# MEDICAL DEVICE DANGERS: CHOOSING IGNORANCE IN THE COURTS AND AT THE FDA

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ABSTRACT

*Medical devices save lives and improve well-being but have caused as many as 83,000 deaths and 1.7 million injuries in a recent decade. Decisions of critical importance—patients' decisions whether to have a device implanted, doctors' decisions about which device to use, insurers' decisions whether to reimburse for those devices—depend on information about risk that is provided by manufacturers. But producing this information is costly. Injured patients, through private lawsuits under state products liability theories, can incentivize device manufacturers to incur these costs and to produce and disclose information about device risk. Unfortunately, courts are making it increasingly unlikely that this will occur. Using a new empirical analysis of cases that have interpreted "comment k," a sixty-year-old liability shield set out in the* Restatement (Second) of Torts*, this Article shows that over the past quarter-century courts have aggressively limited device manufacturers' exposure to liability and thus have reduced one of their main incentives to invest in the production of information about device risk. And worse, these courts' decisions have not been required by statute or by precedent; rather, courts have been choosing to interpret comment k in ways that keep us ignorant*

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*of the dangers posed by medical devices. These decisions have a synergistic effect with the Supreme Court's decisions that have preempted state law actions against many devices and with the limits on the FDA's ability to require manufacturers to produce information about risk. As a result, patients and physicians, as well as insurers, regulators, courts, and juries, are all being forced to make decisions based on unnecessarily limited information.*

*Unfortunately, straightforward solutions, such as Congress augmenting the FDA's authority to require clinical trials or courts changing the way in which they are interpreting comment k, are unlikely to succeed. This Article evaluates an alternative set of potential solutions that may help put critical medical decisions on more solid ground.*

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## INTRODUCTION

In early 2023, I found myself considering whether to have partial knee replacement surgery. I was fortunate to have good health insurance that would cover most of the costs and a supportive family network who would help me through the recovery process. My surgeon assured me that I would be able to return to activities I loved. But my thoughts returned time and again to concerns about safety; there is nothing like years of medical practice followed by years of work as an FDA law and torts scholar to make one doubt the wisdom of having any medical device permanently implanted into your body. Seeing just a small sliver of the nearly 83,000 deaths and 1.7 million injuries that may have been caused by medical devices over a recent ten-year period[1] is enough to give one pause. How likely was it that the implant would fail during ordinary use,[2] or release toxic levels of heavy metals into my body,[3] or harm me in any of the myriad ways that we have seen similar devices harm others in the past or even in ways we have not yet identified? Before agreeing to go under the knife, I needed enough information to weigh the dangers posed by the particular medical device I would receive against the potential benefits it offered.

No medical device can be made perfectly safe; indeed, we want some devices that can cause significant harm to be available for use under the right conditions because of the great benefits they offer. Thus, regulation seeks to ensure that devices present an acceptable risk-benefit ratio.[4] For the FDA's determination that a device may

1. U.S. GOV'T ACCOUNTABILITY OFF., GAO-24-106699, MEDICAL DEVICES: FDA HAS BEGUN BUILDING AN ACTIVE POSTMARKET SURVEILLANCE SYSTEM 1 (2024); *Medical Devices Harm Patients Worldwide as Governments Fail on Safety*, INT'L CONSORTIUM OF INVESTIGATIVE JOURNALISTS (Nov. 25, 2018), https://www.icij.org/investigations/implant-files/medical-devices-harm-patients-worldwide-as-governments-fail-on-safety/ [https://perma.cc/UKZ8-MZZ5].

2. *See* Mei Lin Tay, Sue R. McGlashan, A. Paul Monk & Simon W. Young, *Revision Indications for Medial Unicompartmental Knee Arthroplasty: A Systematic Review*, 142 ARCHIVES ORTHOPAEDIC & TRAUMA SURGERY 301, 307 (2022) (discussing failure rates and modes for partial knee replacement devices).

