater, rather than less, regulatory oversight and

⁶¹ See *TSCA Chemical Substance Inventory: How to Access the TSCA Inventory*, *supra* note 18. For an accessible summary of EPA's regulatory requirements, see *Highlights of Key Provisions in the Frank R. Lautenberg Chemical Safety for the 21st Century Act*, EPA, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/highlights-key-provisions-frank-r-lautenberg-chemical> [https://perma.cc/JZG7-QFBM].

⁶² *Id.*

⁶³ See, e.g., WAGNER, *supra* note 36, at 143–46, 149.

⁶⁴ Only five chemicals have been banned since 1976. Noah M. Sachs, *Jumping the Pond: Transnational Law and the Future of Chemical Regulation*, 62 VAND. L. REV. 1817, 1830 (2009).

⁶⁵ See, e.g., Steve C. Gold & Wendy E. Wagner, *Filling Gaps in Science Exposes Gaps in Chemical Regulation*, 368 SCI. 1066, 1067–68 (2020); Philippe Grandjean, *Delayed Discovery, Dissemination, and Decisions on Intervention in Environmental Health: A Case Study on Immunotoxicity of Perfluorinated Alkylate Substances*, 17 ENV'T HEALTH 62, 62 (2018).

⁶⁶ See, e.g., Birnbaum & Grandjean, *supra* note 33, at A104.

⁶⁷ This is particularly true for existing chemicals. Under the 2016 Lautenberg Amendments, the EPA was granted broader authority to require testing on untested chemicals. Pub. L. No. 114-182, 130 Stat. 448 (2016) (codified as amended at 15 U.S.C. § 2603(a)(2) (2018)).

restrictions. Unstructured experimentation on humans (and the environment) becomes the primary way for society to learn about chemical hazards.⁶⁸

In sum, existing law creates a protected sanctuary that allows and even encourages human experimentation in lieu of responsible testing and analysis of unreasonable chemical hazards. Humans not only serve as the unwitting guinea pigs, but their sacrifices are also generally not dignified with systematic data collection in an effort to identify possible hazards post-market. Moreover, the growing number of synergistic and cumulative reactions from multiple unanalyzed chemical products makes the ability to learn from human experimentation still less likely.⁶⁹ Ironically, the greater the number of untested hazards that human guinea pigs are exposed to, the more difficult it will be for scientists to learn about individual product risks post-market.

IV. NEXT STEPS

As Professor Shapo observes, “the power of experimenters to control risk, and . . . the ignorance and helplessness of victims[]replicate themselves in many environments” and warrant more coherent legal intervention.⁷⁰ So what to do?

At a general level, “[t]he experimental society needs mechanisms that enable government to get out in front of problems identified with all kinds of experimentation.”⁷¹ Responsibility must be placed on manufacturers to incorporate safety considerations into their innovative processes for chemical-based products. And, if manufacturers fail to do this, the legal consequences must be far greater than the benefits manufacturers enjoy by proceeding in ignorance.

Both regulatory and tort adjustments are needed, but an overhaul of chemical regulation is of highest priority, since proactive regulation has the potential to be the most direct, enforceable, and comprehensive solution. Consistent with Professor Shapo’s normative principles, the nature of this general reform would be straightforward: before keeping or releasing a chemical product on the market, the manufacturer must be required, at least, to rigorously assess the long-term risks based on the existing available information.⁷² Manufacturers should also be tasked with collecting and

⁶⁸ SHAPO, *THE EXPERIMENTAL SOCIETY*, *supra* note 2, at 127–29.

⁶⁹ See Sanne H. Knudsen, *Regulating Cumulative Risk*, 101 MINN. L. REV. 2313, 2332–37 (2017) (describing some of the particular challenges of assessing cumulative risk from “multiple exposure pathways”).

⁷⁰ SHAPO, *THE EXPERIMENTAL SOCIETY*, *supra* note 2, at 357.

⁷¹ *Id.* at 40.

⁷² See, e.g., WAGNER, *supra* note 36, at 149–57.

assessing post-market data continuously in order to monitor unexpected hazards. These adjustments fully comport with Professor Shapo's *An Injury Law Constitution*.⁷³ While humans may continue to serve in some settings as the unwitting subjects of post-market experimentation, manufacturers will at least be required to limit this role to hazards that cannot be reasonably anticipated or prevented.

To ensure the manufacturers' safety assessments are reliable, technical rules are also needed to dictate the terms of scientifically acceptable risk analyses and testing.⁷⁴ For example, the manufacturers should be required to use standardized protocols and computational models that have been designed by prominent expert panels. And manufacturers must be required to compare their products against the safest substitutes and explain the resulting findings in scientifically rigorous yet accessible ways. Regulatory requirements in both Europe and California have already moved in this general direction;⁷⁵ although, to be effective, regulatory oversight must be still more demanding.

Any reformed regulatory program, however, necessarily runs the risk of leaving gaps—for example, perhaps regulators will fail to implement or enforce these requirements or will overlook an unreasonably dangerous chemical for a variety of reasons. As we have learned from the last century, these inevitable cracks in regulatory oversight provide a central reason why it is important to keep state tort law in place, without any preemption.⁷⁶ Accordingly, expansions and adjustments to the common law, in theory, are also needed.

Some courts have attempted to address the perverse incentive problem in tort law by adjusting the plaintiffs' causation burden in a subset of cases where there is strong evidence that the defendant–manufacturers

⁷³ See SHAPO, *supra* note 3, at 215, 269.

