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(Almost) No Bad Drugs: Near-Total Products Liability Immunity for Pharmaceuticals Explained

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* Anita and Stuart Subotnick Professor of Law, Brooklyn Law School. This Article benefited from a range of contributions, foremost from my Brooklyn colleagues Karen Porter, who invited its creation for a symposium that she led in 2018, and Brian Lee, Christopher Beauchamp, and Neil Cohen, whose thoughtful comments and questions strengthened its announced explanatory claim. William Riggin and Benjamin Black provided excellent research assistance. Thanks also to the Brooklyn Law School faculty research support program.

I. Introduction

To say that pharmaceuticals enjoy near-total products liability immunity may invite an eyebrow or two to rise. The industry does not think of itself as immune from anything, and alarms about what products liability does to it have filled news reports for decades.[1] One important American newspaper regularly runs editorials about liability devastating the sector.[2] Almost every major manufacturer has shelled out millions in Department of Justice settlements—some have paid more—for misconduct related to the marketing of a prescription drug.[3] Add scandals,[4] bad press,[5] alarm about the death of innovation,[6] and

1. *See* Han W. Choi & Jae Hong Lee, *Pharmaceutical Product Liability*, *in* PRINCIPLES AND PRACTICES OF PHARMACEUTICAL MEDICINE 688, 688 (Lionel D. Edwards et al. eds., 2011) (observing that "[p]roducts liability actions against pharmaceutical companies are among the most widely publicized classes of suits in the United States and Europe").

2. *See Fighting a Tort Plague*, WALL ST. J., Jan. 7, 2019, at A16 (discussing an improper drug warning label case pending before the Supreme Court); *More Lawsuits = Higher Drug Prices*, WALL ST. J., Dec. 19, 2018, at A18 (expressing the view that more prescription drug litigation raises the cost of prescription drugs).

3. *See infra* Part II.A.

4. *See, e.g.*, Gardiner Harris & Duff Wilson, *Glaxo to Pay $750 Million for*

throw in a multibillion-dollar opioid crisis whose consequences in the law have commenced to round out a picture of the prescription drug industry in today's United States.[7] Prescription drugs are indeed deemed unacceptably bad in numerous venues, including popular discourse[8] and the boardrooms where decisions

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Sale of Bad Products, N.Y. TIMES (Oct. 26, 2010), https://perma.cc/6HFS-RKFH (last visited Nov. 2, 2019) (reporting on drug giant GlaxoSmithKline's operation of a plant in Puerto Rico that produced contaminated antidepressants, diabetes medications, and acid reflux drugs) (on file with the Washington and Lee Law Review).

5. *See, e.g.*, John LaMattina, *Pharma's Reputation Continues to Suffer—What Can Be Done to Fix It?*, FORBES (Jan. 18, 2013, 8:27 AM), https://perma.cc/X4PY-YLB8 (last visited Nov. 2, 2019) (attributing a lack of transparency in corporate activities and prioritizing profits over fair pricing practices to the pharmaceutical industry's poor reputation) (on file with the Washington and Lee Law Review).

6. *See, e.g.*, Clifton Leaf, *How Stale Is Innovation in Drug Discovery? Think: 5-Year-Old Yogurt*, FORTUNE (Mar. 6, 2018), https://perma.cc/Y9A6-NDDN (last visited Nov. 2, 2019) (pointing out that on average, thirty large and small biotech companies got just eleven percent of their 2017 revenue from drugs developed within the past five years) (on file with the Washington and Lee Law Review); *see also infra* Part IV.D.1 (discussing investors' frustrations with limited innovation in the development of new antibiotics).

7. This crisis has not yet manifested much accountability for the sector. *See* BARRY MEIER, PAIN KILLER: AN EMPIRE OF DECEIT AND THE ORIGIN OF AMERICA'S OPIOID EPIDEMIC 155–72 (2d ed. 2018) (corroborating this proposition); *see also* Rebecca L. Haffajee & Michelle M. Mello, *Drug Companies' Liability for the Opioid Epidemic*, 377 NEW ENG. J. MED. 2301, 2305 (2017) (observing that "opioid litigation has yet to financially dent the $13-billion-a-year opioid industry" and that opioid litigation "victories have all taken the form of settlements"). *See generally* Richard C. Ausness, *The Current State of Opioid Litigation*, 70 S.C. L. REV. 565 (2019) (provisioning a thorough and recent review of case law grouped under "opioid litigation" that omits personal injury actions altogether, confining itself to actions initiated by governments); Anita Bernstein, *Formed by Thalidomide: Mass Torts as a False Cure for Toxic Exposure*, 97 COLUM. L. REV. 2153 (1997) (concluding that units of government are safer than human plaintiffs from attacks on their prudence and entitlements to collect money); Jef Feeley, *Drugmakers Balk at Funding Opioid Epidemic Fix; Counting on Court Wins*, INS. J. (May 4, 2018), https://perma.cc/4AUP-YJST (last visited Oct. 12, 2019) (explaining that "[d]rug companies are in no rush to finance a solution to the opioid epidemic," preferring "to take their chances in court rather than pay billions of dollars to settle lawsuits blaming them for addictions") (on file with the Washington and Lee Law Review).

8. *See* Alison Kodjak, *Poll: Americans Support Government Action to Curb Prescription Drug Prices*, NPR (Mar. 1, 2019), https://perma.cc/K6EN-8SC8 (last visited Nov. 2, 2019) (discussing a nonpartisan poll which concluded that "a

to withdraw or pay up for injurious products get made.[9] Affronting genteel museums in New York and London so much that they turn down cash money is hard for a rich donor to do, but the opioid-profiteering Sackler family pulled off this dubious achievement in 2019 when the stench of its notorious prescription drug, OxyContin, grew too severe to overlook.[10] Law-based adversities that the drug sector continues to experience include product recalls,[11] criminal and civil penalties for violating the False Claims Act,[12] and governmental refusals to approve new

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majority [of Americans] welcome government action to help cut the cost of medications" because they think prescription drug prices are too high) (on file with the Washington and Lee Law Review).

9. *See* Angelica LaVito, *Johnson & Johnson Faces a Crucial Hearing Monday over Thousands of Talc Baby Powder Lawsuits*, CNBC (July 22, 2019, 10:52 AM), https://perma.cc/N858-CGJZ (last updated July 22, 2019, 2:23 PM) (last visited Nov. 2, 2019) (noting that it was Johnson & Johnson's decision to fight charges against it in court) (on file with the Washington and Lee Law Review).

10. *See* Elizabeth A. Harris, *The Met Will Turn Down Sackler Money amid Fury over the Opioid Crisis*, N.Y. TIMES (May 15, 2019), https://perma.cc/8FJP-HZZ7 (last visited Oct. 12, 2019) (reporting that the Metropolitan Museum of Art in New York City was going to "stop accepting gifts from members of the Sackler family linked to the maker of OxyContin" and that the Tate Modern in London and the Solomon R. Guggenheim in New York City had taken similar steps to distance themselves from the family) (on file with the Washington and Lee Law Review); Alex Marshall, *Museums Cut Ties with the Sacklers as Outrage over Opioid Crisis Grows*, N.Y. TIMES (Mar. 25, 2019), https://perma.cc/NYA8-Q79M (last visited Oct. 12, 2019) (reporting that Britain's National Portrait Gallery decided to cancel a planned $1.3 million donation from longtime Sackler benefactors) (on file with the Washington and Lee Law Review); Soo Youn, *NYU Langone No Longer Accepting Donations from the Sacklers, the Family that Owns Oxycontin Maker Purdue Pharma*, ABCNEWS (June 12, 2019, 2:57 PM), https://perma.cc/QT76-CW3Z (last visited Oct. 12, 2019) ("NYU Langone Health now says it is no longer taking money from the [Sackler] family—and it says it is 'evaluating' whether its Sackler Institute of Graduate Biomedical Sciences will hold on to its name.") (on file with the Washington and Lee Law Review).

11. *See, e.g.*, Sheila Kaplan, *Blood Pressure Medicine is Recalled*, N.Y. TIMES (July 16, 2018), https://perma.cc/C54Y-EE7G (last visited Oct. 18, 2019) (announcing the recall of a prescription blood pressure medicine by the Food and Drug Administration) (on file with the Washington and Lee Law Review).

12. 31 U.S.C. §§ 3729–3733 (2018). *See, e.g.*, Katie Thomas, *Insys, the Opioid Drug Maker, to Pay $225 Million to Settle Fraud Charges*, N.Y. TIMES (June 5, 2019), https://perma.cc/C5G6-ZURV (last visited Oct. 18, 2019) (covering opioids manufacturer Insys Therapeutics' $225 million settlement for a False Claims Act violation) (on file with the Washington and Lee Law Review).

drug applications and marketing strategies.[13] The locus of this Article, however, is liability—products liability in particular—where a court concludes that a manufactured object is defective or could be called defective by a factfinder following a trial. Drug manufacturers enjoy near-immunity from this consequence. This simple fact on the products liability ground continues to escape notice.

In clarifying an ill-understood state of the law, this Article holds back on overt condemnation of what it observes. Skepticism about the fit between products liability and prescription drugs certainly could be defended. Judges and juries competent enough to assess a more mundane product—a Coke bottle[14] or a power tool marketed to home hobbyists,[15] for example—might be unsuited to the task of determining defectiveness of a prescription drug. Instead of lamenting the absence of products liability redress for injured drug consumers, this Article pursues transparency about what it reports.

Transparent legal immunity for product-caused harm has elsewhere been attained. For example, Congress has chosen to block tort redress for persons injured by gun shootings and for municipalities that spend money on gun emergency services.[16] Closer to our subject, Congress enacted an alternative

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13. *See, e.g.*, Adam Feuerstein, *Sarepta Stumbles on FDA Rejection of a New Drug to Treat Duchenne Muscular Dystrophy*, STAT NEWS (Aug. 19, 2019), https://perma.cc/P63P-MFCJ (last visited Nov. 2, 2019) (detailing the FDA's rejection of a market application for a second drug that aimed to treat children with a rare muscle-wasting disease) (on file with the Washington and Lee Law Review).

14. *See generally* Escola v. Coca Cola Bottling Co., 150 P.2d 436 (Cal. 1944) (involving a products liability claim against a bottling manufacturer for an exploding bottle of Coke).

15. *See generally* Greenman v. Yuba Power Prods., Inc., 377 P.2d 897 (Cal. 1963) (en banc) (involving a defective power tool that could be used as a saw, drill, or wood lathe).

16. *See* Protection of Lawful Commerce in Arms Act, 15 U.S.C. §§ 7901–03 (2018)

> [A] purpos[e] of this chapter [is] as follows: to prohibit causes of action against manufacturers, distributors, and importers of firearms or ammunition products, and their trade associations, for the harm solely caused by the criminal or unlawful misuse of firearm products or ammunition products by others when the product functioned as designed and intended.

compensation scheme for harms linked to vaccines.[17] Agree or disagree with legislative decisions to insulate guns and vaccines from products liability, one can look up the particulars of these shelters. They state what they forbid and permit. Activists who succeeded in getting these exceptions enacted know what they achieved; opponents who wish to undo or modify these reforms understand what they have to change; injured persons can try to work around their barrier to redress.[18]

The prescription-drug version of immunity is different. Foremost, it is not absolute. All doctrinal tickets to court available for injuries by other products exist in principle for this one, and American courts are ostensibly willing to hear complaints that use any doctrine available elsewhere in products liability.[19]

Modern products liability identifies three categories of product defect;[20] courts insulate drug manufacturers from responsibility for all three.[21] The simplest type of defect is the manufacturing kind, where the product as made and sold did not conform to what its maker intended. Lapses of this kind are rare.[22] When a lapse occurs, it is trivial—cheap to defend, I

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17. *See* National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 *et seq.* (2018) (establishing "the National Vaccine Injury Compensation Program . . . under which compensation may be paid for a vaccine-related injury or death").

18. *See, e.g.*, Soto v. Bushmaster Firearms Int'l, LLC, No. FBTCV156048103S, 2016 WL 8115354, at *4 (Conn. Super. Ct. Oct. 14, 2016), *aff'd in part, rev'd in part*, 202 A.3d 262 (Conn. 2019), *and cert. denied*, Remington Arms Co. v. Soto, No. 19-168, 2019 WL 5875142, at *1 (U.S. 2019) (offering a novel application of negligent entrustment).

19. *See generally* Freeman v. Hoffmann-LaRoche, Inc., 618 N.W.2d 827 (Neb. 2000) (engaging with seven distinct liability doctrines).

20. *See* DAVID G. OWEN, PRODUCTS LIABILITY LAW 534–52 (2d ed. 2005) (summarizing the three types of product defects—manufacturing flaws, design flaws, and insufficient warnings of danger and instructions on safe use).

21. *Id.* at 549; *see also* Aaron D. Twerski, *The Demise of Drug Design Litigation: Death by Federal Preemption*, 68 AM. U. L. REV. 281, 281 (2018) (explaining that manufacturers of generic drugs are insulated from failure to warn and design defect claims).

22. Manufacturing defects are rare in part because drug-sector regulators impose quality standards that demand care in manufacture. *See* STEVEN GARBER, ECONOMIC EFFECTS OF PRODUCT LIABILITY AND OTHER LITIGATION 18 (2013) (noting that although manufacturing defect claims are uncommon, several were brought against drug manufacturers in the late 2000s). Every now and then a manufacturing plant runs into trouble with the FDA over quality

mean—because it injures only one unfortunate victim at a time. Plaintiffs impugn a deviation, not an entire line.

Because the next two types of defect are found in every unit that rolls into commerce, judicial willingness to accept either of them matters to manufacturers. Fortunately for them, courts are hostile to both defective design and defective warning claims. The former hostility is better known than the latter: scholars steadily report that design defect is almost unavailable to drug plaintiffs.[23] As Part II will soon document: yes indeed. The doomed nature of warning claims in drug products liability litigation is a subtler condition, but here too plaintiffs seldom succeed.

By any quantitative measure, plaintiff victories in drug litigation add up to insignificance. Manufacturing defects rarely happen and when they occur they have no impact on defendants' bottom line. Design defects almost never exist, as far as courts are concerned, and warning defects only slightly less infrequently exist. The next Parts build an explanation for this near-total immunity in two stages.

Manufacturer-friendly doctrine reviewed in Part III offers a necessary start, but it is only the first pass. "Because two Restatements favor manufacturers," "because preemption does the same," and "because causation is a high hurdle for plaintiffs" are not enough to explain near-total immunity.[24] They are true statements, but where did these stances come from? All have been resisted in litigation, scholarship, and Restatement fights inside the American Law Institute.[25] These struggles all could

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control. *See* R.D. McDowall, *Quality Assurance Implications for Computerized Systems Following the Able Laboratories Inspection*, 10 QUALITY ASSURANCE J. 15 (2006) (reporting that Able Labs ceased manufacturing operations, recalled its entire product line, and withdrew seven abbreviated new drug applications for failing to comply with regulations following an FDA inspection).

23. *See* OWEN, *supra* note 20, at 549 (suggesting that for purposes of products liability, drug design defects "simply [don't] matter"); *see also* Twerski, *supra* note 21, at 304 (writing that "drug design . . . has played only a minor role in drug litigation").

24. *See infra* Part III (discussing insulations from liability for drug manufacturers and barriers to redress for plaintiffs).

25. *See infra* Part III.A (discussing Restatement disagreements within the American Law Institute; *infra* Part III.B (exploring the role of federal preemption in prescription drug products liability cases); *infra* Part III.C (examining the role of causation as an element in a prescription drug products

have come out more favorably to consumers and plaintiffs. The drug sector scores low on popularity,[26] and numerous individuals get hurt by what it so profitably sells, the (relatively) rich and powerful pill-swallowing American senior citizenry prominent among them.[27] Why do judges, legislators, and attentive members of the public consistently let it win in court?

The current state of the law, I will argue, appears healthier than it really is because unexamined premises about the no-liability status quo sound plausible and soothing. Figurative pillars expounded on in Part IV hold up a barely-seen exception to accountability under the law. Prescription drugs look worthier of indulgence than other products, I contend, because they purport to increase welfare beyond the satisfaction of individual preferences.

Non-drug products warrant very little approval beyond the pleasure they give their users. If you like your ladder, shampoo brand, video game, power tool, automobile and so on, that's nice, but the rest of us have scant reason to care about the possibility that this object of your affection will leave the market for any reason, including too much liability. What you want to remain available for your purchase until you move on to something else holds value for you, but not necessarily for others.

Drugs are different.[28] In contrast to other products that purport only to give buyers what they want, this genre purports to give every one of us what we need. Judgments that transfer money to individuals at the expense of a savior-sector seem perverse. From there, a deferential-to-manufacturers consensus

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liability cases).

26. *See* Robert Cyran, *Big Pharma on the Hot Seat*, N.Y. TIMES (Jan. 12, 2017), https://perma.cc/NLA6-MUEX (last visited Oct. 20, 2019) (explaining that high prescription drug prices have made the pharmaceutical industry unpopular with the vast majority of Americans) (on file with the Washington and Lee Law Review).

27. On wealth held by the age cohort likely to take prescription drugs, see *The Rising Age Gap in Economic Well-being*, PEW RESEARCH CTR. (Nov. 7, 2011), https://perma.cc/2SNE-27YB (last visited Oct. 20, 2019) (observing that over the last quarter-century, "[t]he [o]ld [h]ave [p]rosper[ed] [r]elative to the [y]oung") (on file with the Washington and Lee Law Review).

28. *See* James A. Henderson, Jr. & Aaron D. Twerski, *Drug Designs Are Different*, 111 YALE L.J. 151, 168 (2001) (advocating an approach that takes the consumer interests of all potential patients into account, not just the welfare of those helped by a particular drug's proper prescription and consumption).

has emerged and holds steady. Part IV of this Article, which like the preceding Part includes the word "questionable" in its heading, explores four beliefs about supposed pharma-benevolence that appear shared by more than the industry, reaching the level almost of conventional wisdom. The figurative pillars help support one-sided results in court. As this Part elaborates, all four need attention. Every one of the pillars on examination turns out at least a bit shaky. Putting them forward for review starts a necessary discussion.

II. Case Law Reports Almost No Wins for Plaintiffs

Phrases like "almost no wins" and "near-total immunity" call for attention to a numerator and denominator.[29] For this purpose, the numerator is the number of wins in decisional law for plaintiffs—a win defined tolerantly as any judicial decision in which a court in the United States allowed an allegation of any kind of defect that would cover all manufactured units of a prescription drug (that is to say, design defect or warning defect) to reach a jury. The denominator is the total number of prescription drugs on the American market within reach of products liability. For different reasons, both numbers elude precise count. Enough information exists, however, to support a bottom-line conclusion: The ratio between the numerator and denominator is tiny—not zero wins for plaintiffs, but almost none.[30]

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29. *See generally* Eugene Kontorovich & Steven Art, *An Empirical Examination of Universal Jurisdiction for Piracy*, 104 AM. J. INT'L L. 436 (2010) (using this approach to study how often the international crime of piracy is prosecuted).

30. Several readers of this Article have commented that good results for plaintiffs extend beyond the "wins" or "numerator" that I have gathered. In an era of the so-called vanishing trial, almost all the action in litigation certainly occurs in settlements rather than outcomes that judges publish. *See generally* Marc Galanter, *The Vanishing Trial: An Examination of Trials and Related Matters in Federal and State Courts*, 1 J. EMPIRICAL LEGAL STUD. 459 (2004) (discussing the decline in the number of cases resolved by a jury trial in the United States). Moreover, as Neil Cohen has reasonably queried, what if the quality of prescription drugs is good? Even a tiny numerator could be too large in relation to the merits of contentions about defect. I agree. Yet even in a settlement perspective, it still bears notice that drug plaintiffs very seldom prevail in actions an outsider like me can know about—if only because limited

A. Cases That Could Qualify as Plaintiff Wins

No tallies undertake to count drug products liability actions decided in American courts. Aided by research assistants, I combed two broad sources of data: First, judicial decisions as gathered in Westlaw (including those classified as both published and unpublished), and second, the copyrighted text *Drugs in Litigation*, a compendium first published in 1976 and regularly updated on Lexis.[31] The first search worked with variations on familiar search terms—drug, prescription, product, design, warning, defect, pharmaceutical, liability—that we repeated until this jargon ceased to yield new hits. *Drugs in Litigation* lists names of pharmaceutical products in alphabetical order. Each of the two sources yielded cases not found in the other.

Neither *Drugs in Litigation* nor the Westlaw searches done for this Article put an age limit on materials eligible for inclusion, but the oldest cases present in both sources were decided in the 1970s. This result is consistent with the emergence of robust modern products liability during that decade,[32] and the scarcity until then of judicial decisions featuring drug-manufacturer defendants in particular. Courts did not instantly follow bold midcentury innovation from California and the American Law Institute on products liability,[33] and they added another level of delay before putting prescription drugs in the category.[34]

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success in court drives down the value of claims that negotiation resolves. *See* Uri Weiss, *The Regressive Effect of Legal Uncertainty*, 2019 J. DISP. RESOL. 149, 150–51 (2019) (discussing possible systematic biases).

31. *See* RICHARD PATTERSON, DRUGS IN LITIGATION: DAMAGE AWARDS INVOLVING PRESCRIPTION AND NONPRESCRIPTION DRUGS (Matthew Bender ed., 2018) (providing a "compilation of personal injury cases involving adverse reactions of prescription and nonprescription drugs" for legal and medical professionals).

32. *See* OWEN, *supra* note 20 at 23 (remarking that 1965 was "the birth of modern products liability law in America").

33. Most states did not adopt strict products liability as first recognized in *Greenman v. Yuba Power Products, Inc.*, 377 P.2d 897 (Cal. 1963), until several years after the Restatement (Second) of Torts formally set forth the doctrine in 1965. *See, e.g.*, Stewart v. Budget Rent-A-Car Corp., 470 P.2d 240, 243 (Haw. 1970) ("Although this court has never had the occasion to rule on this matter, it is the modern tread and the better reasoned view that strict liability in tort is a sound legal basis for recovery in products liability cases."); Johnson v. Am. Motors Corp., 225 N.W.2d 57, 66 (N.D. 1974) ("The status of the law . . . may be best clarified by the express adoption of the rule of strict liability in tort, as set

Some of the cases that turned up in the first haul ended up deleted. I removed vaccine cases from the tally because Congress went on to take this product out of the reach of products liability.[35] Also on the cutting-room floor landed cases from *Drugs in Litigation* where the drug in litigation was non-prescription; pro-plaintiff decisions that went on to be reversed; and decisions where courts focused on the culpability of individuals to the exclusion of attention to the drug. The much-cited *Lance v. Wyeth*,[36] in which the Pennsylvania Supreme Court made a rare choice to let a design defect claim survive, left the roster because the FDA had hustled the defective drug (a constituent of the notorious fen-phen) from the market nine years before the plaintiff filed her action:[37] *Lance* fell under the label of moot.

This preamble in place, approximately thirty brand names of drugs can stand for plaintiff wins in the sense that at least one injured person convinced a court to permit a claim of design defect or warning defect to survive summary judgment, and that decision in the plaintiff's favor was not overruled: Accutane,[38] Androgel,[39] Bendectin,[40] Chymopapain,[41] Clomid,[42] Delalutin,[43]

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forth in § 402A [of the Restatement of Torts] . . . ."); West v. Caterpillar Tractor Co., 336 So. 2d 80, 87 (Fla. 1976) ("We adopt the doctrine of strict liability as stated by the . . . Restatement (Second) of Torts § 402A.").

34. *Cf.* Paul D. Rheingold, *The Expanding Liability of the Product Supplier: A Primer*, 2 HOFSTRA L. REV. 521, 533 n.34 (1974) (arguing that the plaintiffs' bar got lucky in the 1960s when one defendant, Sterling Drug, persisted in appealing "a rather losing set of facts" in multiple courts, generating decisions that nurtured the fledgling doctrine of failure to warn).

35. *See supra* note 17 and accompanying text.

36. 85 A.3d 434 (Pa. 2014).

37. *See id.* at 437 (confirming that in September 1997, the FDA had announced that the drug at issue "would no longer be made available in the United States" and characterizing the personal injury and wrongful death lawsuits that followed as "a tidal wave of litigation").

38. Freeman v. Hoffman-La Roche, Inc., 618 N.W.2d 827, 846 (Neb. 2000).

39. *In re* Testosterone Replacement Therapy Prods. Liab. Litig., No. 14 C 1748MDL No. 2545, 2017 WL 2313201, at *7–11, (N.D. Ill. May 29, 2017).

40. Bendectin is a doubtful win. The plaintiff did prevail in *Mekdeci v. Merrell National Laboratories*, 711 F.2d 1510 (11th Cir. 1983) but subsequent decisional law, especially *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, (9th Cir. 1995), dealt a death knell to liability going forward.

41. Pollard v. Ashby, 793 S.W.2d 394, 403 (Mo. Ct. App. 1990).

42. Sullivan v. Aventis, Inc., No. 14-cv-2939-NSR, 2015 U.S. Dist. LEXIS 107360, at *33 (S.D.N.Y. Aug. 13, 2015).

Depakote,[44] Depo Medrol,[45] Dilantin,[46] Duphaston,[47] Duragesic,[48] Effient,[49] Elidel,[50] Halcion,[51] Isotretinoin,[52] Levaquin,[53] MER/29,[54] Ortho-Novum,[55] Panalba,[56] Parlodel,[57] Paxil,[58]

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43. Barson ex. rel. Barson v. E.R. Squibb & Sons, 682 P.2d 832, 841 (Utah 1984).

44. Barron v. Abbott Labs., Inc., 529 S.W.3d 795, 797 (Mo. 2017) (en banc); *see also* Smalley v. Lobas, JVR No. 359699, 1998 WL 1060870 (Pa. Oct. 1, 1998).

45. Proctor v. Davis, 682 N.E.2d 1203, 1215 (Ill. App. Ct. 1997).

46. PATTERSON, *supra* note 31, cites Mooney v. Parke, Davis & Co., No. 77-355-NPZ (Mich. Ct. Cl. Dec. 12, 1979); Alboher v. Parke-Davis, Inc., No. 80 Civ. 0046 (E.D.N.Y. Dec. 29, 1983); and Keenan v. Parke, Davis & Co., No. 84-1667 (R.I. Super. Ct. July 18, 1990), along with several wins for the manufacturer.

47. Glass v. Philips Roxane, No. C0270-762 (Cal. Super. Ct. Dec. 12, 1983)., *in* PATTERSON, *supra* note 31, at "Dydrogesterone."

48. Duragesic is a fentanyl patch. *See* Erony v. Alza Corp., 913 F. Supp. 195, 197 (S.D.N.Y. 1995) (allowing a failure to warn claim). *Janssen Pharmaceutical Products L.P. v. Hodgemire*, a decision that focused mainly on the admissibility of plaintiff's expert testimony, accepted a design defect claim. 49 So. 3d 767, 769 (Fla. Dist. Ct. App. 2010). In *DiCosolo v. Janssen Pharmaceuticals., Inc.*, the plaintiff brought what the court called a "nonspecific defect" claim and won an $18 million judgment, which was affirmed on appeal. 951 N.E. 2d 1238, 1245 (Ill. App. Ct. 2011).