3. *See* Jason W. Romesburg, Paul L. Wasserman & Candace H. Schoppe, *Metallosis and Metal-Induced Synovitis Following Total Knee Arthroplasty: Review of Radiographic and CT Findings*, J. RADIOLOGY CASE REPS., Sep. 2010, at 7, 8.

4. *See* David G. Owen, *Defectiveness Restated: Exploding the "Strict" Products Liability*

be marketed in the United States, this means that a device must satisfy the statutory standard of a reasonable assurance of safety and effectiveness.[5] For any of us thrust into the role of a patient, this means deciding whether the potential benefits exceed our individual risk tolerance.

Regardless of who is performing a risk-benefit analysis, for that analysis to be more than mere guesswork, device risk must be characterized as precisely as possible. The term "risk" actually encompasses three related concepts: hazards, risks, and risk uncertainties.[6] All devices pose certain known hazards—that is, every device can cause specific kinds of harms. For devices used in partial knee replacements, these include failure of the connection between the device and the patient's bone ("aseptic loosening") and infection.[7] Device risks—that is, the likelihood of these hazards materializing[8]—can be estimated, typically through clinical studies. One study of partial knee replacements found that the risk of aseptic loosening was 2.4 percent[9] and another found that the risk of infection was 0.9 percent.[10]

But this information about hazards and risks masks a great deal of uncertainty.[11] Devices may pose hazards that have not yet been identified, even after clinical studies and, in some cases, even after

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*Myth*, 1996 U. ILL. L. REV. 743, 754 ("When safety is properly conceived of in *a priori* terms, as a prediction of the avoidance of future injury from some condition, it is necessarily a matter of probability and, hence, degree.").

5. *See* 21 U.S.C. § 360c(a)(1) (establishing that the standard for each risk class of devices is a "reasonable assurance of the safety and effectiveness of the device").

6. *See* Timothy D. Lytton, *Known Unknowns: Unmeasurable Hazards and the Limits of Risk Regulation*, 76 OKLA. L. REV. 857, 863 (2024); David Spiegelhalter, *Risk and Uncertainty Communication*, 4 ANN. REV. STATS. & ITS APPLICATION 31, 32 (2017).

7. *See* Tay et al., *supra* note 2, at 307.

8. *See* Lytton, *supra* note 6, at 863; Spiegelhalter, *supra* note 6, at 32-33.

9. Curtis A. Robb, Gulraj S. Matharu, Khalid Baloch & Paul B. Pynsent, *Revision Surgery for Failed Unicompartmental Knee Replacement: Technical Aspects and Clinical Outcome*, 79 ACTA ORTHOPAEDICA BELGICA 312, 313-14, 314 tbl. I (2013) (reporting twelve incidents of aseptic loosening out of a total of 494 patients).

10. Philip Winnock de Grave, Justine Barbier, Thomas Luyckx, Alexander Ryckaert, Paul Gunst & Luc Van den Daelen, *Outcomes of a Fixed-Bearing, Medial, Cemented Unicondylar Knee Arthroplasty Design: Survival Analysis and Functional Score of 460 Cases*, 33 J. ARTHROPLASTY 2792, 2796 tbl. 2 (2018).

11. *See* Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 CORN. L. REV. 773, 776, 798-99 (1997) (dividing these uncertainties into those that are "trans-scientific," those that cannot be addressed by scientific study, and those that are "preventable," that is, those that can be reduced or eliminated by scientific study).

long use in clinical practice.[12] And the seemingly concrete values for device risks that are derived from clinical studies are really just point estimates that sit within a range of possibilities. For example, the risk of needing a reoperation for any reason within ten years of a knee replacement was reported in one study to be 5.8 percent, but a closer reading of the data found that there was a 95 percent likelihood that the actual risk fell somewhere between 2.5 percent and 13.2 percent.[13]

These "risk uncertainties" have important real-world implications. A patient considering whether to have surgery might come to a different decision if told that their risk of needing a second, more complex operation fell at the low end of that 2.5 percent to 13.2 percent range as opposed to the high end.[14] Likewise, a physician's decision to implant a certain device, an insurer's decision to reimburse the use of a device, and a jury's determination of whether a device was defective might well be different depending on which set of numbers they were provided. Because information with this range of uncertainty can support diametrically opposed risk-benefit conclusions, many critical decisions may be little more than

12. *See* Jenya Godina, *Left to Their Own Devices: How the Dangers of Power Morcellators Went Undetected by FDA for Two Decades*, 74 FOOD & DRUG L.J. 128, 130 (2019) (discussing the absence of reports of subsequently-recognized spread of malignant cells by power morcellators over a twenty-two-year period following the first FDA clearance of such devices).