⁷⁴ Cf. Henry T. C. Hu, *Disclosure Universes and Modes of Information: Banks, Innovation, and Divergent Regulatory Quests*, 31 YALE J. ON REG. 565, 636 (2014) (offering parallel types of recommendations for financial disclosure regulation that inspired the reforms for chemical regulation proposed here); see also SHAPO, *supra* note 3, at 215, 269 (discussing the economic incentives and legal analysis performed when analyzing level of risk).

⁷⁵ See, e.g., Safer Consumer Products Regulations, CAL. CODE REGS. tit. 22 (2013) (summarized at Dep't of Toxic Substances Control, *What Are the Safer Consumer Products Regulations?*, CA.GOV, <https://dtsc.ca.gov/what-are-the-safer-consumer-products-regulations/> [<https://perma.cc/3U5V-6QR7>]); Commission Regulation (EC) 1907/2006, 2006 O.J. (L 396) 1.

⁷⁶ SHAPO, *supra* note 3, at 93–94. The 2016 TSCA amendments include intricate preemption provisions, but the savings clause included in those provisions seems likely to preserve most state tort claims. See, e.g., Liza Magley & Richard Weber, *Toxic Tort and Environmental Litigation: What Does a Reformed TSCA Mean for Private Rights of Action Under State Law?* (9/16), JD SUPRA (Sept. 14, 2016), <https://www.jdsupra.com/legalnews/toxic-tort-and-environmental-litigation-79945/> [<https://perma.cc/R9D5-4EFZ>].

unreasonably exposed a plaintiff to untested but potentially significant exposures.⁷⁷ However, thus far, these trial-and-error adjustments to the causation requirement still yield a risk of too many false positives in favor of plaintiffs, with a credible risk of unwarranted, opportunistic litigation.⁷⁸

As a result, adjustments to the remedies (and associated claims) available in tort law are better suited to offer promising reforms to this challenge. For example, Professor Alexandra Lahav isolates a “knowledge remedy” that has been made available in several cases and could become more routine in the future.⁷⁹ Rather than providing victims with compensation for harm or even medical monitoring, a knowledge remedy provides unconsenting victims of chemical risks with injunctive-type relief that requires the manufacturer to conduct reasonable research on the hazards. This court-mandated testing can then seed more lucrative injury claims down the road. This ingenious proposal would likely still be limited to hazards that appear to cause human harms, but the additional deterrent could add more counterweight to the existing legal incentives that favor human experimentation.

Along these same lines, public nuisance claims—filed by government entities that aggregate the human hazards in their jurisdiction traced to a particular unreasonable hazard—are capable of side-stepping some of the causal difficulties faced in individualized suits. For example, the City of San Francisco succeeded in obtaining compensation from two paint companies for the remediation of hazardous (but undisclosed) lead paint in buildings throughout the city dating back to the mid-1900s.⁸⁰ In a similar vein, the Attorney General of Oklahoma succeeded against Johnson & Johnson at the trial level in a public nuisance claim seeking compensation for the state’s public health expenses resulting from opioid addictions traced to careless marketing practices by the company.⁸¹

⁷⁷ See, e.g., *Zuchowicz v. United States*, 140 F.3d 381, 390 (2d Cir. 1998) (“To say that [the defendant’s drug] caused [the plaintiff’s] injuries is only half the story, however. In order for the causation requirement to be met, a trier of fact must be able to determine . . . that the defendant’s *negligence* was responsible for the injury.”).

⁷⁸ See, e.g., *Williams v. Utica Coll. Syracuse Univ.*, 453 F.3d 112, 120–22 (2d Cir. 2006) (significantly narrowing the causation test propounded in *Zuchowicz*).

⁷⁹ Alexandra D. Lahav, *The Knowledge Remedy*, 98 TEX. L. REV. 1361, 1366–75 (2020).

⁸⁰ See Joshua Schneyer, *California Settles Decades-Long Lawsuit Over Lead Paint, but Outcome Is Bittersweet*, REUTERS (July 17, 2019, 3:27 PM), <https://www.reuters.com/article/us-usa-lead-california/california-settles-decades-long-lawsuit-over-lead-paint-but-outcome-is-bittersweet-idUSKCN1UC2H5> [<https://perma.cc/2RX6-ZK7K>].

⁸¹ See John Culhane, *The Little Known Legal Doctrine Making Big Pharma Pay for the Opioid Crisis*, POLITICO (Aug. 28, 2019), <https://www.politico.com/magazine/story/2019/08/28/johnson-and-johnson-decision-opioids-227913> [<https://perma.cc/9MHU-44UW>].

Ultimately, the most effective reforms will entail a combination of both tort and regulatory law, consistent with the “New Torts” identified by Professor Shapo back in 1970.⁸² A temporary amnesty for manufacturers from all legal sanctions may be needed for several years while they incorporate long-term safety considerations into their products and practices. Other adjustments may be necessary as well to shift the equilibrium in favor of manufacturer responsibility for unreasonable chemical hazards. However the reforms are crafted, some relatively radical changes to existing law seem necessary in the short-term.

CONCLUSION

Professor Shapo’s work illuminates a complicated thicket of liability and regulatory rules that create perverse incentives for human experimentation in the manufacture of chemical-based products. Only by mapping out these overlapping legal programs and tracing how they affect the incentives of manufacturers can we see how current laws perversely tolerate and even encourage human experimentation in areas of chemical-based products. While there is still a long way to go in collapsing this sanctuary for human experimentation, Professor Shapo has forged a path through the legal forest. All we need to do is follow it to the end.

⁸² SHAPO, A NATION OF GUINEA PIGS, *supra* note 2, at 338.