49. Estate of DeMoss v. Eli Lilly & Co., 234 F. Supp. 3d 873, 879–80 (W.D. Ky. 2017).

50. Weiss v. Fujisawa Pharm. Co., 464 F. Supp. 2d 666, 669 (E.D. Ky. 2006).

51. Carlin v. Upjohn Co., 920 P.2d 1347, 1355 (Cal. 1996).

52. McCarrell v. Hoffmann-La-Roche, Inc., 153 A.3d 207, 225 (N.J. 2017); Mason v. Hoffman-LaRoche, No. 01-2416-CA (Fla. Escambia County Ct. Oct. 11, 2007), *in* PATTERSON, *supra* note 31 at "Isotretinoin."

53. Schedin v. Ortho-McNeil-Janssen Pharms., Inc., No. 08-5743 (JRT) (D. Minn. Dec. 7, 2010), *in* PATTERSON, *supra* note 31 at "Levofloxacin."

54. Successful litigation against MER/29 took place long enough ago that products liability diction had not yet found a home in case law. *See* Toole v. Richardson-Merrell Inc., 60 Cal. Rptr. 398, 418 (Cal. Ct. App. 1967) (affirming compensatory and punitive damages award without reference to defect). *See generally* Paul D. Rheingold, *The MER/29 Story—An Instance of Successful Mass Disaster Litigation*, 56 CAL. L. REV. 116 (1968) (providing a frontlines account of MER/29 litigation).

55. Brochu v. Ortho Pharm. Corp., 642 F.2d 652, 655 (1st Cir. 1981); McEwen v. Ortho Pharm. Corp., 528 P.2d 522, 544 (Or. 1974); Wooderson v. Ortho Pharm. Corp., 681 P.2d 1038, 1065 (Kan. 1984).

56. Miller v. Upjohn Co., 465 So. 2d 42, 47 (La. Ct. App. 1985).

57. Sandoz Pharms. Corp. v. Roberts, No. 94-CA-2757-MR (Ky. Ct. App. Aug. 9, 1996), *in* PATTERSON, *supra* note 31, at "Bromocriptine Mesylate."

58. Estates of Tobin v. Smithkline Beecham Pharms., 164 F. Supp. 2d 1278, 1287–90 (D. Wyo. 2001).

Phenergan,[59] Posicor,[60] Prempro,[61] Thyalis,[62] Topamax,[63] Vioxx,[64] Xanax,[65] Xarelto,[66] and Yutopar.[67]

Of foremost interest in this list is what is not on it. Opioids, for starters, are mostly though not entirely absent.[68] An especially salient omission is the most vilified of prescription opioids, OxyContin.[69] Its manufacturer, Purdue Pharma, has beaten numerous plaintiffs in decisional law.[70] Vioxx, the most infamous brand name present on the roster,[71] generated zero

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59. Wyeth v. Levine, 555 U.S. 555, 581 (2009).

60. Bryant v. Hoffmann-La Roche, Inc., 585 S.E.2d 723, 730 (Ga. Ct. App. 2003).

61. Fraser v. Wyeth, Inc., 992 F. Supp. 2d 68, 83 (D. Conn. 2014); Rivera-Adams v. Wyeth, No. 03-1713 (JAF), 2010 WL 5072541, at *3 (D.P.R. Dec. 8, 2010).

62. United States v. Lanpar Co., 293 F. Supp. 147, 154–55 (N.D. Tex. 1968).

63. Gurley v. Janssen Pharms., Inc., 113 A.3d 283, 295 (Pa. Super. Ct. 2015).

64. Humeston v. Merck & Co., No. ATL-L-2272-03-MT (N.J. Atlantic County Ct. Nov. 3, 2005); Garza v. Merck & Co., No. DC-03-841 (Tex. Dist. Ct. Apr. 21, 2006), *in* PATTERSON, *supra* note 31, at "Rofecoxib."

65. Shanks v. Upjohn Co., 835 P.2d 1189, 1196 (Alaska 1992).

66. *In re* Xarelto (Rivaroxaban) Prods. Liab. Litig., No. 2592, 2017 WL 1395312, at *4 (E.D. La. Apr. 13, 2017).

67. Tobin v. Astra Pharm. Prods., 993 F.2d 528, 545 (6th Cir. 1993).

68. Duragesic falls in the opioid category. *See* Erony v. Alza Corp., 913 F. Supp. 195, 197 (S.D.N.Y. 1995) (noting that Duragesic is a skin patch that contains the opioid fentanyl).

69. *See* Sujata S. Jayawant & Rajesh Balkrishnan, *The Controversy Surrounding Oxycontin Abuse: Issues and Solutions*, 1 THERAPEUTICS & CLINICAL RISK MGMT. 77, 78 (2005) (noting that OxyContin has received substantial attention for its "addiction liability and abuse potential").

70. *See*, *e.g.*, Bodie v. Purdue Pharma L.P., 236 F. App'x 511, 521 (11th Cir. 2007) (rejecting plaintiff's failure to warn claim); McCauley v. Purdue Pharma L.P., 331 F. Supp. 2d 449, 465 (W.D. Va. 2004) (ruling against OxyContin plaintiffs on causation); Williams v. Purdue Pharma Co., 297 F. Supp. 2d 171, 176 (D.D.C. 2003) (concluding that plaintiffs' OxyContin injury was not cognizable).

71. This painkiller generated litigation costly to its manufacturer. *See* Alex Berenson, *Merck Agrees to Settle Vioxx Suits for $4.85 Billion*, N.Y. TIMES (Nov. 9, 2007), https://perma.cc/U8Z2-TP5U (last visited Oct. 23, 2019) (noting Merck agreed to pay $4.85 billion to settle 27,000 lawsuits by individuals who were harmed by Vioxx) (on file with the Washington and Lee Law Review). Deciding to withdraw this drug wiped out $26.8 billion from Merck's market capitalization. *See* Walter T. Champion, Jr., *A Tale of Two Cities: A Commentary on the Media's Response to Personal Injury "Feeding Frenzies" as a*

published judicial conclusions on what about it could be deemed defective; the citations above are to two unpublished decisions. No thalidomide on the list either. Diethystylbestrol (DES), a never-patented hormone, was costly to its sellers in the 1980s,[72] but to this day lacks any judicial analysis of its defectiveness or manufacturer negligence because courts that ruled for DES plaintiffs seemed to presume product defect or breach of duty without discussing the issue.[73]

Several names that fill the list of plaintiff wins would be equally at home in the list of plaintiff losses. Patients who took some of these drugs, including but not limited to Bendectin, Dilantin, Duragesic, Ortho-Novum, and Paxil, brought personal-injury actions in court that failed.[74] Delalutin later went on to be exonerated by later studies and thus was not defective, said a New Jersey court after the *Barson* win for plaintiffs in Utah.[75]

The numerator is misleadingly large in other respects. The majority of the wins alleged warning defect, a cause of action increasingly vulnerable to preemption.[76] Design defect wins are extra tiny in number. The significant and enduring design defect win for plaintiffs—a case to take seriously not only when it was

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Result of the Vioxx and Silicosis Litigation, 31 WHITTIER L. REV. 47, 53 (2009) ("As a result of Merck's withdrawal of Vioxx, the company was forced to forgo any future profits from a recorded $2.5 billion in sales in 2003, and erasing $26.8 billion from its market capitalization.").

72. Anita Bernstein, *Markets of Mothers*, *in* TORTS STORIES 151, 165 (Robert L. Rabin & Stephen D. Sugarman eds., 2003).

73. *See id.* at 157 (noting that judges typically began by presuming that DES manufacturers could be found liable if the identification problem were resolved); *see also* Abel v. Eli Lilly & Co., 343 N.W.2d 164, 176 (Mich. 1984) (accepting plaintiffs' allegations as sufficient without discussing breach).

74. *See* Ealy v. Richardson-Merrell, Inc., 897 F.2d 1159, 1164 (D.C. Cir. 1990) (Bendectin loss); Eck v. Parke, Davis & Co., 256 F.3d 1013, 1024 (10th Cir. 2001) (Dilantin loss); Miller v. ALZA Corp., 759 F. Supp. 2d 929, 945 (S.D. Ohio 2010) (Duragesic loss); Lindsay v. Ortho Pharm. Corp., 637 F.2d 87, 95 (2d Cir. 1980) (Ortho-Novum loss). Dolan v. GlaxoSmithKline LLC, 901 F.3d 803, 816 (7th Cir. 2018) (Paxil loss).

75. Zweig v. E.R. Squibb & Sons, Inc., 536 A.2d 1280, 1283 (N.J. Super. Ct. App. Div. 1988).

76. *See infra* Part III.B (discussing preemption as an insulation to liability). Design defect claims are also vulnerable. *See* Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 493 (2013) (concluding that design defect claims are preempted when the drug is generic).

decided but going forward—is *Fraser v. Wyeth, Inc.*,[77] in which a Connecticut federal court wrote a published decision accepting a design defect claim for Prempro, a synthetic hormone still marketed as a menopause treatment.[78] Prempro actions came together in a robust multidistrict litigation in Arkansas;[79] the successor of Wyeth announced in 2012 that it expected to pay out more than $1.2 billion for the harms of this product.[80] But even this triumph for plaintiffs has a counter-record. Ample decisional law disagrees with *Fraser* and sides with the manufacturer.[81] The billion-plus settlement expense was announced two years before a court approved a design-defect claim,[82] suggesting that products liability was relatively insignificant even in drug design-defect liability's greatest hit.

Did my searches find every drug win that plaintiffs achieved in court? No: they are a first round of counting. That said, two concluding remarks about the numerator.

First, other searches could well cause the total to drop rather than rise, because a drug that suffers under decisional law can turn its fortunes around. The manufacturer of Bendectin—a marginal example of a drug deemed bad, but one I decided to leave in—took this morning-sickness pill off the U.S. market in

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77. 992 F. Supp. 2d 68 (D. Conn. 2014).

78. *See id.* at 84 (declining to grant defendant-manufacturer's motion for judgment as a matter of law as to plaintiffs' design defect claim).

79. *See generally In re* Prempro Prods. Liab. Litig., 549 F. Supp. 2d 1398 (J.P.M.L. 2008).

80. Jef Feeley, *Pfizer Paid $896 Million in Prempro Settlements*, BLOOMBERG NEWS (June 12, 2012), https://perma.cc/2JBT-AJ39 (last visited Oct. 23, 2019) (noting that the settlement resolved only about sixty percent of the lawsuits filed against Prempro) (on file with the Washington and Lee Law Review). The multidistrict litigation wrapped up in 2016. *See* Order, *In re* Prempro Prods., No. 03-CV-1507 (E.D. Ark. Mar. 9, 2016), ECF No. 3315 (closing the action "since all substantive issues have been resolved").

81. *See, e.g.*, Torkie-Tork v. Wyeth, 757 F. Supp. 2d 567, 573 (E.D. Va. 2010) (finding for defendant-manufacturer); Tsavaris v. Pfizer, Inc., No. 15-cv-21826, 2016 WL 375008, at *6 (S.D. Fla. Feb. 1, 2016) (granting defendant-manufacturer's motion to dismiss); Bailey v. Wyeth, Inc., 37 A.3d 549, 585 (N.J. Super. Ct. Law Div. 2008) (granting defendant-manufacturer's motion for summary judgment).

82. *Compare* Feeley, *supra* note 80 (announcing the settlement amount in 2012), *with Fraser*, 992 F. Supp. 2d at 84 (approving a design defect claim in a decision published in 2014).

1983 when claims grew profuse,[83] but Bendectin regained FDA approval and is back under another name.[84] Observers have applied the label of "junk science" to Bendectin plaintiffs' proffered evidence about defect and causation.[85] Second, because the list includes decisional law that merely denied summary disposition rather than entered judgments for plaintiffs, the wins list includes cases that may well have gone on to defeats.

B. The Enormous Denominator

Difficulties of how and what to count continue in what this Article calls the denominator—the population of prescription drugs that could have been accused in court of defectiveness. One way to think about the denominator is to consider the dollar size of this market. Estimates vary; all are high. In 2002, the Congressional Budget Office stated that over the next decade, Americans over the age of sixty-five would spend $1.8 trillion on prescription drugs.[86] More recently, a student author observed that "[c]onsumer spending on pharmaceutical drugs in the United States is nearly $425 billion per year and is estimated to top $600 billion by 2020."[87] Another student-authored assessment priced

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83. *See* Dennis Thompson, *Doctors Divided over Report That Popular Morning Sickness Drug Doesn't Work*, CHI. TRIB. (Jan. 18, 2018), https://perma.cc/Z6NX-994F (last visited Oct. 23, 2019) (reporting that the drug was voluntarily pulled from the market in the 1980s over concerns that it was linked with birth defects) (on file with the Washington and Lee Law Review).

84. Bendectin now goes by the rather odd name of Diclegis. *See* Margaret F. Steele, *FDA Allows Return of Drug for Morning Sickness*, WEBMD (Apr. 9, 2013), https://perma.cc/3N5Z-YWV4 (last visited Oct. 23, 2019) (stating that the revamped drug is "the only medication specifically approved to treat the stomach upset many women suffer from during pregnancy") (on file with the Washington and Lee Law Review).

85. *See* Lucinda M. Finley, *Guarding the Gate to the Courthouse: How Trial Judges Are Using Their Evidentiary Screening Role to Remake Tort Causation Rules*, 49 DEPAUL L. REV. 335, 338–39 (1999) (stating that the Bendectin litigation was a "significant source of controversy" regarding expert opinions "not well-founded in scientific methodology" and "departures from the mainstream of scientific opinion").

86. *See* Chad D. Silker, *America's New War on Drugs: Should the United States Legalize Prescription Drug Reimportation?*, 31 J. LEGIS. 379, 381 (2005) (estimating that Americans spent $140.6 billion on outpatient prescription drugs in 2001 alone).

87. Daniel Burke, Note, *An Examination of Product Hopping by*

American prescription drug spending at $323 billion in 2016, "after rebates and discounts."[88] A third of a trillion in 2017, said a U.S. government report.[89]

A more apples-to-apples approach looks for the number of drugs in the denominator. The Food and Drug Administration publishes lists of approved drugs in a reference nicknamed the Orange Book.[90] This text provides names, dosages, and data to guide substitution decisions for patients, but no count.[91] I tasked a research assistant with the laborious work of going through the Orange Book to estimate its tally, excluding entries that repeated the name of a drug with a different dosage. While a drug approved at both, say, ten milligram and fifty milligram doses could defensibly be counted as two separate products, I counted each named drug only once. The total of prescription drugs yielded was just over 15,000.

The real denominator is bigger, and not only because different numbers of milligrams do bespeak different products.[92] The FDA drops from the Orange Book drugs that lost their approval because of safety or efficacy concerns.[93] Such drugs were marketed before they left the compendium. Their number, though not officially known or counted, is greater than zero.[94]

Brand-Name Prescription Drug Manufacturers: The Problem and a Proposed Solution, 66 CLEV. ST. L. REV. 415, 419 (2018).

88. Cami R. Schiel, Comment, *Leveraging Pharma to Lower Premiums: Medical Loss Ratio Regulation in the Pharmaceutical Industry*, 2018 BYU L. REV. 205, 208 (2018).

89. *See* CTRS. FOR MEDICARE AND MEDICAID SERVS., NAT'L HEALTH EXPENDITURES 2017 HIGHLIGHTS 1 (2017), https://perma.cc/VQ7T-TVHD (PDF) (stating that prescription drug spending increased 0.4 percent to $333.4 billion).

90. *See* U.S. FOOD & DRUG ADMIN., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (2019) [hereinafter Orange Book] (identifying drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug, and Cosmetic Act).

91. *Id*. at 3-1–3-452.

92. *See id.* (separating different prescription drugs by milligram base).

93. *See id.* at iv ("The main criterion for the inclusion of any product is that the product is the subject of an application with an approval that has not been withdrawn for safety or efficacy reasons.").

94. Nicholas S. Downing et al., *Postmarket Safety Events Among Novel Therapeutics Approved by the US Food and Drug Administration Between 2001 and 2010*, 317 J. AM. MED. ASS'N, 1854, 1856 (2017).

Thirty divided by 15,000 equals 0.002. Imprecision in both numerator and denominator makes me hesitate to say that roughly 99.8% of prescription drugs are, as far as courts that hear products liability claims are concerned, good enough: but this percentage is close to accurate. One-fifth of one percent amounts to almost no bad drugs and near-total products liability immunity. I turn now to explaining this result.

III. Questionable Doctrinal Supports for Immunity

Doctrinal supports for drug manufacturers examined in this section are two Restatements of Torts, preemption of state-law tort claims against manufacturers, and causation as an element of a products liability prima facie case. These three sources are hardly the only advantages for defendants in this battleground, but they have interesting traits in common. What makes them questionable is more than just the trenchant and persuasive criticism they have been receiving for decades,[95] only some of which I review here. Separately and together, they reinforce the denial of redress while appearing relatively neutral on the surface. Three separate headwinds for plaintiffs and tailwinds for defendants have more force in combination than apart.

A. Restatement Insulations from Liability

American courts have at hand a uniquely American creation to aid their consideration of claims that litigants bring: Restatements.[96] Though published by a private nonprofit organization rather than a legislature or other state actor,[97] Restatements as published by the American Law Institute (ALI)

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95. *See, e.g.*, Joseph A. Page, *Generic Product Risks: The Case Against Comment k and for Strict Tort Liability*, 58 N.Y.U. L. REV. 853, 864 (1983) (offering a now 37-year-old critique of comment k to Section 402A of the Second Restatement).

96. *See* Charles E. Clark, *The Restatement of the Law of Contracts*, 42 YALE L.J. 643, 649–52 (1933) (examining the origin of the Restatements).

97. *See id.* at 644 (discussing the American Law Institute's role in drafting the Restatements).

strongly influence judge-made law. Through its Restatements, the ALI has installed "an unofficial form of codification."[98]

Judges who decide drug products liability actions continue to cite two Restatements of Torts.[99] The ALI published the original Restatement (here the "Second") in 1965 after committing to it in 1964.[100] The new one (the "Third" or the "Products Liability Restatement") came out in 1998 following ALI approval in 1997.[101]

Section 402A of the Second Restatement, the provision on products liability prepared by William Prosser, is the ALI's greatest hit; no other Restatement rule on any subject has been cited as much.[102] Decades after the arrival of a newer Restatement, courts continue to cite this creation. Section 402A does not say much about prescription drugs but what it does contain—a disquisition by Prosser labeled comment k—has also won considerable approval in the form of ample and ongoing citation.[103] This section has even entered statutory law.[104]

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98. *See* Arthur T. Von Mehren, *Some Reflections on Codification and Case Law in the Twenty-first Century*, 31 U.C. DAVIS L. REV. 659, 669 (1998) (noting that although the Restatements are only persuasive authority, they significantly influence the administration of justice).

99. *See, e.g.*, Burnham v. Wyeth Labs. Inc., 348 F. Supp. 3d 109, 112 (D. Mass. 2018) (relying on the Second Restatement of Torts in discussion of a design defect claim for a drug product); Freeman v. Hoffman-La Roche, Inc., 618 N.W.2d 827, 837–38 (Neb. 2000) (engaging with the Third Restatement in a consideration of drug product liability).

100. *See* RESTATEMENT (SECOND) OF TORTS (AM. LAW. INST. 1965) (stating that this text was approved for publication in 1963, except for an amendment of section 402A authorized in 1964).

101. *See* Robert D. Klein, *A Comparison of the Restatement (Third) of Torts: Products Liability and the Maryland Law of Products Liability*, 30 U. BALT. L. REV. 273, 276 (2001) (recounting that in May 1997, the membership of the American Law Institute approved publication of the Third Restatement).

102. FRANK J. VANDALL, A HISTORY OF CIVIL LITIGATION: POLITICAL AND ECONOMIC PERSPECTIVES 49 (2011); *see also* Andrew F. Popper, *Restatement Third Goes to Court*, 35 TRIAL 54, 56 n.13 (1999) (stating that according to records maintained by the ALI, § 402A has been cited more times than any other Restatement section).

103. *See, e.g.*, *In re* DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig., 888 F.3d 753, 772 (5th Cir. 2018) ("[T]he Texas Supreme Court has incorporated § 402A into its common law . . . and has considered comment k in the prescription-drug context." (internal citation omitted)); Smith v. Howmedica Osteonics Corp., 251 F. Supp. 3d 844, 848 (E.D. Pa. 2017) (discussing at length the applicability of comment k to the facts of the case); *In re* Testosterone

The other Restatement has different and complementary virtues. Prosser wrote Section 402A almost on a blank slate: "virtually no case authority and relatively little scholarship" underlaid his announcement of strict liability for this category of injury.[105] When the Third Restatement came out, products liability was a well-established subfield of torts.[106] From the start, the Products Liability Restatement could include extensive case citations in its Reporter's Notes. Although James Henderson and Aaron Twerski drafted some of their Restatement to codify the doctrinal outcomes they favored rather than those that courts had manifested in decisional law,[107] their blackletter rests much more on precedent than did its predecessor. It is also much fuller. Prescription drugs fall into the margin of Section 402A—just one comment among many—but occupy all of Section 6 in the Third Restatement.[108]

Judges and lawyers working in prescription drug liability appear well provisioned on the Restatement front, in short. Section 402A gives them famous, influential, and extraordinarily durable blackletter with a discussion of prescription drugs appended. Section 6 of the Third Restatement gives them specialist expertise in products liability and a base in modern cases. Neither Restatement's treatment of prescription drugs provides effective support for near-total products liability immunity, however.

Replacement Therapy Prods. Liab. Litig., No. 14 C 1748MDL No. 2545, 2017 WL 1836435, at *19 (N.D. Ill. May 8, 2017) (confirming that California, Tennessee, and Oregon "appear to have adopted" comment k).

104. *See* OR. REV. STAT. § 30.920 (2017) (codifying the substance of section 402A of the Second Restatement); *see also* S.C. CODE ANN. § 15-73-30 (2012) (codifying section 402A).

105. David A. Logan, *When the Restatement Is Not a Restatement: The Curious Case of the "Flagrant Trespasser"*, 37 WM. MITCHELL L. REV. 1448, 1457 (2011).

106. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY intro. (AM. LAW. INST. 1998) (acknowledging that when drafting the Third Restatement, the "Institute had before it thousands of judicial decisions that had fine-tuned the law of products liability in a manner hardly imaginable when Restatement Second was written").

107. OWEN, *supra* note 20, at 255–56.

108. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (AM. LAW. INST. 1965); RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 (AM. LAW. INST. 1998).

1. The Original Restatement

Liability provisioned in § 402A "extends to any product sold in the condition, or substantially the same condition, in which it is expected to reach the ultimate user or consumer."[109] Some examples: "an automobile, a tire, an airplane, a grinding wheel, a water heater, a gas stove, a power tool, a riveting machine, a chair, and an insecticide."[110] What about a prescription drug? Here the acclaimed text becomes—and remains—coy.

Prescription drugs as an object of regulation through liability turn up only in one of the comments to Section 402A, and the category is not labeled clearly. "Unavoidably unsafe products," begins comment k: "There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs."[111] Comment k then names as its example of this category the rabies vaccine developed in 1885 by the great French microbiologist Louis Pasteur: "Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous."[112] And then come the only explicit references to prescription drugs in the Second Restatement: "The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician."[113]

The products liability scholars who worked to supersede this provision have written that "Comment k to § 402A of the Restatement, Second, of Torts has caused confusion in prescription drug litigation, seemingly without end. Bidding farewell to Comment k is both justifiable and overdue."[114] Hard to disagree, starting with the caption of "unavoidably unsafe products." If we grant that the category exists, how do we know whether a particular product should be classified there? Prosser's

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109. RESTATEMENT (SECOND) OF TORTS § 402A (AM. LAW. INST. 1965).

110. *Id.* cmt. d.

111. *Id.* cmt. k.

112. *Id.*

113. *Id.*

114. James A. Henderson, Jr. & Aaron D. Twerski, *Drug Design Liability: Farewell to Comment k*, 67 BAYLOR L. REV. 521, 522 (2015).

poorly bounded diction—phrasing like "many other drugs, vaccines, and the like" and "many of which"—invites courts to regard prescription drugs as unavoidably unsafe but also permits them to reach a contrary conclusion. Paralleling the awkward drafting of Section 402A blackletter, which condemns "any product in a defective condition unreasonably dangerous," comment k says an unavoidably unsafe product "is not defective, nor is it *unreasonably* dangerous." What does this disjunctive mean? Is there a difference between being defective and being unreasonably dangerous? The text does not say.[115]

To the writers of the rival younger Restatement, the central wrongness of comment k lies in its misdescription of everything in products liability, not just the subset ostensibly identified in the exception it asserts. Comment k begins with "Unavoidably unsafe products" as its banner and then says a fraction of products fall into under this rubric.[116] Actually all of them do, Henderson and Twerski argue: "All products carry with them categorical risks of injury that cannot be eliminated by re-design without destroying the product's utility."[117] In other words, "not just *some* products"—the category that comment k purports to talk about—"but *all* products, are categorically dangerous."[118]

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115. In an article-length critique of comment k that goes beyond prescription drugs, still salient despite its advanced age, Joseph Page explains some of the incoherence of this comment with reference to drafting history inside the ALI. *See* Page, *supra* note 95, at 864 (suggesting that the genesis of comment k may help explain its blurred distinctions and "other mysteries"). Disagreement about whether to exempt prescription drugs from § 402A liability divided participants. *Id.* at 865–66. Members of the ALI introduced motions to write exemptions into the blackletter and the comments, all of which failed to pass. *Id.* Prosser drafted comment k after these proceedings, but what he wrote was neither a compromise between two positions nor a clarification of the debate. *Id.* at 864–68. James Henderson and Aaron Twerski, who jettisoned this provision, speculate that Prosser found the gray-zone status of a comment, neither a stark rule nor an exclusion, politically expedient when he worked to get his bold Restatement approved. *See* Henderson & Twerski, *supra* note 114, at 529 n.30 ("Restatement Reporters have, on occasion, agreed to address an issue in a [c]omment in order to bolster political support among the ALI membership for more salient positions in the black letter.").

116. *See* RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (AM. LAW. INST. 1965) ("There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use.").

117. Henderson & Twerski, *supra* note 114, at 526.

118. *Id.* at 527.

From there new layers of errors follow. Prosser captioned his comment "unavoidably unsafe products" rather than "prescription drugs." This diction choice made an open question about whether prescription drugs—some of them? all? most?—fall under the comment k nonliability rule with respect to design defect. The best-known judicial decision on this issue, issued by the California Supreme Court in 1988, concluded that all prescription drugs qualify as unavoidably unsafe products and thus are exempt from design defect liability.[119] But comment k does not say so explicitly, and other courts disagree.[120]

The trouble with comment k does not stop with the lack of clarity in it that rises to the level of incoherence. Restatements do not themselves change decisional law. Like a bad law review article or an unsound assertion in a treatise, problematic drafting in these works starts out as harmless error, so to speak. The living, ongoing, vital trouble with comment k is that judges still like what it has to say about liability for defective prescription drugs. Multiple decades after its publication—and also two decades after the ALI supplanted it with new Restatement blackletter—they cite it as authority. This implicit tribute is an honor for secondary writing deep in its middle age, but it confounds judges and lawyers who need answers.

2. The Newer Restatement

In contrast to the elusive, hard-to-parse comment k of the Second Restatement, Section 6 of the Third Restatement offers a full and cogent treatment of prescription drug liability. It has five subsections. The first announces that defective products of this

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119. *See* Brown v. Super. Ct., 751 P.2d 470, 482–83 (Cal. 1988) (concluding that "a manufacturer is not strictly liable for injuries caused by a prescription drug so long as the drug was properly prepared and accompanied by warnings of its dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution").

120. *See, e.g.*, Moss v. Wyeth Inc., 872 F. Supp. 2d 162, 174 (D. Conn. 2012) (deciding that the comment k exemption "applies on a case-by-case basis"); Bryant v. Hoffmann-La Roche, 585 S.E. 2d 723, 726 (Ga. Ct. App. 2003) ("[T]he *Brown* decision reflects the minority view among those jurisdictions to have considered the language of [c]omment k."); Shanks v. Upjohn Co., 835 P.2d 1189, 1193 (Alaska 1992) (declining to adopt *Brown*); Toner v. Lederle Labs, 732 P.2d 297, 308 (Idaho 1987) (refusing to find that comment k applies to all drugs).

category give rise to liability.[121] The second reiterates the tripartite conception of defect that pervades this Restatement: manufacturing defect, defective design, and inadequate instructions or warnings.[122] The third, Section 6(c), offers a novel standard for design defect: A prescription drug is defectively designed only if "reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients."[123] The fourth covers warning,[124] and the fifth subsection discusses retailers as sellers.[125] All blackletter in this section is clear.

The trouble with the Third Restatement lies in its "any class of patients" subsection, which has gained by far the most scholarly attention of the five.[126] While a prominent drug scholar gives it high praise, contending that if this rule has a shortcoming it is its insufficient attention to the interests of manufacturers,[127] most of this literature has expressed disagreement.[128] One scholar-critic calls its bottom line "overly protective of manufacturers."[129]

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121. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(a) (AM. LAW. INST. 1998) ("A manufacturer of a prescription drug or medical device who sells or otherwise distributes a defective drug or medical device is subject to liability for harm to persons caused by the defect.").

122. *Id.* § 6(b).

123. *Id.* § 6(c). On this literature, see OWEN, *supra* note 20, at 548–60 (gathering numerous citations from law reviews).

124. *Id.* § 6(d).

125. *Id.* § 6(e).

126. *See* George W. Conk, *Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?*, 109 YALE L.J. 1087, 1104 (2000) ("Academic commentators criticized the ALI's proposed rule for drugs as setting a 'super-negligence' standard of liability."); Dustin R. Marlowe, Note, *A Dose of Reality for Section 6(c) of the Restatement (Third) of Torts: Products Liability*, 39 GA. L. REV. 1445, 1446 (2005) (noting that the provision has received an "onslaught of criticism that questioned the provision's soundness and legitimacy in various law reviews and journals").

127. *See* Lars D. Noah, *This Is Your Products Liability Restatement on Drugs*, 74 BROOKLYN L. REV. 839, 848 (2009) (phrasing this point as "incomplete protection against inappropriate claims of defective design").

128. *See, e.g.*, Conk, *supra* note 126, at 1118 (discussing the shortcomings of a special liability regime for medical products); George W. Conk, *The True Test: Alternative Safer Designs for Drugs and Medical Devices in a Patent-Constrained Market*, 49 UCLA L. REV. 737, 737 (2002) (opining that the new Restatement's broader construction of design defect is inadequate); Richard L. Cupp, Jr., *Rethinking Conscious Design Liability for Prescription Drugs: The*

Henderson and Twerski started their Restatement work favoring complete and explicit immunity on design defect for this product.[130] They were going to recognize the other two types of defect for prescription drugs—manufacturing and warning—but deny judicial redress for design claims.[131] They softened their stance in the rule they eventually composed.[132] Section 6(c) of the Third Restatement makes it very difficult—though not quite impossible—for a plaintiff to bring this type of claim.

In contrast to what one finds in the law journals, judge-written writings on Section 6(c) cannot be called a rich literature. Courts had time before the 1998 issuance of the Third Restatement to absorb the teaching of this rule: in a pre-publication period, drafts of the entire Restatement circulated among the bench and bar.[133] Judges have not accepted Section 6(c) and they have not engaged with it much.[134] Here I review the record of thirty-two decisions.[135]

Restatement (Third) Approach Versus a Negligence Approach, 63 GEO. WASH. L. REV. 76, 80 (1994) (criticizing an early version of the Restatement's approach); Michael D. Green, *Prescription Drugs, Alternative Designs, and the Restatement (Third): Preliminary Reflections*, 30 SETON HALL L. REV. 207, 207 (1999) (calling the § 6(c) standard "idiosyncratic" and arguing for more attention to § 6(d), on warnings); Marlowe, *supra* note 126, at 1446 (suggesting that the belief that the new standard would promote uniformity in the law has yet to come to fruition).

129. Cupp, *supra* note 128, at 80.

130. *See* James A. Henderson, Jr. & Aaron D. Twerski, *A Proposed Revision of Section 402A of the Restatement (Second) of Torts*, 77 CORNELL L. REV. 1512, 1543 (1992) (noting that comment k exempts all prescription drugs from design claims).

131. *See id.* at 1536 (stating that their "first alternative version of comment k reflects a disposition to exclude judicial inquiry").

132. *See id.* at 1514 (allowing for manufacturer liability for design defect under certain conditions).

133. *See* James A. Henderson, Jr. & Aaron D. Twerski, *The Politics of the Products Liability Restatement*, 26 HOFSTRA L. REV. 667, 668 n.2 (1998) (describing years of discussion among sixty members "drawn from the bench, bar, and academia").

134. *See* Marlowe, *supra* note 126, at 1467 (opining that courts have failed to thoroughly consider or adopt Section 6(c)).

135. This record reached me first via a data set of thirty decisions curated by Aaron D. Twerski, current as of December 2017. Two new cases joined the list following Westlaw searches in September 2019. I thank Elaina Mansley for her assistance in the task of updating. Eight decisions are designated as unpublished; continuing to cast my net wide, *see supra* Part II.A., for the sake of including all available judge-written treatments of Section 6(c) in case law, I

Only one constituent of decisional law contains full-throated enthusiasm for Section 6(c).[136] In it the presiding judge of the Georgia Court of Appeals advocates for acceptance of Section 6(c); contrasts its rule favorably to its Second Restatement predecessor, comment k; quotes *Drug Designs are Different*,[137] the extended Henderson and Twerski defense of their rule, at some length; and justifies the choice of the Third Restatement to use risk-utility balancing as the test for design defect for most products while providing a separate rule for prescription drugs.[138] Judge Andrews did everything that careful and hard-working Reporters could want done with their blackletter, in short. But the Andrews opinion in *Bryant* is a concurrence; its embrace of Section 6(c) does not speak for the court.

Next most supportive of the design-defect test provisioned by Section 6(c) in the data set are decisions that say nothing bad about it. Courts write that their state has accepted the larger Third Restatement and so they are willing to go along with Section 6(c).[139] Arizona is prominent here. Five judicial decisions say that Arizona accepts the Restatement, good enough;[140] one

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include them.

136. *See* Bryant v. Hoffmann-La Roche, 585 S.E. 2d 723, 731–34 (Ga. Ct. App. 2003) (Andrews, J., concurring) (discussing § 6(c) at length and urging its adoption as the test for prescription drug design defects).

137. Henderson & Twerski, *supra* note 114.

138. *See Bryant*, 585 S.E.2d at 734 ("The test for prescription drug design defects set forth in . . . § 6(c) establishes a better reasoned alternative to the design defect test adopted by the majority . . . .").

139. *See, e.g.*, Madsen v. Am. Home Prods. Corp., 477 F. Supp. 2d 1025, 1037 (E.D. Mo. 2007) (acknowledging that Missouri has adopted the Third Restatement).

140. *See* D'Agnese v. Novartis Pharm. Corp., 952 F. Supp. 2d 880, 889 n.7 (D. Ariz. 2013) (quoting the Restatement (Third) of Torts); Gebhardt v. Mentor Corp., 191 F.R.D. 180, 185 (D. Ariz. 1999) ("[A]lthough no Arizona case has formally adopted the Restatement (Third) of Torts, Arizona has demonstrated a willingness to look to the Restatement (Third) as the current statement of the law." (internal citation omitted)); Staub v. Breg, Inc., No. CV 10-02038, 2012 WL 1078335, at *4 (D. Ariz. Mar. 30, 2012) (quoting the Restatement (Third) of Torts); Placencia v. I-Flow Corp., No. CV 10-2520, 2012 WL 5877624, at *3 (D. Ariz. Nov. 20, 2012) ("Courts in this District apply the Restatement (Third) of Torts to medical device design defect claims." (internal citation omitted)); Mills v. Bristol-Myers Squibb Co., No. CV 11-00968, 2011 WL 4708850, at *2 (D. Ariz. Oct. 7, 2011) ("Although plaintiff's design defect claim is pled pursuant to Restatement (Second) of Torts § 402(a), this no longer appears to be the correct standard . . . .").

expresses skepticism about Section 6.[141] One approval of Section 6(c) in a footnote talks only about the learned intermediary doctrine, not defective design.[142] An Iowa Supreme Court concurrence-and-dissent cites Section 6(c) with approval, but only to say that this blackletter establishes a "duty of care to balance risks and benefits of prescription drugs with respect to design."[143] Risk-utility balancing was what the Reporters wrote Section 6(c) to reject, not to impose. A New York federal trial court mentions Section 6(c) by-the-bye as an example of federally-regulated products in tort litigation.[144] An Iowa federal trial court observes that both the plaintiff and the defendant cited Section 6(c) when disagreeing about an affirmative defense, but the decision does not engage with the substance of this blackletter.[145] This cluster of case law expresses no approval of the Reporters' choice on design defect, and the content of Section 6(c) has no effect on the results.[146]

The last group of cases expresses mild hostility toward Section 6(c). In *Tersingi v. Wyeth*,[147] the First Circuit refused to apply Section 6(c) but did so in response to an eccentric reading of it as supposedly more pro-plaintiff than the risk-utility test.[148] In an unpublished federal decision, defendants urged the trial court

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141. *See* Harrison v. Howmedica Osteonics Corp., No. CIV 06-0745, 2008 WL 615886, at *1–2 (D. Ariz. Mar. 3, 2008) (requiring supplemental briefing on the applicability of Section 6(c)).

142. Rimbert v. Eli Lilly & Co., 577 F. Supp. 2d 1174, 1223 n.6 (D.N.M. 2008).

143. Huck v. Wyeth, Inc. 850 N.W.2d 353, 394 (Iowa 2014) (Hecht, J., concurring and dissenting).

144. *See In re* Methyl Tertiary Butyl Ether (MTBE) Prods. Liab. Litig., 438 F. Supp. 2d 291, 300–01 (S.D.N.Y. 2006) (ruling that federal regulation will not preclude a products liability action).

145. *See* Nicholson v. Biomet, Inc., 363 F. Supp. 3d 931, 937 (N.D. Iowa 2019) (limiting discussion of Section 6(c) to the parties' briefs on the issue). *Nicholson*, an action complaining about an artificial hip joint, mentions prescription drugs nowhere. *Id.* at 935.

146. *See, e.g.*, *Huck*, 850 N.W.2d at 394; *Adams*, 576 So. 2d at 732; *In re* MBTE Prods. Liab. Litig., 438 F. Supp. 2d at 300–01; *Nicholson*, 363 F. Supp. 3d at 937.

147. 817 F.3d 364 (1st Cir. 2016).

148. *See id.* at 369 ("Tersigni asks us to assume . . . that Massachusetts courts would recognize his negligent design claim, . . . and those same courts would grant a heretofore unrecognized exception to the general requirement of proof of a reasonable alternative design.").

to embrace Section 6(c), in response to which the court wrote that "the standard set forth in § 402A, as interpreted in recent Colorado Supreme Court cases, remains the governing standard as to a design defect theory."[149] In another unpublished federal court decision—this one from Texas—defendants also pointed to Section 6(c) to support their position, but the court would not accept it because its own "research had failed to unearth any Texas or Fifth Circuit authority applying the standard articulated in § 6(c) in the context of a design defect claim."[150] A couple of years later, a West Virginia federal court said the same thing: Texas law does not accept Section 6(c).[151] Going further, a Florida federal court refused to apply Section 6(c) while acknowledging that Florida had accepted the Restatement test for design defect for other products.[152]

A few courts have expressed open antipathy to the design defect test of Section 6(c). The Southern District of New York, refusing to apply its "any class of patients" test,[153] along the way called the Restatement "a treatise" in a tone that did not sound complimentary: "As a federal court sitting in diversity, the Court is hesitant to stitch into decades of Florida tort law one section of a treatise that its courts have shown no apparent interest in adopting over the past twelve years."[154]

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149. Lynch v. Olympus America, No. 18-cv-00512, 2018 WL 5619327, at *9 n.7 (D. Colo. Oct. 20, 2018). Like *Nicholson*, *Lynch* is a medical device case. *Id.* at *1–2.

150. Lea v. Wyeth LLC, No. 1:03-CV-1339, 2011 WL 13192701, at *12 (E.D. Tex. Oct. 28, 2011).

151. *See In re* Ethicon, Inc. Pelvic Repair, Sys. Prods. Liab. Litig., No. 2:12-cv-4301, 2014 WL 186869, at *6 (S.D. W. Va. Jan. 15, 2014) (rejecting Ethicon's contention that because several Texas cases rely on the Restatement (Third) regarding general products liability claims, Section 6(c) should be applied).

152. *See* Tillman v. C.R. Bard, Inc., 96 F. Supp. 3d 1307, 1345 (M.D. Fla. 2015) ("[R]egardless of whether the Third Restatement applies under Florida law in other contexts, in a medical device case such as this, Florida law does not apply this [i.e. Section 6(c)'s] standard.").

153. *See In re* Fosamax Prods. Liab. Litig., 742 F. Supp. 2d 460, 471 (S.D.N.Y. 2010) (specifying that the "any class of patients" test is met when the "foreseeable risks of harm posed by the drug are so high in comparison to the benefits that reasonable health-care providers, knowing of such foreseeable risks . . . would not prescribe the drug . . . for any class of patients").

154. *Id.* at 472.

The best-known reception of Section 6(c) in the courts is blunt speech from the Nebraska Supreme Court: "We conclude that § 6(c) has no basis in the case law. We view § 6(c) as too strict of a rule, under which recovery would be nearly impossible. Accordingly, we do not adopt § 6(c) of the Third Restatement."[155] The opinion for the court in *Bryant*, mentioned above to note a concurrence that contains the most pro-Section 6(c) judicially-authored language in the United States,[156] agreed with this bottom line, summarizing the Nebraska condemnation:

> In particular, § 6(c) has been criticized for its failure to reflect existing case law, its lack of flexibility with regard to drugs involving differing benefits and risks, its unprecedented application of a reasonable physician standard, and the fact that a consumer's claim could easily be defeated by expert opinion that the drug had some use for someone, despite potentially harmful effects on a large class of individuals.[157]

This negative reception should itself be received with caution. Judicial aversion to Section 6(c) does not mean that Section 6(c) gets design-defect law wrong.[158] Authors of opinions citing this blackletter do not know as much about products liability as the Reporters of the Restatement.

Shakiness here, in my view, is not substantive error within the Restatement but rather its lack of guidance for courts. Decisions about liability ought ideally to align with blackletter that judges and litigators consume to inform their work. No such guidance is present in doctrinal material that is still academic, so to speak, after having had more than twenty years to win judicial followers.

In sum, both the original treatment of products liability in the Restatement of Torts and its 1998 successor have in different

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155. Freeman v. Hoffmann-La Roche, Inc., 618 N.W.2d 827, 840 (Neb. 2000).

156. *See supra* notes 136 and 138 and accompanying text (discussing the Andrews concurrence praising Section 6(c)).

157. Bryant v. Hoffmann-La Roche, Inc., 585 S.E.2d 723, 727 (Ga. Ct. App. 2003) (citing *Freeman*, 618 N.W.2d at 840).

158. *See* Richard L. Cupp Jr., *Preemption's Rise (and Bit of a Fall) as Products Liability Reform:* Wyeth*,* Rigel*,* Altria*, and the Restatement (Third)'s Prescription Product Design Defect Standard*, 74 BROOK. L. REV. 727, 755–58 (2009) (arguing that just because courts have not looked fondly upon Section 6(c) does not mean the provision does not accurately capture courts' "general pulse" on design defect).

ways proved unsatisfactory as sources of guidance to courts. The Second Restatement's contribution to drug law is incoherent and has sowed confusion in American courts; the Third Restatement has failed to convince judges of its correctness. By including pharma-favoring doctrines, the Restatements have, however, helped to underscore a message that one particular product ought to be spared the hardships of products liability. This work has been functional enough to enlarge immunity.

B. Preemption as Insulation from Liability

American drug regulation has to live with a risk that oversight or even deceit by manufacturers will cause the agency in charge, the Food and Drug Administration, to approve or condone the sale of dangerous products.[159] Any regulatory design that depends on candor, accuracy, and diligence from the regulated sector needs safeguards against omissions and misstatement. Liability has traditionally been one such safeguard, but preemption impedes this opportunity to make prescription drugs safer.[160]

When accepted as an affirmative defense in court, preemption decrees that a drug-defect plaintiff will receive no relief, no matter how defective or dangerous the pharmaceutical product may be.[161] Obliteration of what would otherwise be a good legal claim is powerful medicine, and so one would think it needs a good reason to exist. At least in principle, state (tort) and federal (regulatory) law bring separate strengths to the task of

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159. *See* Mary J. Davis, *Time for a Fresh Look at Strict Liability for Pharmaceuticals*, 28 CORNELL J.L. & PUB. POL'Y 399, 436–37 (2019) (noting pressure from the pharmaceutical industry on the FDA).

160. *See id.* at 422 ("Federal preemption of state product[s] liability laws has dramatically limited the ability of consumers injured by pharmaceuticals to recover for those injuries . . . ."); *see also* David G. Owen, *Federal Preemption of Products Liability Claims*, 55 S.C. L. REV. 411, 413 (2003) ("[A]ny state law that *in fact* interferes with the operation of a federal statue or regulation thereunder contravenes the Supremacy Clause of the United States Constitution.").

161. *See* Hawkins v. Leslie's Pool Mart, Inc., 184 F.3d 244, 256 (3d Cir. 1999) (recognizing preemption as an affirmative defense); *see also* Owen, *supra* note 160, at 413 (discussing the effect of preemption in pharmaceutical products liability cases).

protecting health and safety.[162] And again in principle, a presumption against preemption holds up the state-law half of this partnership.[163]

The United States Supreme Court has issued several decisions on preemption of personal injury claims against prescription drug manufacturers.[164] The first of them ruled in favor of an injured plaintiff, holding that the Federal Food, Drug, and Cosmetic Act did not preempt a state-law failure to warn claim.[165] Because FDA regulations expressly permit manufacturers to alter an agency-approved drug warning unilaterally to reflect newly acquired information about risks and safety, the Court concluded that "impossibility preemption"—the kind of preemption that blocks a personal injury claim because the defendant could not have given the warning the plaintiff wanted while complying with what the FDA ordered at the same time[166]—did not bar a patient from seeking tort redress in the Vermont courts.[167] And so it appeared in 2009 that preemption doctrine has room for judicial redress of the injuries that prescription drugs cause.

Two other Supreme Court drug-preemption decisions, however, soon went on to block this opportunity. *PLIVA, Inc. v. Messing*[168] held in 2011 that failure-to-warn claims are

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162. *See* Amalea Smirniotopoulos, *Bad Medicine: Prescription Drugs, Preemption, and the Potential for a No-fault Fix*, 35 N.Y.U. REV. L. & SOC. CHANGE 797, 797–98 (2011) (describing the relationship as "symbiotic").

163. Like the separate-strengths premise, the presumption against preemption is honored in the breach. *See* Mary J. Davis, *Unmasking the Presumption in Favor of Preemption*, 53 S.C. L. REV. 967, 968, 1028 (2002) (attributing the "supposed presumption against preemption of state regulation" to the states' traditional police powers).

164. *See, e.g.*, Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 487 (2013); PLIVA, Inc. v. Messing, 564 U.S. 604, 626 (2011); Wyeth v. Levine, 555 U.S. 555, 581 (2009).

165. *See Wyeth*, 555 U.S. at 581 (concluding that the plaintiff's claim did not "obstruct the federal regulation of drug labeling").

166. *See* Michael M. Gallagher, *Clear Evidence of Impossibility Preemption After* Wyeth v. Levine, 51 GONZ. L. REV. 439, 476 (2016) (explaining that to succeed on an impossibility preemption, a drug company must demonstrate that complying with both federal and state regulation cannot be done).

167. *See Wyeth,* 555 U.S. at 573 ("Wyeth has failed to demonstrate that it was impossible for it to comply with both federal and state requirements.").

168. 564 U.S. 604 (2011).

preempted when the injurious drug is generic rather than brand-name,[169] and *Mutual Pharmaceutical Co. v. Bartlett*,[170] decided two years later, concluded that design-defect claims against generic-drug manufacturers are also preempted.[171] Eighty percent of drug prescriptions are for generics.[172] The pro-plaintiff holding in *Wyeth*, addressing the brand-name drug Phenergan, landed on a manufacturer in the minority.[173]

Lower courts continue this work of redress-blocking in their holdings on state-law fraud-on-the-FDA claims, where an injured consumer seeks to show that informed expertise did not guide approval of the defendant's drug.[174] Misstatements or material omissions made initially in a new-drug application, or later on in reports about adverse experiences, could steer the agency from the disapproval or prohibition that it would have chosen absent this intentional conduct by a manufacturer.[175] The reason for preemption is deference to agency competence, not judicial support for dishonesty.[176] And yet federal circuit courts, instead of uniting around preemption's central value and rejecting extensions of the doctrine that abet deceit, are split on

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169. *See id.* at 613, 626 ("[B]rand-name and generic drug manufacturers have different federal drug labeling duties.").

170. 570 U.S. 472 (2013).

171. *See id.* at 487, 493.

172. Robert C. Baker III, *Requiem for a Remedy: The Law and Economics of* Mutual Pharmaceutical v. Bartlett*'s Over-Preemption*, 74 MD. L. REV. ENDNOTES 81, 81–82 (2015).

173. *See id.* at 106 (explaining that even the FDA took notice of the "arbitrary disparity" resulting from *Wyeth* and *PLIVA*).

174. *See, e.g.*, Lofton v. McNeil Consumer & Specialty Pharm., 672 F.3d 372, 379 (5th Cir. 2012) (affirming summary judgment where plaintiff's theory of fraud rested solely on the FDA disclosure requirements).

175. For a different judicial concern on point, see Jennifer A. Surprenant, Note, *Should Preemption Apply in a Pharmaceutical Context? An Analysis of the Preemption Debate and What Regulatory Compliance Statutes Contribute to the Discussion*, 77 FORDHAM L. REV. 327, 359 n.250 (2008) (noting the Supreme Court in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), was concerned that requiring too much disclosure would burden the FDA in subsequent approvals). In *Buckman*, the plaintiffs complained of injuries resulting from the use of orthopedic bone screws. *Buckman*, 531 U.S. at 343. The Court concluded that state law fraud-on-the-FDA claims "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id.* at 350.

176. Baker, *supra* note 172, at 89.

preemption of state-law fraud-on-the-FDA claims.[177] Cases finding preemption of prescription drug claims extend a 2001 Supreme Court decision about fraud-on-the-FDA claims with respect to medical devices.[178] Medical device claims are expressly preempted, however, and drug claims are not.[179]

If skeptics on the federal bench fear that plaintiffs' lawyers will fling fraud accusations at defendants without care or justification, preemption by judicial inference (rather than by the express version of preemption) is not the solution to this problem. Twenty-first century federal pleading rules discourage litigation abuse of this stripe.[180] If these safeguards are for any reason insufficient, robust sanctions of attorney (and client) misconduct add more deterrence.[181] Applying preemption to block claims of fraud on the only agency with enough expertise to deliver safety and effectiveness in prescription drugs harms a carefully formed regulatory design and increases the risk of injury to persons who depend on these products.[182]

The preemption trendline has moved in only one direction since the early years of the century that brought *Wyeth v. Levine*. In 2002, the FDA for the first time in its hundred-year history

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177. *Compare* Garcia v. Wyeth Ayerst Labs., 385 F.3d 961, 966 (6th Cir. 2004) (preempted), *and* Lofton v. McNeil Consumer & Specialty Pharm., 672 F.3d 372, 380 (5th Cir. 2012) (same), *with* Desiano v. Warner-Lambert & Co., 467 F.3d 85, 97 (2d Cir. 2006) (not preempted); *see also* Christine A. Gaddis, Buckman *Extended: Federal Preemption of State Fraud on the FDA Statutes*, 69 FOOD & DRUG L.J. 113, 125–35 (2014) (evaluating the circuit split).

178. *See* Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 348 (2001) (holding plaintiffs' state-law fraud-on-the-FDA claims conflicted with federal law and were thus "impliedly pre-empted").

179. *See* Gaddis, *supra* note 177, at 116 ("The M[edical] D[evice] A[mendments] include[] an express preemption provision relating to medical devices.").

180. *See* Arthur R. Miller, *From* Conley *to* Twombly *to* Iqbal*: A Double Play on the Federal Rules of Civil Procedure*, 60 DUKE L.J. 1, 12 (2010) (commenting on the end of "notice pleading," which permits plaintiffs to assert claims relatively easily, and the rise of summary judgment for defendants).

181. *See* FED. R. CIV. P. 11 (establishing sanctions in litigation); MODEL RULES OF PROF'L CONDUCT r. 3.1 (AM. BAR ASS'N 1983) (provisioning a disciplinary rule on "meritorious claims and contentions").

182. *Cf.* Catherine M. Sharkey, *Direct-to-Consumer Genetic Testing: The FDA's Dual Role as Safety and Health Information Regulator*, 68 DEPAUL L. REV. 343, 344–45 (2019) (recognizing that the regulatory design and oversight allows the FDA to both promote health and safety and create innovative policy).

announced that its prescription drug regulations preempt personal injury claims.[183] Before 2002, the agency had taken the position that liability and regulation provide complementary, rather than conflicting, sources of consumer protection.[184] As for *Wyeth*, in 2019 the Supreme Court narrowed its generosity to plaintiffs with a follow-up decision that enlarged impossibility preemption.[185]

The FDA's ability to keep defectively-designed drugs from the market—and, going beyond design, to protect the consuming public from preventable harms caused by prescription drugs—depends on conditions that are separate from its good faith and regulatory competence. The agency needs adequate funding, independence from the sector it regulates, and the power to write meaningful standards that support its safety-and-effectiveness statutory mandate.[186] Preemption notwithstanding, it needs the complimentary function of tort

183. *See* Mary J. Davis, *The Battle over Implied Preemption: Products Liability and the FDA*, 48 B.C. L. REV. 1089, 1090–91 (2007) (explaining that state common law typically does not "treat federally approved prescription drug labeling as conclusive on the question of the label's adequacy").

184. *See id.* at 1094–95 ("Before 2002, the FDA maintained the position that its product approval process and state tort liability usually operate independently—each providing a significant, yet distinct, layer of consumer protection.").

185. *See* Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1679 (2019) (concluding that so long as the FDA is acting within the scope of its congressionally delegated authority, FDA labeling standards preempt state law). This outcome was anticipated. *See* Ian Millhiser, *Supreme Court Considers Whether Drug Companies Can Poison Patients and Get Away with It*, THINKPROGRESS (Jan. 4, 2019, 9:25 AM), http://perma.cc/P6ZY-L3T3 (last visited Oct. 11, 2019) ("There is a very good chance that it was actually impossible for Merck to comply with both federal and state law.") (on file with the Washington and Lee Law Review).

186. *See* Alison R. McCabe, *A Precarious Balancing Act—The Role of the FDA as Protector of Public Health and Industry Wealth*, 36 SUFFOLK U. L. REV. 787, 814 (2003) ("A lack of adequate funding to support the FDA's various functions and its specialized staff frustrates the agency's achievement of this balance."); *see also* Marc A. Rodwin, *Compensating Pharmaceutical Injuries in the Absence of Fault*, 69 FOOD & DRUG L.J. 447, 459 n.54 (2014) (suggesting that the Supreme Court's decision in *Buckman* was largely attributed to protecting the FDA's independence); Ariele Lessing, *A Supplemental Labeling Regime for Organic Products: How the Food, Drug, and Cosmetic Act Hampers a Market Solution to an Organic Transparency Problem*, 18 MO. ENVTL. L. & POL'Y REV. 415, 464 (2011) (emphasizing the need for manageable standards in supplemental label regulation).

liability to deliver what agency competence cannot supply on its own.[187] The trajectory of these necessary accompaniments is in decline.

C. Causation Doctrine as a Barrier to Redress

Pharmaceutical products illustrate how causation as an element of the products liability prima facie case advantages defendants and disadvantages plaintiffs. A consumer who can show that a drug is defective has more work to do before she wins: She must prove by a preponderance of the evidence that the defect caused the consequence she experienced.[188] Drugs almost never inflict a signature harm. When they increase risks of injury, whatever they cause usually could have occurred without exposure to the drug.[189] Exposure and injury are not enough for courts to conclude that the former caused the later.[190]

Vioxx offers an example of the problem. According to expert estimates, tens of thousands of individuals, perhaps 139,000, "suffered cardiac arrests that they would not have suffered absent Vioxx exposure. But who?"[191] Personal injury doctrine applies the preponderance standard to conclude that nobody may recover.[192] Merck had a different experience with Vioxx, of course,

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187. *See* Davis, *supra* note 183, at 1091 ("[M]ore exacting state tort law standards of care do not conflict, but operate concurrently with the federal requirements.").

188. *See* Sterling v. Velsicol Chem. Corp., 855 F.2d 1188, 1200 (6th Cir. 1988) (describing each individual plaintiff's responsibility to show "his or her specific injuries or damages were proximately caused" by the defendant).

189. *See id.* at 1235–36 (emphasizing the importance of physicians' differential diagnosis testimony in proving specific causation); Michel Auriche & Elizabeth Loupi, *Does Proof of Causality Ever Exist in Pharmacovigilance?*, 9 DRUG SAFETY 230, 230 (1993) (illustrating the non-uniqueness of drug defect injuries).

190. *See* Barbara J. Evans, *Seven Pillars of a New Evidentiary Paradigm: The Food, Drug, and Cosmetic Act Enters the Genomic Era*, 85 NOTRE DAME L. REV. 419, 438 (2010) (explaining that correlation studies are useful, but insufficient to show causation).

191. Nora Freeman Engstrom, *The Lessons of* Lone Pine, 129 YALE L.J. 2, 49 (2019).

192. *See* Keith A. Findley, *Defining Innocence*, 74 ALB. L. REV. 1157, 1203 (2011) ("[T]he preponderance standard typically defines that [proof of innocence] quantum in personal injury actions.").

and agreed to a $4.85 billion settlement after losing a few bellwether trials that followed aggregation.[193]

Going down the MDL road with a large settlement at the end of the journey is an exception rather than the rule, however. Most plaintiffs are stuck with doctrine that leaves them uncompensated when they cannot fulfill an element of their claim and once again we see Almost No Bad Drugs as a bottom-line result accounted for with reference to a barrier that seems neutral. Plaintiffs lose because courts apply preemption doctrine to their claims, we learned, and because Restatement blackletter makes it hard for them to win.[194] Now they lose also because their claims fail on causation.

Must they? Different causation doctrine—like different decisional law on preemption and different Restatement rules—would permit these persons to succeed. Denying compensation for harm whose existence is certain in the aggregate on the ground that individual plaintiffs cannot prove that the harm happened to them not only disadvantages hurt persons but also nurtures pollution and social disutility.[195] Scholars have proposed alternatives to the pro-defendant causation status quo.[196] In addition to the untaken option of contrary tort rules, different understandings of professional responsibility could require defense lawyers, consistent with their duty of candor to the court, to acknowledge that a dangerous drug caused injury at large notwithstanding the absence of evidence that it injured a particular individual.[197]

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193. Engstrom, *supra* note 191, at 51.

194. *See supra* Parts III.A and III.B.

195. *See* Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 CORNELL L. REV. 773, 775–76 (1997).

196. *See, e.g.*, *id.* at 833–40 (developing a standard that would (1) place the initial burden on manufacturers to show that they have conducted "minimal safety testing" on their products and (2) entitle plaintiffs to a presumption that an insufficiently tested product caused the harm); Engstrom, *supra* note 191, at 49 n.205 (giving as examples explicitly probabilistic causation, abandonment of the entire element of the prima facia case, and replacement of tort with a legislative-administrative compensation program).

197. *See* Frank M. McClellan, *The Vioxx Litigation: A Critical Look at Trial Tactics, the Court System, and the Role of Lawyers in Mass Tort Litigation*, 57 DEPAUL L. REV. 509, 525–30 (2008) (juxtaposing the competing responsibilities of candor to the court and loyalty to the client).

Causation doctrine is the subtlest of the three sources of near-total products liability immunity for pharmaceuticals surveyed here. The Third Restatement and the rise of preemption have long been characterized in law review writing as tendentious activism that favors defendants.[198] Both the Third Restatement and vigorous preemption are younger than the old school negligence prima facie case,[199] which makes their political antecedents easier to observe. Saddling plaintiffs with the cost of uncertainty or ignorance about causation appears on the surface conservative in a less partisan sense of the term.

IV. Questionable Beliefs and Premises Support the Supports

To review: Doctrinal barriers between injured consumers and redress in court surveyed in the last Part are not fixed facts of nature. Alternatives to all three of them—that is, oppositions to Restatement stances, preemption in its current ascendancy, and causation as a burden on plaintiffs—amply exist.[200] I move here to a second-order explanation of near-total products liability immunity for pharmaceuticals. Why these anti-plaintiff conditions persist in the face of articulate and principled opposition is the subject of this Part, whose headings recite shaky beliefs.

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198. *See, e.g.*, George W. Conk, *Punctuated Equilibrium: Why Section 402A Flourished and the Third Restatement Languished*, 26 REV. LITIG. 799, 804–06 (2007) (arguing that the Third Restatement's revision of products liability has fallen especially severely on consumers of medical products); Catherine M. Sharkey, *The Anti-Deference Pro-Preemption Paradox at the U.S. Supreme Court: The Business Community Weighs In*, 67 CASE W. RES. L. REV. 805, 835–36 (2017) (adverting to a strong stance on preemption of drug and medical device claims by the Product Liability Advisory Council, a trade association of manufacturers).

199. *Cf.* LAWRENCE M. FRIEDMAN, A HISTORY OF AMERICAN LAW 470–72 (2d ed. 1985) (discussing the history of modern causation doctrine); Robert Cary, *Torts: Playing the Blame Game: The Division of Fault Between Negligent Parties in Minnesota*—Daly v. McFarland, 39 WM. MITCHELL L. REV. 275, 278 (2012) (remarking that the history of this prima facie case spans many years and court decisions).

200. *See supra* Parts III.A–III.C.

A. "We Don't Need Liability, Because Consumers Can't Buy This Product Without a Learned Permission Slip."

Federal law in the United States provides that a prospective user needs permission from a licensed prescriber before she can buy a prescription drug.[201] Mandatory cooperation from a well-informed third party to make sales of this product lawful suggests that dangerous products can—again, at least in principle—be kept from harming consumers without any need for judicial condemnation.[202] Personal injury law that governs other products presupposes only a willing seller and buyer as needed to deliver an object alleged to have caused injury. Most of the time, nobody stands between the decision to sell and the impulse to buy.

This pillar underlying current law posits a barrier that distinguishes this product from others. Working at a professional distance from both buyer and seller, an expert has the power to veto a purchase of this good. Physicians and nurse practitioners who fulfill this barrier role with discernment and vigilance fend off danger. If consumers can acquire this product and ingest it without the learned approval that federal law demands, a premise about safety gets weaker.

They can. Strong evidence for the scalable prescription wall comes from the General Accounting Office (GAO), the federal agency tasked with assessing costs and benefits of federal policy.[203] The GAO has investigated breaches of the prescription wall between drug buyers and sellers.[204] Vendors sell prescription drugs to customers who lack prescriptions, the GAO has confirmed.[205] They also dispense prescriptions that are sham in

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201. 21 U.S.C. § 829 (2018).

202. *Cf.* KATHRYN B. ARMSTRONG & JENNIFER A. STAMAN, CONG. RESEARCH SERV., R43609, ENFORCEMENT OF THE FOOD, DRUG, AND COSMETIC ACT: SELECT LEGAL ISSUES 3–6 (2018) (explaining federal agency enforcement as provided in the Federal Food, Drug, and Cosmetic Act).

203. *See About GAO*, U.S. GOV'T ACC. OFFICE, https://perma.cc/HSJ2-M828 (last visited Oct. 14, 2019) (on file with the Washington and Lee Law Review).

204. *See* U.S. GEN. ACC. OFFICE, GAO-01-69, INTERNET PHARMACIES: ADDING DISCLOSURE REQUIREMENTS WOULD AID STATE AND FEDERAL OVERSIGHT 10–11 (2000), https://perma.cc/P4SF-SXNB (PDF) [hereinafter GAO DISCLOSURE] (detailing the GAO investigation).

205. *See id.* at 11 (explaining that at least twenty-five internet pharmacies

the sense of originating with these vendors rather than the buyer's physician and lacking attention to the welfare of the buyer as a patient.[206] In a series of separate reports, all titled "Internet Pharmacies" followed by a subtitle, the GAO has focused mostly on problems other than the scalable prescription wall (for example counterfeit drugs and authentic but inadvisable drugs sold online,[207] and the difficulty of holding offshore suppliers to United States law[208]) but along the way it has confirmed the widely held belief that what one needs to buy prescription drugs is less a doctor's note than a browser and a credit card.[209]

If you, Reader, want proof of a sort about widespread distribution of prescription drugs away from oversight by patients' physicians, peek at the spam that your web-based e-mail account filtered lately. I am writing about a fast-changing issue and so this generalization may be obsolete by the time you read it, but at the moment prescription drugs have been flogged aggressively online for decades without letup.[210] A research assistant generously risked drawing unwanted electronic attention to himself (I did warn him about the danger[211]) by

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included in the GAO study dispensed prescription drugs without prescriptions).

206. *See id.* at 12–13 ("The ability to buy prescription drugs from Internet pharmacies not licensed in the state where the customer is located and without appropriate physician supervision, including an examination, means that important safeguards related to the doctor/patient relationship and intrinsic to conventional prescribing are bypassed.").

207. *See id.* at 11 ("Internet pharmacies place consumers at risk from counterfeit or unapproved drugs, or drugs that were manufactured or stored under poor conditions.").

208. *See* U.S. GEN. ACC. OFFICE, GAO-14-386T, INTERNET PHARMACIES: MOST ROGUE SITES OPERATE FROM ABROAD, AND MANY SELL COUNTERFEIT DRUGS 4–5 (2014), https://perma.cc/F49G-H73U (PDF) (describing the mechanisms rogue internet pharmacies use to evade customs officials).

209. *See* GAO DISCLOSURE, *supra* note 204, at 11 (highlighting that individuals were able to obtain prescriptions with as little information as a credit card).

210. *See* Robert F. Forman, *Narcotics on the Net: The Availability of Websites Selling Controlled Substances*, 57 PSYCHIATRIC SERVS. 24, 25 (2006) (characterizing illicit online drug sales as a challenge for substance-abuse treatment).

211. *See generally* FRANK PASQUALE, THE BLACK BOX SOCIETY: THE SECRET ALGORITHMS THAT CONTROL MONEY AND INFORMATION (2015) (assembling evidence that businesses gather data about what individuals search and then

typing "ambien without prescription" and "viagra without prescription" into the search box in the upper right corner of his computer screen. His hit count was 3.6 million and 5.2 million respectively. Your mileage will vary but everyone's total will be large.

Some attempts to scale the prescription wall with an internet connection admittedly do fail.[212] The GAO found gaps between the number of purported sellers and the quantities of drugs delivered.[213] One of its studies identified thirteen popular prescription drugs, including the opioids OxyContin and Percocet—as well as blander stuff like Lipitor—and set out to place up to ten orders of each product from an array of online pharmacies located both inside and outside the U.S.[214] The GAO obtained sixty-eight units in its harvest, representing eleven of the thirteen drugs, but did not receive six orders it had paid for.[215]

Even taking into account this failure rate, however, the GAO's research provides ample data to refute the pillar-premise that prudent and well-schooled intermediaries familiar with their patients' bodies shelter them from the consequences of an improvident desire to buy and consume a dangerous product. "Most of the drugs—45 of 68—were obtained without a patient-provided prescription."[216] The GAO designed its study to include drugs that call particularly for learned-intermediary attention because their side effects can be severe or their

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exploit this information for profit).

212. *See* GAO DISCLOSURE, *supra* note 204, at 14 (describing increased enforcement efforts by the Justice Department).

213. *See* U.S. GEN. ACC. OFFICE, GAO-04-888T, INTERNET PHARMACIES: SOME POSE SAFETY RISKS FOR CONSUMERS AND ARE UNRELIABLE IN THEIR BUSINESS PRACTICES 4 (2004), https://perma.cc/BP2N-6L2X (PDF) [hereinafter GAO BUSINESS PRACTICES] (noting that researchers were able to obtain the "majority" but not all of the requested prescriptions).

214. *See id.* at 2 (explaining that most Internet pharmacies purported or appeared to be located in the United States, Canada, "and other foreign countries").

215. *See id.* at 17 (noting that the six unreceived orders "were for Clozaril, Humulin N, and Vicodin, and cost over $700 in total"). Several of the shipments arrived in shaky shape, without necessary temperature controls or in punctured blister packs. *Id.* at 4–5.

216. *Id.* at 7.

potential for abuse and addiction is high.[217] Buyers easily scaled the prescription wall to acquire drugs that really do need a barrier between demand and supply for the sake of safety, in short, at least circa 2004 when the GAO published "Business Practices." In the ensuing decade and a half, no significant change to law and regulation has made prescription drugs harder to buy without a learned permission slip.

Consumers scale the prescription wall not only by buying online but also by traveling. In 1992 the now defunct (but peer-reviewed and to this day respectably indexed on the National Institutes of Health website) *Western Journal of Medicine* published a study by two El Paso-based physicians who investigated their patients' habit of crossing the border to acquire prescription medications.[218] Most respondents surveyed said they bought drugs in Mexico, citing as their reasons lower prices and their ability to make purchases without a prescription.[219]

Similar to the ease of buying pharmaceutical products online, apparently unchanged since the GAO study of 2004, the appeal of traveling from the United States to Mexico for prescription drugs also persists, as a tour through travel websites will confirm.[220] Mexican law treats a few drugs as stringently controlled substances and will not permit their sale to visitors without a Mexican prescription,[221] but American tourists report easily buying over the counter a range of drugs that are prescription-only in the United States and paying only a fraction of the northern price.[222]

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217. *See id.* (stating that "physician supervision is of particular importance [for particular drugs] due to the possibility of severe side effects . . . .").

218. Paul R. Casner & Luis G. Guerra, *Purchasing Prescription Medication in Mexico Without a Prescription: The Experience at the Border*, 165 W.J. MED. 458, 512 (1992).

219. *See id.* at 513 ("81% stated that they had purchased medications in Mexico at one time or another, and 79% stated they were still [at that time] purchasing medications in Mexico.").

220. *See* Judy Hedding, *Buying Prescription Drugs in Mexico*, TRIPSAVVY, https://perma.cc/9XRY-E98C (last updated Dec. 31, 2018) (last visited Oct. 14, 2019) (providing tips for travelers going to Mexico to buy prescriptions) (on file with the Washington and Lee Law Review).

221. *See id.* (warning that although consumers may purchase most drugs in Mexico, it is illegal to carry them over the U.S. border without a prescription).

222. *See id.* (noting that most American tourist-purchasers are from states with convenient access to the Mexican border, primarily "Arizonians,

B. "We Don't Need Liability, Because Medically Informed Expertise Controls the Selection of Prescribed Therapies."

Very strong immunity rests on faith in expert knowledge.[223] Applied to the products liability category of failure to warn, this faith supports the learned intermediary rule, a doctrine that directs drug sellers to relay their warnings to physicians rather than patients—and that also withholds redress from patients who were not themselves warned—on the ground that physicians are abler than patients to understand the risks and the benefits of a particular drug therapy.[224] Although the Third Restatement expresses cautious support for warning patients directly about some drug risks,[225] judge-written exceptions to the learned intermediary rule that entitle consumers to receive warnings about the drugs they ingest remain rare.[226]

Deference to learned intermediaries also curbs design-defect liability.[227] Just as expert knowledge enables physicians to construe a warning intelligently and tailor the message in it to meet the needs of their patients, so too does that authority guide them to eschew unsound design in a drug and decline to prescribe it.[228] Section 6(c) of the Third Restatement writes esteem for expert knowledge into its blackletter.[229] Its test for design defect

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Californians, New Mexicans, and Texans").

223. *See infra* Parts IV.B.1 and IV.B.2 (addressing the role of expert physicians to cure demand-side and supply-side ignorance).

224. OWEN, *supra* note 20, at 608.

225. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d)(2) (AM. LAW INST. 1998) (providing that a manufacturer must warn the patient directly when it has reason to know that health care providers will not be able to reduce the risks about which warnings would give information).

226. *See* OWEN, *supra* note 20, at 610–14 (examining three exceptions—mass immunization programs, birth control pills, and direct-to-consumer advertising—where courts have written in an exception for the learned intermediary doctrine).

227. *See* Richard C. Ausness, *When Warnings Alone Won't Do: A Reply to Professor Phillips*, 26 N. KY. L. REV. 627, 647 (1999) ("I would conclude that the FDA's strict licensing process and the availability of trained personnel to serve as learned intermediaries provide adequate protection for consumers.").

228. *See id.* at 651 (noting that almost all jurisdictions recognize the learned intermediary doctrine as an efficient way to pass information to patients).

229. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(c) (AM. LAW INST. 1998) (discussing the foreseeability of harm).

posits "reasonable health-care providers" who know the "foreseeable risks and therapeutic benefits" of the pharmaceutical products they prescribe.[230] Although very few—arguably zero—courts have accepted the pro-defendant Section 6(c) test for design defect,[231] for this kind of defect the bottom line of almost no liability is consistent with a deference hypothesis.

Learned intermediaries, who populate defective-warning law officially and defective-design law, by tacit consensus that non-learned persons lack authority to opine on a molecular configuration, are understood to look out for the purchaser's interests through efforts that include, but are not limited to, their veto.[232] Their presumed refusal to supply prescription drugs that will do more harm than good is only the beginning of their work. According to this pillar-premise applied to failure to warn, learned intermediaries follow up on their initial prescription decisions by monitoring the health of the consuming patient and maintain big-picture awareness of how each prescribed drug interacts with other medications that the patient takes.[233]

To the extent that ignorance, rather than "learned" anything, guides decisions about buying and consuming a prescription drug, this rationale for the current pro-defendant state of doctrine becomes weaker. The word ignorance here refers to low levels of knowledge pertinent to the question of whether to choose or reject a therapeutic agent. Ignorance about prescription drugs is most obviously present within the lay patient as decider—I'll call this

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230. *Id.*

231. *See* cases cited *supra* notes 136–157 and accompanying text.

232. *See* Richard B. Goetz & Karen R. Growdon, *A Defense of the Learned Intermediary Doctrine*, 63 FOOD & DRUG L.J. 421, 434 (2008) ("The physician helps the patient understand which possible risks are most pertinent to the patient's specific situation."); *see also* Richard C. Ausness, *Will More Aggressive Marketing Practices Lead to Greater Tort Liability for Prescription Drug Manufacturers?*, 37 WAKE FOREST L. REV. 97, 109 (2002) (claiming that a medically trained prescriber is more capable than a patient to choose the right prescription drugs).

233. *See* Reyes v. Wyeth Labs., 498 F.2d 1264, 1276 (5th Cir. 1974) ("The choice [a prescribing physician] makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative."); *see also* Timothy S. Hall, *Reimagining the Learned Intermediary Rule for the New Pharmaceutical Marketplace*, 35 SETON HALL L. REV. 193, 242–43 (2004) (noting that for the rule to work, a patient must "have an ongoing opportunity to engage the physician in a dialogue about the efficacy of the treatment prescribed").

the condition of "demand-side ignorance"—but physicians also manifest it.

1. Demand-side Ignorance

Laypeople have no way to know much about the benefits and risks of prescription drugs they consume, and the rise of direct-to-consumer advertising has increased the consequences of their naïveté.[234] To say that when American drug sellers bypass physician intermediaries and promote their wares directly to the public they exploit and foment ignorance calls for some caution. The statement is correct enough, but a point of history deserves mention.

When it was newly formed, the American Medical Association, which tasks itself with speaking for physicians in the United States,[235] embraced scorn for all therapies "advertised directly to the laity" long before it ever insisted on clinical evidence for safety and effectiveness as necessary for a pharmaceutical product to deserve respectable dispensation.[236] Nineteenth-century therapeutic drugs fell into two groups. The "ethical" kind got listed somberly in a book called the United States Pharmacopoeia.[237] Patent medicines, whose undisclosed ingredients were mostly water, occupied the other category.[238]

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234. *See* Julie Donohue, *A History of Drug Advertising: The Evolving Roles of Consumers and Consumer Protection*, 84 MILBANK Q. 659, 677 (2006) ("A letter published in the New England Journal of Medicine said that DTC [advertising] 'may tend to undermine physician control over prescribing' and that 'most lay people are ill equipped to evaluate the efficacy or toxicity of drugs.'").

235. *See* Hayley Rosenman, Note, *Patients' Rights to Access Their Medical Records: An Argument for Uniform Recognition of a Right of Access in the United States and Australia*, 21 FORDHAM INT'L L.J. 1500, 1508 n.59 (1998) (citing the AMA's Membership Facts).

236. Donohue, *supra* note 234, at 665.

237. *See id.* at 664 (explaining that "ethical pharmaceuticals" were not advertised to consumers in part because of the efforts of organized medicine).

238. *See id.* ("Patent medicine . . . advertisements routinely made exaggerated claims about the effectiveness of their products and seldom disclosed their ingredients or risks.").

We moderns would probably not wish to swallow Lydia Pinkham's Vegetable Compound or "Kick-a-poo Indian Sagwa"[239] for what ails us, but the other nineteenth-century category was not much better: Today only a few drugs listed in the first edition of the buttoned-down Pharmacopoeia, published in 1820, are regarded as safe and effective.[240] Neither the 1900 decision of the *Journal of the American Medical Association* that urged physician readers not to prescribe any therapeutic agent sold by its maker directly to the lay public, nor its decree of the same approximate date that medical journals must reject advertisements for that type of product, originated in clinical rigor. This caveat noted, a 1997 shift certainly enlarged ignorance in the selection of prescription therapies by easing a particular type of direct-to-consumer advertising.[241]

American drug law never barred drug manufacturers from speaking directly to patients about their products, but throughout almost all the twentieth century pharmaceutical manufacturers confined their marketing efforts to physicians.[242] After the rise of a consumer movement in the 1970s that encouraged patients to think of themselves as buyers entitled to information, drug manufacturers shifted their efforts to speak to this customer base.[243] The FDA's 1997 announcement of conditions that in its view made broadcast direct-to-consumer advertising acceptable encouraged these businesses to move their spending into television commercials.[244] The 1997 directive, in place for the

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239. *See id.* (giving examples of patent medicines sold under trademarked names).

240. *See id.* (listing "digitalis, morphine, quinine, diphtheria antitoxin, aspirin, and ether").

241. *See id.* at 685–86 (detailing the FDA's 1997 Draft Guidance, which permitted broadcast advertisements of prescription drugs).

242. *See id.* (identifying a shift in the early 1900s wherein the AMA's focus centered on deference to professional medical judgment).

243. *See* Livia Gershon, *Should Drug Makers Advertise?*, JSTOR DAILY (Mar. 8, 2018), https://perma.cc/K4XG-FQ6K (last visited Oct. 27, 2019) ("[I]n the '70s, new consumer rights groups like Ralph Nader's Public Citizen began agitating for more patient-directed information, resulting in the requirement of patient package inserts.") (on file with the Washington and Lee Law Review).

244. Wayne L. Pines, *DTC TV Ad Policy Faces Challenges*, FDA ADVERT. & PROMOTION MANUAL NEWSL., June 2017, at 20.

most part today, rested on a belief that compliance would curb deception and manipulation in these communications.[245]

When a team at Yale University undertook to review all English-language direct-to-consumer advertisements aired in the United States from January 2015 to 2016 to investigate how well they hew to FDA criteria,[246] the researchers disapproved of what they found: "Few broadcast DTC ads were fully compliant with FDA guidelines. The overall quality of information provided in ads was low, and suggestions of off-label promotion"[247]—a move that flat-out violates the Federal Food, Drug, and Cosmetic Act as it is understood by the FDA and in the courts[248]—"were common for diabetes medications."[249] The 2017 expenditure of $6.1 billion on direct-to-consumer advertising bought a great deal of (mis)communication.[250] Back in the late 1990s, when both the FDA advertising directive and Restatement were new, drug

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245. *See* FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS 2 (1999), https://perma.cc/EV2N-V4GU (PDF) ("The approach presumes that such advertisements . . . . [p]resent a fair balance between information about effectiveness and information about risk . . . . [and] [c]ommunicate all information relevant to the product's indication (including limitations to use) in consumer-friendly language.").

246. Kristina Klara et al., *Direct-to-Consumer Broadcast Advertisements for Pharmaceuticals: Off-label Promotion and Adherence to FDA Guidelines*, 33 J. GEN. INTERNAL MED. 651 (2018).

247. *Id.*

248. *See, e.g.*, *In re* Neurontin Mktg. & Sales Practices Litig., 712 F.3d 21 (1st Cir. 2013) (prohibiting fraudulent or misleading marketing of off-label uses for FDA-approved drugs); United States ex rel. Bergman v. Abbot [sic] Labs., 995 F. Supp. 2d 357 (E.D. Pa. 2014) (same). On the FDA's understanding of the statute, see U.S. FOOD & DRUG ADMIN., MEDICAL PRODUCT COMMUNICATIONS THAT ARE CONSISTENT WITH THE FDA-REQUIRED LABELING—QUESTIONS AND ANSWERS: GUIDANCE FOR INDUSTRY (2018) https://perma.cc/WHL4-XGUH (PDF) [hereinafter MEDICAL PRODUCT COMMUNICATIONS].

249. Klara, supra note 246, at 655.

250. *See* Laura Entis, *DTC Pharma Ad Spending Slipped 4.6% in 2017: Kantar*, MM&M (Mar. 12, 2018), https://perma.cc/FS3L-DYQZ (last visited Oct. 27, 2019) (reporting that magazine and digital advertisement spending suffered big hits and fell 22.7% and 34.4% respectively) (on file with the Washington and Lee Law Review); *but see* Beth Snyder Bulik, *AbbVie, Pfizer Drive 2017 Pharma Ad Spending Above 2016's Tally*, FIERCEPHARMA (Jan. 12, 2018, 11:39 AM), https://perma.cc/5Z9F-AXCQ (last visited Oct. 27, 2019) (reporting that pharma spending on national television advertisements in 2017 climbed by more than $330 million from the previous year) (on file with the Washington and Lee Law Review).

manufacturers had spent much less on this advertising.[251] Whatever quantity of consumer confusion and ignorance these ads sow is correlatively much greater now.

Readers who have seen commercials for drugs on television might feel inclined to shrug because the products advertised in this medium are so banal. Prescription drugs for heartburn, hay fever, and high cholesterol may or may not be well formulated but they seem unlikely to end up accused in court of defectiveness, if only because it is hard to imagine them doing enough mischief to draw contingent-fee litigation.

But this industry, which takes a MeToo approach to intellectual-property innovation,[252] favors familiarity and repetition also in its efforts to increase sales.[253] Drug manufacturers habitually return to old products and old approaches to marketing rather than try something new, and their recourse to direct-to-consumer television advertising has followed the same pattern: allergies on TV yesterday, more of the same plus cancer and Alzheimer's disease added today.[254] A newer arrival in the roster of television-commercial conditions, constipation that results from heavy use of opioids, seems to hark back to the old era because constipation is only discomfort, not a fatal illness.[255] Not all versions of this gastric condition have the same import for products liability law, however. Targeting new

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251. *See* CONG. BUDGET OFFICE, PROMOTIONAL SPENDING FOR PRESCRIPTION DRUGS 1 (2009) https://perma.cc/6KQT-K5ZF (PDF) ("Until the late 1990s, pharmaceutical manufacturers confined their marketing efforts largely to physicians and other health care providers.").

252. *See infra* Part IV.D.1.

253. *See* Kalman Applbaum, *Pharmaceutical Marketing and the Invention of the Medical Consumer*, 3 PLOS MED. 445, 446 (2006), https://perma.cc/LF43-44BP (PDF) ("Promoting consumer familiarity with drugs is one example of the very broad influence of the pharmaceutical industry.").

254. *See* Bruce Horovitz & Julie Appleby, *Prescription Drug Costs Are Up; So Are TV Ads Promoting Them*, USA TODAY (Mar. 16, 2017), https://perma.cc/X6PK-XAGJ (last visited Oct. 27, 2019) ("For years, the DTC industry was mostly focused on drugs that relieved long-term, typically non-fatal afflictions like heartburn (Nexium), allergies (Claritin) and high cholesterol (Lipitor).") (on file with the Washington and Lee Law Review).

255. *See id.* ("More recently . . . advertising has focused on cancer and illnesses affecting seniors, such as Alzheimer's disease. Ads for drugs that target constipation caused by other drugs—opioids—hit the scene last year, reflecting the large numbers of people taking painkillers.").

drug advertisements to a population whose judgment is relatively likely to be impaired by dependency or addiction will, *ceteris paribus*, increase risks in the aggregate. Unwise choices refute the understanding—stated expressly in the Third Restatement and held tacitly elsewhere—that "reasonable health-care providers" who know about "foreseeable risks and therapeutic benefits" steer the rudder of the drug-decision ship.[256]

As for the effects of demand-side ignorance in particular, direct-to-consumer advertising received early praise as an alleviator of this problem in the commercial-speech decision known informally as *Virginia Pharmacy*,[257] which, in 1976, invalidated on First Amendment grounds a state prohibition on pharmacists' advertising the price of prescription drugs.[258] Virginia's prohibition of advertising meant that consumers had been "kept in ignorance," wrote Justice Blackmun for the Court.[259] Today, direct-to-consumer advertising does indeed relay some useful information to laypeople who benefit from what they learn.[260]

But it also misinforms. According to one review, this genre of advertising implicitly and unhelpfully denies that behavior modification could work better than a drug to alleviate the patient's medical condition.[261] Half the consumers who responded to a survey reported their inaccurate belief that drug ads must be approved by the government before they may air.[262] FDA

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256. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(c) (AM. LAW INST. 1998).

257. Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748 (1976).

258. *See id.* at 776–77 (holding that the ban could not be justified on the basis of Virginia's interest in "maintaining a high degree of professionalism on the part of licensed pharmacists").

259. *Id.* at 769.

260. *See* C. Lee Ventola, *Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic?*, 36 PHARMACY & THERAPEUTICS 669, 673 (citing evidence that exposure to advertising enlarges the dialogue between patients and physicians, and causes "small, but statistically significant" increases in patient compliance).

261. *See id.* at 674 ("By promoting a drug as the solution to a health problem, these advertisements may lead viewers to believe that adopting healthy behaviors, such as a good diet and exercise, are ineffective or unnecessary.").

262. *See id.* (confirming that consumers "place unwarranted trust in DTC

disciplinary records identify a pattern related to the focus of this Article: In the aggregate, advertisements targeted to consumers overstate the benefits and understate the detriments of prescription drugs.[263]

Even "ask your doctor," the helpful-sounding tagline that has dangled on many ads for decades,[264] turns out misinformative on the ground. For starters, there isn't much time to ask. Researchers estimate that the average American consumer spends many more hours a year hearing drug commercials than talking to a physician.[265] Although a perception that the number of minutes per office visit has been dropping is not accurate,[266] physicians consistently report in surveys that they lack enough time in office visits, especially for preventive care.[267]

In 1995, when the current direct-to-consumer advertising era was young, the FDA contrasted what it intends "ask your doctor" to mean with how patients interpret this phrase.[268] The FDA said it wants to warn consumers that "specific vigilance" is necessary for a safe and effective encounter with this product—in other words, that they should ask their doctors for the guidance they

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ads").

263. *See id.* (stating DTC advertisements encourage drug over-utilization and promote new drugs before safety profiles and adverse effects are fully known).

264. *See* Sidney Kessler et al., *The Genesis of Robitussin's "Ask Your Doctor" Campaign—The Prevalent Theme of Pharmaceutical Advertising for Four Decades*, 9 INNOVATIVE MARKETING 69, 69–75 (2013).

265. *See* David C. Vladeck, *The Difficult Case of Direct to Consumer Drug Advertising*, 41 LOY. L.A. L. REV. 259, 269–70 (2007) ("[T]he average American now views 'as many as 16 hours of prescription drug advertisements per year, far exceeding the average time spent with a primary care physician.'").

266. *See* Meredith K. Shaw et al., *The Duration of Office Visits in the United States, 1993 to 2010*, AM. J. MANAGED CARE (Oct. 16, 2014), https://perma.cc/A2VG-DC3J (last visited Nov. 1, 2019) ("From 1993 through 2010, reported visit duration increased over time from 17.9 minutes to 20.3 minutes for primary care visits (P <.001) and from 19.0 minutes to 21.0 minutes for specialized visits (P <.001).") (on file with the Washington and Lee Law Review).

267. *See id.* ("Time constraints are one of the most cited reasons by physicians for not providing preventive care as often as guidelines would dictate.").

268. *See* Public Hearing Notice, 60 Fed. Reg. 42,581 (Aug. 16, 1995) (soliciting patient feedback on the direct-to-consumer promotion of prescription drugs to better understand their views and concerns).

need[269]—but consumers hear "general reassurance" that the advertised drug will treat their conditions safely and effectively. "Ask your doctor" comes across to consumers as "seek this product from the authority figure who can give it to you." One study asked patients what they would do if they requested a prescription and their doctor refused.[270] Almost half of respondents hewed to the FDA ideal by saying they would accept this answer, but a quarter said they would try to talk the doctor into complying and another quarter said they would seek the prescription from another provider.[271]

Online ratings of physicians, written and posted (ostensibly) by patients, increase the impact of demand-side ignorance.[272] These scores and commentary undeniably furnish pertinent information. Old school personal referrals on which patients would otherwise have to rely could omit or downplay what they want to know; testimony about experiences in a medical office can have unique value for prospective patients who peruse online lists of providers.[273] As judgments of physician competence, however, these reviews give wrong answers. One recent study of physicians in eight specialties found that although consumer ratings are consistent across platforms, they do not align with better-informed assessments of physician quality, including expert-written performance measures, peer-review scores by

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269. *See* Barbara J. Tyler & Robert A. Cooper, *Blinded by the Hype: Shifting the Burden When Manufacturers Engage in Direct to Consumer Advertising of Prescription Drugs*, 21 VT. L. REV. 1073, 1097 (1998) (urging readers that 'specific vigilance' is needed to protect the consumer from risks associated with the drug").

270. Michael S. Wilkes et al., *Direct-to-Consumer Prescription Drug Advertising, Trends, Impact, and Implications*, 19 HEALTH AFFAIRS 110, 119 (2000).

271. *See id.* (reporting that "25 percent [of people] anticipated that they would try to change their physician's mind, 24 percent thought that they might attempt to obtain the prescription from a different doctor, and 15 percent thought that they might switch to a new doctor").

272. *See* Andrew Ibbotson, *Patients Trust Online Reviews As Much As Doctor Recommendations (And Other Shocking Facts About Transparency in Healthcare)*, HEALTH IT OUTCOMES (Nov. 9, 2018), https://perma.cc/J62Y-2T44 (last visited Nov. 1, 2019) ("When asked if they trusted online ratings and reviews *more* than personal recommendations, 83.3 percent of patients said yes.") (on file with the Washington and Lee Law Review).

273. *See id.* (attributing patients' trust in online reviews to "healthcare's unique opacity").

fellow physicians, and assessments by medical administrators.[274] Another study, published in 2012, reported a more alarming finding: High patient satisfaction ratings are associated with greater expenses and increased mortality.[275]

If the providers who get graded were indifferent to their popularity scores, or if patients reliably refrained from lashing out at physicians who disappoint them by not giving them the drug they want in response to Ask Your Doctor, then patterns like these could be separated from the problem of demand-side ignorance as a source of personal injury. But providers experience these opinions as judgments that have power. In response to a study that went out as a survey to all physician members of a state-level medical society filled out anonymously online,[276] most respondents reported that their compensation was linked to patient satisfaction and a large majority said that "patient satisfaction surveys moderately or severely affected their job satisfaction."[277] Of the fifty-two qualitative responses that came in, only three were positive.[278]

Recall that a significant fraction of patients feel disappointed when their physicians decline to write the prescription they seek.[279] This feeling of theirs does not escape would-be prescribers, as most of the 141 emergency room physicians who responded to a 2013 survey reported they felt pressure to write opioid prescriptions.[280] Not all of it came from patient

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274. *See* Timothy J. Daskivich et al., *Online Physician Ratings Fail to Predict Actual Performance on Measures of Quality, Value, and Peer Review*, 25 J. AM. MED. INFORMATICS ASS'N. 401, 401–04 (2018) (finding no meaningful association between consumer ratings scores and specialty-specific performance scores, primary care physician peer-review scores, and administrator scores).

275. Joshua J. Fenton et al., *The Cost of Satisfaction: A National Study of Patient Satisfaction, Health Care Utilization, Expenditures, and Mortality*, 172 ARCHIVES INTERNAL MED. 405, 406 (2012), https://perma.cc/NG9N-EKZX (PDF).

276. Aleksandra Zgierska et al., *Impact of Patient Satisfaction Ratings on Physicians and Clinical Care*, 8 PATIENT PREFERENCE & ADHERENCE 437, 437 (2014).

277. *Id.*

278. *Id*.

279. Wilkes, *supra* note 270.

280. *See* Sharon Kelly et al., *"Pressured to Prescribe": The Impact of Economic and Regulatory Factors on South-Eastern ED Physicians When Managing the Drug Seeking Patient*, 9 J. EMERGENCY TRAUMA SHOCK 58, 59 (2016) ("Of the ED physicians surveyed . . . 71% reported a perceived pressure to

demand—respondents cited other factors, among them fear of civil liability and administrative concerns about adequate pain management[281]—but this pressure took several distinct forms. Respondents worried about patient complaints to state medical boards, patient complaints to the hospital administration, and reduced reimbursement based on lower patient satisfaction scores.[282] Demand-side ignorance has a complement or partner on the supply side that makes its effects worse, to which we now turn.

2. Supply-side Ignorance

As was noted, the Products Liability Restatement speaks of "reasonable health-care providers" who know the "foreseeable risks and therapeutic benefits" of a prescription drug.[283] This ideal sets a high standard. Busy clinicians who did not design the substances they prescribe cannot reasonably be expected to immerse themselves in the particulars of everything named in the current Physicians' Desk Reference. What would a reasonable health care provider, licensed to write prescriptions under real-world conditions, achieve with respect to the selection and monitoring of a pharmaceutical course of action? Here are three plausible inclusions.

This provider ought to know that which a reasonable provider knows about clinical medicine. Faced with a complaint or presentation in the examining room, our exemplar can identify the condition that calls for treatment and whether prescription drugs in a general sense (in contrast to the characteristics of any

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prescribe opioid analgesics to avoid administrative and regulatory criticism . . . .").

281. *See id.* at 61 (discussing several factors, including (1) physicians' concerns that reporting "doctor shopping" patients to law enforcement could result in HIPAA violations, but failing to report could trigger civil liability, (2) "administrative expectations . . . that ED physicians will insure adequate pain management," and (3) other "[r]egulatory concerns for over- and under- prescribing opioids").

282. *See id.* (reporting that 46% of physicians expressed concerns that their failure to treat a patient's pain could result in a potential board of medicine complaint).

283. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(c) (AM. LAW INST. 1998).

particular product) exist to alleviate or improve it. She is competent to practice medicine, in short. One medical-journal paper about competence in cardiology speaks about clinical medicine generally when it calls for "proper application of science to individualized treatment decisions, based upon the compilation of historical clues, physical examination abnormalities, and laboratory results."[284] Whether contemporary physicians perform well or poorly on this front is unknown,[285] because this profession, like most, does not insist on competence as a condition of retaining a license to practice.[286]

Second, the competent provider needs knowledge of pharmacology to inform prescription choices.[287] Questions she ought to be able to answer: How do pharmaceutical products address medical pathologies? What are the risks of interactions between multiple drugs that the patient is taking? When the patient reports or manifests a side effect from a drug, is this condition trivial or worrisome, and how should the provider respond?

The record of American physicians and medical education in pharmacology is better known than their record of clinical skill. Better known, not better. The American College of Clinical Pharmacology published a position paper in 2015 decrying a current "dangerous lack of pharmacology education."[288] As the

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284. Mary Ellen Beliveau et al., *Physician Competence: A Perspective from the Practicing Cardiologist,* 10 METHODIST DEBAKEY CARDIOVASCULAR J. 50, 51 (2014).

285. So said an influential thinker in the field of health care quality assessment in a 1976 lecture, published decades later around the time of his death. *See* Avedis Donabedian, *Evaluating Physician Competence*, 78 BULL. WORLD HEALTH ORG. 857, 859 (2000) ("Testing for competence is a broad and complex subject in which I have no competence.").

286. *See* Alma Saravia, *Determining Whether a Physician Is Competent to Practice Medicine Is Complex*, HCPLIVE (Sept. 8, 2017), https://perma.cc/DN3J-D2WU (last visited Nov. 2, 2019) ("Physicians are granted a license to practice medicine and it is presumed they will remain 'competent' to treat patients throughout their careers.") (on file with the Washington and Lee Law Review).

287. *See* Peter H. Wiernik, *A Dangerous Lack of Pharmacology Education in Medical and Nursing Schools: A Policy Statement from the American College of Clinical Pharmacology*, 55 J. CLINICAL PHARMACOLOGY 953, 953 (2015) ("Consequently, correct prescribing of medicines today requires a complete knowledge of the pharmacokinetics, pharmacodynamics . . . .").

288. *See id.* at 953–54 (emphasizing the value of education in clinical

quantity of pharmaceuticals on the market has increased in recent years, medical schools and nursing schools in the United States—institutions where persons allowed to write prescriptions, physicians and nurse practitioners, are trained—have been reducing rather than increasing their coverage of pharmacology.[289] European medical education manifests the same inadequacy, suggesting that transnational exchanges and collaborations cannot improve the problem in the near term.[290]

Supply-side ignorance continues in a third domain pertinent to informed prescribing: knowledge of what to infer from factual data. For decades, scholars have lamented the skimpy command of foundations like statistical significance and Bayesian decision analysis that physicians and medical students possess, not only in the United States but around the world.[291] Studies of the problem have focused on bad consequences that follow from physician confusion about what the results of laboratory tests mean[292] and implications that extend to (mis)prescribing drugs.[293]

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pharmacology for health care professionals).

289. *Id.* at 953.

290. *See* D.J. Brinkman et al., *Pharmacology and Therapeutics Education in the European Union Needs Harmonization and Modernization: A Cross-sectional Survey Among 185 Medical Schools in 27 Countries*, 102 CLINICAL PHARMACOLOGY & THERAPEUTICS 815, 815–16 (2017) (explaining concerns regarding EU medical graduates who "are not adequately prepared for their prescribing duties").

291. *See, e.g.*, Ward Casscells et al., *Interpretation by Physicians of Clinical Laboratory Results*, 299 NEW ENG. J. MED. 999, 999–1,000 (1978) (exposing the inability of Harvard Medical School physicians to know the odds of a false positive result); David R. Matthews & Klim McPherson, *Doctors' Ignorance of Statistics*, 294 BRIT. MED. J. 856, 856 (1987) (reporting woeful findings about doctors' knowledge of "elementary statistical expressions" like standard deviation); Susan Miles et al., *Statistics Teaching in Medical School: Opinions of Practising Doctors*, 10 BMC MED. EDUC. 75, 75 (2010) (summarizing a British survey of physicians that agreed on the need for better education in light of "advances in information technology and the increasing importance of evidence-based medicine").

292. *See* Bailey Kuklin, *Probability Misestimates in Medical Care*, 59 ARK. L. REV. 527, 528–36 (2006) (examining how patients' treatments suffer as a result of common physician mistakes in probabilistic reasoning).

293. *See, e.g.*, Judith G. Edersheim & Theodore A. Stern, *Liability Associated with Prescribing Medications*, 11 PRIMARY CARE COMPANION J. CLINICAL PSYCHIATRY 115, 115–19 (presenting a case scenario where a primary

Doctors learn about pharmaceutical products from sales representatives, sometimes called "detailers," who visit their offices with samples, literature, and occasional gifts.[294] A 2007 medical journal paper reported that about 90,000 people worked in the United States as detailers whose employers spent an average of $15,000 per physician on this marketing.[295] Representatives not only sell their employers' products but also purport "to provide busy physicians up-to-date information about the pros and cons of using the promoted drugs and to keep them abreast with the cutting-edge advances in the field in general," writes a public health scholar, adding that "[t]he borderline between genuine recommendation and profit-oriented persuasion is thin."[296]

In its regulation of what detailers may tell physicians about the pharmaceutical items they promote, the FDA requires that these communications be consistent with what it has approved for the product.[297] People who listen to detailing need the ability to hear what the sales representative is saying (and not saying) about the drug and to recognize artful claims about safety, effectiveness, or the suitability of the substance for classes of patients. Ignorance on their part makes this dialogue a source of danger.

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care physician might be liable for the injuries of his patient and the downstream harm to an innocent bystander injured in a motor vehicle accident a week after he prescribed his 80-year-old patient with heart disease and hypertension an "atypical antipsychotic medication" for his anxiety and insomnia).

294. *See* Adriane Fugh-Berman & Shahram Ahari, *Following the Script: How Drug Reps Make Friends and Influence Doctors*, 4 PLOS MED. 621, 625 (2007) ("Physicians view drug information provided by reps as a convenient, if not entirely reliable, educational service."); *see also* Lars Noah, *Doctors on the Take: Aligning Tort Law to Address Drug Company Payments to Prescribers*, 66 BUFF. L. REV. 855, 872–73 (2018) (exploring the influence of gifts on prescribers' treatment decisions).

295. Susan Chimonas et al., *Physicians and Drug Representatives: Exploring the Dynamics of the Relationship*, 22 J. GEN. INTERNAL MED. 184, 184 (2007).

296. Avinash R. Patwardhan, *Physicians-Pharmaceutical Sales Representatives Interactions and Conflict of Interest: Challenges and Solutions*, 53 INQUIRY 1, 1 (2016).

297. *See* 21 C.F.R. § 202.1(e)(1) (2008) ("Advertisements broadcast through media such as radio, television, or telephone communications systems shall include information relating to the major side effects and contraindications of the advertised drugs in the audio or audio and visual parts of the presentation . . . .").

3. Enlarging Ignorance: Overpromotion

The word overpromotion will sound relatively harmless to the American ear, which hears the prefix "over" as connoting too much of a good thing. Do it, but don't overdo it. "Overdeception," "overmistreatment," and "overjeopardy" are not English nouns. If words like these existed, they would describe drug-manufacturer conduct more accurately than the anodyne "overpromotion."

Twenty-first century American overpromotion settlements are narratives replete with deception, mistreatment, and imperiling of patient welfare. Because overpromotion functions to tell physicians at best baselessly—and sometimes with clear intent to deceive—that a pharmaceutical product is safe and effective enough to treat a medical condition, as a behavior by drug manufacturers it increases supply-side ignorance by spreading and entrenching false information.

Below I group together illustrative patterns of industry misconduct that came to light under the overpromotion rubric. In all of them, pharmaceutical manufacturers chose to settle civil and criminal actions under the False Claims Act and thereby conceded the truth of accusations—at least implicitly, but also on some occasions in the form of explicit admissions. These actions fall outside products liability, a domain in which there are (almost) no bad drugs, but they lost manufacturers money. Although prescription-drug overpromotion also took place well before the turn of the current century,[298] the settlement accounts I have gathered are all younger than age fifteen, suggesting that the problem continues.

Promotion for uses that a manufacturer knew would not work, or was told by the FDA that it could not lawfully recommend. After the FDA approved a drug called Actimmune to

298. *See, e.g.*, Stevens v. Parke, Davis & Co., 507 P.2d 653, 662 (Cal. 1973) (faulting a manufacturer for "'watering down' its warnings and so over-promoting"); Proctor v. Davis, 682 N.E. 2d 1203, 1217 (Ill. App. Ct. 1997) (awarding compensatory and punitive damages for a claim of defective warning that included overpromotion). For a review of drug overpromotion—now more than twenty years old, but informative—see Marilyn A. Moberg et al., *Surfing the Net in Shallow Waters: Product Liability Concerns and Advertising on the Internet*, 53 FOOD & DRUG L.J. 213, 220–21 (1998) (addressing overpromotion as dilutive of FDA-approved warnings).

treat two rare conditions,[299] its manufacturer launched research trials to learn whether Actimmune could also treat the more common disease of pulmonary fibrosis. These trials ended after evidence came in that Actimmune did not work for this purpose.[300] Its manufacturer, InterMune, promoted this drug for pulmonary fibrosis anyway, and paid a $36.9 million settlement to resolve criminal and civil charges.[301] In a much costlier example of this phenomenon, the manufacturer Amgen promoted its drug Aranesp at higher doses that the FDA had expressly rejected.[302] Amgen's settlement of overpromotion claims that covered Aranesp and two of its other products cost the company $612 million.[303]

Promotion for pediatric uses that were never approved by the FDA, thereby putting young children at risk. Forest Laboratories promoted the antidepressant Celexa—approved by the FDA only for adult depression—as a treatment for children and adolescents.[304] A $313 million settlement covered this overpromotion along with unlawful marketing of two other drugs.[305] The FDA had approved Loprox for fungicide treatment

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299. *See* Andrew Pollack, *Drug Maker Stops Work on Lung Disease Medicine*, N.Y. TIMES (Mar. 6, 2007), https://perma.cc/6P6S-EFZY (last visited Oct. 27, 2019) ("Actimmune, also known as interferon gamma, is approved to treat two extremely rare diseases—chronic granulomatous disease and severe malignant osteopetrosis.") (on file with the Washington and Lee Law Review).

300. *See id.* (reporting that the company halted the 826-patient trial after an interim analysis showed that 14.5% of the patients receiving Actimmune had died, compared to only 12.7% of those getting the placebo drug).

301. The federal government charged InterMune with promoting an off-label use in violation of the Federal Food, Drug, and Cosmetic Act. *Id.*

302. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Amgen Inc. Pleads Guilty to Federal Charge in Brooklyn, NY; Pays $762 Million to Resolve Criminal Liability and False Claims Act Allegations (Dec. 19, 2012), https://perma.cc/B2DJ-YWD5 (last visited Oct. 5, 2019) (noting that Amgen also tried to market Aranesp for an off-label treatment that the FDA had never approved) (on file with the Washington and Lee Law Review).

303. Amgen also submitted false claims to government insurance programs for off-label uses of Enbrel and Neulasta. *Id.*

304. *See* Natasha Singer, *Forest, Maker of Celexa, to Pay More Than $313 Million to Settle Marketing Case*, N.Y. TIMES (Sept. 15, 2010), https://perma.cc/M2M5-CDFW (last visited Oct. 27, 2019) (reporting that Forest illegally marketed the drug for off-label uses, including headaches and cerebral palsy in children and failed to disclose negative results of a study on Celexa in adolescents) (on file with the Washington and Lee Law Review).

305. *See id.* ("In addition, federal prosecutors accused Forest of paying

of children over age ten; Medicis Pharmaceutical promoted this drug for diaper rash, and paid $9.8 million to settle a whistleblower-brought federal action that brought this overpromotion to light.[306]

Selling epilepsy medication to treat more than epilepsy. About three and a half million people in the United States are currently treated for epilepsy,[307] and this level of therapeutic attention is apparently lower than the pharmaceutical sector wants. We may infer as much from how hard manufacturers have worked to convince physicians to prescribe drugs to treat other conditions after the FDA had approved these drugs only for the treatment of epilepsy.[308] And here when I say "how hard manufacturers have worked," by "how hard" I mean "how unlawfully." Penalties for this misconduct have been steep. The most notorious overpromotion in the epilepsy category involved Neurontin, which Parke-Davis marketed to treat bipolar disorder, migraines, and non-epilepsy seizures, among other disorders.[309] This manufacturer paid more than $430 million to settle civil and criminal charges.[310]

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doctors to induce them to prescribe Celexa and another antidepressant, Lexapro.").

306. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Medicis Pharmaceutical to Pay U.S. $9.8 Million to Resolve False Claims Allegations (May 8, 2007), https://perma.cc/T8G3-4SHB (last visited Oct. 5, 2019) ("Loprox . . . is not a 'medically accepted indication' for the treatment of diaper dermatitis and other skin disorders in children under 10.") (on file with the Washington and Lee Law Review).

307. *More Americans Have Epilepsy than Ever Before*, CTRS. FOR DISEASE CONTROL (Aug. 10, 2017, 1:00 PM), https://perma.cc/J628-YMB7 (last visited Oct. 27, 2019) (on file with the Washington and Lee Law Review).

308. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Warner-Lambert to Pay $430 Million to Resolve Criminal & Civil Health Care Liability Relating to Off-label Promotion (May 13, 2004), https://perma.cc/R8KJLFUJ (last visited Oct. 5, 2019) ("The drug Neurontin was approved by the Food and Drug Administration in December 1993 solely for adjunctive or supplemental anti-seizure use by epilepsy patients.") (on file with the Washington and Lee Law Review).

309. *See id.* (confirming that Neurontin was marketed to treat eight different disorders that had not been approved by the FDA, including the degenerative nerve disease ALS, restless leg syndrome, and attention deficit disorder).

310. *Id.*

When the Department of Justice (DoJ) announced what it called the "largest health care fraud settlement in history,"[311] overpromotion of an epilepsy drug was included in the fraudulent conduct so sanctioned.[312] Pfizer, Inc. marketed Lyrica, which the announcement described as "an anti-epileptic drug," to treat other conditions.[313] This epilepsy penalty was attached to a separate "criminal fine of $1.195 billion, the largest criminal fine ever imposed in the United States for any matter,"[314] said DoJ, for misconduct amenable to being classified with the first grouping of this list, FDA-vetoed assertions: "Pfizer promoted the sale of Bextra for several uses and dosages that the FDA specifically declined to approve due to safety concerns."[315] Another manufacturer peddled its epilepsy-only approved product as a treatment of "anxiety, insomnia and pain."[316] Other epilepsy drugs have joined the roster of overpromotion settlements.[317]

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311. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Justice Department Announces Largest Health Care Fraud Settlement in Its History (Sept. 2, 2009), https://perma.cc/JG8N-KXJ4 (last updated Sept. 15, 2014) (last visited Oct. 9, 2019) (reporting that Pfizer agreed to pay $2.3 billion for the fraudulent marketing) (on file with the Washington and Lee Law Review). This dollar record went on to be broken. *See infra* note 318 (discussing the $1.415 billion Zyprexa settlement).

312. *See id.*

313. *Id.*

314. *Id.*

315. *Id*.

316. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Biopharmaceutical Company, Cephalon, to Pay $425 Million & Enter Plea to Resolve Allegations of Off-label Marketing (Sept. 29, 2008), https://perma.cc/5CXR-KJB5 (last visited Oct. 9, 2019) (summarizing settlement of charges for Food, Drug, and Cosmetic Act violations related to drug Gabitril) (on file with the Washington and Lee Law Review).

317. *See, e.g.*, Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Two Johnson & Johnson Subsidiaries to Pay over $81 Million to Resolve Allegations of Off-label Promotion of Topamax (Apr. 29, 2010), https://perma.cc/3E6V-AK9U (last updated Sept. 15, 2014) (last visited Oct. 9, 2019) (involving the Topamax overpromotion settlement) (on file with the Washington and Lee Law Review); Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Novartis Pharmaceuticals Corp. to Pay More than $420 Million to Resolve Off-label Promotion and Kickback Allegations (Sept. 30, 2010), https://perma.cc/36B3LQYU (last updated Sept. 15, 2014) (last visited Oct. 9, 2019) (involving the Trileptal overpromotion settlement) (on file with the Washington and Lee Law Review); Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Pharmaceutical Companies to Pay $214.5 Million to Resolve Allegations of Off-label Promotion of Zonegran (Dec. 15, 2010),

Selling psychiatric drugs to treat more than the psychiatric conditions for which manufacturers had FDA approval. As a penalty reminiscent of the billion-plus that Pfizer had to suffer for its overpromotion of Bextra, Eli Lilly paid $1.415 billion for its off-label promotion of Zyprexa, a drug that the FDA had approved first for bipolar disorder and later schizophrenia.[318] Apparently unsatisfied with this limited marketing opportunity, Lilly decided unilaterally—and unlawfully—to pitch Zyprexa to nursing homes and assisted-living facilities as a treatment of "dementia, Alzheimer's dementia, depression, anxiety, and sleep problems, and behavioral symptoms such as agitation, aggression, and hostility."[319] This sum was topped by a $3 billion array of penalties imposed on GlaxoSmithKline for misconduct pertaining mostly, but not entirely, to the psychotropic drugs Paxil and Wellbutrin.[320]

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https://perma.cc/N2GU-YRT3 (last updated Sept. 15, 2014) (last visited Oct. 9, 2019) (involving the Zonegran overpromotion settlement) (on file with the Washington and Lee Law Review); Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, U.S. Subsidiary of Belgian Pharmaceutical Manufacturer Pleads Guilty to Off-label Promotion; Company to Pay More than $34 Million (June 9, 2011), https://perma.cc/5MBP-XS86 (last updated Oct. 22, 2014) (last visited Oct. 9, 2019) (involving the Keppra overpromotion settlement) (on file with the Washington and Lee Law Review); Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Abbott Labs to Pay $1.5 Billion to Resolve Criminal & Civil Investigations of Off-label Promotion of Depakote (May 7, 2012), https://perma.cc/WTE9-GJBL (last updated Oct. 22, 2014) (last visited Oct. 9, 2019) (involving the Depakote overpromotion settlement) (on file with the Washington and Lee Law Review); Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data (July 2, 2012), https://perma.cc/T2N5-BJ5P (last updated May 22, 2015) (last visited Oct. 9, 2019) [hereainafter *GlaxoSmithKline*] (involving the Lamictal overpromotion settlement) (on file with the Washington and Lee Law Review).

318. Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Eli Lilly and Company Agrees to Pay $1.415 Billion to Resolve Allegations of Off-Label Promotion of Zyprexa (Jan. 15, 2009), https://perma.cc/ZV62-WJCP (last updated Oct. 22, 2014) (last visited Feb. 11, 2020).

319. *Id*.

320. *See GlaxoSmithKline*, *supra* note 317 (characterizing the multi-billion dollar settlement as "unprecedented in both size and scope" and underscoring the Attorney General's "firm commitment to protecting the American people and holding accountable those who commit health care fraud").

Our quick tour through overpromotion has looked at just a fraction of the twenty-first century total. A page titled "List of off-label promotion pharmaceutical settlements" on Wikipedia starts with the $430 million Neurontin settlement in 2004 and (as of late 2019) continues with another 38 actions, all brought under the False Claims Act.[321] No other industry has its own wiki-list of False Claims Act episodes, and the roster includes the biggest and most famous drug manufacturers.[322] One Big Pharma name conspicuous by its absence from this overpromotion settlements compendium, the Swiss giant Roche, is very much present in false-statement personal injury case law under a predecessor corporate identity: In 2000 the Nebraska Supreme Court ruled that its marketing of Accutane, which "misled the medical community with incomplete and inaccurate information regarding the safety of the drug," supported a cause of action for fraudulent misrepresentation.[323]

Drug companies commonly overpromote their products, in short. The "over-" prefix of the word implies deviation, but overpromotion is so frequent as to be close to the norm. Regulators declare "You may say only *X* about your product," and the sector—well aware that crossing this line violates the law and has generated significant-looking penalties for dozens of pharmaceutical companies—routinely says *X* and *Y* and *Z*.

As an industry practice, overpromotion shows part of what is wrong with the leading blackletter test for drug design defect.

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321. *List of Off-label Promotion Pharmaceutical Settlements*, WIKIPEDIA, https://perma.cc/9ULR-ZMKR (last updated Sept. 21, 2019) (last visited Nov. 1, 2019) [hereinafter WIKIPEDIA] (on file with the Washington and Lee Law Review).

322. *See* Monique Ellis, *Who Are the Top 10 Pharmaceutical Companies in the World? (2019)*, PROCLINICAL (Mar. 20, 2019), https://perma.cc/U6B6-YKF3 (last visited Oct. 10, 2019) (listing the ten pharmaceutical companies with the highest revenues world-wide) (on file with the Washington and Lee Law Review); *Top 50 Global Pharmaceutical Companies by Prescription Sales and R&D Spending in 2018 (in Billion U.S. Dollars)*, STATISTA, https://perma.cc/GT85-A2GG (last visited Oct. 16, 2019) (on file with the Washington and Lee Law Review).

323. Freeman v. Hoffmann-La Roche, Inc., 618 N.W.2d 827, 844–45 (Neb. 2000). This decision, which reports a rare success in the annals of prescription-drug products liability, is used in a torts casebook to illustrate pharmaceutical liability generally. JOHN C.P. GOLDBERG ET AL., TORT LAW: RESPONSIBILITIES AND REDRESS 971–82 (4th ed. 2016).

Recall that the Third Restatement says that a prescription drug is defectively designed only if "reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients."[324] This test looks out for the health of a small and vulnerable cohort.[325] If a drug is the treatment of choice for even a tiny number of patients—the class has no minimum size, suggesting that one person would suffice—then its design is good enough, says the Restatement, and the drug deserves to remain in the marketplace of treatments.[326]

But the pharmaceutical sector emphatically does not want to live with a tiny market. Like every other maker of a product offered in commerce, it is in the business of selling units—and not just selling, of course, but selling *more*. Unlike manufacturers of other products, many of which items are relatively cheap and easy to bring to market, drug manufacturers have to spend millions of dollars and wait patiently through rounds of trials before they can pursue customers for a new commodity.[327] Any such business will want to hustle as thoroughly as it can to gain returns on its investment; being told by a regulator that it may say only *X* about this commodity rather than *X* and *Y* and *Z* will chafe. Overpromotion may not be quite baked into its marketing plan, but bigger promises will appear attractive for any drug whose FDA-approved recommendations do not reach enough customers to slake the thirst of its seller.

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324. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(c) (AM. LAW INST. 1998).

325. *See* Cupp, *supra* note 128, at 96–97 (stating that the Third Restatement allows design liability "only in the few cases in which the prescription product is so lacking in utility and so steeped in risk that a reasonable medical provider would not prescribe it to any class of patients").

326. *See id.* (affirming the highly limited nature of product design liability for prescription drugs).

327. *See* Ellis, *supra* note 322 ("Being a research-driven industry, approximately $150 billion is spent by pharmaceutical companies every year on research and development projects. Out of thousands of compounds, only a small percentage gain regulatory approval to be used by patients to treat disease . . . .").

C. A Rhetorical Question: Who Is a Judge or Juror or Litigator to Disapprove of a Product After Independent Expert Authority Has Said It Is Both Safe and Effective?

Here we return to a topic addressed earlier under the rubric of preemption and can be brief. Whereas most products travel directly from design and manufacture to placement in the stream of commerce without premarketing review by the government, experts at the Food and Drug Administration examine the design of this product and must approve it before it can reach customers.[328] Congress has charged the FDA with an obligation to satisfy itself that a new product of this category is both safe and effective before customers may buy it,[329] and FDA regulation of this product continues after its launch on the market.

Litigants who complain about a prescription drug thus challenge an informed judgment that its design and accompanying verbiage were good enough to pass analysis that resembles the risk-utility test for the design defect. By deeming the drug safe enough to be lawfully sold, the FDA made a favorable judgment about its risk level and deeming it effective implies a favorable judgment about its utility.[330] Defenders of near-immunity can contend plausibly that persons in the United States who consume prescription drugs have already enjoyed significant protection from the risk of defectiveness. Nevertheless, condoning of a drug by the FDA does not suffice to show that no defect is present.

The Reporters who drafted a nearly immunizing rule conceded in a comment to their rule that "unqualified deference" to this agency would be unwise,[331] and in their scholarly writing

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328. 21 U.S.C. § 355 (2018).

329. *See id.* § 355(d) (requiring that test results confirm the drug is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof" before FDA approval can be granted).

330. *See* James A. Henderson Jr., *Prescription Drug Design Liability Under the Proposed Restatement (Third) of Torts: A Reporter's Perspective*, 48 RUTGERS L. REV. 471, 481 (1998) ("[S]ubstantial deference to a marketplace for prescription drugs that appears to function almost perfectly [due to FDA regulation] is warranted.").

331. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(c) cmt. b (AM. LAW INST. 1998) (acknowledging that a "growing number of courts" consider this deference unjustified).

they have hewed to this position.[332] Indeed, they came to put it in sharper terms. Whereas in the Restatement they wrote simply that "the FDA occasionally makes mistakes,"[333] by 2015 they worried that "the FDA relies almost exclusively on data developed by private drug manufacturers."[334] Agency decisions to approve new drug applications "are thus vulnerable, to an extent that judicial decisions are not, to being influenced by understatements and misstatements of the relevant risks."[335]

Congress enlarged FDA vulnerability to manufacturer influence in late 2016 by passing the 21st Century Cures Act,[336] a statute that relaxed standards for approval of new pharmaceutical drugs and devices.[337] This legislation wrote exceptions to the familiar demand that the drug manifest safety and effectiveness through randomized clinical trials: instead, for some applications "real world evidence"—which can include insurance records and loosely gathered observational studies—will suffice for FDA approval.[338] It furnished a shortcut to approval by dropping a requirement that the FDA analyze

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332. *See* Dan Farber, *Preemption and Prescription Drugs*, LEGAL PLANET (Jan. 6, 2012), https://perma.cc/2MF9-5ZK5 (last visited Oct. 12, 2019) (arguing that blindly trusting the FDA's opinion on the safety and effectiveness of a drug is becoming less plausible and suggesting that state tort law simply balances the risks and benefits differently, rather than second guessing the FDA's scientific judgment) (on file with the Washington and Lee Law Review).

333. *See* Henderson & Twerski, *supra* note 114, at 162–63 (arguing that section 6(c) of the Restatement realizes the FDA may occasionally "approv[e] worthless drugs that no competent provider would prescribe").

334. Henderson & Twerski, *supra* note 114, at 538.

335. *Id.*

336. 21st Century Cures Act of 2016, Pub. L. No. 114-255, § 3093(f)(1), 130 Stat. 1033.

337. *See, e.g.*, 21 U.S.C. § 360ff-1 (2018) (stating the purpose of this section of the Cures Act: "to facilitate the development, review, and approval of genetically targeted drugs . . . to address unmet medical need in one or more patient subgroups . . . .").

338. *See* Trudy Lieberman, *With Media Watchdogs on the Sidelines, Pharma-Funded Advocacy Groups Pushed Cures Act to the Finish Line*, HEALTH NEWS REV. (Dec. 6, 2016), https://perma.cc/8EQX-UFH5 (last visited Oct. 12, 2019) ("[The 21st Century Cures Act] loosen[s] regulation over drug and device makers, reduce[s] the number of clinical trials needed to approve a drug, and permit[s] advertising for off-label drug uses, all of which would help drug and device makers expand their markets.") (on file with the Washington and Lee Law Review).

study results independently, permitting manufacturers to submit data summaries instead.[339] Medical devices have long been held to a more lenient standard for approval than the one for drugs;[340] the 21st Century Cures Act expanded this lenity by recognizing "combination products" that contain both drugs and devices and blesses them with the lower standard used for devices.[341] An analyst quoted in the New York Times soon after this legislation passed called it "a holiday win" for health-sector businesses and investors.[342]

Twenty-seven years ago, a separate piece of federal legislation took effect to similar effect: The Prescription Drug User Fee Act[343] compels the FDA to charge pharmaceutical manufacturers for reviewing new drug applications.[344] The consumer activist group Public Citizen, contending that this enactment makes the FDA in effect a customer of the sector it regulates, has followed post-1993 approved drugs and in 2011 reported that the FDA had withdrawn twenty of them.[345] Continuing reauthorization of this statute has meant that manufacturers finance agency review of the applications they submit.[346] As of 2020 the FDA is charging a flat fee of $2,942,965

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339. *See id*. ("New drugs could be approved on the basis of data summaries rather than requiring the FDA to independently analyze study results for a new drug indication.").

340. *See generally* RICHARD A. MERRILL, REGULATION OF DRUGS & DEVICES: AN EVOLUTION (1994), https://perma.cc/2JG9-5BPR (PDF) (explaining that Congress sought to create a more relaxed framework for medical devices in order to facilitate innovation, but suggesting that external pressures and internal practices may soon bring device regulation "closer to the 'drug model'").

341. *See* Lieberman, *supra* note 338 ("A combination product that's part drug and part device such as infusion pumps could be approved based on the less stringent rules for device regulation [rather] than the tougher rules for drugs.").

342. Jennifer Steinhauer & Robert Pear, *Sweeping Health Measure, Backed by Obama, Passes Senate*, N.Y. TIMES (Dec. 7, 2016), https://perma.cc/J6E9-9WHT (last visited Feb. 21, 2020) (on file with the Washington and Lee Law Review).

343. 21 U.S.C. § 379h (2018).

344. *See id*. § 379h(a) (authorizing the FDA to assess and collect fees for drug testing on human subjects).

345. *Update on Withdrawals of Dangerous Drugs in the U.S.*, WORST PILLS, BEST PILLS (Jan. 2011), https://perma.cc/AZ2P-UA6G (last visited Nov. 2, 2019) (on file with the Washington and Lee Law Review).

346. *See Prescription Drug User Fee Amendments*, FOOD & DRUG ADMIN.,

per application that needs clinical data, half that for an application that needs no clinical data, plus a $325,424 "program fee" for most applications.[347] Manufacturers, especially ones that pay for numerous reviews, have reason to think that the FDA is working for them.

Sharing henhouse-oversight power with foxes has generated injuries that go beyond the approval of dangerous drugs. Researchers at John Hopkins University learned in 2018 that when the FDA decided to expand its authorization of fentanyl treatments to benefit a larger class of patients, it turned over management of the distribution to a private entity that worked with manufacturers.[348] Whereas the FDA had permitted furnishing these fentanyl products only to patients with cancer and demonstrated high tolerance for opioids,[349] this intermediary gave it out liberally to patients with other complaints.[350] Some of them died.[351] The program enriched manufacturers with prescriptions billed at more than $30,000 each for a month's supply.[352]

(May 23, 2018), https://perma.cc/XWA7-NJ8C (last updated Aug. 16, 2019) (last visited Oct. 12, 2019) (describing the multiple reauthorizations of the PDUFA) (on file with the Washington and Lee Law Review).

347. *Id.*

348. *See* Emily Baumgaertner, *F.D.A. Did Not Intervene to Curb Risky Fentanyl Prescriptions*, N.Y. TIMES (Aug. 2, 2018), https://perma.cc/LT8S-FF8M (last visited Oct. 12, 2019) (describing the FDA's failure to enforce off-label prescription of fentanyl) (on file with the Washington and Lee Law Review).

349. *See id.* (noting that the FDA's Center for Drug Evaluation and Research had information that "seems to indicate people who aren't cancer patients are getting [the class of fentanyl drugs] and people who aren't opioid tolerant are getting this").

350. *See id.* (reporting that one patient was prescribed fentanyl for "chronic back pain from two car accidents and a fibromyalgia diagnosis" while another suffered from a degenerative spinal disease).

351. *See id.* (citing several instances where patients died of drug toxicity, including one whose toxicology report revealed that "the fentanyl in [the patient's] blood was between 15 and 20 times the appropriate level").

352. *Id.*

D. The Belief That Tort Liability Lamentably Thwarts the Sector's Significant Contributions to Public Health

Unlike the last section, this concluding discussion for the Part will not be brief; the belief examined here is the furthest-reaching of the four and warrants the deepest dive. To condemn a drug design or warning in court is to say that every unit is defective now,[353] with every user positioned to seek redress that in the aggregate can be powerful enough to drive a product from the market.[354] A prescription drug might be sufficiently profitable for sellers to laugh off the price of tort liability, but not all are.[355] Tort, when costly enough, can send valuable products into oblivion, lost to patients forever.[356]

Consider collective and social impacts. Prescription drugs are routinely chosen for other people, including children, hospital patients, and adult consumers who do not participate actively in their health decisions.[357] In this way they are useful to bystanders and third-party purchasers, not only the people who pay for them or ingest them. Beyond this decision-making circle, some prescription drugs improve public health.[358] Medications

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353. *See* OWEN, *supra* note 20, at 553–60 (explaining broad-scale consequences of litigation over drug design or warning).

354. *See* Brown v. Superior Ct., 751 P.2d 470, 479 (Cal. 1988) ("If drug manufacturers were subject to strict liability, they might be reluctant to undertake research programs to develop some pharmaceuticals that would prove beneficial or to distribute others that are available to be marketed, because of the fear of large adverse monetary judgments.").

355. *See id.* (citing "a host of examples of products which have greatly increased in price or have been withdrawn or withheld from the market because of the fear that their producers would be held liable for large judgments").

356. *See, e.g.*, *id.* ("Benedictin, the only antinauseant drug available for pregnant women, was withdrawn from sale in 1983 because the cost of insurance almost equaled the entire income from the sale of the drug . . . . [Likewise] [d]rug manufacturers refused to supply a newly discovered vaccine for influenza on the ground that mass inoculation would subject them to enormous liability.").

357. *See, e.g.*, Baumgaertner, *supra* note 348 (describing one patient's "complete trust" in her doctors' decision to prescribe fentanyl for her chronic back pain and fibromyalgia).

358. *See Brown*, 751 P.2d at 479 ("Public policy favors the development and marketing of beneficial new drugs, even though some risks, perhaps serious ones, might accompany their introduction, because drugs can save lives and reduce pain and suffering.")

and preventatives for transmittable diseases heal both individuals and the body politic.[359] The value of a drug extends beyond what it does for its buyers.

These truths about prescription drugs form a pillar that ascribes benevolence to the industry.[360] Differing from other consumer-product manufacturers that make take-'em-or-leave-'em items—to support transportation, manufacture, hobbies, aesthetics, household tasks, entertainment, and so on—this sector makes commodities necessary for health.[361] Partnered almost synonymously with wealth, its rhyme, health is a central constituent of public welfare.[362] "Leave the sector alone," says this pillar to tort liability, except in the unusual circumstance where forcing it to pay damages is desirable. It keeps us alive and well.

How merited is this shelter from liability? Putting aside the special case of vaccines, a unique drug category outside the scope of this Article that probably did warrant its 1986 rescue from the reach of tort,[363] it is impossible to know whether any prescription drug that increases health needed the boost of exceptionally favorable products liability doctrine to reach the public. We do, however, have reason to conclude that many offerings from this sector have brought relatively little to the array of health-generating treatments on the market.[364] The industry engages in useful activity, to be sure. But it does much more than

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359. *See id.* (deeming penicillin and cortisone "two of the greatest medical boons to the human race").

360. *See supra* Parts III.A–III.C.

361. *See Brown*, 751 P.2d at 478 (distinguishing prescription drugs from lawnmowers and perfumes because unlike other consumer products, prescription drugs "may be necessary to alleviate pain and suffering or sustain life").

362. *See id.* at 478–79 (pointing out the "broader public interest in the availability of drugs at an affordable price").

363. *See* National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 *et seq.* (2018) (establishing a scheme under which compensation may be paid for vaccine-related injuries or deaths).

364. *See, e.g.*, Nicholas Florko, *'Everyone Is at Fault:' With Insulin Prices Skyrocketing, There's Plenty of Blame to Go Around,* STAT NEWS (Feb. 19, 2019), https://perma.cc/C36M-6NHY (last visited Oct. 12, 2019) (reporting that the pharmaceutical industry has "hundreds of unexpired patents" for insulin, but still charges extraordinarily high prices for trivially modified variations of the century-old drug) (on file with the Washington and Lee Law Review).

make people better off. One of its notoriously bad products has made the public worse off.

1. MeToo Drugs and Other Dubious Intellectual Property

According to this pillar supporting near-total products liability immunity, a kindly industry needs extra tolerance so that it can invent and sell its health-giving new ideas. The large majority of ostensibly new drugs in the United States "are not new at all," observed Marcia Angell, longtime editor-in-chief of the New England Journal of Medicine; Angell called them "merely variations of older drugs already on the market."[365] Innovation occurs, but the sector gains new patents and profits without creating anything fresh.[366] "If I'm a manufacturer and I can change one molecule and get another twenty years of patent rights," said Sharon Levine, an expert interviewed on a television special, "and convince physicians to prescribe and consumers to demand the next form of Prilosec, or weekly Prozac instead of daily Prozac, just as my patent expires, then why would I be spending money on a lot less certain endeavor, which is looking for brand-new drugs?"[367]

The gallery of MeToo consists mostly of trivial novel innovations, but some add even less to public well-being. The notorious OxyContin should never have been granted a patent, argues a Harvard-based team of three scholars credentialed in law, medicine, and public health.[368] We encountered OxyContin

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365. MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT xxiv (2004).

366. *See* Efthimios Parasidis, *Health Outcomes Metrics and the Role of Financial Derivative Instruments in the Health Care Industry*, 10 IND. HEALTH L. REV. 447, 462 (2013) ("Studies have documented the lack of innovative medical products and [the pharmaceutical] industry's focus on me-too drugs, which are drugs that mimic successfully marketed products.").

367. RASHMI AGGARWAL & RAJINDER KAUR, PATENT LAW AND INTELLECTUAL PROPERTY IN THE MEDICAL FIELD 30 (2017) (quoting Sharon Levine).

368. *See* Ameet Sarpatwari et al., *The Opioid Epidemic: Fixing a Broken Pharmaceutical Market*, 11 HARV. L. & POL'Y REV. 463, 468 (2017) (attributing Purdue's success to "low patenting standards" illustrated by the fact that Oxycontin's constituent elements had been developed "decades earlier" and were first introduced in the United States in 1939).

earlier in this article and it will soon return.[369] Here it serves as an example of dubious intellectual property.[370] Years before it came up with OxyContin, its manufacturer Purdue Pharma had developed a technology known as Contin whose function is to control the release of a drug from a tablet.[371] Purdue applied Contin to the un-patentable morphine to form MS Contin, and MS Contin became its top-selling drug.[372] The idea behind OxyContin was to apply Contin to the similar-to-morphine oxycodone; "the combination of Contin and oxycodone would have been obvious to any pharmaceutical chemist."[373]

The United States Patent and Trademark Office duly rejected Purdue's patent application as obvious, but the company found a slight and obscure difference between extended-release oxycodone and other extended-release opioid analgesics and won its patent.[374] Purdue continued its aggressive deployment of intellectual property by patenting an abuse-deterrent version of OxyContin, ceasing to manufacture its original formulation to force customers into the new design, and pressing the FDA successfully to forbid generic versions of the original OxyContin, ostensibly on safety grounds.[375] Manufacturers of generic OxyContin eventually succeeded in challenging the secondary

369. *See supra* notes 69–70 and accompanying text; *infra* notes 437–450, 458–460 and accompanying text.

370. *See* Sarpatwari, *supra* note 368, at 471–72 (explaining that "non-rigorous patent standards" have enabled pharmaceutical companies to obtain patents and extend market exclusivity).

371. *Id.* at 469.

372. *See id.* ("[E]xtended release morphine (MS Contin)—quickly became [Purdue's] highest grossing drug, generating annual sales of approximately $170 million in the early 1990s.").

373. *Id.* at 470.

374. *See id.* (explaining that the USPTO accepted Purdue's contention that "a person of ordinary skill would not have sought to use a narrower dosage range for extended-release oxycodone than for other extended-release opioid analgesics" and that this narrower dosage range "provided pain relief for ninety percent of patients"); *see also* Purdue Pharma, L.P. v. Endo Pharms. Inc., 438 F.3d 1123, 1126 (Fed. Cir. 2006) (providing a more detailed explanation of Purdue's patents for its controlled-release oxycodone formulation).

375. *See* Sarpatwari, *supra* note 368, at 471 (describing Purdue's attempts to extend its market exclusivity for its extended-release drug).

patents, but Purdue won precious time to set up elaborate promotion.[376]

Lack of innovation in the sector, a condition long lamented by investors who buy stock in pharmaceutical companies,[377] is ironically highlighted by innovation that this community of critics has created: Investment prospects are so bleak that the much-derided tool of a derivative makes sense as a policy fix.[378] According to one scholarly proposal presented as reparative rather than gimmicky, derivatives markets could offer a long position that a drug innovation will fail and a short position that it will capture significant market share.[379] Meanwhile, investors remain frustrated by the sector's apparent inability to formulate what to them appears a simple innovation, new antibiotics in response to antibiotic resistance,[380] and a major financial services advisor has reported a negative feedback loop where drug companies lower their spending on research and development because they lack confidence that this investment will pay off, a decision that reduces their innovation.[381]

Investors' disappointing portfolio returns may be of limited interest to the rest of us, but all persons have a stake in the welfare that innovative drugs deliver and that most new drugs lack.[382] When innovation is absent in a new drug, the public not

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376. *See In re* Contin Antitrust Litig., 994 F. Supp. 2d 367, 438 (S.D.N.Y. 2014) (finding that one secondary patent was not infringed and invalidating the other as obvious).

377. JIE JACK LI, BLOCKBUSTER DRUGS: THE RISE AND DECLINE OF THE PHARMACEUTICAL INDUSTRY 171 (2014).

378. *See* Parasidis, *supra* note 366, at 462–63 ("HOI [health outcomes indices]-based derivatives can spur innovation by allowing innovators to hedge risk.").

379. *Id.*

380. *See* Lori Ioannou, *Big Pharma's Billion Dollar Scramble to Invest in Start-ups to Fuel Innovation*, CNBC (Mar. 28, 2018, 8:00 AM), https://perma.cc/SSV7-PGD8 (last updated Mar. 28, 2018, 11:52 AM) (last visited Oct. 12, 2019) (describing the need for antibiotics that can fight drug resistant bacteria) (on file with the Washington and Lee Law Review).

381. *See* DELOITTE CTR. FOR HEALTH SOLUTIONS, MEASURING THE RETURN FROM PHARMACEUTICAL INNOVATION 8 (2015), https://perma.cc/TGS9-6HZJ (PDF) 8 ("[C]ompanies continue to struggle to deliver new assets with sufficient value to offset losses through failure or increasing costs.").

382. *See, e.g.*, Inannou, *supra* note 380 (emphasizing the public need for a new generation of antibiotics, reporting that "more than 700,000 people die each year from infections resistant to most or all [current] antibiotics" with

only fails to benefit but can also suffer. Jerry Avorn, a physician and pharmacologist, has drafted a bit of boilerplate that deserves to be slapped on many drug labels: "This new medication has not been shown to be better than currently available products, and has a much more limited safety record. There is no evidence that its higher price is accompanied by any demonstrated therapeutic advantage."[383]

2. Industry-generated Lowering of Thresholds for Chronic Conditions

Pharmaceutical manufacturers have come up with an idea of how to increase sales when they lack an idea. Chronic diseases make money for the sector because patients live long enough to keep buying but do not get well enough to walk away from their prescription. Patent rents as a reward, writes the intellectual property scholar Samuel Murumba, encourage manufacturers to invest their research energies in this type of pathology rather than in vaccines or cures, "both of which wipe out the disease and thus destroy the goose guaranteed to lay the golden egg."[384]

In this setting, one way to make more new money selling prescription drugs without innovation in design is to enlarge this market, whose customers—all of them relatively unlikely to have their diagnosis undone—take daily doses.[385] According to a 2012 review, sixity percent of the medications most often prescribed in the United States are for three such chronic conditions: hypertension or high blood pressure, hyperlipidemia or high cholesterol, and diabetes.[386] All three are diagnosed with reference to numerical cutoffs.[387] This much systolic and diastolic

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antimicrobial resistance "projected to kill more people than cancer by 2050").

383. JERRY AVORN, POWERFUL MEDICINES 365 (2004).

384. SAMUEL MURUMBA, HUMAN RIGHTS AND INTELLECTUAL PROPERTY: A TRI-REGIME ACCOUNT AND THE CHALLENGE OF PERVERSE INCENTIVES 15 (2018).

385. *See* Linda M. Hunt et al., *The Changing Face of Chronic Illness Management in Primary Care: A Qualitative Study of Underlying Influences and Unintended Outcomes*, 10 ANNALS OF FAM. MED. 452, 455 (2012) (listing medications frequently taken by people with common chronic conditions).

386. *Id.* at 452.

387. *See id.* at 453 (showing a table of the numerical diagnostic cutoffs for each condition).

pressure as measured in numbered units, or this many milligrams of cholesterol or glucose, take a patient over the disease threshold.[388]

Quantitative minimums to qualify for all three diagnoses have been reduced in the last couple of decades.[389] Fasting glucose of 126 now marks the transition to diabetes in contrast to the 1992 cutoff, which had been 140.[390] The year 1992 lacked a disease of today called "prediabetes," a condition that these days receives pharmaceutical treatment.[391] For patients without diabetes, blood pressure can go as high as 160/95 without reaching a diagnostic threshold; today the nondiabetic cutoff is 140/90, and for persons with diabetes, 130/80.[392] "Pre-diabetes," a label that arrives when patients score a fasting plasma glucose of 100–125 milligrams per deciliter,[393] should be treated with lifestyle modifications, not medication, said the American Diabetes Association in 2003;[394] five years later, the organization switched to an official endorsement of drug therapy.[395] High-cholesterol diagnostic thresholds dropped from 280 milligrams per deciliter to 240, with a de facto minimum of 200 now guiding many physicians' decisions to prescribe a statin pill.[396]

Ostensibly independent expert panels write the decisions to define diagnostic criteria, but the pharmaceutical sector has left visible fingerprints on lowered minimums. After a National Institutes of Health panel recommended dropping the threshold

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388. *Id.*

389. *See id.* (confirming a "pronounced lowering of diagnostic thresholds for chronic conditions" resulting in a dramatic rise in diagnosis and treatment "notably [for] diabetes and hypertension").

390. *Id.*

391. *See id.* ("Revised guidelines encourage treatment of preconditions.").

392. *Id.* The recommendation applies to some classes of these patients. *Id.*

393. Meta J. Kreiner & Linda M. Hunt, *The Pursuit of Preventive Care for Chronic Illness: Turning Healthy People into Chronic Patients*, 36 SOC. OF HEALTH & ILLNESS 870, 882 n.1 (2013).

394. *Id.* at 874.

395. *See id.* ("[T]he 2008 ADA guidelines recommend medications for pre-diabetic individuals who have other risk factors such as obesity, family history or certain racial/ethnic identities.").

396. *See* ANGELL, *supra* note 365, at 85–86 (discussing this instance as among the dubious methods used to prop up a lucrative drug).

for hyperlipidemia and had its recommendation accepted, the former editor in chief of the New England Journal of Medicine pointed out that "most panel members who helped write the recommendations"—two out of nine—"had financial ties to the pharmaceutical companies that stood to gain enormously from increased use of statins."[397] Nine out of eleven physician panelists who in 2003 joined an official recommendation to lower the criteria for high blood pressure had similar ties to drug companies in the form of research funding, stock ownership, or payments for consulting work.[398]

The drug sector benefits from lowered thresholds other than those that increase sales of chronic-condition medications. In a memoir about her life in the weight classification of "super morbidly obese," Roxane Gay observes that the National Heart, Lung, and Blood Institute decided to reduce the body-mass index number that declares weight to be normal to 25, "thereby doubling the number of obese Americans."[399] A stated reason for this choice: "A round number like 25 would be easy for people to remember."[400] No drug-business influence like research funding or consulting income here, but a similar stake for rent seeking: Obesity is lucrative because vendors sell not only prescription drugs but prepared foods, dietary supplements, gym memberships and exercise regimens, books with orders about what to eat and not eat, and other commodities pointed at weight loss.[401] The most effective treatment for obesity, bariatric surgery, is so costly that according to a study published in the Journal of the American Medical Association, this intervention "does not reduce overall health care costs in the long term,"[402]

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397. Jerome Kassirer, *Why Should We Swallow What These Studies Say?*, WASH. POST, Aug. 1, 2004, at B3.

398. RAY MOYNIHAN & ALAN CASSELS, SELLING SICKNESS: HOW THE WORLD'S BIGGEST PHARMACEUTICAL COMPANIES ARE TURNING US ALL INTO PATIENTS 86–88 (2006).

399. *See* ROXANE GAY, HUNGER: A MEMOIR OF (MY) BODY 11–12 (2017) (discussing the arbitrary nature of many medical designations).

400. *Id.*

401. *See* Alice Juler, *The Political Economy of Obesity: The Fat Pay All*, *in* FOOD AND CULTURE: A READER (Carole Counihan & Penny Van Esterik eds., 3d ed. 2013) 546, 551–52 (examining the marketing structure centered around obesity).

402. Matthew L. Maciejewski & David E. Arterburn, *Cost-effectiveness of*

even though researchers have estimated the cost of obesity itself as more than $209.7 billion in health care expenses alone, not counting other consequences like job absenteeism.[403] The more people are taken out of the leave-them-alone "normal" weight category, the more customers emerge.[404]

Lowered minimums for established diseases is a mundane way for an idea-free manufacturer to make money; Eli Lilly did much better by recasting its old drug as the cure for a new disease.[405] Just when Prozac, the brand name for fluoxetine hydrochloride, was about to go off patent, its manufacturer won FDA approval to rebrand this active ingredient as Sarafem.[406] Sarafem contains the exact same fluoxetine hydrochloride as in Prozac and patients consume it in the same dose—twenty milligrams a day[407]—but it travels to a different therapeutic goal.[408] Instead of depression, Sarafem addresses premenstrual dysphoric disorder ("PMDD"), a label that the FDA started to recognize as a mental disorder in 1998,[409] following a Lilly-funded meeting of four FDA officials with six Lilly executives.[410]

Bariatric Surgery, 310 J. AM. MED. ASS'N 742, 742 (2013).

403. *See* John Cawley & Chad Meyerhoefer, *The Medical Care Costs of Obesity: An Instrumental Variables Approach*, 31 J. HEALTH ECON. 219, 227 (2012).

404. *See* GAY, *supra* note 399, at 11–12 (attributing the increased number of Americans now considered obese to the shift in the BMI calculation structure).

405. *See* Alicia Rebensdorf, *The Pimping of Prozac for PMS*, ALTERNET (June 12, 2001), https://perma.cc/T8DY-54HX (last visited Oct. 15, 2019) ("[It] has to do with money, with commerce, with, basically, sly marketing.") (on file with the Washington and Lee Law Review).

406. *See id.* (discussing the history of Sarafem as the successor of Prozac).

407. *See id.* ("Sarafem/Prozac both require 20 mg. doses . . . . You don't take Sarafem any less often. You don't take it [in] any smaller doses.").

408. *See id.* ("The company . . . turned the depression-stigmatized label Prozac to the oh-so-feminine name Sarafem" to treat PMDD).

409. *See* JAMES DAVIES, CRACKED: THE UNHAPPY TRUTH ABOUT PSYCHIATRY 76 (2013) (recalling the history of premenstrual dysphoric disorder).

410. *See* John Fauber et al., *For One Condition, the Drugs Came Before the Disorder*, MILWAUKEE J.-SENTINEL (Nov. 15, 2016, 11:02 PM), https://perma.cc/SU5M-MCPC (last updated Jan. 7, 2016, 3:43 PM) (last visited Oct. 29, 2019) (explaining that the meeting led the FDA and drug executives to conclude, on their own, that premenstrual dysphoric disorder was a clinical disorder necessitating selective serotonin reuptake inhibitors as treatment) (on file with the Washington and Lee Law Review).

The American Psychiatric Association did not recognize PMDD as a distinct psychiatric condition until 2013—"a determination that was based on the recommendation of a panel on which nearly 70% of the members had drug company ties."[411] Lilly rolled out Sarafem in pink instead of Prozac's green.[412] No accident: Drug designers know better than to make erectile-dysfunction pills in pink, writes the psychotherapist James Davies, or "a menstruation pill that is dark red."[413]

3. Which Drug Stands in for the Sector's Products?

When William Prosser named only one pharmaceutical product in comment k to his Section 402A of the Second Restatement, the drug he chose was the heroically formed Pasteur rabies vaccine.[414] The item is so excellent that even though it cannot be safe, Prosser suggested, it is never unreasonably dangerous.[415]

Louis Pasteur moved to rabies in 1885 after working on other important applications of microbiology.[416] He gave the vaccine he had synthesized to a nine-year-old boy who had been bitten severely by feral dogs.[417] Pasteur had done nothing resembling safety tests of his invention, but without an experimental treatment young Joseph Meister was headed for a swift death.[418] About a century and a half later, rabies still has no cure; it remains a fatal, painful disease that medicine cannot even alleviate, let alone reverse.[419] Prevention in the form of

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411. *Id.*

412. *See* Rebensdorf, *supra* note 406 (suggesting that Eli Lilly changed the pill color from green to pink to appeal to female customers).

413. DAVIES, *supra* note 409, at 79.

414. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (AM. LAW INST. 1965).

415. *Id.*

416. *See* GERALD L. GEISON, THE PRIVATE SCIENCE OF LOUIS PASTEUR 181 (1995) (narrating Pasteur's shift in focus from anthrax to rabies).

417. *Id.* at 206–07.

418. *See id.* at 206–12 (stating that Pasteur's administration of the rabies vaccine to Meister was the first administration of the vaccine to a human being; prior to the attack, Pasteur had treated only dogs).

419. *See* Shimau Zhu & Caiping Guo, *Rabies Control and Treatment: From Prophylaxis to Strategies with Curative Potential*, 8 VIRUSES 279, 293 (2016)

vaccination is the hope for persons vulnerable to rabies following a traumatic impact like an animal bite.[420] And so Prosser spoke for a consensus when he wrote in comment k that terrible side effects do not make this product defective, unreasonably designed, or in any way deserving of condemnation in court.[421]

This noble substance embodies therapeutic drugs at their best. It saves lives when all alternatives would fail.[422] Its inventor created it out of wholly benevolent motives.[423] To the extent it does harm, its harm is necessary. Prosser coined the phrase "unavoidably unsafe" to describe an urgent need that can be met nowhere else.[424]

Full props to Pasteur and his vaccine, but one drug—a substance invented in France back when Grover Cleveland was president of the United States and that has been superseded in current rabies therapy[425]—cannot stand in for the entire output of the sector. Any equating of prescription drugs with gains to social welfare à la comment k has to reckon with what this entire category of product does, rather than confine itself to one triumph. A counterpoint to the sole useful item for one painful and fatal disease, I suggest, is a drug at the other end of the utility-and-benevolence spectrum.

Here are a few numbers about what routinely—and accurately—gets called an epidemic. In 2018, a nonprofit health research institute announced its estimate of the cost of a crisis in the United States from 2001 to 2017: more than a trillion

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(noting that rabies still does not have a cure).

420. *See id.* at 280 (explaining that rabies can be prevented through the administration of a vaccine after exposure to the virus).

421. *See* RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (AM. LAW. INST. 1965) ("Since the disease invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified . . . .").

422. *See* Zhu & Gho, *supra* note 419, at 279 (stating that vaccination "is the only approved, effective method for post-exposure prophylaxis against rabies in humans").

423. *But see generally* GEISON, *supra* note 416 (criticizing Pasteur for shortcomings of ethics and research methods).

424. *See id.* (recognizing that vaccines have a high level of inherent, unavoidable risk).

425. *See* Zhu & Gho, *supra* note 419, at 280 (discussing the development of live-attenuated virus-based rabies vaccines, which emerged long after the Pasteur invention and are safer and more effective for post-exposure prophylaxis).

dollars.[426] An estimated two to four million persons in the United States suffered from opioid disorders in 2016,[427] and 72,000 persons died of drug overdoses (not all from opioids and some of them from mixes of opioids and other drugs) in 2017, a record number.[428] "According to the Centers for Disease Control and Prevention, nearly half of all opioid overdose deaths involve a prescription opioid,"[429] writes a student commentator, "and in 2013, providers wrote nearly 250,000,000 opioid prescriptions—enough for every adult in the United States to have his 'own bottle of pills.'"[430] Recent years marked an extraordinary reduction in life expectancy in the United States,[431] a development that experts have attributed to increased opioid-overdose deaths.[432] The catastrophe at issue here ranks among the worst public health disasters in American history.[433]

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426. *See Economic Toll of Opioid Crisis in U.S. Exceeded $1 Trillion Since 2001*, ALTARUM (Feb. 13, 2018), https://perma.cc/249N-UEXL (last visited Oct. 16, 2019) [hereinafter ALTARUM] (discussing the cost of the opioid epidemic as inclusive of lost wages, lost productivity, lost tax revenue, health care costs, and additional spending across different sectors) (on file with the Washington and Lee Law Review).

427. Margot Sanger-Katz, *Bleak New Estimates in Drug Epidemic: A Record 72,000 Overdose Deaths in 2017*, N.Y. TIMES (Aug. 15, 2018), https://perma.cc/X5HA-WM6E (last visited Oct. 16, 2019) (on file with the Washington and Lee Law Review).

428. *See id.* (finding that drug overdose deaths reached a record high due to higher levels of opioid use and deadlier drug combinations).

429. Alyssa M. McClure, Note, *Illegitimate Overprescription: How* Burrage v. United States *Is Hindering Punishment of Physicians and Bolsters the Opioid Epidemic*, 93 NOTRE DAME L. REV. 1747, 1750–51 (2018) (citations omitted).

430. *Id.*

431. *See* Grace Donnelly, *Here's Why Life Expectancy in the U.S. Dropped Again This Year*, FORTUNE (Feb. 9, 2018), https://perma.cc/7M67-UJUJ (last visited Nov. 22, 2019) (reporting that the new average life expectancy for Americans is 78.7 years, "which puts the U.S. behind other developed nations[,]" including "Canada, Germany, Mexico, France, Japan, and the U.K.") (on file with the Washington and Lee Law Review).

432. *See id.* (finding that the reduction in life expectancy is partially due to drug overdoses).

433. *See* BETH MACY, DOPESICK: DEALERS, DOCTORS, AND THE DRUG COMPANY THAT ADDICTED AMERICA 9 (2018) (deeming the opioid crisis the "worst drug epidemic in American history"); *see also* Neil Howe, *America's Opioid Crisis: A Nation Hooked*, FORBES (Nov. 30, 2017, 1:42 PM), https://perma.cc/3MRW-8KPR (last visited Oct. 16, 2019) (deeming opioid crisis the "worst public health crisis in American history") (on file with the Washington and Lee Law Review).

Prescription opioids are at least as worthy as the Pasteur rabies vaccine to serve as the industry exemplar in an overview of American drug products liability law and policy. They are more American in their origin, more recently invented (yet established enough to have a track record in health policy and law), more visible in contemporary litigation and law enforcement,[434] more significant within the national economy,[435] and much more widely consumed.[436] Moving as needed between the drug named OxyContin in particular and all prescription opioids in general, let us consider some contrasts between them and the Pasteur vaccine.

Amenability to dangerous misuse. No user can alter a dose of rabies vaccine to make it more dangerous. The only way to

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434. *See* Ausness, *supra* note 7 (reviewing opioid actions filed by governments); *see also* Haffajee & Mello, *supra* note 7, at 2302–03 (providing a summary of opioid litigation around the country); Thomas Sullivan, *Opioid Class Action Suit Filed in Five States*, POL'Y & MED. (last updated May 14, 2018), https://perma.cc/42D5-BWCG (last visited Oct. 17, 2019) (summarizing lawsuits filed against opioid distributors and the subsequent allegations) (on file with the Washington and Lee Law Review).

435. *See, e.g.*, Douglas L. Leslie et al., *The Economic Burden of the Opioid Epidemic on States: The Case of Medicaid*, AM. J. MANAGED CARE (July 30, 2019), https://perma.cc/2F2H-8GDC (last visited Dec. 9, 2019) (estimating that the overall societal cost of opioid use disorders—including health care, criminal justice, and workplace costs—reached $78.5 billion in 2016) (on file with the Washington and Lee Law Review).

436. The significance of this product is suggested by the long list of books about it as a crisis published in the last couple of years, a roster not limited to CHARLES ATKINS, OPIOID USE DISORDER: A HOLISTIC GUIDE TO ASSESSMENT, TREATMENT, AND RECOVERY (2018); NICHOLAS BUSH, ONE BY ONE: A MEMOIR OF LOVE AND LOSS IN THE SHADOWS OF OPIOID AMERICA (2018); J.N. CAMPBELL & STEVEN ROONEY, A TIME-RELEASE HISTORY OF THE OPIOID EPIDEMIC (2018); BRIAN ALLEN CARR, OPIOID, INDIANA (2019); MAUREEN CAVANAGH, IF YOU LOVE ME: A MOTHER'S JOURNEY THROUGH HER DAUGHTER'S OPIOID ADDICTION (2020); RYAN HAMPTON, AMERICAN FIX: INSIDE THE OPIOID ADDICTION CRISIS—AND HOW TO END IT (2018); TIFFANY JENKINS, HIGH ACHIEVER: THE INCREDIBLE TRUE STORY OF ONE ADDICT'S DOUBLE LIFE (2019); MACY, *supra* note 433; MEIER, *supra* note 7; LIZ MOORE, LONG BRIGHT RIVER (2020); HARRY NELSON, THE UNITED STATES OF OPIOIDS: A PRESCRIPTION FOR LIBERATING A NATION IN PAIN (2019); YNGVILD OLSEN & JOSHUA M. SHARFSTEIN, THE OPIOID EPIDEMIC: WHAT EVERYONE NEEDS TO KNOW (2019); TRAVIS RIEDER, IN PAIN: A BIOETHICIST'S PERSONAL STRUGGLE WITH OPIOIDS (2019); TERENCE G. SCHILLER, OPIOID EPIDEMIC: A NATIONAL PLAN TO STOP IT (2018); DANIEL SKINNER & BERKELEY FRANZ, NOT FAR FROM ME: STORIES OF OPIOIDS AND OHIO (2019); KIMBERLY SUE, GETTING WRECKED: WOMEN, INCARCERATION, AND THE AMERICAN OPIOID CRISIS (2019); EILENE ZIMMERMAN, SMACKED: A STORY OF WHITE-COLLAR AMBITION, ADDICTION, AND TRAGEDY (2020).

misuse this drug is to administer it to someone who has experienced no exposure to rabies. This unfortunate individual will suffer harmful side effects and gain no benefit.

OxyContin as a lab creation differed from rival painkillers like Vicodin and Percocet in its longer-acting formulation.[437] Approving it as a new drug in 1995, the FDA permitted the manufacturer to claim that the long-acting design "was believed to reduce" OxyContin's appeal to drug abusers.[438] No clinical evidence backed this claim; the agency was simply willing to accept without evidence that shorter-acting design meant a faster hit that abusers would value.[439] Purdue, its manufacturer, "trained sales representative to tell doctors that OxyContin was less addictive and prone to abuse than competing opioids, claims beyond the one approved by the F.D.A."[440]

Users easily learned that OxyContin contained significantly higher narcotic levels than its shorter-acting rivals, and they learned how to abuse it.[441] The long-acting Purdue opioid called MS Contin was written up in a 1996 medical journal as a favorite of addicts who had learned how to extract morphine from MS Contin and inject it.[442] In 1998, Purdue learned about a study published in a medical journal that identified MS Contin as addicts' favorite opioid, for the same high-narcotics condition found also in OxyContin.[443] Purdue did not report what it had

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437. *See* Barry Meier, *Origins of an Epidemic*, N.Y. TIMES (May 29, 2018), https://perma.cc/7C96-L49E (last visited Oct. 16, 2019) (reporting that the FDA allowed Purdue Pharma to uniquely claim that OxyContin's long-acting formulation posed less of a threat of abuse than other painkillers) (on file with the Washington and Lee Law Review).

438. *Id.*

439. *See id.* ("The [FDA] decision was not based on findings from clinical trials, but a theory that drug abusers favored shorter-acting painkillers because the narcotic they contained was released faster and so produced a quicker 'hit.'").

440. *Id.*

441. *See id.* (explaining that the long-acting Oxycontin could be snorted or injected intravenously).

442. *See id.* (detailing abusers' process of extracting morphine from MS Contin in Australia and New Zealand).

443. *See id.* (referencing an article from the *Journal of the Canadian Medical Association* reporting that MS Contin sold for $40 per 30-milligram tablet on the illegal drug market—the highest price of any prescription opioid).

learned to the FDA, and expanded its marketing campaign.[444] The method of dangerous misuse started soon after the OxyContin launch in 1996 and continued until 2010.[445]

Addicts and abusers learned to crush this pill to obtain full delivery of the opioid without the delay installed by its time-release feature.[446] Crushed (meaning pulverized) OxyContin could be snorted, smoked, or dissolved in water and then injected.[447] In 2010, Purdue reformulated OxyContin to defeat this alteration, and today's OxyContin when pounded turns into a gummy gel rather than an easy-to-ingest powder.[448] Users have passed around trips to defeat gummification of the opioid—including baking it, freezing it, and soaking it in a variety of solvents—but few of these modifications seem to work.[449] Frustrated by Purdue's reformulation, a significant number of these users abandoned their crush technique, which would have been a positive development if they had moved to abstinence from opioids rather than to heroin and other narcotics.[450]

Overpromotion. Sellers cannot overpromote a rabies vaccine, or at least they have never in known history been observed trying to overpromote this drug.[451] Patients who receive it as a

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444. *See id.* (reporting that Purdue instead gave the FDA and its sales officials an older survey that contradicted the Canadian study because "the company did not consider the small study's results significant").

445. *See* William N. Evans et al., *How the Reformulation of OxyContin Ignited the Heroin Epidemic,* 101 REV. ECON. & STAT. 1, 1 (2019) (arguing that Purdue's reformulation of OxyContin in 2010 made the drug less appealing to drug abusers).

446. *See* Abby Goodnough & Katie Zezima, *Drug Is Harder to Abuse, but Users Persevere*, N.Y. TIMES (Jun. 15, 2011), https://perma.cc/U3KH-9PBR (last visited Oct. 17, 2019) (stating that pre-2010, users discovered that crushing OxyContin tablets "produced an instant high as powerful as heroin").

447. *Id.*

448. *See id.* (noting that the reformulation is intended to deter abuse and many patients are frustrated by their inability to crush and inject the drug).

449. *Id.*

450. *See id.* (observing that Opana, a time-release painkiller similar to Oxycontin, "is showing up increasingly in police reports and has been blamed for a rash of overdose deaths"); *see also* Evans, *supra* note 445, at 1 (arguing that many drug abusers switch to heroin because it offers a cheaper and more accessible high than modified OxyContin).

451. *See* Zhu & Guo, *supra* note 419, at 280–81 (providing a brief history of the rabies vaccine).

treatment need it urgently. Externalities of its distribution and use exist—that was Prosser's point when he used it to stand in for all prescription drugs—but by hypothesis they are as low as possible because only people who must have this substance will buy it.[452]

Opioids, by contrast, went to patients for whom this drug would do harm, and it reached them because manufacturers chose an extraordinarily aggressive marketing strategy.[453] Opioid overpromotion reached its most egregious heights with OxyContin. Purdue hosted more than forty pain management symposia between 1996 and 2001, paying all expenses for more than 5,000 physicians, nurses, and pharmacists to be trained for a national speaker bureau.[454] Purdue also paid bonuses to its detailers to make sales calls to physicians identified in a database as the highest prescribers of opioids in the country.[455] It handed out approximately 34,000 coupons for a free prescription of its drug, and an array of branded promotional items for physicians that the Drug Enforcement Administration said was unprecedented in the history of opioid sales.[456] Although Purdue directed most of its marketing budget toward prescribers, it also promoted OxyContin to the public through a website called Partners Against Pain.[457]

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452. *See id.* at 281 ("Unlike most other vaccines . . . rabies vaccines are designed to be . . . administered primarily in a post-exposure manner.").

453. *See supra* notes 294–295 and accompanying text.

454. Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 AM. J. PUB. HEALTH 221, 221–22 (2009).

455. *See id.* at 222 (documenting the targeting of specific providers by Purdue Pharma salespeople to encourage OxyContin prescriptions).

456. *See id.* (noting Purdue Pharma's distribution of coupons for a free limited-time prescription for a 7- to -30 day supply of OxyContin); *see also* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-04-110, PRESCRIPTION DRUGS: OXYCONTIN ABUSE AND DIVERSION AND EFFORTS TO ADDRESS THE PROBLEM 25 (2003), https://perma.cc/YS8K-2LC4 (PDF) (recognizing that marketing techniques used by Purdue Pharma to sell OxyContin were unprecedented among schedule II opioids).

457. *See* Joseph B. Prater, Comment, *West Virginia's Painful Settlement: How the OxyContin Phenomenon and Unconventional Theories of Tort Liability May Make Pharmaceutical Companies Liable for Black Markets*, 100 NW. U.L. REV. 1409, 1430 n.172 (2006) (revealing that "Partners Against Pain . . . offered information about chronic pain and its treatments to the general public").

The manufacturer of OxyContin paid for other misbehaviors that included but were not limited to overpromotion,[458] and other drug manufacturers also overpromoted opioids.[459] Purdue had an agreement with the bigger and more established Abbott Laboratories to engage in joint promotion of OxyContin, paying Abbott a commission on sales.[460] Cephalon paid $425 million to settle federal charges that it engaged in overpromotion in the form of recommending unauthorized off-label uses of its opioid Actiq.[461] Another manufacturer paid less, just a tenth of the Cephalon sum, to settle Justice Department allegations that it "paid health care providers to induce them to promote or prescribe" Kadian, its opioid.[462] In 2019, law enforcement in this area escalated when executives of Insys Therapeutics, manufacturer of a transmucosal immediate-release fentanyl product, were convicted of federal racketeering charges for conduct that included bribing physicians to prescribe this opioid.[463]

Incentives for cohorts to join in socially destructive conduct. Just as the rabies vaccine cannot be modified to become more

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458. *See* Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, N.Y. TIMES (May 10, 2007), https://perma.cc/EM6N-3NQT (last visited Oct. 17, 2019) (reporting that Purdue Pharma executives pleaded guilty to misbranding OxyContin's true level of addictiveness) (on file with the Washington and Lee Law Review).

459. *See supra* notes 298, 317 and accompanying text.

460. *See* Howland v. Purdue Pharma L.P., 821 N.E.2d 141, 143 (Ohio 2004) (mentioning the agreement to share promotion obligations and profits from OxyContin net sales).

461. *See* Evan Hughes, *The Pain Hustlers*, N.Y. TIMES MAG. (May 2, 2018), https://perma.cc/ZN47-LXR6 (last visited Feb. 4, 2020) (pointing out that the criminal guilty plea and settlement did not stop Cephalon from being acquired for $6.8 billion just three years later) (on file with the Washington and Lee Law Review).

462. Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Alpharma to Pay $42.5 Million to Resolve False Claims Act Allegations in Connection with Promotion of Drug Kadian (Mar. 16, 2010), https://perma.cc/W44H-WXVG (last updated Sept. 15, 2014) (last visited Oct. 17, 2019) (on file with the Washington and Lee Law Review).

463. *See* Gabrielle Emmanuel & Katie Thomas, *Top Executives of Insys, an Opioid Company, Are Found Guilty of Racketeering*, N.Y. TIMES (May 2, 2019), https://perma.cc/LE97-Z57R (last visited Jan. 7, 2020) (reporting that federal authorities also recently filed "felony drug trafficking charges against a major pharmaceutical distributor" of opioids and two of its former executives) (on file with the Washington and Lee Law Review).

dangerous to a user, it also does not invite other populations into deleterious behaviors that a drug manufacturer starts. Opioids endangered the public not only through misconduct by their manufacturers, but by in effect recruiting constituencies into harm.[464] Actions by physicians, patients, and drug distributors compounded the dangers that manufacturers initiated.[465]

Physicians compound the harm of overpromotion when they choose to overprescribe this drug.[466] This pattern inverts the trope of the learned intermediary, which in the law of warning defect posits the physician as an intelligent inhibitor of ignorance and impulse on the part of patients.[467] Examples of opioid overpromotion noted in this Article were investments that paid off: doctors responded to these marketing initiatives by writing scripts.[468] Criminal, occupational-regulatory, and tort sanctions can befall physicians for wrongs related to drug prescriptions.[469] All these sanctions have been applied to opioid over-prescribers,[470] but the magnitude of the crisis greatly

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464. *See* Van Zee, *supra* note 454, at 222–23 (reviewing the great lengths to which Purdue Pharma went to convince health care providers that OxyContin was a safe treatment for chronic, non-cancer-related pain).

465. *See id.* at 223 (finding that drug distributors' marketing tactics encouraged physicians to prescribe opioids in unprecedented amounts).

466. *See id.* (documenting high prescribing areas by geography, with Maine, West Virginia, eastern Kentucky, southwestern Virginia, and Alabama prescribing opioids "5 to 6 times higher than the national average" by the year 2000).

467. *See supra* Part IV.B; *see also* Ben A. Rich & Lynn R. Webster, *A Review of Forensic Implications of Opioid Prescribing with Examples from Malpractice Cases Involving Opioid-related Overdose*, 12 PAIN MED. S59, S62 (2011) (noting physicians' professional responsibility regarding the safety and efficacy of treatment options).

468. *See* Van Zee, *supra* note 454, at 223 (reporting that after Purdue started promoting OxyContin for non-cancer pain, prescriptions increased almost tenfold, "from about 670,000 in 1997 to about 6.2 million in 2002"). For a review of the evidence that overpromotion increases prescribing, see *supra* note 294 and accompanying text (discussing the influence of promotional gifts on physicians' prescribing practices).

469. *See* 21 U.S.C. § 841(a) (2018) (imposing criminal penalties under the Controlled Substances Act); *see also* Rich & Webster, supra note 467, at S62–S63 (listing various theories of physician liability, including medical malpractice).

470. *See, e.g.*, United States v. Kohli, 847 F.3d 483, 486 (7th Cir. 2017) (affirming the conviction of a physician for violating the Controlled Substances Act); Koon v. Walden, 539 S.W.3d 752, 775 (Mo. Ct. App. 2017) (upholding a

exceeds the rate and severity of consequences that physicians have suffered.[471]

Continuing the actions of manufacturers that overpromote and physicians who over-prescribe, *patients* expand the harmful effects of this product by over-consumption.[472] The drug seeker who persuades a physician to write an opioid prescription for something other than physical pain is familiar to public health.[473] Refraining from blaming this category of patient, the medical ethicists Kelly Dineen and James DuBois take issue with the "duped" trope that faults physicians for believing complaints of severe pain.[474] Dineen and Dubois report that efforts to train subjects to tell the difference between fake and real pain fail, and note the unfortunate finding of "a connection between emotional intelligence and susceptibility to deception."[475] A student author faults patients more overtly. Most of the harm of OxyContin, he notes, stemmed from deliberate misuse: consumers bought this drug in an illegal market and sought it for recreation.[476]

According to litigation initiated around the country by both prosecutors in federal court and by cities and counties in state courts, *pharmaceutical distributors* expanded the harms of this

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$15,000,000 punitive damages award for negligent over-prescription of opioids); *Doctor Gives Up License After Opioid Allegations*, CHERRY HILL COURIER-POST (Apr. 17, 2018, 8:08 PM), https://perma.cc/Y9LH-AGS9 (last updated Apr. 20, 2018, 1:07 PM) (last visited Oct. 17, 2019) (covering a physician who agreed to stop practicing medicine after being accused of recklessly prescribing painkillers) (on file with the Washington and Lee Law Review).

471. *See Opioid Overdose*, CTR. FOR DISEASE CONTROL & PREVENTION, https://perma.cc/P73H-24FW (last updated Dec. 19, 2018) (last visited Dec. 9, 2019) (reporting that "on average, 130 Americans die every day from an opioid overdose") (on file with the Washington and Lee Law Review).

472. *See supra* notes 427–428 and accompanying text.

473. *See, e.g.*, Kelly K. Dineen & James M. DuBois, *Between a Rock and a Hard Place: Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanction?*, 42 AM. J.L. & MED. 7, 9 (2016) (providing examples of "frequent flier" patients and those who fool physicians into prescribing pain medication with the intent to sell the prescription).

474. *See id.* at 11 (defining a "duped" physician as one who "inadvertently supplies drugs to a drug abuser because the physician has been deceived by a drug abuser posing as a patient").

475. *Id.* at 13.

476. *See* Prater, *supra* note 457, at 1411 (referencing West Virginia's $10 million settlement with Purdue Pharma for harms caused by Oxycontin's recreational use).

drug.[477] These businesses, plaintiffs claim, shipped excessive quantities of opioids to pharmacies in violation of the Controlled Substances Act,[478] which required them to report suspicious orders.[479] Mallinckrodt, Inc., McKesson Corporation, Kinray LLC, and Cardinal Health, Inc. all settled federal actions accusing them of violating this statute not only by failing to report, but by failing to implement an effective detection system (a lapse by Mallinckrodt),[480] failing to abide by an earlier agreement with the federal government to monitor sales (McKesson),[481] and violating state recordkeeping laws (Kinray and Cardinal Health).[482]

Collateral effects. Whenever the rabies vaccine causes harm, this injury stops at the body of the one who takes it; the harm of opioids goes beyond a physical impact on one person.[483] Take HIV. One study begins by noting that opioid dependence and HIV have been linked from the start in the United States, with heroin users at risk of contracting the virus from sharing and reusing

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477. *See* Haffajee & Mello, *supra* note 7, at 2302–03 (providing a summary of opioid litigation around the country); Sullivan, *supra* note 434 (summarizing lawsuits filed against opioid distributors and the subsequent allegations); *see also* Emmanuel & Thomas, *supra* note 463 (reporting federal drug trafficking charges brought against an opioid distributor).

478. 21 U.S.C. § 832 (2018).

479. *See id.* (delineating the reporting requirements for pharmaceutical distributors).

480. *See* Lenny Bernstein et al., *Mallinckrodt Reaches Settlement with 'Bellwether' Counties in Mammoth Opioid Lawsuit*, WASH. POST (Sept. 6, 2019, 4:15 PM), https://perma.cc/B2BN-N42M (last visited Nov. 22, 2019) ("Under the deal, Mallinckrodt would pay [two Ohio] counties $24 million in cash and donate $6 million in drugs, including addiction treatment medications.") (on file with the Washington and Lee Law Review).

481. *See* Haffajee & Mello, *supra* note 7, at 2303 (noting that McKesson's settlement agreement included an agreement to modify its marketing and distribution practices).

482. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of the Controlled Substances Act (Dec. 23, 2016), https://perma.cc/SDQ5-4PVG (last visited Nov. 22, 2019) ("[T]he Southern District of New York has entered into a separate settlement agreement . . . in which Cardinal agreed to resolve allegations that Kinray, Inc., a subsidiary distributor, failed to report suspicious orders by pharmacies in the Kinray service area.") (on file with the Washington and Lee Law Review).

483. *See* ALTARUM, *supra* note 426 (discussing the impact of opioid abuse on individuals, their families, the health care system, and society in general).

syringes.[484] Heroin is not the only opioid, as we know, and this study went on to find that users of oxycodone (the generic name for the drug that started its life named OxyContin) had sex with more partners than did heroin users, a behavior the authors called high risk for the spread of HIV.[485] Individuals who start their opioid use with prescriptions and then switch to injecting heroin move to a much riskier drug experience, as is taught in reverse by a United Nations study that found that substituting non-injected opioids for injected drugs lowered the risk of HIV transmission by fifty-four percent.[486]

Just as the pathologies of prescription opioids are not limited to what they do to the human body when ingested, the drugs they enlist as agents of harm are not limited to their original incarnations. Dependency can follow from prescriptions that are too easy to obtain and renew;[487] when crackdowns make this release harder to obtain lawfully, users move to cheaper and more accessible substitutes like heroin and illegal fentanyl.[488] Evidence supports this gateway-drug contention.[489] Writing about

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484. *See* Christina S. Meade et al., *HIV Risk Behavior in Opioid Dependent Adults Seeking Detoxification Treatment: An Exploratory Comparison of Heroin and Oxycodone Users*, 18 AM. J. ADDICTION 289, 289 (2009) (tracking the link between HIV and heroin use to the early 1980s).

485. *See id.* at 293 (suggesting that HIV prevention efforts should be targeted to oxycodone users as well as heroin users).

486. JOINT U.N. PROGRAMME ON HIV/AIDS, MILES TO GO: CLOSING GAPS, BREAKING BARRIERS, RIGHTING INJUSTICES 51 (2018), https://perma.cc/NF43-48MV (PDF).

487. *Cf.* Haffajee & Mello, *supra* note 7, at 2302 (highlighting cases in which prescribed opioid users were misled by companies' misrepresentations of the addictiveness of their drugs).

488. *See* Sarpatwari, *supra* note 368, at 477 (noting the "burgeoning" use of heroin and illicit opioids as a substitute for prescribed opioids).

489. *See* Theodore J. Cicero et al., *The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years*, 71 J. AM. MED. ASS'N PSYCHIATRY 821, 822 (2014) (citing the "growing evidence" that prescription opioid users "graduate or shift to heroin"); *see also* Wilson M. Compton et al., *Relationship Between Nonmedical Prescription-Opioid Use and Heroin Use*, 374 NEW ENG. J. MED. 154, 156–159 (2016) (citing national-level, general-population data showing that a sizeable majority of persons who recently started to use heroin—one study counted 77.4% and the other 79.5%—had been prescribed opioids nonmedically); *Heroin*, NAT'L INST. ON DRUG ABUSE, https://perma.cc/QCH4-QDYH (last updated June 2018) (last visited Nov. 7, 2019) ("Research now suggests that misuse of [opioid] medications may actually open the door to heroin use.") (on file with the Washington and Lee Law

the role of physicians as opioid over-prescribers, a psychiatrist adverts to a second gateway hypothesis: the possibility that a "fundamental biological mechanism based on the chemical composition of the [prescription opioid] drug itself" leads a user to move to street drugs.[490] Illicit drug markets bring social harms beyond what the substances themselves do when ingested.[491]

Another collateral consequence of prescription opioids has been significant in a nation where more than thirty percent of all persons, and more than forty percent of older adults, suffer from chronic pain.[492] Centers for Disease Control guidelines published in 2016 steered physicians to prescribe lower doses of opioids[493] at the same time that state laws, Medicare rules, and large pharmacy chains made prescriptions harder to refill.[494] Anguish that would not have occurred but for the so-called opioid epidemic ensued and remains in place. A physician-neuroscientist notes the lamentable nature of this suffering: "While diversion and illicit use is real, the great majority of individuals abusing opioids (usually young people) are getting 'high' taking grandma's Oxycontin®, stealing it or buying it from their friends or relatives and do not get them by prescription from an MD."[495] Constraints take prescriptions from people in physical distress.[496] One news

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Review).

490. ANNA LEMBKE, DRUG DEALER MD 22 (2016).

491. *See, e.g.*, Meade, *supra* note 484, at 289 (addressing the risks of contracting and spreading HIV associated with illicit opioid use).

492. Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 NEW ENG. J. MED. 1253, 1253 (2016).

493. Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, CTR. DISEASE CONTROL MORBIDITY & MORALITY WKLY. REP. 2016;65 (NO. RR-1): 1–49.

494. *See* Terrence McCoy, *'Unintended Consequences': Inside the Fallout of America's Crackdown on Opioids*, WASH. POST (May 31, 2018), https://perma.cc/6VFP-DSWN (last visited Oct. 18, 2019) ("Dozens of states, Medicare and large pharmacy chains . . . have since announced or imposed restrictions on opioid prescriptions.") (on file with the Washington and Lee Law Review).

495. Howard L. Fields, *The Doctor's Dilemma: Opiate Analgesics and Chronic Pain*, 69 NEURON 591, 592 (2011).

496. *See* McCoy, *supra* note 494 (sharing stories of chronic pain patients whose prescriptions were tapered—"some by 50 percent, others by 90"—to bring them within CDC guidelines).

story about the prescriptions crackdown quoted a nurse practitioner who decided to close her pain practice because she could no longer tolerate having to "choose between hurting patients by providing inadequate prescriptions and going to prison for exceeding CDC guidelines."[497]

Numerous other collateral effects have spread past individuals who used opioids themselves. Tens of thousands of children of addicted parents have gone to foster care.[498] Fentanyl, which killed the popular musicians Prince and Tom Petty[499] and which in its FDA-regulated version has functioned as both a gateway to illicit drugs and an alternative to prescribed opioid pills when they become unavailable,[500] has street versions with names like Apache, China Girl, Dance Fever, and Murder 8. Street fentanyls dominate the death tally for this drug, which rose by 540% in the three years ending in 2016.[501] One Brookings Institute study attributes to opioids about a fifth of the decline in men's labor force participation since 2007.[502] Another Brookings paper attributes extraordinary and unprecedented violence in the Mexico to north-of-the-border demand for opiates.[503]

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497. *Id.*

498. *See* Jeanne Whalen, *The Children of the Opioid Crisis,* WALL ST. J. (Dec. 15, 2016, 10:46 AM), https://perma.cc/3C6E-4XCS (last visited Oct. 18, 2019) (reporting that many of the children are "growing up in mayhem") (on file with the Washington and Lee Law Review).

499. *See* David Browne, *Music's Fentanyl Crisis: Inside the Drug That Killed Prince and Tom Petty*, ROLLING STONE (June 20, 2018, 2:51 PM), https://perma.cc/T76L-C8V3 (last visited Oct. 18, 2019) (confirming that Prince and Petty, who had both been prescribed fentanyl, died from overdosing on the drug) (on file with the Washington and Lee Law Review). In Petty's case, "two other, more dangerous derivatives" of the prescribed fentanyl were found in his system, suggesting an acquisition from the black market. *Id.*

500. *See supra* note 489 and accompanying text.

501. *See* Josh Katz, *The First Count of Fentanyl Deaths in 2016: Up 540% in Three Years*, N.Y. TIMES (Sept. 2, 2017), https://perma.cc/8Y4K-M5X8 (last visited Nov. 7, 2019) ("[D]eaths involving synthetic opioids, mostly fentanyls, have risen to more than 20,000 from 3,000 in just three years.") (on file with the Washington and Lee Law Review).

502. *See* Alan B. Krueger, *Where Have All the Workers Gone? An Inquiry into the Decline of the U.S. Labor Force Participation Rate*, BROOKINGS PAPERS ON ECON. ACTIVITY, Fall 2017, at 49 ("[T]he increase in opioid prescriptions could perhaps account for a 0.6 percentage point decline in male labor force participation, which is 20 percent of the observed decline during this period.").

503. *See* Vanda Felbab-Brown, *Hooked: Mexico's Violence and U.S. Demand for Drugs*, BROOKINGS INST. (May 30, 2017), https://perma.cc/A4DX-HQJ7 (last

The question of innovation. Pasteur innovated to make his vaccine;[504] OxyContin was enough of a copycat not to deserve the patent that Purdue got for it.[505] Dubious entitlement to be called novel is hardly the worst sin of this drug, but it warrants attention because innovation by the sector is so central to Pillar #4. Pharmaceutical companies profit from the notion that they work devotedly to offer the next cure.[506]

Sometimes they do just that. Vaccines in general, not just the Pasteur exemplar, have made the world a healthier place.[507] Contemporary drugs for Hepatitis C offer another example.[508] Since 2014, treatment for this disease has moved from mostly failure to cures for the large majority of patients treated, with a new class of medications—direct-acting antivirals—earning the credit.[509] At the other side of the ledger, next to OxyContin, sit numerous drugs approved by the FDA even though they do not make patients better off.[510] Naming opioids as illustrative of prescription drugs fills in a mixed picture that has at least as much non-innovation in it as health-generating novelty.

The question of effectiveness. Any assessment of a prescription drug's safety necessarily must engage with its

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visited Oct. 18, 2019) (identifying "the rising taste in the United States for opiates" as a driver for escalating violence in Mexico) (on file with the Washington and Lee Law Review).

504. *See generally* GEISON, *supra* note 416.

505. *See* Sarpatwari, *supra* note 368, at 468 (observing that Purdue's patent for extended-release oxycodone contained the same constituent elements of Contin).

506. *See, e.g.*, *id.* at 467 (explaining how Purdue "turned extended-release oxycodone into a blockbuster"); *cf.* LaMattina, *supra* note 5 (listing reasons for negative views of the pharmaceutical industry).

507. *See Vaccines*, NAT'L INST. ALLERGY & INFECTIOUS DISEASES (last updated July 1, 2019), https://perma.cc/T3AN-GEB9 (last visited Nov. 7, 2019) ("Vaccines provide a safe, cost-effective and efficient means of preventing illness . . . .") (on file with the Washington and Lee Law Review).

508. *See Take a Bow, Pharma, for the Hepatitis C Drugs*, MANAGED CARE (Mar. 28, 2018), https://perma.cc/G59M-BEMU (last visited Nov. 7, 2019) (noting that hepatitis C treatment "has gone from failure rates as high as 70% to success rates as a high as 99%") (on file with the Washington and Lee Law Review).

509. *See id.* (reporting that the direct-acting antivirals Olysio and Sovaldi "drove the sustained viral response—no detectable virus after 12 weeks of therapy—to 80% and 90% of patients, respectively").

510. *See supra* Part IV.D.1.

effectiveness, the upside counterpart to the downside of inevitable risk. Rabies vaccines do a good job of warding off rabies.[511] Opioids perform less well at their task of killing pain.[512]

Evidence for this conclusion comes from a host of studies. Patients in Veterans Affairs primary clinics suffering from two types of chronic pain achieved no more relief from opioids than non-opioid drugs.[513] Emergency room patients experiencing moderate to severe pain gained as much relief from acetaminophen and ibuprofen, also known by their brand names Tylenol and Advil, as they did from opioids.[514] A significant minority of patients in another study, about twenty percent, reported that the opioids they took did not alleviate their pain; its author identified what he called "46 possible pathologic causes" for this ineffectiveness.[515]

That opioids succeed in reducing pain when taken for extended periods is unlikely. A 2017 meta-analysis that reviewed sixty-seven studies examining eight intervention categories concluded that no published finding has ever compared long-term opioid therapy (defined as taking this medication for more than one year) with "placebo, no opioid, or nonopioid therapies."[516] One telling datum on the ineffectiveness of prescription opioids:

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511. *See* Charles E. Rupprecht et al., *Rabies Vaccines, in* PLOTKIN'S VACCINES 918, 938 (7th ed. 2018) (examining the effectiveness of rabies vaccines).

512. *See, e.g.*, Andrew K. Chang et al., *Effect of a Single Dose of Oral Opioid and Nonopioid Analgesics on Acute Extremity Pain in the Emergency Department: A Randomized Clinical Trial*, 318 J. AM. MED. ASS'N 1661, 1662–63 (2017) (comparing the effects of opioids with nonopioids on patients in emergency departments and finding "no statistically significant or clinically important differences in pain reduction").

513. *See* Erin E. Krebs et al., *Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients with Chronic Back Pain or Hip or Knee Osteoarthritis Pain: The SPACE Randomized Clinical Trial*, 319 J. AM. MED. ASS'N 872, 881 (2018) ("Treatment with opioids was not superior to treatment with nonopioid medications for improving pain-related function over 12 months.").

514. Chang, supra note 512, at 1663–64.

515. Forest Tennant, *Why Oral Opioids May Not Be Effective in a Subset of Chronic Pain Patients*, 17 J. PAIN MGMT. S39 (2016).

516. Joseph W. Frank et al., *Patient Outcomes in Dose Reduction or Discontinuation of Long-Term Opioid Therapy: A Systematic Review*, 167 ANNALS INTERNAL MED. 181, 181 (2017).

Although prescriptions have dropped in recent years, levels of reported pain are unchanged.[517]

V. Conclusion

Of all sources of physical injury to human bodies in the United States, the sector that occupies in this Article enjoys especially powerful shelter from legal accountability for the harm it causes.[518] Prescription drugs unquestionably contribute to the public good. That value noted, the rule of law ought to extend to them. Products liability law furnishes well-established causes of action to right this wrong.[519]

Here, "the rule of law" means being within reach of legal sanctions. Products liability law governs products. A few categorical exceptions to products liability recourse do exist, but they are written explicitly into legislation. Guns and vaccines illustrate the category of explicit statutory immunity.[520] The immunity enjoyed by prescription drugs is the opposite of explicit. Persons injured by one type of defective product turn out almost certain to gain nothing in court even though all products liability causes of action are in principle available to them.[521]

Experience teaches that transparent immunity for prescription drugs can be achieved. Federal legislation addressing the closely related category of vaccine injury tells

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517. *See* Robert Gebelhoff, *The Opioid Epidemic Could Turn into a Pandemic if We're Not Careful*, WASH. POST (Feb. 9, 2017, 3:16 PM), https://perma.cc/R5HE-3SM5 (last visited Oct. 18, 2019) ("Despite no change in the amount of pain reported in the United States, abuse of prescription painkillers and heroin has exploded.") (on file with the Washington and Lee Law Review).

518. *See supra* Parts III.A–III.C.

519. OWEN, *supra* note 20, at 552.

520. *See supra* notes 16–17 and accompanying text.

521. This reality makes a recent proposal from a prominent products liability scholar especially bold. Mary Davis contends that liability for pharmaceuticals ought to be strict, rooted in "causation and damage alone." Davis, *supra* note 159, at 447; *see also id.* at 448 (announcing a query: "ultimately, the question remains: should every patient who suffers an adverse side effect be recognized as having suffered an injury in law?" and answering the question "yes"). At present, tort liability barely exists even when an injured plaintiff can prove defect or fault.

claimants explicitly what they hold and lack by way of a remedy.[522] Judicial readings of the vaccine statute have continued this clarity by stating that claims for design defect and failure to warn are expressly preempted.[523] Even implied preemption of claims against drug manufacturers, though more veiled than the express kind, is clearer than the shadowy yet comprehensive immunity reported in this Article. Attorneys who represent plaintiffs and defendants in drug cases routinely prepare for the prospect of summary judgment based on preemption as an affirmative defense.[524]

If products liability immunity for any object sold in commerce is a good idea, let that immunity be known and intelligible. If immunity is not desirable, then the object ought to face reckoning in the courts. This Article has moved toward better reckoning first by identifying (Almost) No Bad Drugs as a bottom-line result and then by setting out to find origins of this extraordinary state of the law. Near-total insulation from products liability had to be laid out in these pages because it is not bounded by any statute, regulation, judicial decision, or even another secondary writing.

Supports for my conclusion of "(almost) no bad drugs" exist at three levels. First, numbers. Even the capacious criteria for inclusion that I used yielded only a few pharmaceutical products that have ever met with judicial condemnation in a personal injury action. Second, both decisional law and torts Restatements treat drug manufacturers with exceptional indulgence. The third and most elusive support needed the longest exposition in this Article. Pharmaceutical products, I argued, fare exceedingly well in personal-injury liability law because widely held beliefs about

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522. *See supra* note 17 and accompanying text.

523. *See* Bruesewitz v. Wyeth LLC, 562 U.S. 223, 243 (2011) (holding that design defect claims brought against vaccine manufacturers are preempted); *see also* Holmes v. Merck & Co., 697 F.3d 1080, 1084 (9th Cir. 2012) (extending *Bruesewitz* by determining that failure to warn claims are also preempted, and that preemption eliminates tort redress for the parents of a vaccine-injured child).

524. *See* Arameh O'Boyle & Clancy Galgay, *"Newly Acquired Information" and Federal Preemption Defenses in Pharmaceutical Products Liability Cases*, AM. BAR ASS'N (July 19, 2019), https://perma.cc/746T-NH4B (last visited Oct. 18, 2019) ("Federal preemption remains the holy grail of defenses in pharmaceutical products liability cases. A successful preemption defense can dispose of cases in their entirety and often quite rapidly.") (on file with the Washington and Lee Law Review).

the value of shelter from accountability prop them up. Even before one particular type of prescription drug inflicted catastrophic harm on American public health and welfare, these premises earned the questioning they received here.