13. *See* Winnock de Grave et al., *supra* note 10, at 2795 (reporting a ten-year Kaplan-Meier survivorship from need for revision surgery of 94.2 percent and a 95 percent confidence interval of 86.8 percent to 97.5 percent). These uncertainties are compounded by the fact that different studies may yield very different results. *See* Tay et al., *supra* note 2, at 307 (summarizing the outcome of a metanalysis of cohort and registry-based studies).

14. Using the range of values about the need for reoperation from the Winnock de Grave study and the range of values for patient satisfaction from other studies, a patient could be presented with a 2.5 percent risk of needing reoperation and an 86 percent likelihood of long-term satisfaction, or a 13.2 percent risk of reoperation and a 70 percent likelihood of satisfaction, based on the same clinical trials. *Cf.* Robb et al., *supra* note 9, at 313-14, 314 tbl. I (listing aseptic loosening, pain, infection, and other causes of reoperation); Winnock de Grave et al., *supra* note 10, at 2795, 2796 tbl. 2 (estimating likelihood of remaining free from need for reoperation at ten years between 2.5 percent and 13.2 percent and listing infection and other complications that lead to reoperation); Tay et al., *supra* note 2, at 307 (reporting aseptic loosening and progression of osteoarthritis as most common modes of failure); Robert B. Bourne, Bert M. Chesworth, Aileen M. Davis, Nizar N. Mahomed & Kory D. J. Charron, *Patient Satisfaction After Total Knee Arthroplasty: Who is Satisfied and Who is Not?*, 468 CLINICAL ORTHOPAEDICS & RELATED RSCH., 57, 60 (2010) (reporting patient satisfaction after knee replacement between 70 percent and 84 percent for activities of daily living and between 72 percent and 86 percent for pain relief).

guesswork. What is needed is more robust information that narrows these ranges—that reduces the risk uncertainty—enough to make risk-benefit analysis meaningful.

This kind of information, which we expect manufacturers to provide,[15] comes at a steep cost in terms of time, effort, and money.[16] Even a small clinical device trial can cost tens of millions of dollars and take years to conduct.[17] And manufacturers have significant market-based incentives not to generate this information: A study that shows a device causes more harm than expected or offers lower-than-anticipated benefits can diminish market share or end the development of a new product.[18] Two important regulatory systems—FDA premarket gatekeeping and state products liability law[19]—incentivize device manufacturers to produce and disclose information bearing on device dangers.[20] For some devices (notably,

15. *See* Wagner, *supra* note 11, at 798-800 (explaining why manufacturers are best positioned to generate information on the dangers of their products).

16. *See* Aylin Sertkaya, Rebecca DeVries, Amber Jessup & Trinidad Beleche, *Estimated Cost of Developing a Therapeutic Complex Medical Device in the US*, JAMA NETWORK OPEN, Sep. 2022, at 1, 7, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2796179 [https://perma.cc/VAV3-UKSH] (estimating that the average pivotal study period needed for FDA approval lasted fifty-seven months and cost $31 million).

17. *Id.*

18. *See* Wagner, *supra* note 11, at 784. Wagner provides an apt illustration of the force of the incentives not to test products by showing that a complete or partial health hazard assessment had been conducted for just 36 percent of drugs and excipients. *Id.* at 783 fig. 1.

19. Characterizing private litigation under state products liability theory as regulation is widely accepted. *See* Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 521 (1992) ("The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy." (quoting San Diego Bldg. Trades Council v. Garmon, 359 U.S. 236, 247 (1959))); *see also Regulation*, BLACK'S LAW DICTIONARY (12th ed. 2024) (defining regulation as the exercise of "[c]ontrol over something by rule or restriction"); Michelle M. Mello, Carly N. Kelly & Troyen A. Brennan, *Fostering Rational Regulation of Patient Safety*, 30 J. HEALTH POL., POL'Y & L. 375, 376 (2005) (defining regulation as "any organized and deliberate leveraging of power or authority to effect changes in the behavior").

20. *See* Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMMS. & TECH. L. REV. 345, 347 (2007) (describing "the important structural role that drug regulation has come to play in *promoting* a valuable form of pharmaceutical innovation—the development of credible information about the effects of drugs"); Anna B. Laakmann, *A Property Theory of Medical Innovation*, 56 JURIMETRICS 117, 120 (2016) ("[A] primary function of FDA regulation is to compel firms to aggregate and disclose socially valuable information about their products that would not be distributed in an unregulated market. This includes positive clinical results whose value manufacturers cannot sufficiently appropriate through exercise of proprietary rights, as well as negative clinical results."); George Horvath, *Emergent Regulatory Systems and Their Challenges: The Case of Combination Medical Products*, 94 WASH. L. REV. 1697, 1717-23 (2019).

new high-risk devices regulated under the "premarket approval," or PMA pathway), FDA approval is generally contingent upon the production of extensive amounts of this kind of information, including "a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device" and clinical trials that provide a reasonable assurance of safety and effectiveness.[21] And private litigation under state products liability laws can incentivize the production of information that can reduce the risk uncertainties of medical devices and can force the disclosure of information that already exists.[22]

Ideally, FDA premarket gatekeeping and state products liability law would complement one another, with each providing incentives to produce information that the other only weakly incentivizes.[23] As Part I explains, the Supreme Court's preemption decisions in medical device cases partially achieve this goal.[24] Manufacturers of high-risk devices that are regulated under the PMA pathway receive strong incentives—or, more precisely, are required—to produce information bearing on the risk uncertainty of those devices, while the manufacturers of intermediate-risk devices, a much larger cohort that is regulated under the 510(k) pathway, receive far weaker incentives.[25] Conversely, most products liability suits against PMA devices are preempted, while suits against 510(k) devices are able to proceed.[26] Thus, products liability law can incentivize the production and disclosure of information on device risk almost exclusively for the devices that FDA regulation least incentivizes (510(k) devices).

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21. 21 U.S.C. § 360e(c)(1).

22. *See* Aaron S. Kesselheim & Jerry Avorn, Commentary, *The Role of Litigation in Defining Drug Risks*, 297 JAMA 308, 308 (2007).

23. In the pharmaceutical context, former FDA Commissioner David Kessler wrote that during the entire seventy-seven years prior to his writing, the Agency had viewed litigation under failure-to-warn theories as complementing the FDA's premarket evaluation by "help[ing] uncover and assess risks that are not apparent to the agency during a drug's approval process," and he claimed that "this 'feedback loop' enabled the agency to better do its job." David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461, 462-63 (2008).

24. *See infra* Part I.C.

25. *See infra* Part I.A.

26. *See infra* Parts I.B-I.C.

Unfortunately, the preemption framework creates a large regulatory gap: PMA devices may be modified and may receive FDA approval through one of several "PMA supplement" pathways.[27] These pathways rarely require clinical trial evidence of safety and effectiveness, but the same preemption shield that applies to PMA devices also applies to PMA supplement devices.[28] Neither FDA regulation nor private litigation under products liability law provides incentives to manufacturers to produce information that reduces the risk uncertainty of these devices, even when they are modified dozens or hundreds of times.

My focus here is on a second regulatory gap. The ability of products liability law to provide incentives to produce information is also under threat from a sixty-year-old doctrinal bar on strict liability for some products set out in comment k to section 402A of the *Restatement (Second) of Torts*. