

Exhibit 97

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Voluntary Recalls

Anita Bernstein[†]

INTRODUCTION

Everybody wins in the voluntary recall of a defective product,¹ one might suppose. The item summoned back has harmed relatively few consumers at this early stage. If the measure proceeds according to plan, nobody else will be hurt. A recall confronts a danger to the public with can-do authority. The solution it renders is upbeat, at least in contrast to the alternative that is on the players' (especially the repeat players') minds: it avoids the disappointment and frustration that its chief rival on the defective-products front, liability, doles out to both sides of the "v" in court captions.²

Recalling defective products gives affected persons and entities much of what they want at a relatively low cost.³ The

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¹ By "voluntary recalls," this Article refers only to recalls of products that manufacturers undertake to reduce the risk of physical injury among the population of individual consumers. Manufacturers recall consumer products for other reasons, including flaws that cause the item to perform inadequately or shut down but do not increase risks of bodily harms. Another caveat about scope: the Article discusses only product recalls commenced with reference to statutory law and that manifest attention to legal compliance. An example of what I mean to exclude: A painter of landscapes writes to six collectors of his work volunteering to take back his paintings and refund what these collectors paid because he worries—eccentrically, based on nothing factual—that the paint he used emits toxic fumes. We are left with enough to consider. For more on scope, see Part I.A.

² See Anita Bernstein, *The Communities That Make Standards of Care Possible*, 77 *Chi Kent L. Rev.* 735, 738–39 (2002) (noting how a lawsuit can make both sides feel that they lost).

³ Research by economist Nicholas Rupp shows the difficulty of knowing the full cost of a recall. Rupp constructed an index of automobile company stock prices and found that certain categories of recalls in this sector were associated with a loss of equity not

players have their disagreements and divergences, of course, but they unite around one premise: Better to prevent injury than to let it happen and try to fix it later.

For consumers, product recalls offer a mix of rescue and choice. The measure protects their bodies from what has been deemed an unreasonable risk of harm. Manufacturers must spend money on this measure, but even an expensive recall is understood as cheaper than liability.⁴ In the aggregate, recalls are also cheaper for manufacturers than compliance with safety standards.⁵

As for the agency with authority over the measure,⁶ a recall offers opportunity to both sides of its binary, the public and the industry it regulates: One half of “voluntary recall” is “recall,” a response that consumers endangered by defective products perceive as benevolence, and the other half is “voluntary,” an adjective expressing respect for what the product manufacturer desires. The adjective also reminds manufacturers that the

otherwise explained by industry conditions. It becomes fair to infer that recalls can have an effect on the stock price of a publicly traded corporation. See Nicholas G. Rupp, *The Attributes of a Costly Recall: Evidence from the Automotive Industry*, 25 Rev Indus Org 21 (2004).

⁴ Cheaper than liability does not, of course, mean cheap. See *id.* See also Andrew S. Krulwich, ed, *Recalls: Legal and Corporate Responses to FDA, CPSC, NHTSA, and Product Liability Considerations*, 39 Bus Law 757 (1984) (providing an edited transcript of an ABA meeting on the interactions between regulations and product recalls).

⁵ Teresa M. Schwartz and Robert S. Adler, *Product Recalls: A Remedy in Need of Repair*, 34 Case W Res L Rev 401, 463 (1984) (noting that in comparison to standards, recalls apply only to unsafe products and may impose less burdensome demands of recordkeeping).

⁶ Agencies with authority over product recalls include: the Consumer Product Safety Commission (CPSC), the National Highway Traffic Safety Administration (NHTSA), the Food Safety and Inspection Service of the Department of Agriculture (FSIS), the Food and Drug Administration (FDA), the US Coast Guard, the Department of Housing and Urban Development (HUD), and the Environmental Protection Agency (EPA). See 15 USC § 2064(d) (authorizing mandatory recalls by the CPSC of most types of consumer products); 49 USC § 30118 (authorizing, in the first grant of such authority, the NHTSA to order recalls of automobiles and replacement of equipment—like car seats—related to motor vehicle safety); United States Department of Agriculture, Food Safety and Inspection Service, *Recall of Meat and Poultry Products*, FSIS Directive 8080.1 Rev 6 *1–2 (Oct 26, 2010), online at <http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8080.1.pdf> (visited Sept 15, 2013) (noting that, under FSIS authority, which covers meat, poultry, and eggs, “it is a firm’s decision to recall [a] product” and that recalls of these foods are not mandatory, though FSIS may reserve or detain adulterated products); 21 USC § 350i (granting mandatory recall authority to the FDA only for food, not drugs); 46 USC § 4310(f) (providing recall authority to the Coast Guard for boats); 24 CFR § 3282.406, promulgated under 42 USC § 5401 (providing recall authority to HUD for manufactured homes); 7 USC § 136a(c)(8) and 42 USC § 7541 (providing recall authority to the EPA for pesticides and automobiles when the danger relates to emissions). See also Part I.A.

government has practiced restraint. It could coerce them, and it has chosen not to.

The American public appears to like product recalls too.⁷ Product recalls as a species of regulation align with “communal voluntarism,” a blend of individualism and conformity manifest in the national culture of the United States.⁸ Recalls deliver safety through a rubric that adds options to what authorities declare. Members of the public can decide what they want. They hear the announcement and the reason for the recall, goes the plan. Check out the product in possession; consider whether to turn it in or keep it; live with the result. Similar to the recalled product itself, a recall competes for the fickle attention of consumers. It is an offer more than a prohibition. It gives.

Keep looking, however, and the serene surface of a voluntary recall starts to appear roiled. The most striking difficulty comes from the adjective.⁹ Voluntary recalls are not really voluntary, I argue, because neither manufacturers nor consumers have enough choice to make their acquiescence in the recall meaningful.¹⁰ The antonym or complement of voluntary recalls—mandatory recalls—doesn’t quite exist either, because the state almost never officially or formally forces manufacturers to take back the dangerous products they have sold.

“Recall” itself is almost as slippery a term as the adjectives that modify it. Although numerous federal agencies can compel

⁷ Consider Karlyn Bowman, *The Public View of Regulation, Revisited* (American Enterprise Institute Jan 2011), online at <http://www.aei.org/files/2011/01/19/2011-REG-01-g.pdf> (visited Sept 15, 2013) (reporting decades of opinion research suggesting wariness toward regulation mixed with approval of rules to enhance health and safety).

⁸ See Claude S. Fischer, *Made in America: A Social History of American Culture and Character* 99 (Chicago 2010).

⁹ The difficulty remains even when one sidesteps the philosophical question of whether human beings ever act voluntarily, making choices as expressions of their will. The literature says they do not and cannot. For examples of this argument, see generally Alex Rosenberg, *The Atheist’s Guide to Reality: Enjoying Life without Illusions* (WW Norton 2011) (advancing this position); Michael Norwitz, *Free Will and Determinism* (Philosophy Now Mar–Apr 2013), online at http://philosophynow.org/issues/1/Free_Will_and_Determinism (visited Sept 15, 2013) (presenting the issue as a debate).

¹⁰ For a sample of Orwellian diction used here, see United States Department of Agriculture Food Safety and Inspection Service, *Fact Sheet: Food Recalls* (Oct 14, 2011), online at <http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/production-and-inspection/food-recalls/food-recalls> (visited Sept 15, 2013) (“All recalls are voluntary. However, if a company refuses to recall its products, then FSIS has the legal authority to detain and seize those products in commerce.”).

or facilitate a product recall, no consistent usage unites this word as it appears in the United States Code and the Code of Federal Regulations. One leading treatise on products liability offers a definition—a recall is “a notification to consumers of a product hazard and procedures for accomplishing its repair”¹¹—only to identify a problem with that definition immediately.¹² Other proffered definitions founder on over-breadth or under-breadth. For example, the contention that this word means “a very specific device by which a manufacturer, seller . . . or other entity in the chain of distribution . . . advises purchasers, users or anyone else in the possession or control of a product as well as the public at large” of “certain activities [that] should be undertaken with respect to such product”¹³ includes too much because it equates recalls with warnings. Another writer defines a product recall as the offer of a refund, a repair, or a replacement to consumer-owners at no cost:¹⁴ this definition is probably too narrow.¹⁵

From the premise that it is hard—perhaps impossible—to participate voluntarily in a legally regulated activity without knowing quite what that activity is or can include, I argue that the voluntary recall concept demands more clarity and more choices for product manufacturers and consumers than either cohort now enjoys. A shift toward clarity would bring product recalls in line with other ostensibly voluntary paths provided in American law. Transparency is at least as important to these paths as the presence of more than one option. Actions labeled voluntary that impose legal consequences in the United States—such as plea bargains, purchases of goods and services, waivers of rights, and enlistment into the armed forces—may deliver

¹¹ David G. Owen, *Products Liability Law* 760 (West 2d ed 2008).

¹² The difficulty with the definition is the possibility of a “silent recall,” where a manufacturer communicates only with dealers and not consumers. *Id.* at 760 n 33 (“‘Silent recalls’ are somewhat different, but even this peculiar form of secret retrofit by dealers involves a form of recall via dealers.”).

¹³ Louis R. Frumer, Melvin I. Friedman, and Cary S. Sklaren, *Products Liability* § 57.01 (Matthew Bender 2012).

¹⁴ David L. Ramp, *The Impact of Recall Campaigns on Products Liability*, 44 *Ins Counsel J* 83, 86 (1977).

¹⁵ See below notes 110, 126, 132, and 135 and accompanying text (providing alternative definitions of “recall” that include other actions).

unpleasant surprises to volunteers, but the transactions themselves are explained to participants.¹⁶

My thesis is developed below in three parts. Part I gives a primer of recalls in United States law. I start with a review of federal agencies' authority to encourage and order recalls and then consider consequences that a recall decision has for liability to consumers who file actions under state law. The next two Parts explore the non-voluntary nature of this legal landscape. Part II focuses on manufacturers and Part III on consumers. Suggestions of how to make product recalls more voluntary (and effective) occupy Part IV, whose premise is that the "everybody wins" notion behind voluntary recalls contains enough merit to be worth keeping as policy. That regulators should consider incentives, options, flexible responses, and other alternatives to command-and-control diktat is a truism. Expanding voluntariness would expand the virtues of what product recalls now offer.

I. THE LAW OF RECALLS: A PRIMER

A. Products and Agencies

1. Consumer products.

Of all the items for whose recall federal law contains provisions, the most varied and elaborate regulatory authority relates to consumer products. Several statutes authorize the Consumer Product Safety Commission (CPSC) to impose recalls of products. The Consumer Product Safety Act of 1972, which established the CPSC, provided for extraordinarily broad recall powers.¹⁷

2. Food.

Federal authority to recall food products is divided between two agencies, depending on the kind of foodstuff in question. The Food Safety and Inspection Service (FSIS), a division of the Department of Agriculture, oversees recalls of meat, eggs, and

¹⁶ See generally Kent Greenfield, *Free Will Paradigms*, 7 Duke J Const L & Pub Pol 1 (Special Issue 2011) (exploring voluntariness in the law).

¹⁷ Consumer Product Safety Act (CPSA), Pub L No 92-573, 86 Stat 1207 (1972), codified at 15 USC § 2051 et seq. See also Schwartz and Adler, 34 Case W Res L Rev at 428-29 (cited in note 5).

poultry.¹⁸ Recalls of other food products are governed by the Food and Drug Administration (FDA).¹⁹

3. Prescription and nonprescription drugs, cosmetics, and veterinary products.

Recalls of prescription and nonprescription drugs, cosmetics, and veterinary products fall under the aegis of the FDA. Although the FDA has worked actively in drug recalls for many decades, its power to compel them is oddly sparse. Congress has never granted this agency plenary authority to mandate recalls over drugs, cosmetics, and veterinary products, even though it has mandatory recall power over food products.²⁰ The FDA can compel recalls of medical devices, however.

4. Automobiles and on-road vehicles.

The National Traffic and Motor Vehicle Safety Act of 1966 (“the Safety Act”) was the first US statute to grant an agency the power to order something resembling a recall.²¹ Originally, the Safety Act compelled manufacturers only to write to purchaser-owners with a description of the defect and reparative measures,²² but amendments in 1974 enlarged the set of protected owners and compelled manufacturers to repair the defect without charge.²³

¹⁸ For grants of this authority, see United States Department of Agriculture, Food Safety and Inspection Service, *Recall of Meat and Poultry Products*, FSIS Directive 8080.1 Rev 6 *1–2 (Oct 26, 2010), online at <http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8080.1.pdf> (visited Sept 15, 2013).

¹⁹ 21 USC § 350*l* (granting mandatory recall authority to the FDA only for food, not drugs).

²⁰ See 21 USC § 350*l*.

²¹ National Traffic and Motor Vehicle Safety Act, Pub L No 89-563, 80 Stat 718 (1966), codified at 49 USC § 301 et seq. See also Schwartz and Adler, 34 Case W Res L Rev at 403 (cited in note 5) (noting that another agency, the Food and Drug Administration, had ordered recalls before 1966, but it lacked statutory authority to do so).

²² National Traffic and Motor Vehicle Safety Act, § 113, 80 Stat 725–726.

²³ National Highway Traffic Safety Administration, Confidential Business Information, 71 Fed Reg 210 (2006) (noting that Congress repealed and removed the statute from Title 15 to Title 49 of the United States Code). See also Schwartz and Adler, 34 Case W Res L Rev at 404–05 (cited in note 5).

5. Miscellaneous recall authority.

Federal law assigns to other agencies the authority over recalls of a few other products. The Department of Housing and Urban Development (HUD) is empowered to determine that mobile homes contain safety hazards or serious defects and order remediation.²⁴ The United States Coast Guard can order and guide recalls of marine vehicles and items used around boats, such as life jackets.²⁵ Airplane recalls fall under the aegis of the Federal Aviation Administration (FAA).²⁶ The Environmental Protection Agency (EPA) has authority over recalls of pesticides, rodenticides, and fungicides.²⁷

As previously noted, the EPA can also order the recall of motor vehicles, but only with respect to emission-related components or systems.²⁸ The agency uses the term “voluntary service campaigns” to describe announcements by manufacturers inviting owners to bring in their cars for attention should a problem become apparent.²⁹ Auto manufacturers might not use the word “recall” to announce what they are recommending, but a voluntary service campaign is considered a recall if it involves an emission-related part and must be reported to the EPA as a recall.³⁰

Section 5 of the Federal Trade Commission Act, which provides that “[u]nfair methods of competition in or affecting

²⁴ 24 CFR § 3282.407.

²⁵ See 46 USC § 4310(f).

²⁶ 14 CFR § 39.11 (“Airworthiness directives specify inspections you must carry out, conditions and limitations you must comply with, and any actions you must take to resolve an unsafe condition.”).

²⁷ 7 USC § 136q.

²⁸ See 7 USC § 136a(c)(8) (providing recall authority to the EPA for pesticides and automobiles when the danger relates to emissions); 42 USC § 7541 (same). See, for example, United States Environmental Protection Agency, *2009 Annual Summary of Emission-Related Recall and Voluntary Service Campaigns Performed on Light-Duty Vehicles and Light-Duty Trucks* *1 (EPA.gov Jun 2010) online at <http://epa.gov/otaq/cert/recall/420b10007b.pdf> (visited Sept 15, 2013).

²⁹ See United States Environmental Protection Agency, *2009 Annual Summary of Emission-Related Recall and Voluntary Service Campaigns Performed on Light-Duty Vehicles and Light-Duty Trucks* at *1 (EPA.gov Jun 2010) online at <http://epa.gov/otaq/cert/recall/420b10007b.pdf> (visited Sept 15, 2013). (“[T]hese are still considered recalls, but are listed separately because the manufacturer is telling the owner to bring the car in for repair only if the problem is apparent.”).

³⁰ Id (“Manufacturers voluntarily recall vehicles for various reasons, such as safety or customer satisfaction, but if they affect emission-related parts, they still must be reported to EPA.”).

commerce, and unfair or deceptive acts or practices in or affecting commerce, are [] declared unlawful,”³¹ has generated a kind of *sub rosa* recall power for the Federal Trade Commission (FTC). This statutory authority has spurred the FTC to order the recall-like category of “repairs, replacements, and refunds” when it determines that sellers have marketed a product with an implicit representation that the product did not contain a defect that it actually contained.³² Exactly which powers Congress granted the agency under § 5 is unclear,³³ but the FTC has played an especially active role with respect to representations made by automobile manufacturers.³⁴

B. Consequences of Recalls in the Courts

Products liability law (rooted in state-level common law) and product safety regulations (written by legislatures and agencies) work concurrently in the United States. Occasionally they collide. Although product recalls fall into the category of regulation, they also generate consequences in the courts.

1. The limited common law duty to recall.

Returning to the Second Restatement’s famed treatment of products liability, which had contained no black-letter law about recalls,³⁵ the Reporters of the current Restatement (Third) of Torts: Products Liability decided to add coverage of the topic notwithstanding what they called a paucity of case law.³⁶ According to § 11 of the Third Restatement, sellers cannot be liable in tort for failure to recall a product unless one of two

³¹ 15 USC § 45.

³² Krulwich, ed, 39 Bus Law at 773–74 (cited in note 4) (transcribing remarks on the subject of the FTC by Nancy L. Buc, former Chief Counsel of the Food and Drug Administration).

³³ See *Heater v FTC*, 503 F2d 321, 327 (9th Cir 1974) (concluding that the FTC lacks the power to order refunds).

³⁴ Krulwich, ed, 39 Bus Law at 773–74 (cited in note 4).

³⁵ See generally Restatement (Second) of Torts § 402A (1965). One might find recalls hinted at when the Second Restatement observes that “some chattels [] are so unsafe for the uses to which they are likely to be put” that warnings will not suffice to constitute reasonable care. Consider Restatement (Second) of Torts § 389 cmt f (1965).

³⁶ See Restatement (Third) Torts: Products Liability § 11 cmt d (1998) (“There is a paucity of authority discussing the legal effect of the efforts of a manufacturer to recall its products when such efforts are not successful in avoiding injury due to the fact that either dealers or purchasers do not take advantage of the recall.”).

conditions is present: either a governmental directive ordered the seller to recall the product in question—so that the failure to recall defied an authoritative order—or the seller undertook to recall a product and did so negligently.³⁷

The first possibility, a government-ordered recall, almost never happens, as will be elaborated below.³⁸ One law review article published in 2003 noted that “[v]irtually all modern product recalls in the United States would not qualify for section 11, and the advocates who persuaded the American Law Institute (ALI) to adopt section 11(a)(1) were probably quite aware” that the blackletter addressed the nearest thing to a null set.³⁹ Five years later, Congress enacted legislation that strengthened the powers of the CPSC to compel recalls,⁴⁰ but since its formation in 1972, the agency has attempted mandatory recalls only a handful of times, all attempts ending in a negotiated or otherwise extrajudicial outcome.⁴¹ Another agency with authority to compel product recalls, the National Highway Traffic Safety Administration (NHTSA), told the General Accounting Office that of its thousands of recalls, only seven have been mandatory.⁴² In sum, the Restatement, by insisting that in order to create tort duties of care a recall must be “a governmental directive issued pursuant to a statute or administrative regulation” that “specifically requires the seller or distributor to recall the product,”⁴³ makes a criterion out of something that could in principle exist but on the ground does not.

The next subsection in § 11 says little—only that manufacturers will seldom be liable for failure to recall—but it seems to have provoked and sowed confusion.⁴⁴ Treatise writer David G. Owen faults the § 11 rule for imposing liability for

³⁷ Restatement (Third) Torts: Products Liability § 11 (1998).

³⁸ See Parts II.B and II.C.

³⁹ James T. O'Reilly, *Product Recalls & the Third Restatement: Consumers Lose Twice from Defects in Products and in the Restatement Itself*, 33 U Memphis L Rev 883, 891 (2003).

⁴⁰ Schwartz and Adler, 34 Case W Res L Rev at 428–29 (cited in note 5).

⁴¹ See note 173.

⁴² United States Government Accountability Office, *Auto Safety: NHTSA Has Options to Improve the Safety Defect Recall Process* *8 (June 2011), online at <http://www.gao.gov/assets/320/319698.pdf> (visited Sept 15, 2013).

⁴³ Restatement (Third) Torts: Products Liability § 11(a)(1).

⁴⁴ See *id.*

negligent performance of a recall voluntarily undertaken. Owen argues that § 11(a)(2) “unwisely” declines to require that a plaintiff “establish detrimental reliance on the negligent undertaking or show it otherwise increased the plaintiff’s risk of harm.”⁴⁵ But that requirement does exist. The Restatement covers causation in a separate section.⁴⁶ A judge can enter summary judgment for a defendant manufacturer when a plaintiff says nothing about reliance on the negligently performed recall. To another author, Douglas Richmond, the assumed duty rule of § 11(a)(2) “is unfair and makes for bad policy”⁴⁷ because it discourages manufacturers from choosing recalls. However, one page later, eschewing a recall becomes good policy: “A common law duty to recall should simply not be recognized. Recalls are burdensome and expensive, and they are not certain to prevent the harm to which they are linked.”⁴⁸

These critical readings of the Restatement rule become clearer when they are understood as exploring the voluntariness question that this Article has broached. Owen worries that the “absolute denial” of a common law duty pressures manufacturers to eschew recalls even though “special circumstances might exist”⁴⁹ to make a recall the best response to a particular hazard. Richmond also finds pressure in § 11(a)(2), but worries that a voluntary undertaking becomes a source of new liability exposure.⁵⁰ Both writers, in their very different criticisms, find voluntariness diminished by the black letter of § 11.

2. Vanishingly unlikely liability for failure to recall or negligent performance of a recall.

The Third Restatement declared that a manufacturer never has a tort duty to recall its defective product unless regulators have compelled the manufacturer to do so. Regulators that have the power to compel a recall do not use it. Accordingly, tort

⁴⁵ Owen, *Products Liability Law* at 762 (cited in note 11).

⁴⁶ Restatement (Third) Torts: Products Liability § 15 (1998) (placing the causation rule in Chapter 4: Provisions of General Applicability).

⁴⁷ Douglas R. Richmond, *Expanding Products Liability: Manufacturers’ Post-Sale Duties to Warn, Retrofit and Recall*, 36 Idaho L Rev 7, 80 (1999).

⁴⁸ Id at 81.

⁴⁹ Owen, *Products Liability Law* at 762 (cited in note 11).

⁵⁰ Richmond, 36 Idaho L Rev at 81 (cited in note 47).

liability for failure to recall will arise only if a jurisdiction declines to follow the Restatement or if the manufacturer undertakes a recall voluntarily and is negligent in carrying it out.

Neither possibility is robust. Judges might in the future regard manufacturers as responsible for failing to recall, but to date, their expressions of willingness have been confined almost entirely to dicta.⁵¹ Manufacturers are virtually never held liable for that breach of duty. Similarly—and unsurprisingly—case law presents very few illustrations of the maladroit recall, where a manufacturer undertakes this post-sale rectification but performs it negligently. Although numerous courts have faulted manufacturers for post-sale misbehaviors, a negligently performed recall has only rarely been among them.⁵² From the record of published decisional law, it appears that consumers almost never even attempt to complain about a bad recall as a stand-alone basis for tort liability.

3. Voluntary recalls as impediments to individuals' claims after they are filed.

Recalling one's product can impede one's adversary in pending litigation. Courts that ruled in favor of defendants have relied on voluntary recalls that were initiated after plaintiffs filed claims. Two recent decisions illustrate the possibility. In *Winzler v Toyota Motor Sales USA, Inc*,⁵³ the plaintiff, an owner of a 2006 Corolla that she had reason to think had a propensity to stall without warning, sought equitable relief grounded in Utah tort law.⁵⁴ Arrienne Mae Winzler asked for an order "requiring Toyota to notify all relevant owners of the defect and then to create and coordinate an equitable fund to pay for

⁵¹ See *Braniff Airways, Inc v Curtiss-Wright Corp*, 411 F2d 451 (2d Cir 1969); *Downing v Overhead Door Corp*, 707 P2d 1027, 1033 (Colo App 1985). But see, for one outlier, *In re Mentor Corp ObTape Transobturator Sling Products Liability Litigation*, 2010 WL 4386902, *6 (MD Ga 2010) (concluding that California law recognizes liability for failure to recall and denying summary judgment to the defendant).

⁵² Rare successes for plaintiffs include *Lowe v General Motors Corp*, 624 F2d 1373, 1380 (5th Cir 1980) (applying negligence per se to fault GM for sending an untimely and inadequate recall letter); *John Deere Co v May*, 773 SW2d 369, 376 (Tex App 1989) (upholding a determination of negligence on the part of a manufacturer that had reason to believe a consumer had not received a recall letter, yet did not follow up).

⁵³ 681 F3d 1208 (10th Cir 2012).

⁵⁴ *Id* at 1208.

repairs.”⁵⁵ After the district court dismissed her complaint, holding that it failed to state a claim, Winzler appealed and Toyota announced a recall of the model in question, undertaken under the auspices of the NHTSA.⁵⁶

The Tenth Circuit held that this recall rendered Winzler’s complaint moot and dismissed it.⁵⁷ Winzler acknowledged that what she sought from the courts appeared duplicative of a recall, but argued that the actions undertaken by Toyota had not yet effected the relief she wanted.⁵⁸ Rejecting these arguments, the court took judicial notice of the recall filings. It concluded that “with the *act* of notifying NHTSA of a defect and announcing a recall, Toyota set into motion the statutorily mandated and administratively overseen national recall process.”⁵⁹ Winzler next argued, equally unavailing, that the “voluntary” nature of the recall gave Toyota too much control.⁶⁰ In response, the court said that whether voluntary or involuntary, the result of a recall is the same.⁶¹ For her final argument, Winzler noted that a NHTSA recall did not provide safeguards or penalties as strong as those available by judicial decree.⁶² On that point the court evoked comity, ceding to what the executive branch has had at hand to achieve equitable relief.⁶³ The court said it would defer to a coordinate branch of government.⁶⁴

Thus, for the Tenth Circuit, a voluntary recall can render an action moot. For other courts, it precludes class certification. The Seventh Circuit in *In the Matter of Aqua Dots Products*

⁵⁵ Id at 1209 (discussing the lower court’s opinion).

⁵⁶ Id at 1211.

⁵⁷ *Winzler*, 681 F3d at 1215.

⁵⁸ See id at 1213–14.

⁵⁹ Id at 1212 (emphasis in original).

⁶⁰ Id at 1213.

⁶¹ *Winzler*, 681 F3d at 1213.

⁶² Id at 1214 (“[S]he says, a judicial decree would give her a firmer whip hand to ensure Toyota fulfills its recall duties.”).

⁶³ Id at 1210–14.

⁶⁴ Id. Other courts, asserting their choice to defer to NHTSA, have also refused to certify classes following automobile recalls. *Chin v Chrysler Corp*, 182 FRD 448, 464 (D NJ 1998); *Ford Motor Co v Magill*, 698 S2d 1244, 1245 (Fla App 1997). See also *American Suzuki Motor Corp v Superior Court*, 37 Cal App 4th 1291, 1299–1300 (1995) (overruling the trial court’s decision to certify a class of plaintiffs who had objected to the alleged rollover propensity of the Suzuki Samurai and suggesting that these owners “petition the National Highway Traffic Safety Administration (NHTSA),” which had not ordered a recall, “for a defect investigation”).

*Liability Litigation*⁶⁵ refused to certify a class of plaintiffs who had bought a toy deemed defective and were dissatisfied with all the fixes that the manufacturer offered—including, for many, a cash refund.⁶⁶ These plaintiffs (who had suffered no injury attributable to the defect) wanted a refund plus punitive damages.⁶⁷ The trial court refused to certify the class on the ground that the recall available was superior to a class action: the recall gave these customers refunds while sparing them the cost of attorneys' fees.⁶⁸ Judge Frank Easterbrook, writing for the appellate panel, approved of the trial court's decision but not its reasoning.

The superiority criterion for class certification, Judge Easterbrook wrote, authorizes judges to compare only one form of adjudication to another—a single suit versus multiple suits—and because a recall is not adjudication, it cannot be compared to class certification.⁶⁹ To support his insistence on judicial alternatives only, Judge Easterbrook relied on dicta from a 1973 Third Circuit decision.⁷⁰ One commentator, disagreeing with this interpretation, has argued that the language of Rule 23(b)(3), demanding that class certification be “superior to [all] other available methods for fairly and efficiently adjudicating the controversy,” states clearly enough that “other available methods” are not limited to adjudication.⁷¹ Nine federal district courts have compared refund programs to class actions and refused to certify classes on the ground that the superiority

⁶⁵ 654 F3d 748 (7th Cir 2011).

⁶⁶ The manufacturer preferred to remedy the defect by giving the customer a replacement toy with the defect cured or a comparably priced alternative toy but gave refunds to customers who insisted. *Id.* at 750.

⁶⁷ *Id.*

⁶⁸ *Id.* at 751, discussing *In re Aqua Dots Products Liability Litigation*, 270 FRD 377, 384 (ND Ill 2010) (“[N]othing that the class could hope to receive in court under the guise of compensatory damages or restitution would be superior to that remedy—or even comparable, since counsel would, at all events, have to be paid out of the damages award.”). See also generally FRCP 23(b)(3). The superiority criterion does not govern every type of class action, just 23(b)(3) actions.

⁶⁹ *In re Aqua Dots*, 654 F3d at 751.

⁷⁰ See *id.* at 752, citing *Amalgamated Workers Union of Virgin Islands v Hess Oil Virgin Islands Corp*, 478 F2d 540 (3d Cir 1973). See also Eric P. Voigt, *A Company's Voluntary Refund Program for Consumers Can Be a Fair and Efficient Alternative to a Class Action*, 31 Rev Litig 617, 629–30 (2012) (citation omitted).

⁷¹ Voigt, 31 Rev Litig at 625–28 (cited in note 70) (reviewing Advisory Committee notes, a statement by Rules author Charles Alan Wright, and the omission of any textual requirement that the alternative be a judicial proceeding).

criterion was not met.⁷² Not every recall offers a refund,⁷³ but those that do are well positioned to fend off class certification.

Even if a court refuses to deem a recall superior to a class action under Rule 23(b)(3), it has other authority at hand to support its refusal to certify a class, as presented by Judge Easterbrook. *In re Aqua Dots* found recall-related support elsewhere in Rule 23. “A representative who proposes that high transaction costs (notice and attorneys’ fees) be incurred at the class members’ expense to obtain a refund that already is on offer,” the court declared, “is not adequately protecting the class members’ interests.”⁷⁴ The recall becomes fatal to certification on the ground that plaintiffs who have eschewed a good remedy in favor of a quixotic and expensive quest do not “fairly and adequately protect the interests” of putative class members.⁷⁵

Class certification efforts after a recall fare no better when plaintiffs, unlike those in *Winzler* and *In re Aqua Dots*, allege physical injury from the recalled product. Illustrative here is *Pagan v Abbott Laboratories, Inc.*⁷⁶ In 2010, Abbott recalled five million containers of its infant formula, Similac, after discovering contamination by beetles and beetle larvae.⁷⁷ Dissatisfied with this response, plaintiffs sought declaratory and injunctive relief under state deceptive-practices law and also alleged that their children had been made ill by contaminated Similac.⁷⁸ Post-recall testing showed that 1 in about 625 returned containers of Similac contained beetle fragments.⁷⁹ This low rate of contamination undermined the class certification effort on both numerosity and commonality: not many children could have been harmed, the court concluded, and individual plaintiffs made ill by Similac had to be atypical among customers.⁸⁰ Similar to the Tenth Circuit decision in

⁷² Id at 630–31. See, for example, *Webb v Carter’s Inc*, 272 FRD 489, 505 (CD Cal 2011); *In re Conagra Peanut Butter Products Liability Litigation*, 251 FRD 689, 701 (ND Ga 2008); *In re Phenylpropanolamine Products Liability Litigation*, 214 FRD 614, 623 (WD Wash 2003).

⁷³ See note 66 and accompanying text.

⁷⁴ *In re Aqua Dots*, 654 F3d at 752.

⁷⁵ Id, citing FRCP Rule 23(a)(4).

⁷⁶ 287 FRD 139 (EDNY 2012).

⁷⁷ Id at 142.

⁷⁸ Id.

⁷⁹ Id at 148.

⁸⁰ *Pagan*, 287 FRD at 148.

Winzler, courts have also concluded that the Similac recall mooted individual plaintiffs' claims for damages brought under deceptive trade practices statutes.⁸¹

Another action alleging injury from contaminated-and-recalled Similac also failed to win class certification. The court in *Brandner v Abbott Laboratories, Inc.*,⁸² applying Louisiana law, was willing to consider the plaintiff's claim for "redhibition"—a Louisiana doctrine amounting more or less to a lemon law⁸³—but not class certification of that claim, again because most units of Similac sold did not contain fragments of beetles.⁸⁴ The same fate met the plaintiff's efforts to certify a class under the Louisiana Products Liability Act.⁸⁵

4. Failure to respond reasonably to a recall as harmful or fatal to a personal injury claim.

From a manufacturer's perspective, voluntarily recalling a product can yield desirable consequences for yet-unfiled personal injury claims. Courts have interpreted recalls as providing pertinent safety information about products to consumers and the public. Product recalls function as a kind of warning, and case law has long endorsed William Prosser's famous declaration that sellers who warn of a danger "may reasonably assume" that their warning "will be read and heeded,"⁸⁶ even though consumers notoriously do not, in fact, heed warnings.⁸⁷ Gains to manufacturers can emerge at different points of the actions they defend.

Proximate cause is such an early point. Courts have said that failure to respond reasonably to the announcement of a

⁸¹ See, for example, *Jovine v Abbott Laboratories, Inc.*, 795 F Supp 2d 1331 (SD Fla 2011); *Tosh-Surryhne v Abbott Laboratories, Inc.*, 2011 WL 4500880 (ED Cal). But see *Leonard v Abbott Laboratories, Inc.*, 2012 WL 764199 (EDNY) (refusing to deem the action moot on the ground that some of the governing state statutes provided for minimum statutory damages that a recall would not deliver to the plaintiffs).

⁸² 2012 WL 27696 (ED La).

⁸³ See Hester Glostion-Hilliard, Comment, *Used Car Purchases, Pitfalls, and Protection*, 33 S U L Rev 227, 230 (2005).

⁸⁴ *Bradner*, 2012 WL 27696 at *4–5.

⁸⁵ *Id.*

⁸⁶ Restatement (Second) of Torts § 402A (1965) cmt j.

⁸⁷ See Howard Latin, "Good" Warnings, Bad Products, and Cognitive Limitations, 41 UCLA L Rev 1193 (1994); Gregory Klass, *Meaning, Purpose, and Cause in the Law of Deception*, 100 Georgetown L J 449, 467–68 (2012).

recall can break the alignment between the product defect and the consequences that a user suffered.⁸⁸ In *Blossman Gas Co v Williams*,⁸⁹ the alignment-breaker was a dealer in water heaters that did not relay to consumers the news of a manufacturer-initiated recall.⁹⁰ In *Rekab, Inc v Frank Hrubetz & Co*,⁹¹ the court faulted the owner of an amusement park who did not install a replacement shaft for a Ferris wheel that the manufacturer sent with instructions to replace the old part, an undertaking that this manufacturer, expressing worries about “strains which were not originally considered,” volunteered to pay for.⁹² Whether a recall severs proximate cause is usually a jury question rather than a certain route to summary judgment for defendant manufacturers, who can lose as well as win.⁹³

In a related consequence, failure to cooperate with an announced recall can also fulfill the elements of a plaintiff’s-conduct defense. Overlap exists here between contributory negligence and proximate cause. The Eleventh Circuit, for example, approved summary judgment for a recalling manufacturer after it deemed the plaintiff’s failure to obtain the repairs recommended in a recall to be contributory negligence *and* assumption of the risk *and* an absence of proximate cause.⁹⁴ A trial court in this circuit received a request to charge the jury with an instruction that also united proximate cause and plaintiff negligence:

If you find that [plaintiff] received a recall notice, but failed to exercise ordinary care in responding to that

⁸⁸ See *Ford Motor Co v Wagoner*, 192 SW 2d 840 (Tenn 1946) (holding that distribution by Ford of latches to hold down automobile hoods, a kind of proto-recall, relieved Ford of responsibility for the accident that resulted; failure to install the latch was a superseding cause); *Springmeyer v Ford Motor Co*, 60 Cal App 4th 1541, 1558 (1998) (agreeing, on appeal, with defendants that a jury can determine that a recall breaks proximate cause, but declining to overturn a judgment based on a verdict for the plaintiff).

⁸⁹ 375 SE 2d 117 (Ga App 1988).

⁹⁰ *Id* at 118–20.

⁹¹ 274 A2d 107, 144 (Md 1971).

⁹² *Id*.

⁹³ See, for example, *Ontario Sewing Machine Co v Smith*, 571 SE 2d 533, 536 (Ga 2002) (observing that the terms of the recall might have been too burdensome for a customer to comply with, and so a jury ought to consider whether they were reasonable); *Springmeyer*, 60 Cal App 4th at 1559 (upholding jury’s apportionment of fault between a manufacturer and a former owner of a recalled truck).

⁹⁴ *JHOC v Volvo Trucks North America, Inc*, 303 Fed Appx 828 (11th Cir 2008).

notice, then you should also determine whether her alleged negligence in responding to Recal [sic] 24 is an intervening act sufficient to break any connection between the alleged negligence of Chrysler and injuries suffered by [plaintiff] and is thus sufficient to become the sole proximate cause of [plaintiff's] injuries.⁹⁵

5. The treatments of recalls as subsequent remedial measures under Federal Rule of Evidence 407.

Rule 407 of the Federal Rules of Evidence provides that evidence of subsequent remedial measures is not admissible to prove negligence, culpable conduct, or a defect in the warning or design of a product.⁹⁶ This provision also appears in the evidentiary rules of almost every state.⁹⁷ Official commentary explains that this exclusion “rests on a social policy of encouraging people to take, or at least not discouraging them from taking, steps in furtherance of added safety.”⁹⁸

The Rules do not expressly classify recalls as a type of subsequent remedial measure, but courts generally agree that evidence of a recall may not be admitted to establish negligence or the existence of a product defect. Decisional law has focused on two types of recalled products: motor vehicles⁹⁹ and medical products.¹⁰⁰ For both categories, courts interpret Rule 407 to block evidence of a recall. Consistent with the text of the rule,

⁹⁵ *Denton v DaimlerChrysler Corp*, 645 F Supp 2d 1215, 1223 (ND Ga 2009) (quoting the jury instruction). Although the court refused this instruction, it did instruct the jury extensively on “assumption of risk, avoidance of consequences, contributory negligence, and comparative negligence.” *Id* at 1223–24.

⁹⁶ FRE 407. In the context of products liability, this evidentiary rule is sometimes called “the repair doctrine.” Owen, *Products Liability Law* at 410–11 (cited in note 11).

⁹⁷ See Owen, *Products Liability Law* at 411 n 156 (cited in note 11) (observing that the sole exception appears to be Rhode Island).

⁹⁸ FRE 407, Advisory Committee Notes (1972).

⁹⁹ See, for example, *Olson v Ford Motor Co*, 410 F Supp 2d 869, 872–75 (D ND 2006) (refusing to admit evidence of the recall on varied grounds); *Kucik v Yamaha Motor Corp, USA*, 2010 WL 2694962 *6 (ND Ind), citing FRE 407 (refusing to admit evidence of a recall of motorcycle's intake valves); *Walton v Bridgestone/Firestone, Inc*, 2009 WL 2778441 *4–7 (D Ariz), citing FRE 407 (refusing to admit evidence of a tire recall); *Mohammad v Toyota Motor Sales, USA, Inc*, 947 A2d 598, 613–14 (Md App 2008) (citing Maryland's version of Rule 407 regarding the recall of a Toyota Tundra pickup truck).

¹⁰⁰ See, for example, *Pusey v Becton Dickinson and Co*, 794 F Supp 2d 551, 560–62 (ED Pa 2011) (refusing to allow evidence of the recall of a syringe); *Cothren v Baxter Healthcare Corp*, 798 F Supp 2d 779, 782–83 (SD Miss 2011) (refusing to allow evidence of a recall of home dialysis technology). See also *Velazquez v Abbott Laboratories*, 2012 WL 5330931 *9–11 (D PR) (excluding evidence of a recall of infant formula).

however, evidence of a recall may be admissible to show something other than negligence or a defect.¹⁰¹

6. Summary, noting a non-doctrinal contrary force: the Vioxx Effect.

Summing up what this Part has gathered: Product recalls take place under the auspices of federal administrative agencies and also have effects on claims brought under state law against manufacturers by consumers. So far, the litigation-related law of recalls appears almost entirely favorable to manufacturers. To start, courts generally find no common law (or Restatement-provided) duty to recall, which means that manufacturers can expect to face no adverse litigation-related consequences should they fail to choose this option.¹⁰²

Manufacturers who do choose this option suffer virtually zero doctrinal consequences and can gain advantages. In principle, a manufacturer can execute its recall carelessly and be liable for breach of its voluntarily undertaken duty, but courts almost never impose liability for such breach. Choosing to recall one's product can pay off in litigation. With respect to actions alleging no personal injury, such as those brought under deceptive-trade statutes, a recall can render plaintiffs' claims moot and thwart their attempts to win class certification. For actions alleging personal injury, a recall can cause claims to fail under the rubrics of proximate cause, comparative negligence, and assumption of risk. Federal and state evidentiary rules also prevent plaintiffs from introducing evidence of a recall to show negligence or product defect.¹⁰³

This mass of one-sided doctrine notwithstanding, a voluntary action that has been labeled a recall can have devastating litigation-related consequences for manufacturers. "The Vioxx effect," a phrase improvised for present purposes, remembers an especially costly episode.¹⁰⁴ Vioxx was a prescription painkiller that generated billions in revenues for its

¹⁰¹ See Krulwich, ed, 39 Bus Law at 765 (cited in note 4).

¹⁰² See Part I.B. But see *In re Mentor Corp ObTape Transobturator Sling Products Liability Litigation*, 2010 WL 4386902 at *6 (concluding that California law recognizes liability for failure to recall and denying summary judgment to defendant).

¹⁰³ See Part I.B.5.

¹⁰⁴ I thank Adam Hoeflich, moderator of the Product Recalls panel at the Symposium, for broaching constructively this fraught precedent.

manufacturer, Merck, during its five years on the market.¹⁰⁵ In September 2004, Merck withdrew Vioxx, citing safety concerns. This withdrawal sent a powerful signal to the plaintiffs' bar. Relatively few Vioxx-related personal injury claims had been filed before 2004:¹⁰⁶ this docket would have gone away fairly cheaply but for the invitation implicit in the withdrawal. Merck went on to pay \$4.85 billion to settle a Vioxx class action.¹⁰⁷

The Vioxx experience, argues economic analyst Omri Ben-Shahar, demonstrates that "liability distorts incentives of manufacturers to recall products."¹⁰⁸ It may not go that far. Unquestionably, as Professor Ben-Shahar puts the point, pulling a drug from the market might be "taken as a public 'confession' on behalf of the manufacturer that the product is harmful," and from there "it attracts the attention of victims, plaintiffs' lawyers, and juries, and operates to increase the scope of liability for harm suffered by victims who previously used the product, victims who might otherwise not sue, and even victims whose harm was possibly caused by other sources."¹⁰⁹

But was the death of Vioxx a recall? Here Professor Ben-Shahar, reasonably enough, uses the word to reference a manufacturer's decision to stop selling its product. What Merck chose was to pull a popular and arguably toxic pharmaceutical commodity that consumers had been ingesting for years. The FDA does define "recall" broadly enough to make this action fit the term,¹¹⁰ but in practice the recalls of prescription drugs under FDA auspices typically involve an irregularity present in discrete units.¹¹¹ Drugs that manufacturers recall, in other words, usually contain what products liability jargon calls a

¹⁰⁵ Warren Allen, *The Unexpected Regulator: Regulation Through Settlement After Vioxx and Bextra*, 6 Brooklyn J Corp Fin & Comm L 565, 565 (2012).

¹⁰⁶ Barnaby J. Feder, *Lawyers Organizing for Mass Suits Over Vioxx*, NY Times C1 (Nov 5, 2004).

¹⁰⁷ Heather Won Tesoriero, Sarah Rubenstein, and Janey Heller, *Vioxx Settlement for \$4.85 Billion Largely Vindicates Merck's Tactics*, Wall St J A1 (Nov 11, 2007).

¹⁰⁸ Omri Ben-Shahar, *How Liability Distorts Incentives of Manufacturers to Recall Products* (U Mich Olin Center Working Paper No 05-002, Dec 2004), online at <http://www.law.umich.edu/centersandprograms/lawandeconomics/abstracts/2005/Documents/05-002benshahar.pdf> (visited Sept 15, 2013).

¹⁰⁹ *Id.* at *3-4 (defining victims as those who used the product, those who would not have sued, and those who may have been injured by other sources).

¹¹⁰ The FDA defines recall as "removal or correction." See Part II.A.

¹¹¹ For a representative sampling of FDA drug recalls, see <http://www.fda.gov/drugs/drugsafety/DrugRecalls/default.htm> (visited Sept 15, 2013).

“manufacturing defect,” not the design and warning defects that Merck identified in Vioxx. Manufacturing defects have always been the least costly subset of defects that products liability law can remedy. They hurt few consumers. Professor Ben-Shahar’s hordes of “victims” found in the case of Vioxx would be far smaller—and much cheaper to deal with—in the context of true recalls in contrast to withdrawals. The Vioxx effect, in sum, remains hypothetical: Vioxx does not offer a historical instance of how recalling a product can generate adverse litigation-related consequences for a manufacturer.

Hypothetical though it is, the Vioxx effect usefully illustrates three themes that pervade this Article. Foremost, voluntary withdrawals, just like voluntary recalls, are rife with compulsion. Merck presumably wanted to keep selling its high-profit painkiller.¹¹² Pulling Vioxx from the market not only forfeited a lot of sales revenue but increased the odds of costly litigation ahead: any manufacturer would—and ought to—worry about spurring consumers to file claims that would never have emerged but for the publicity inherent in a withdrawal. Other manufacturers may wish to enhance public safety, but when the Vioxx effect would make a safety-enhancing action unsafe for their bottom lines, they become encouraged to act contrarily to this wish.

A second theme of the Article is the paradox, also present in the Vioxx effect. Recalls fail when news of them does not reach the public.¹¹³ The Vioxx effect finds failure in the opposite result, communication of a “confession”¹¹⁴ that reaches the public all too successfully.

A final point present in the Vioxx effect relates to the word “recall.” I just asserted that Merck did not recall Vioxx but instead withdrew it. The definitions of “recall” gathered in the Introduction are consistent with my conclusion about Vioxx¹¹⁵—they all presume that consumers hold the recalled product in tangible form and can turn it in for a replacement unit, a cash

¹¹² Anita Bernstein and Joseph Bernstein, *An Information Prescription for Drug Regulation*, 54 Buff L Rev 569, 591 n 70 (2006) (noting that announcing the withdrawal of Vioxx cost Merck \$25 billion in market capitalization).

¹¹³ See Part III.

¹¹⁴ Ben-Shahar, *How Liability Distorts Incentives of Manufacturers to Recall Products* at *3 (cited in note 108).

¹¹⁵ See Introduction.

refund, or a modification that makes the product safer—but none states authoritatively what this word means. All of them come from secondary sources that do not outrank the work of Professor Ben-Shahar. If a scholar like Ben-Shahar favors a working definition of “recall” broad enough to include the decision to stop selling a product¹¹⁶—rather than take back flawed units or supply a corrective—he may be entitled to it, even though confusion will ensue.

These three themes present in the Vioxx effect—non-voluntariness, paradox, and uncertainty about what “recall” means—highlight different facets of the same problem. Voluntariness demands clarity: one does not truly volunteer for that which one does not understand. In an effort to foster clarity, this Part described the law of product recalls with attention to both agency authority and the effects that recalls have on litigation. With this background in place, the next two Parts explore in more detail what is not so voluntary about a voluntary recall.

II. HOW VOLUNTARY RECALLS ARE NOT QUITE VOLUNTARY FOR MANUFACTURERS

In the context of product recalls, “voluntary” contains mysteries that I will explore in a moment, but first, a look at the noun. Obscurity in the word “recall” impedes voluntariness just as much as the hidden coercion present in the adjective; lack of clarity impedes the possibility that a manufacturer can recall a product voluntarily. True choice, as I repeat in this Part, cannot occur unless choosers understand what the path they pick will deliver to them and what it will forgo. Thus, the trouble with voluntary recalls is not only that they are imposed more than chosen, but that the meaning of “recall” remains so elusive.

A. Lack of Clarity on What “Recall” Means

American law deems disclosure and awareness integral to substantive rights and entitlements. The same reasoning is applied in the United States to actions available as legally-supported options: whenever a decision imposes legal

¹¹⁶ See generally Omri Ben-Shahar, *How Liability Distorts Incentives of Manufacturers to Recall Products* (cited in note 108).

consequences for deciders it is expected to have a definition, or at least some kind of pertinent meaning, that they can look up.

According to a *Popular Mechanics* story, part of “Why Product Recalls Make You Less Safe” is that “[e]ven the word ‘recall’ turns out to be defective.”¹¹⁷ “Recall” is a defective term of art mainly because it lacks a unitary definition. Statutes, administrative regulations, scholarship, and journalistic treatments of the subject disagree on what the word means.¹¹⁸

Navigating www.recalls.gov, a federal government website, brings visitors to a self-described “one stop shop” for information about recalls.¹¹⁹ The site, produced with input from what it references as six federal agencies,¹²⁰ offers seven tabs for consumers to click: “Consumer Products,” “Motor Vehicles,” “Boats,” “Food,” “Medicine,” “Cosmetics,” and “Environmental Products.”¹²¹ Recalls.gov does not name the six agencies but it identifies the CPSC, the NHTSA, the Coast Guard, the FDA, the Department of Agriculture, and the EPA as having authority over product recalls.¹²² Our search for a legal definition of the word begins with these agencies and the recall authority given to them in federal statutes. Bewilderment ensues.

Taking the products tabs in order: First up, consumer products. The Consumer Product Safety Act (CPSA) adverts to the possibility of a recall and uses the term without defining it.¹²³ Section 2064(d) of the statute, subtitled “Repair; replacement; refunds; action plan,” seems to encompass actions that a manufacturer or consumer would think of as resembling a recall, but the word “recall” does not appear in it. The CPSC does, however, use the term “recall action” in its description of

¹¹⁷ Dan Koeppl, *Why Product Recalls Make You Less Safe* (Popular Mechanics June 21, 2012), online at <http://www.popularmechanics.com/technology/gadgets/news/why-product-recalls-make-you-less-safe-8347658> (visited Sept 15, 2013).

¹¹⁸ In the panel entitled *Frontiers of Consumer Protection: Federalization of Consumer Protection* at the University of Chicago Legal Forum Symposium on November 2, 2012, Sarah Rudolph Cole noted that the Federal Arbitration Act supports arbitration without defining it. See generally Sarah Rudolph Cole, *The Federalization of Consumer Arbitration: Possible Solutions*, 2013 U Chi Legal F 271.

¹¹⁹ Recalls.gov, *Your Online Resource for Recalls*, online at <http://www.recalls.gov/index.html> (visited Sept 15, 2013).

¹²⁰ Id.

¹²¹ Id.

¹²² Id. Two other agencies named on the site, both under the “food” tab, are the Centers for Disease Control and Prevention and the Department of Health and Human Services. Id.

¹²³ See 15 USC § 2064(c)(1)(D); 15 USC § 2064(i); 15 USC § 2061(b)(1).

the Fast-Track system it pioneered in 1997.¹²⁴ As for regulations codified under the CPSA, rather than saying what “recall” means, they provide definitions for “[m]andatory recall notice” and “[v]oluntary recall notice,” positioning “recall” as an adjective modifying “notice” rather than a noun.¹²⁵ The CPSC has also published an informal definition of recall that is hard to parse.¹²⁶

The next tab on recalls.gov, “Motor Vehicles,” leads to an even more thorough omission of the word “recall”—a curious gap, as the NHTSA was the first federal agency to win mandatory recall authority from Congress.¹²⁷ The statute adverts instead to repair, replacement, and reimbursement of a purchase price.¹²⁸ On to the “Boats” tab: the Coast Guard also avoids the term “recall,” providing authority to the agency for “[r]epair and replacement of defects” in boats.¹²⁹

The “Food” tab allots authority primarily to the Food Safety and Inspection Service (FSIS) of the Department of Agriculture and the Food and Drug Administration.¹³⁰ Here we find the most formal-sounding agency-authored definition of the word “recall.”¹³¹ The FSIS says a recall is “a firm’s action to remove product from commerce (e.g. by manufacturers, distributors, or importers) to protect the public from consuming adulterated or misbranded products.”¹³² This definition cannot apply to recalls noted under the earlier tabs. Consumer products, automobiles,

¹²⁴ United States Consumer Products Safety Commission, *Conditions Under Which the Staff Will Refrain From Making Preliminary Hazard Determinations*, 62 Fed Reg 39827–28 (1997). See also Part IV.B.4.

¹²⁵ 16 CFR § 1102.6(5); 16 CFR § 1102.6(10).

¹²⁶ “What’s a Recall? A recall is a generic term for removing a product from the marketplace, as well as a repair, replacement, or refund of a product.” CPSC, *Fast-Track Recalls*, 3 Consumer Prod Safety Rev 1, 2 (Fall 1998).

¹²⁷ Schwartz and Adler, 34 Case W L Rev at 403–05 (cited in note 5) (describing 1974 amendments to the National Traffic and Motor Vehicle Safety Act of 1966).

¹²⁸ See 49 USC § 30120; 49 CFR § 573.6(c)(8).

¹²⁹ See 46 USC § 4310(d).

¹³⁰ See Introduction (noting FSIS authority over meat, poultry, and eggs and FDA authority over other food, pet food, and animal feed).

¹³¹ Another paradox: whereas the first federal agency to obtain recall authority does not use the word recall and does not define this term, the FSIS has no authority to mandate recalls. See note 127 and accompanying text. See United States Department of Agriculture, Food Safety and Inspection Service, *Recall of Meat and Poultry Products*, at 1 (cited in note 6).

¹³² United States Department of Agriculture, Food Safety and Inspection Service, *Recall of Meat and Poultry Products* (cited in note 6).

and boats when recalled are not “adulterated or misbranded.” Something else is wrong with them.

The next recalls.gov tab, “food,” takes us to a more useful definition. Congress granted mandatory-recall authority to the FDA in 2011 only for food,¹³³ not drugs (although the agency has long been empowered to order the recall of medical devices¹³⁴). “Recall” to the FDA means “a firm’s removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure.”¹³⁵

The last tab, “Environmental Products,” returns us approximately back to where we started. Resembling the CPSA in this respect, the Federal Insecticide, Fungicide, and Rodenticide Act of 1910 (FIFRA) offers no definition of “recall” but uses the word in its blackletter.¹³⁶ Unique among the statutory sources that give recall authority, FIFRA distinguishes voluntary recalls from mandatory ones.¹³⁷ The statute directs the EPA administrator to first consider whether a recall is necessary and then, should this regulator conclude that a voluntary recall “may be as safe and effective as a mandatory recall,” ask the registrant of the pesticide to submit a voluntary recall plan.¹³⁸ EPA recall authority extends also to emissions of motor vehicles. Here the statute speaks not of recalling errant engines or vehicles but “remedying nonconformity” with emission regulations.¹³⁹

In sum: Of the six agencies that hold most of the federal authority to oversee or impose recalls, only two operate under a formal definition of the term. These two definitions are inconsistent with each other. One of them can be applied to recalls overseen by other agencies and one cannot. Statutes

¹³³ Food Safety Modernization Act of 2011, Pub L 111-353, 124 Stat 3885 (2011), codified at 21 USC § 350c(a).

¹³⁴ 21 CFR § 810.

¹³⁵ 21 CFR § 7.3(g). For a critique of this definition, see Edward M. Basile and Beverly H. Lorell, *The Food and Drug Administration’s Regulation of Risk Disclosure for Implanatable Cardioverter Defibrillators: Has Technology Outpaced the Agency’s Regulatory Framework?*, 61 Food & Drug L J 251, 259–61 (2006) (deeming the definition to be overbroad).

¹³⁶ 7 USC § 136q (referencing “[s]torage, disposal, transportation, and recall.”).

¹³⁷ Compare 7 USC § 136q(b)(2) with 7 USC § 136q(b)(3).

¹³⁸ 7 USC § 136q(b)(2).

¹³⁹ 42 USC § 7541(c).

governing two other agencies contain the word “recalls” but never say what a recall is. The statute that imposes the most venerable authority to impose recalls on manufacturers is the one that most thoroughly avoids the word “recall”; the agency with the most pointed lack of mandatory-recall power (the FDA, with respect to drugs) is guided by the most useful definition of the word.

Other definitions of the word offered in secondary sources were examined above. These do a better job of explaining the concept—they could hardly do worse—but are riven with disagreements and contradictions.¹⁴⁰ Describing the cessation of the sale of Vioxx as a recall finds the limits of what the word might mean.¹⁴¹ No units of this painkiller came back to the manufacturer; no relabeling or product alteration took place; no redress was offered to consumers. When the Restatement (Third) of Torts discusses failure to recall, it uses “recalls” as verb, undefined.¹⁴²

“But,” an interlocutor might retort, “so what? Recalling products is something that corporations do. There’s a reason corporate lawyers get paid well. Anyone in any manufacturing business should know how to maneuver whatever regulations govern the industry. Competent in-house lawyers ought to be able to read statutes, translate synonyms or euphemisms for recall (like ‘remedying nonconformity’),¹⁴³ decide what to do when they have a bad product, and deal with the agency in charge. If they can’t, they can hire outside counsel who can. Yes, there’s some opacity here. There always is some. People with skin in the game will figure it out.”¹⁴⁴ Perhaps. The law of recalls, however, has to reckon with costs generated by its current lack of clarity.

¹⁴⁰ See Part I.A.

¹⁴¹ See Part I.B.6.

¹⁴² See Part I.B.1.

¹⁴³ See text accompanying note 139.

¹⁴⁴ See United States Government Accountability Office, *Auto Safety: NHTSA Has Options to Improve the Safety Defect Recall Process* at 18–19 (cited in note 42). Representatives of automobile manufacturers told GAO researchers that they thought “the regulatory requirements are clear” and they understood what they had to do when they or the National Highway Traffic Safety Administration identified a safety defect. *Id.* at 18. These respondents did, however, put particular emphasis on agency personnel when they praised the clarity of the recall process. They credited NHTSA with maintaining “open and cooperative communications” and responding quickly to their drafted defect notification letters. *Id.* at 19.

Costs for manufacturers include a layer of extra difficulty in their work of compliance. If federal law recognized a unitary general category of what “recalls” in the vernacular now covers—prevention-focused responses that manufacturers take after they identify dangers in their products—then lawyers could develop expertise applicable to multiple products, statutes, and agencies.¹⁴⁵ Proactive correction that offers consumers a refund, a replacement unit, or a safety modification, no matter what the product, utilizes similar professional skills that need not be fragmented at the agency level as they now are. Increased clarity about what “recall” means would give businesses more lawyers to choose from to do this work and lawyers a wider base of recall-related services to perform for corporate clients.

Making recalls clearer would also enhance the transparency of businesses in their role as stock issuers. Securities law shares the concern with disclosure that permeates this Article. It insists that potential buyers and sellers of stock have access to information that is material to the value of the business.¹⁴⁶ But because there is no unitary federal definition of the word “recall,” the securities rule on point, Regulation S-K,¹⁴⁷ cannot decree a clear duty to announce the recall. In other words, it is unclear whether the announcement of a recall might be a material disclosure required under securities regulation. Non-uniformity and insufficient clarity surrounding the word “recall” makes the news of a recall-like action by management harder for participants in stock markets to understand.

The effects of this obfuscation expand under conditions of competition for investment among rival businesses. Without uniformity in the terms that entities use to describe the recall-like measures they take, disclosures can reveal this category of material information without enough precision to inform investment decisions. If one publicly traded entity has adopted one recall-like measure while others have taken similar steps, all three can write securities disclosures that, though truthful,

¹⁴⁵ Christopher Doering, *Is Deluge of Recalls Desensitizing Consumers? Social Media Contributes to Better Communication* USA Today 01b (June 11, 2012) (reporting a retail executive’s complaint that there are different recalls systems with unique requirements in the CPSC, USDA and FDA, making compliance particularly difficult for companies).

¹⁴⁶ See generally Securities Act of 1933, Pub L No 112-106, 48 Stat 74, codified at 15 USC § 77a et seq; Securities Act of 1934, Pub L No 112-158, 48 Stat 881, codified at 15 USC § 78b et seq.

¹⁴⁷ See 17 CFR § 229.10 (2011) (delineating guidelines for reporting disclosures).

do not foster comparative examination of their stock offerings. Inadequate descriptions of recall-like actions make it difficult for investors and researchers to know the effects of these measures on market capitalization.¹⁴⁸

Readers unmoved by threats to securities portfolios may take more seriously the possibility that lack of clarity about the meaning of “recall” can harm the physical health of individuals. This problem arises with particular sharpness when the recalled product is a medical device implanted in patients. To lay persons and even some physicians, news that an implantable foreign object has been recalled will sound, as an FDA official once acknowledged, “scary or ominous”—even though the measure might be something as innocuous as new labeling revised to encourage changes in patient behaviors.¹⁴⁹ As long as what the manufacturer did falls within “an effective method of removing or correcting consumer products that are in violation of laws administered by FDA,”¹⁵⁰ the agency can classify the measure as a recall.¹⁵¹

Presumably at least some medical-devices patients react to a recall announcement with Get-it-out-of-me! panic, thereby generating at least more work for physicians, if not risky and medically unnecessary surgeries. The FDA tries to mitigate this harm with soothing language on its website.¹⁵² It could ameliorate more by eschewing the word “recall” for an implanted medical device unless its manufacturer, with input from the agency, has recommended that patients remove the product from their bodies,¹⁵³ but it has not yet done so.

B. Lack of Clarity on “Voluntary” as the Antonym of “Mandatory”

That voluntary recalls lack voluntariness emerges with particular force when the recalled product is a food, drug, or

¹⁴⁸ Rupp, 25 Rev Indus Org 21 (cited in note 3).

¹⁴⁹ Basile and Lorell, 61 Food & Drug L J at 260 (cited in note 135).

¹⁵⁰ 21 CFR § 7.3(g)

¹⁵¹ Basile and Lorell, 61 Food & Drug L J at 260–61 (cited in note 135).

¹⁵² As Basile and Lorell note, “[a] medical device recall does not always mean that you must stop using the product or return it to the company.” Id at 260 (citing language from FDA website).

¹⁵³ Id (reporting that FDA officials admit they have more latitude with respect to the word recall than they use).

medical device.¹⁵⁴ Consider the FDA's just-noted insistence on using the word "recall" to describe a wide range of post-sale corrective actions by manufacturers.¹⁵⁵ Not only does this choice install confusion about what "recall" means, but it also thwarts reasonable, welfare-enhancing wishes that a manufacturer might bring to the problem. This manufacturer might know which different diction would communicate more effectively to patients. FDA regulators, however, insist on applying the word "recall" to a wide swath of manufacturer actions.¹⁵⁶

An especially vivid example of a non-voluntary voluntary recall arose in 2010, when the FDA issued a press release stating that it had sent a letter to a device manufacturer, Baxter Healthcare Corporation, "ordering the company to recall and destroy" almost 200,000 infusion pumps, reimburse consumers for the value of this "recalled device," and help these consumers find a replacement.¹⁵⁷ Four years earlier, the agency had obtained a consent decree forbidding continuing manufacture of these pumps.¹⁵⁸ Baxter released an estimate that the recall would cost \$400 to \$600 million.¹⁵⁹

A less voluntary recall than this one is hard to imagine—one blog headlined the story "It's Not a Section 518 Mandatory Recall, But the Baxter Infusion Pump Comes Close"¹⁶⁰—and yet the FDA hewed to its track record of not using its statutory authority to mandate the recall of a medical device.¹⁶¹ In a question-and-answer webpage, the agency adverted to its "negotiation," rather than imposition, of a Final Order.¹⁶² The

¹⁵⁴ See John M. Packman, *Civil and Criminal Liability Associated With Food Recalls*, 53 Food & Drug L J 437, 439 (1998) ("[L]awyers sometimes refer to [FDA] recalls as voluntary actions, but this characterization is highly misleading.").

¹⁵⁵ See text accompanying note 153.

¹⁵⁶ Basile and Lorell, 61 Food & Drug L J at 260–61 (cited in note 135).

¹⁵⁷ Food and Drug Administration, *FDA Issues Statement on Baxter's Recall of Colleague Infusion Pumps* (May 3, 2010), online at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm210664.htm> (visited Sept 15, 2013).

¹⁵⁸ *Id.* See also Consent Decree Dated July 13, 2010, *United States v Baxter Healthcare Corp.*, Civil Action No 05-C-5852 (ND Ill 2006).

¹⁵⁹ Jeffrey K. Shapiro, *It's Not A Section 518 Mandatory Recall, But The Baxter Infusion Pump Recall Comes Close*, FDA Law Blog (Hyman, Phelps & McNamara, PC 2010), online at http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2010/05/its-not-a-section-518-mandatory-recall-but-the-baxter-infusion-pump-recall-comes-close.html (visited Sept 15, 2013).

¹⁶⁰ *Id.*

¹⁶¹ *Id.*

¹⁶² Food and Drug Administration, *Questions and Answers About the Baxter*

FDA's circa-2006 ban on future manufacture of the infusion pump had also been negotiated with rather than imposed upon Baxter Healthcare.¹⁶³

Another example of the gray area between mandatory and voluntary recalls that involved the FDA comes from a characterization offered by a member of Congress. Representative Edolphus Towns said that the pharmaceutical manufacturer McNeil Consumer Healthcare, a subsidiary of Johnson & Johnson, engaged in a "phantom recall" in 2009 through stealth purchasing.¹⁶⁴ Consistent with drug recalls generally, this action did not involve a Vioxx-like abandonment of an entire product line but addressed deficiency in discrete units. What McNeil did was send people into drugstores to buy up whatever quantities of the painkiller Motrin they found on shelves.¹⁶⁵ McNeil apparently wanted the product gone without undertaking a curative response that would be named a recall in the publicly available FDA Enforcement Reports.¹⁶⁶ After learning about this stealth purchasing program, the FDA ordered an open, non-phantom recall of more than 88,000 Motrin tablets.¹⁶⁷ This response might be deemed mandatory in that a regulatory agency imposed it by fiat, though voluntary in that a manufacturer initiated it.

Other types of recalls that the FDA oversees appear not mandatory in name only. Its definition of "recall" noted above, "a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal

Colleague Recall, Refund, and Replacement Action, Medical Devices FAQ (FDA Sept 3, 2010), online at <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm210768.htm> (visited Sept 15, 2013).

¹⁶³ Food and Drug Administration, *FDA Issues Statement on Baxter's Recall of Colleague Infusion Pumps* (cited in note 157) ("In June 2006, the FDA was obtained [sic] a consent decree of permanent injunction in which Baxter agreed to stop manufacturing and distributing all models of the Colleague pump until the company corrected manufacturing deficiencies and until devices in use were brought into compliance.")

¹⁶⁴ Eleanor G. Tennyson, Note, *A "Phantom Recall" Does Not Comport with FDA's Regulatory Practice—Or Does It?: The Need for More Stringent Mandatory Reporting in FDA Matters*, 97 Iowa L Rev 1839, 1842 (2012).

¹⁶⁵ Parija Kavilanz, *Behind the 'Phantom Recall' of Motrin*, CNN Money (CNN June 2, 2010), online at http://money.cnn.com/2010/06/02/news/companies/mcneil_motrin_phantom_recall/index.htm (visited Sept 15, 2013).

¹⁶⁶ Tennyson, Note, 97 Iowa L Rev at 1844 (cited in note 164).

¹⁶⁷ The FDA labeled the recall Class 2, the intermediate tier, indicating a risk of adverse events. Kavilanz, *Phantom Recall* (cited in note 165).

action, e.g. seizure,”¹⁶⁸ drops an unambiguous hint that the manufacturer had better do what the agency wants—including pull the product from the market, if need be—even though the FDA still lacks formal authority to order recalls of drugs. The FDA has had authority to order recalls of certain foodstuffs since 2011;¹⁶⁹ other food recalls are handled by the Department of Agriculture, which lacks this power to decree a recall. No matter: officials from the latter agency told congressional researchers who asked their opinion that “USDA’s authority to seize and detain products was sufficient and that, therefore, authority to order a recall was not necessary.”¹⁷⁰

While an agency that lacks mandatory recall power can in effect compel a recall over the vehement resistance of a manufacturer, a manufacturer, for its part, can resist some though not all agency-ordered recalls. The General Accountability Office (GAO) has explained that although Congress granted the FDA, the NHTSA, and the CPSC formal authority to compel recalls, the FDA has much more mandatory-recall power than the other two. An FDA mandatory recall stops the sale of a foodstuff or medical device immediately based on the sole judgment of the agency, whereas manufacturers can resist NHTSA and CPSC recall orders in court and continue selling their automobile or consumer product while their judicial challenge is pending.¹⁷¹ Manufacturer power to resist CPSC and NHTSA initiatives does not make a mandatory recall voluntary, but it does complicate and confound both adjectives.

The ability of manufacturers to fight back coupled with the power of agencies to thwart sales through measures like seizure has generated a voluntary-mandatory amalgam for a recall, where neither the regulator nor the regulated entity enjoys control over whether the action will occur and how it will proceed. The GAO has coined another adjective-noun combination, “influenced recalls,” to describe initiatives that originate in agency investigation rather than manufacturers’ post-sale monitoring of their products.¹⁷² The phrase “influenced

¹⁶⁸ See text accompanying note 135.

¹⁶⁹ See Part I.A.2.

¹⁷⁰ United States Government Accountability Office, *Auto Safety: NHTSA Has Options to Improve the Safety Defect Recall Process* at 18 (cited in note 42).

¹⁷¹ *Id.* at 15.

¹⁷² *Id.* at 7.

recalls” does not appear anywhere in the United States Code or the Code of Federal Regulations. Its emergence makes a useful point about what lies midway between voluntary and mandatory, but its lack of a statutory or regulatory definition, or indeed any other pedigree, limits what it can add to the task of clarifying and understanding product recalls.

Voluntary-mandatory adjectival blends also make it impossible to answer a simple question: On which historical occasions, if any, did federal agencies that have the authority to pursue a recall choose the mandatory, or court-compelled, version of this measure? Apparently not even the GAO, a well-regarded and well-funded arm of Congress, can produce a count of these incidents, and nobody else seems to know.

Consider the NHTSA. According to one consumer magazine, the agency’s “use of mandatory recalls is even more rare than CPSC’s. NHTSA hasn’t pursued a mandatory recall since 1979!”¹⁷³ The GAO has put the point more conservatively, stating without any citation that “[a]ccording to NHTSA officials, the agency has not ordered any vehicle recalls since prior to 2000, and since the agency was established, it has ordered seven recalls for motor vehicles or equipment.”¹⁷⁴

The apparent absence of basic data about public proceedings is odd. Why did the GAO rely on interviews with agency personnel to produce a count? Does no one in government have a list of the seven NHTSA-attempted mandatory recalls mentioned? CPSC-initiated mandatory recalls have received no GAO count. My own research located only a handful of mandatory-recall attempts by the CPSC in the last twenty-five years and, in the entire history of the agency, no CPSC petition that resulted in a court order to recall a product.¹⁷⁵ I cannot

¹⁷³ Sara Bongiorno, *Total Recall: Why Product Safety Has Taken A Back Seat*, Consumers Digest (Consumers Digest May 2010), online at <http://www.consumersdigest.com/special-reports/total-recall> (visited Sept 15, 2013).

¹⁷⁴ United States Government Accountability Office, *Auto Safety: NHTSA Has Options to Improve the Safety Defect Recall Process* at 8 (cited in note 42).

¹⁷⁵ In 2001, CNN reported that the CPSC had “started six mandatory recall proceedings” since 1989. CNN, *U.S. seeks recall of 7.5 million BB guns*, CNN Justice (CNN Oct 30, 2001), online at <http://edition.cnn.com/2001/LAW/10/30/bbgun.lawsuit/index.html> (visited Sept 15, 2013). The products were the “Worm Gett’r probe, Central Omega sprinklers, Black and Decker under-the-counter space-saver toasters, Cadet wall heaters, and Sunbeam Fire sprinklers.” *Id.* The year 2012 was an aggressive one for the CPSC; it petitioned for several mandatory recalls. Three involved magnetic toys that the agency deemed a choking hazard. The most publicized was of a product called Buckyballs; the company fought for a few months and yielded in November. See Ruth

know whether I have found the full complement.¹⁷⁶ Other writers resort continually to adverbial imprecision—“rarely,”¹⁷⁷—when they estimate how often federal agencies force manufacturers to recall products. They have no alternative.

III. HOW VOLUNTARY RECALLS ARE NOT QUITE VOLUNTARY FOR CONSUMERS

Non-voluntariness for manufacturers as explored in the last Part considered first the ambiguity and uncertainty contained in the word “recall,” which obscures what a manufacturer has volunteered to do, and second, coercion present in the ostensibly volunteered version of this action. The first of the two characteristics presses even harder on consumers than on manufacturers. Ambiguity about the meaning of the word “recall” vexes both sets of participants, but a manufacturer can receive informed advice about consequences more easily than a consumer.¹⁷⁸

Suehle, *Exclusive Interview: CEO Craig Zucker on the Demise of Buckyballs* (GeekMom Nov 2, 2012), online at <http://www.wired.com/geekmom/2012/11/craig-zucker-buckyballs/> (visited Sept 15, 2013). On the other two mandatory-recall petitions against magnetic toys, see Christie Grymes Thompson, *Three's Company (or a Crowd)? CPSC Files Lawsuit Against Third Magnet Ball Seller* (AD Law Access Dec 20, 2012), online at <http://www.adlawaccess.com/2012/12/articles/consumer-product-safety/threes-company-or-a-crowd-cpsc-files-lawsuit-against-third-magnet-ball-seller/> (visited Sept 15, 2013). CPSC mandatory-recall proceedings against these two other manufacturers were open when this Article went to press. Another CPSC effort of 2012, launched against a baby recliner, ended in an ostensibly voluntary recall. See Latin Times Staff Writer, *Consumer Product Agency Seeks Recall, Mandatory Refund for Nap Nanny Recliner Following Five Infant Deaths*, Latin Times (Latin Times Dec 6, 2012), online at <http://www.latintimes.com/articles/1419/20121206/consumer-product-agency-seeks-recall-mandatory-refund-nap-nanny-recliner-five-infant-deaths.htm> (visited Sept 15, 2013); Consumer Products Safety Commission, *Four Retailers Agree to Stop Sale and Voluntarily Recall Nap Nanny Recliners Due to Five Infant Deaths*, CPSC Website (CPSC Dec 27, 2012), online at <http://www.cpsc.gov/en/Recalls/2013/Four-Retailers-Agree-to-Stop-Sale-and-Voluntarily-Recall-Nap-Nanny-Recliners-Due-to-Five-Infant-Deaths/> (visited Sept 15, 2013).

¹⁷⁶ In October 2012, assisted by Brooklyn Law School librarian Kathleen Darvil, I submitted Freedom of Information Act requests to six agencies: the CPSC, the NHTSA, the FSIS of the Department of Agriculture, the FDA, the Coast Guard, and the EPA. The phrasing of my requests varied depending on the statutory authority of the agency, but each query asked about court petitions that the agency initiated to pursue product recalls. The only agency that cooperated was FSIS; it produced information about only the last two years, November 2010 to November 2012. The other agencies either did not answer or purported to object to the breadth or imprecision of my request.

¹⁷⁷ O'Reilly, 33 U Memphis L Rev at 885 (cited in note 39).

¹⁷⁸ But see the impediments to the practice of recall law noted in Part II.

Moreover, as was detailed in Part I, a recall puts pressure on consumers by impeding their efforts to gain redress in court should they refuse to settle for the recall's fix. Mootness, refusals to certify a class, lack of proximate cause, contributory negligence, and assumption of risk are among the conclusions that courts have drawn to the detriment of consumers in cases where defendant manufacturers recalled their products. Voluntary recalls, accordingly, were presented in Parts I and II as not so voluntary for consumers either.

Pressures to accept the deal aside, a recall presents choices to the consumer. She can, *inter alia*, ignore the announcement, postpone her decision, or consider what the manufacturer has offered and then either accept it or try to push for a sweeter deal. In this sense, a voluntary recall, which is often more or less mandatory from the vantage point of the manufacturer, seems genuinely voluntary at the consumer end. Two impediments to voluntariness for consumers emerge, however. First, individuals frequently do not obtain full information about an announced recall. Second, when the message does get through, a phenomenon dubbed "recall fatigue" may thwart the power of consumers to exercise judgment in response.

A. Flawed Communications from and to Manufacturers

Every recall of a consumer product is an exercise in communication. News of a recall announces warnings and options. Consumer responses, in turn, inform manufacturers and regulators about how the news was heard and heeded. Calling these communications "flawed" expresses not my own criticism but rather the judgment of informed observers who judge the majority of recalls as instances of unsuccessful communication. The CPSC, which has been monitoring the effectiveness of recalls since 1978, continually finds response levels unsatisfactory.¹⁷⁹ Three commissioners at a public hearing in 2012 "expressed concerns about the system's low return rate."¹⁸⁰

¹⁷⁹ A report prepared for the CPSC in 2003 summarized findings through the late 1990s. See generally Heiden Associates and XL Associates, *Recall Effectiveness Research: A Review and Summary of the Literature on Consumer Motivation and Behavior* (CPSC July 2003), online at <https://www.cpsc.gov/PageFiles/101932/recalleffectiveness.pdf> (visited Sept 15, 2013) (submitting a report for the CPSC).

¹⁸⁰ Gary Long, Gary Fowler, and Simon Castley, *CPSC Explores Regulatory*

Food recalls have proved especially tricky to pull off successfully. Perishable food is frequently consumed before consumers have learned about a danger and food with a longer shelf life can sit uneaten and then be ingested after individuals forget about the recall.¹⁸¹ A few consumers proceed in a manner that looks perverse: according to a study sponsored by the Department of Agriculture, 12 percent of the surveyed consumers had eaten food they knew had been recalled.¹⁸²

At the other end of the spectrum, automobile-related recalls generate relatively strong responses. Fewer than a third of consumer products are returned in recalls, according to the CPSC,¹⁸³ and some recalls of consumer products bring back less than 10 percent of the units sold,¹⁸⁴ but as an agency with recall authority, the NHTSA fares better. Automobiles are expensive, giving consumers an incentive to return the product, and child car seats, which fall under the jurisdiction of the NHTSA,¹⁸⁵ appear to claim a relatively high level of attention when recalled. NHTSA has reported that 73 percent of recalled automobiles and 45 percent of recalled child car seats made their way back to manufacturers in 2009.¹⁸⁶ Having the names and addresses of registered automobile owners also facilitates recall communication; manufacturers know where to find owners. Evidence suggests that direct communication with consumers also enhances return rates for products other than automobiles.¹⁸⁷

Priorities Including Reforms to Product Recalls, Lexology (Shook Hardy & Bacon LLP June 28, 2012), online at <http://www.lexology.com/library/detail.aspx?g=04d1d568-4f4f-41cd-ba7c-282e7da65d64> (visited Sept 15, 2013).

¹⁸¹ Lyndsey Layton, *Officials Worry About Consumers Lost Among the Recalls*, Wash Post A01 (July 2, 2010).

¹⁸² William K. Hallman, Cara L. Cruite, and Neal H. Hooker, *Consumer Responses to Food Recalls: 2008 National Survey Report*, Food Policy Institute 10 (Rutgers 2009), online at <http://fpi.rutgers.edu/docs/news/RR-0109-018.pdf> (visited Sept 15, 2013). The researchers followed up by asking why. A majority said they did not believe the food would harm them, but 9 percent said they didn't have anything else to eat. Id.

¹⁸³ Layton, *Officials Worry About Consumers Lost Among the Recalls*, Wash Post A01 (cited in note 181). The return rate is about twice as high for exceptionally expensive products or products whose dangers could be lethal, such as scuba diving equipment. Id.

¹⁸⁴ Mitch Lipka, *10 Dangerous Products You Might Have in Your Home*, Time Business and Money (TIME May 23, 2012), online at <http://business.time.com/2012/05/23/10-dangerous-products-you-might-have-in-your-home> (visited Sept 15, 2013).

¹⁸⁵ See 49 USC § 30118.

¹⁸⁶ Layton, *Officials Worry About Consumers Lost Among the Recalls*, Wash Post at A01 (cited in note 181).

¹⁸⁷ The retailer Costco, which keeps contact information for all customers in its

Whether advances in information technology have enhanced the effectiveness of product recalls has not yet received much attention from researchers. In its Recall Handbook published in 2012, the CPSC has encouraged manufacturers to pursue electronic communication with consumers.¹⁸⁸ It drops a few names of the social media *du jour*: “Facebook, Google +, YouTube, Twitter, Flickr, [and] Pinterest” alongside “company blogger networks, and blog announcements.”¹⁸⁹ The authors of the Recall Handbook appear to be less than fully informed about how these media function.¹⁹⁰ Social media communication about recalls will undoubtedly get better, but current agency guidance is too vague to deserve credit for the improvement.

The great strength of technological innovation for recalls, still underdeveloped, is the filtering and precision that they can achieve.¹⁹¹ Most people do not need to know about all the dozens of recalls that are underway at any point in time. Selective dissemination of information would create a valuable counterpart to the NHTSA recall letters that go directly to automobile owners and manifest both high consumer response rates and manufacturer satisfaction.¹⁹² For example, if a family member of a consumer suffers from a food allergy, that consumer might take steps to learn about recalls related to food contamination by the allergen they know about.¹⁹³

database, sometimes enjoys a response rate of 90 percent. *Id.* A federal law that took effect in 2010 required manufacturers of durable toddler and baby items to include registration cards, building on an older law requiring them for child car seats. *Id.* See Consumer Product Safety Improvement Act (Danny Keysar Child Product Safety Notification Act), Pub L No 110-314, 122 Stat 3028, codified at 15 USC § 2056a.

¹⁸⁸ United States Consumer Product Safety Commission, *Recall Handbook* (CPSC March 2012), online at <http://www.cpsc.gov/PageFiles/106141/8002.pdf> (visited Sept 15, 2013).

¹⁸⁹ *Id.* at 19.

¹⁹⁰ Its rules demand that every notification “contain[] all recall information available in the news release” and “permit[] persons to request remedy [sic] directly from website.” *Id.* at 23. “[C]ompany blogger networks and blog announcements” can cooperate; Twitter and Flickr fit this model less directly; Pinterest has a very different model, focusing on visual images that businesses use to sell new units. For examples of using social media for communications with consumers, see Pinterest for Business, online at <http://business.pinterest.com/> (visited Sept 15, 2013).

¹⁹¹ For example, a Twitter feed from the Department of Agriculture targets consumers of foodstuffs sold only in their state. The CPSC allows consumers to sign up for particular categories of recall, such as child products. An Android application is also available for consumers who choose it. General Services Administration, *Recalls.gov App*, online at <http://apps.usa.gov/product-recalls-2.shtml> (visited Sept 15, 2013).

¹⁹² See text accompanying notes 186–187.

¹⁹³ Dan Flynn, *Complacency, Not Fatigue, the Only Real Recall Danger*, Food Safety

The federal government site noted above, recalls.gov, invites consumers to sign up for notices from the CPSC, the FDA, the FSIS, and the NHTSA.¹⁹⁴ Volunteers sign up by typing in e-mail addresses only; they need supply no other information.¹⁹⁵ Protections linked to the Privacy Act of 1974¹⁹⁶ constrain dissemination of these addresses.¹⁹⁷ This venerable source of protection has not been expanded to encourage more such registration, which might enhance return rates. E-mail coupled with voluntary registration on websites will not suffice, however. Regulators know about—although they have not yet been able to exploit—alternative routes to spread the recall news.¹⁹⁸

B. The Possibility of Recall Fatigue

Observers speculate that consumers who learn about product recalls might tune out the news because they have been bombarded by repetition.¹⁹⁹ The recall fatigue hypothesis proposes that the volume of announcements makes it difficult for consumers to respond to what manufacturers have warned and offered. A *Washington Post* story described recall fatigue as a “twofold” problem: it causes consumers both to tune out the news of the recall and to disbelieve that the recalled product will hurt them.²⁰⁰

Defending the hypothesis, a blog post observed that in one month of 2010 alone, recalls were announced by “McDonald’s,

News (June 12, 2012), online at <http://www.foodsafetynews.com/2012/06/complacency-not-fatigue-the-only-real-recall-danger/> (visited Sept 15, 2013).

¹⁹⁴ See text accompanying note 120.

¹⁹⁵ Id.

¹⁹⁶ Privacy Act of 1974, Pub L No 93-579, 88 Stat 1896, codified at 5 USC § 552a.

¹⁹⁷ See 5 USC § 552a(b) (listing several exceptions, none of which permits disclosure).

¹⁹⁸ Long, Fowler, and Castley, *CPSC Explores Regulatory Priorities* at *1 (cited in note 180) (reporting discussion at a CPSC public hearing of the large number of households that lack access to the Internet but receive text messages on mobile devices and the access that manufacturers have to sales records from loyalty programs).

¹⁹⁹ Doering, *Is Deluge of Recalls Desensitizing Consumers?*, USA Today at 01b (cited in note 145); Natalie Blazer, *Total Recall: Can Too Many Warnings Have the Opposite Effect?*, Product Liability Monitor (Weil, Gotshal & Manges Nov 30, 2010), online at <http://product-liability.weil.com/consumer-product-safety/total-recall-can-too-many-warnings-have-the-opposite-effect/#axzz2JVgmIBdj> (visited Sept 15, 2013) (noting that Class I recalls of medical devices, the highest-risk category, have “skyrocketed in recent years”).

²⁰⁰ Layton, *Officials Worry About Consumers Lost Among the Recalls*, Wash Post at A01 (cited in note 181).

Campbell's, Kellogg's [sic], Maytag, Sony, Bridgestone Tires, Target, Crate & Barrel, and not one, but seven crib-manufacturing companies."²⁰¹ A vivid count, if inexact. Consistent with the larger recalls picture that occupies this Article—we have noted that the most basic data points elude easy retrieval—no one has been able to say precisely how many recalls occur and whether this total is increasing. One news story counted 2,463 product recalls under the auspices of the CPSC, the FDA, and the Department of Agriculture in 2011, a 14 percent increase from the previous year and a 62 percent increase from the 2007 total.²⁰² These numbers omit recalls performed under the authority of other agencies, of which the NHTSA contributes the largest number.²⁰³

Observers debate the existence of recall fatigue. If individuals really cannot cope with the quantity of information around them, says one skeptic, then they would be unable to choose among “an estimated 50,000 items” available in grocery stores.²⁰⁴ A former regulator from the food sector blames consumers for not keeping alert to recalls of products whose dangers affect them: their inattention, he said, comes more from complacency than recall fatigue.²⁰⁵ Another food regulator, however, found “a real phenomenon” of fatigue one year when consumers heard about recalls of chili sauce, spinach, carrot juice, lettuce, peanut butter, and pet food.²⁰⁶ One observer cites

²⁰¹ The month was June 2010. See Juliana Olsson, *Recalls.gov App to Cure “Recall Fatigue,”* Article 3 (July 7, 2010), online at <http://www.article-3.com/recalls-gov-app-to-cure-%E2%80%9Crecall-fatigue%E2%80%9D-9105> (visited Sept 15, 2013) (providing links to the recalls).

²⁰² Doering, *Is Deluge of Recalls Desensitizing Consumers?*, USA Today at 01b (cited in note 145) (counting CPSC, FDA, and USDA). Not all products categories are experiencing increased recall levels. Mike Rozembajgier, *Kids In Danger Report Finds Children's Product Recalls Declined in 2011, But Concerns Remain on Recall Response Rates Due to “Recall Fatigue,”* Expert Recall (Stericycle Apr 9, 2012), online at <http://www.expertrecall.com/kids-in-danger-report-finds-childrens-product-recalls-declined-in-2011-but-concerns-remain-on-recall-response-rates-due-to-recall-fatigue/> (visited on Sept 15, 2013) (noting an estimated decline of 24 percent in recalls of children's products from 2010 to 2011).

²⁰³ See Doering, *Is Deluge of Recalls Desensitizing Consumers?*, USA Today at 01b (cited in note 145).

²⁰⁴ Flynn, *Complacency the Only Real Recall Danger* at *1 (cited in note 193).

²⁰⁵ Id (quoting the former Under Secretary for Food Safety at the Department of Agriculture).

²⁰⁶ Doug Powell, *Recall Fatigue Redux: Does Social Media Help or Hinder?* (Barf Blog June 11, 2012), online at <http://barfblog.com/2012/06/recall-fatigue-redux-does-social-media-help-or-hinder/> (visited Sept 15, 2013).

return rates, which remain low despite manufacturer efforts to enlist new media and incentives to consumers who cooperate, as evidence for recall fatigue.²⁰⁷

The question of whether recall fatigue does or does not exist complicates the voluntariness question only a little. Most consumers who possess products that have been recalled do not, for whatever reasons, turn them in. Regulators blame what I have called flawed communication for low return rates. An apparent consensus holds that recalling entities need to target their communications with consumers more pointedly, using tools at hand: loyalty-card data, mobile devices, electronic mail, social media. Whether recall fatigue exists or not, these efforts will go on.

What recall fatigue raises is the possibility that every announced recall adds an increment of noise to what may in the aggregate be cacophony. If recall fatigue is illusory or exaggerated, then its effect on voluntariness need not occupy regulators' attention. As we have seen, however, other conditions that limit consumer choice—lack of clarity about what “recall” means, adverse doctrinal consequences for those who do not cooperate with a recall and want to proceed in court, and the inadequate communication of recall announcements—make voluntary recalls less than voluntary for consumers as well as manufacturers, irrespective of whether recalls induce fatigue.

Alternatively, if the phenomenon is genuine, then the volume of recalls becomes another impediment to voluntariness. Recall volume is independent of flawed communication, a separate background condition. Even well-crafted messages might induce burnout. Recall fatigue as “a real phenomenon”²⁰⁸ discouraging consumer responses suggests a need to spend more money on the enforcement of federal safety regulations, a possibility to which we now turn.

IV. RECALLS RECOMMENDATIONS IN TWO LEVELS

Product recalls can improve with the aid of federal-level reform. This Part presents its suggestions in a two-tier layout. The first subpart, “Thinking Big,” aspires to accountability,

²⁰⁷ Rozembajgier, *Kids In Danger Report* at *1 (cited in note 202).

²⁰⁸ See text accompanying note 206.

clarity, and the enhanced enforcement of safety regulation. Some ideas appear here for the first time while others, familiar from the recalls literature, have languished unimplemented for years. The second subpart, "Thinking Small," recognizes political and financial costs in effecting meaningful change in the law of product recalls. It makes recommendations that would achieve less but are more attainable.

A. Thinking Big

1. Work to remove "voluntary," "mandatory," and "recall" as much as possible from the United States Code and the Code of Federal Regulations.

As may be needless to add, this recommendation applies only to our context of defective products, not entire codes. The adjectives "voluntary" and "mandatory," along with the noun and verb senses of "recall," retain ample value elsewhere in American law. Should that assumption be misplaced in a particular setting, other observers can recommend expungement. For purposes of reducing danger to consumers, however, all three of the words sow confusion in and from codified law. Revisers should consider replacing them with clearer terms of art.

We have seen that as used to describe product recalls, "voluntary" and "mandatory" confound both sellers and consumers. In ordinary English, these adjectives function more or less as antonyms. In the recall context, they imply two binary types of government-guided safety initiatives. Neither half of the binary actually exists. "Recall" renders more information than "voluntary" or "mandatory," but better diction is available.²⁰⁹

2. Codify a comprehensive federal tort response to the problem of manufacturers' duties post-sale.

Products liability, the court-focused counterpart to the regulatory category of product safety, has been thought of for many decades as a good target for comprehensive statutory reform. The Model Uniform Product Liability Act, published in 1978, launched a campaign to make products liability law more

²⁰⁹ See Part IV.B.2.

consistent and predictable.²¹⁰ This uniform statute failed,²¹¹ as have most efforts to enact comprehensive products liability legislation in Congress: only particular product categories have been subjected to federal regulation.²¹²

Because products liability reform legislation has set out to reduce rather than increase the responsibility of manufacturers and sellers, the effort has been (or at least has been perceived as) a skirmish of defendants against plaintiffs, businesses against consumers, repeat players against novices, and richer against poorer.²¹³ On any measure introduced, legislators can expect lobbying from the tort reform movement and business alliances on one side and trial lawyers and consumer activists on the other. Partisanship not only impedes the chance for new legislation to be enacted but also the content of the reform itself, as each initiative triggers memories of past battles.

Congress could start fresh, or at least fresher, by considering a broad statute covering manufacturers' post-sale duties in tort—with the important proviso that this measure contain more than mere tort immunity for entities that choose recalls. The reason to eschew immunity-and-nothing-more is that experience tells us what it will deliver: an expensive fight staged as a binary partisanship, with probably no legislation to show for the struggle. Instead, the drafters of a statute ought to try for clarity.

Although the content of such a statute is unpredictable from here, the undertaking itself would enhance the recalls landscape. Comprehensive treatment of post-sale duties would unite product recalls with the closely related category of warnings.²¹⁴ Limited immunity would be an option to consider and negotiate: in my opinion, it ought to exist only when the recall in question fulfills stringent criteria, but input from stakeholders would refine this premise. A recalls reform bill also

²¹⁰ Anita Bernstein, *A Model of Products Liability Reform*, 27 Valp U L Rev 637, 660–62 (1993).

²¹¹ *Id.* at 661.

²¹² See F. Patrick Hubbard, *The Nature and Impact of the Tort Reform Movement*, 35 Hofstra L Rev 437, 483 n 213 (2006). For a survey of product-specific federal legislation, see note 6.

²¹³ See Anita Bernstein, *The 2x2 Matrix of Tort Reform's Distributions*, 60 DePaul L Rev 273, 276–77 (2011).

²¹⁴ For one of the rare law review articles about product recalls that give warnings equal time, see Richmond, 36 Idaho L Rev at 81 (cited in note 47).

provides an occasion for Congress to hold hearings, which would increase what policymakers know about how this technology of safety functions.

3. Fund the regulators.

Product safety regulation in the United States has suffered from chronic and perpetual underfunding. Although its origins might be older, the problem dates back at least to 1981, when Reagan-era deregulation provided an ideological base for withholding enforcement monies.²¹⁵ While Congress expanded both powers and appropriations for the CPSC in 2008,²¹⁶ one commissioner in 2013 contended, plausibly enough, that the agency continues to lack the money it needs.²¹⁷ Three months later the chairman endorsed that view, describing the agency as “perpetually underfunded.”²¹⁸

The Food Safety Modernization Act, which went into effect in January 2011, gave another agency, the FDA, important new powers including expansion of its mandatory-recall authority and the prerogative to suspend operations of an errant business.²¹⁹ Expansions of this authority that require funding, however, have lagged. The commissioner of the FDA decried its

²¹⁵ See Teresa M. Schwartz, *The Consumer Product Safety Commission: A Flawed Product of the Consumer Decade*, 51 *Geo Wash L Rev* 32, 36 (1982); E. Marla Felcher, *It's No Accident: How Corporations Sell Dangerous Baby Products* 30 (Common Courage 2002) (attributing skepticism and disapproval about the CPSC to President Jimmy Carter). The CPSC high-water year of funding, in current dollars, was 1974. See Anita Bernstein, *Implied Reverse Preemption*, 74 *Brooklyn L Rev* 664, 696 (2009) (citations omitted). Opposition to robust consumer safety regulation appeared in an important early article co-authored by then-Professor Scalia. See generally Antonin Scalia and Frank Goodman, *Procedural Aspects of the Consumer Product Safety Act*, 20 *UCLA L Rev* 899 (1973).

²¹⁶ Bernstein, 74 *Brooklyn L Rev* at 665 (cited in note 215).

²¹⁷ United States Consumer Product Safety Commission, *Statement of Commissioner Robert Adler on the CPSC Fiscal Year 2013 Operating Plan 2* (Jan 22, 2013) online at <http://www.cpsc.gov/PageFiles/138881/adler01222013.pdf> (visited Sept 15, 2013) (referencing “the continued underfunding of our agency”). See also United States Government Accountability Office, *Traffic Safety: NHTSA's Improved Oversight Could Identify Opportunities to Strengthen Management and Safety in Some States* at 5 (GAO July 2008), online at <http://www.gao.gov/products/GAO-08-788> (visited on Sept 15, 2013) (reporting what NHTSA officials said they could do with more appropriations).

²¹⁸ United States Consumer Product Safety Commission, *Statement of Chairman Inez M. Tenenbaum on the CPSC Fiscal Year 2014 Budget Request* 1 (Apr 18, 2013), online at [http://op.bna.com/pslr.nsf/id/rbom-96vqjz/\\$File/TenenbaumStatementBudget.pdf](http://op.bna.com/pslr.nsf/id/rbom-96vqjz/$File/TenenbaumStatementBudget.pdf) (visited Sept 15, 2013).

²¹⁹ See text accompanying note 133.

food safety budget of \$1.2 billion, an amount she called short by millions in relation to the mandate that Congress enlarged.²²⁰

More money for federal agencies, empowering them to enforce legislation on the books, would do more for public safety than any new rules—or even more money—to support recalls in particular. Product safety costs money that legislators have simply not wished to spend. Intermittent increases in funding seldom make up for earlier cuts, and for many categories of products the total number of units sold, as well as new dangers identified in them, have increased.²²¹ Even the best-run recall, delivered with candor and transparency and resulting in a high return rate, is inferior to warding off danger before it develops. Increased funding of the safety agencies also by hypothesis will serve to increase their recall powers, however, and thus belongs within this Part's set of big-thinking recommendations to improve recalls.

B. Thinking Small

If the recommendations of the last section are too ambitious, costly, or politically challenging to pursue, then reformers might consider more modest federal-level proposals to improve product recalls. Here are four.

1. Phase out “voluntary” and “mandatory” from the United States Code and the Code of Federal Regulations; limit the new uses of “recall” there.

This suggestion is the same as the one offered above under Thinking Big, except that rather than recommend expunging unhelpful terminology from federal compendia, it aspires to reduce this unfortunate verbiage. Federal statutes already use “voluntary” and “mandatory” sparingly to describe product recalls.²²² They can stay on that path. Agencies would be charged with hewing to this policy in their rule-writing going forward. The federal Office of Information and Regulatory

²²⁰ Doering, *Is Deluge of Recalls Desensitizing Consumers?*, USA Today at 01b (cited in note 145).

²²¹ Felcher, *How Corporations Sell Dangerous Baby Products* at 195 (cited in note 215).

²²² FIFRA is the only one. See note 136 and accompanying text.

Affairs, which reviews agency draft regulations before publication,²²³ can oversee this duty.

2. Install “field safety correction” as a supplementary term of art.

An alternative for reformers to consider installing in federal statutes and agency rules in place of the perilous “recall” is a “field safety corrective action,” proposed several years ago by the Global Harmonization Task Force, an international entity that addressed medical-devices rules.²²⁴ The Task Force, disbanded in 2012, had consisted of government regulators and representatives from trade associations from around the world²²⁵—a membership base that raises plausible concerns about the absence of consumer input but that nevertheless rendered value. Its idea offers benefit beyond the category of medical devices and the interests of one particular regulated industry. “Field safety corrective action” permits “recall” to advance from its current catchall status and mean something more useful. In this scheme, a recall would be the strongest possible field safety corrective action.

3. Redesign recalls.gov.

This suggestion has undoubtedly been implemented, but at the moment recalls.gov looks exceptionally unattractive and inhospitable among federal-government websites. Here is a screenshot of its home page as of October 13, 2013:²²⁶

²²³ Executive Order 12866, Regulatory Planning and Review, 3 CFR § 638 (1993), reprinted as amended in 5 USC § 601.

²²⁴ National Competent Authority Report Exchange, *Medical Devices: Post Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form *5* (Report for Study Group 2 of the Global Harmonization Task Force, Sept 15, 2005) (on file with author).

²²⁵ Alexander Gaffney, *GHTF Says Final Goodbyes, Shuttters Website*, Regulatory Focus (Nov. 28, 2012), online at <http://www.raps.org/focus-online/news/news-article-view/article/2586/ghtf-says-final-goodbyes-shuttters-website.aspx> (visited Sept 15, 2013).

²²⁶ Recalls.gov, *Your Online Resource for Recalls*, online at <http://www.recalls.gov/index.html> (visited Oct 13, 2013).

www.Recalls.gov Your Online Resource for Recalls

Consumer Products | Motor Vehicles | Boats | Food | Medicine | Cosmetics | Environmental Products

Recent Recalls To provide better service in alerting the American people to unsafe, hazardous or defective products, six federal agencies with vastly different jurisdictions have joined together to create www.recalls.gov — a “one stop shop” for U.S. Government recalls.

Search for Recalls Follow the tabs above to obtain the latest recall information, to report a dangerous product, or to learn important safety tips.

Sign Up for E-Mail

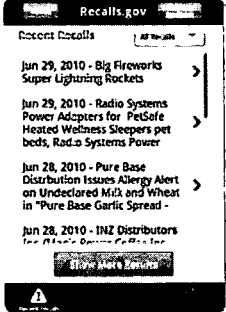
Información en Español

Recalls on the Go


When you're buying and using products, safety comes first. And now, with this product recalls application, you have vital safety information available whenever and wherever you need it - right on your mobile phone, thanks to the [RECALLS.GOV mobile application](#).

Whether you're at your child's day care center or a yard sale, whether you're at a store or at home, you can now type a product's name into your phone and learn immediately whether that product has been recalled because of a safety concern. You can also see photos of recalled products and learn what to do with recalled products in your homes.

Stay informed, stay safe, check for product recalls.



USA.gov
Government of the United States



Consumer Products | Motor Vehicles | Boats | Food | Medicine | Cosmetics | Environmental Products

Privacy and Security Notice. This site is provided as a resource for federal recalls. Please direct questions about specific recalls to the appropriate agencies listed above. Questions about this web site can be directed to webteam@cpsc.gov

One might forgive a dingy gray-white background and amateurish graphics—the only imagery on the home page consists of agency logos—but not the inadequate rendering of information to consumers. The “Consumer Products” tab undoubtedly confuses visitors who wonder why boats and cosmetics, for example, get separate treatment. “Información en Español” excludes much of the content provided in English, including links where consumers can sign up to receive updates.²²⁷ Recalls.gov claims that “six federal agencies”—presumably the six whose logos line the bottom of the page—joined together to create the site, but under the tabs it names more than six.

A better government site might include enhancements like photographs of the most dangerous products currently being

²²⁷ See Recalls.gov, *Información en Español*, online at <http://www.recalls.gov/spanish.html> (visited Sept 15, 2013).

recalled, more languages other than English with fuller content than what the Spanish page now provides, classifications that fit consumer needs better than the present agency-delineated tab division, a one-click option to report a danger (at present the visitor has to hunt for the right tab), audio content to enhance access for visually disabled visitors, buttons to register for newer material like the FSIS Twitter feed and the recalls.gov Android application, and video clips. The video library could start with welcome messages from agency commissioners and later offer news about current product dangers.

4. Expand the Consumer Product Safety Commission's "No PD" innovation to other agencies.

This celebrated reform, dubbed Fast-Track, leverages a point of mutual advantage for the agency and manufacturers who have identified a danger in their product. The CPSC wants to increase safety but lacks the resources to learn about product dangers and push against recalcitrant manufacturers; manufacturers, in turn, know they can fight a CPSC-imposed recall but would prefer not to do so when a cheaper compromise is available: sometimes they are willing to recall and move on. Enter Fast-Track. When taking advantage of this option, a manufacturer prepares a written recall plan and submits it to the CPSC. It identifies the danger and tells the CPSC how it will perform the recall. The quid for this quo is that if the CPSC agrees to the plan, it does not pursue a "preliminary determination" of defect, or PD, which finding manufacturers think of as an invitation to the plaintiffs' bar.²²⁸ The CPSC estimates that about half of its recalls proceed under Fast-Track auspices.²²⁹

Launched as a pilot program in 1995, Fast-Track won the Innovations in American Government Award in 1997.²³⁰ "Industry still has a lot of control over the process," according to the director of product safety for the watchdog Consumer Federation of America,²³¹ but Fast-Track is generally regarded

²²⁸ CPSC, 3 Consumer Prod Safety Rev at 2 (cited in note 126).

²²⁹ Id at 1.

²³⁰ Id at 2. The award, administered at the Kennedy School of Harvard University, delivers a cash prize of \$100,000. CPSC boasted in a newsletter that it was among only ten winners chosen from more than 1400 entrants. Id.

²³¹ Bongiorno, *Why Product Safety Has Taken A Back Seat*, Consumers Digest (cited

as a healthy reform.²³² Its emphasis on making recalls faster could migrate to other agencies.²³³ If manufacturers will cooperate only when they have something to gain,²³⁴ then Congress may have to write a stick-meets-carrot counterpart to the preliminary determination available to the CPSC, and this suggestion perforce moves from Thinking Small to Thinking Big, but the prospect of fending off tougher new rules might suffice to encourage manufacturer cooperation.

V. CONCLUSION

As a legal category, the subject of product recalls needs more attention. Its literature is extraordinarily thin in relation to both the copious federal regulations on point and the money and time it consumes. Few law review articles on the topic have been published. Back in 1998, the Restatement of Torts noted that recalls case law is scant: it has remained scant since. Journalists and bloggers cover the subject, but mostly to report the latest announced recalls than analyze what is difficult about them.

The fundamental difficulty with recalls as a legal category, I have argued, is the terminology that accompanies them. This Article has focused on “voluntary,” arguing that one cannot truly volunteer for that which defies clear understanding, and recalls defy clear understanding. A separate impediment to voluntariness in an ostensibly voluntary recall, especially for a manufacturer, is governmental coercion.²³⁵ Even though

in note 173) (quoting Rachel Weintraub the “director of product safety for Consumer Federation of America—a consumer watchdog group”).

²³² See John D. Donahue, ed, *Making Washington Work: Tales of Innovation in the Federal Government* 19 (Brookings Inst 1999); Consumer Reports, *CR Investigates: The Trouble with Recalls*, Consumer Reports 12 (Aug 1, 2004) (listing Fast-Track under the heading “Positive Steps”).

²³³ Michael T. Roberts, *Mandatory Recall Authority: A Sensible and Minimalist Approach to Improving Food Safety*, 59 Food & Drug L J 563, 577 (2004) (making this suggestion for food recalls).

²³⁴ See Lars Noah, *Administrative Arm Twisting in the Shadow of Congressional Delegations of Authority*, 1997 Wis L Rev 873, 888–89 (1997) (observing that drug manufacturers cooperate with the FDA, even though the agency has no mandatory recall authority, because they fear “more serious enforcement measures authorized by statute, such as product seizures, injunctions and even criminal penalties”).

²³⁵ In *United States v Vitek Supply Corp*, 144 F3d 476 (7th Cir 1997), Vitek Supply Corp. was convicted of criminal importation of banned substances that were later added to animal feed. *Id* at 476. Vitek argued that a named meat processing business had not suffered “loss” when it destroyed its cattle in response to a notice from the FDA that its

statutory and regulatory law governing product recalls makes claims about choice, manufacturers who choose to recall their products typically do so under pressure. Consumers presented with recall offers have choices, but recalls are not truly voluntary in several senses for them either.

In addition to the impediments to voluntariness discussed above, consumers who learn about what gets termed a voluntary recall of a product have little ability to know whether the measure was forced, encouraged, "influenced,"²³⁶ proposed, or ignored by the government agency with authority over the recall. These consumers might ascribe concern or beneficence to a recall described as voluntary until they are bombarded with demonstrations of more supposed voluntariness from other manufacturers. Because the word imputes a desire to the recalling entity that is absent in fact, it adds misinformation to the message.

Entities that recall defective products are of course less vulnerable to this kind of naïveté. As regulated entities, they presumably have a better idea of what the dubious adjectives mean. Should they wonder about the line between voluntary and mandatory, their managers, compliance officers, and in-house counsel enjoy access to legal expertise.

The naïveté problem for entities is one of time and internal cost. Recalls impose channels of communication between sellers and their customers that non-lawyer employees have to staff. These workers may reasonably wonder whether the initiative they administer originated in compulsion. Not-so-voluntariness generates at least confusion, if not cynicism: employees may wonder why their supervisors, in public statements to customers, modify the recall with this adjective. They might resent the extra work that the recall entails, suspecting that managers have commandeered their services for a public relations charade. Jettisoning the adjectives would permit employees of the manufacturer to focus on the remedial measure's substantive undertaking rather than its characterization.

livestock had been fed something illegal. *Id.* at 488. Destruction of the meat had been voluntary, the defendant claimed, and the sentence, which referenced a loss, was thus too heavy. *Id.* at 489–90. The court disagreed: "[W]e would not use the word 'voluntary' to describe the choice between destroying meat and judicially challenging a federal agency's interpretation of its regulations." *Vitek Supply Corp.*, 144 F3d at 488.

²³⁶ See text accompanying note 172.

For “recall” as a term of art, its chief vice and virtue are the same: it sounds an alarm. Regulators note that this word seizes attention like no other descriptor of post-sale rectification. High-decibel clamor in the term, according to one FDA official, is “an attention getter. It wakes up the public, it wakes up the doctors.”²³⁷ As we have seen, however, this agency defines recall very broadly to cover many responses, including relabeling.²³⁸ “The public” and “the doctors” do not need to be jolted awake to learn relatively trivial news.²³⁹

Congress ought to settle on a revision or at least a clearer definition of the word, and direct agencies that hold recall authority to work with this revised content. In place of “recall” I favor (but do not feel wedded to) “field safety correction,” proposed in 2005 but never published.²⁴⁰ Meanwhile, no definition of “recall” in any statute, regulation, or secondary source describes both accurately and generically the measure that product manufacturers take under federal agency auspices. Lack of clarity impedes decision-making for both manufacturers and consumers.

In sum: “Voluntary” needs to go, and take “mandatory” with it. The word “recall” can stay, but formal codifications should use it to describe only the most urgent response that a manufacturer installs after it learns about a danger in its product.²⁴¹ Sounding the loudest alarm less often would let manufacturers and regulators be heard when they say that a

²³⁷ Basile and Lorell, 61 Food & Drug L J at 260 (cited in note 135).

²³⁸ See note 149–151 and accompanying text.

²³⁹ See generally Tim Mullin, *Healthy Debate About “Recall Fatigue”* (Product Safety Blog July 9, 2012), online at <http://productsafetyblog.com/2012/07/healthy-debate-about-%E2%80%99crecall-fatigue%E2%80%9D/> (visited Sept 15, 2013) (noting that “warning principles” favor a hierarchy of differentiated words like danger, warning, and caution to indicate levels of risk).

²⁴⁰ See Part IV.B.2.

²⁴¹ One writer claims that this practice is followed in the United Kingdom. Koepfel, *Why Product Recalls Make You Less Safe* (cited in note 117). The UK consumer safety statute leaves room for interpretation on the point, defining “recall” as “any measure aimed at achieving the return of a dangerous product that has already been supplied or made available to consumers.” See generally The General Product Safety Regulations 2005, SI 2005/1803. Britain codified the General Product Safety Regulations consistent with its obligation to enact provisions mandated in a European Union directive. Directive 2001/95/EC of the European Parliament and of the Council of 3 Dec 2001 on General Product Safety, 2001 OJ (L 11) 5. “Recall shall take place as a last resort,” states the Directive, suggesting that reserving this term for relatively urgent threats to safety, the stance recommended in this Article, is also the policy of the European Union. *Id.* at Article 8, 2.

dangerous product must leave the market. From there, the corrective measures they install would move closer to voluntary for all participants in American consumer commerce.

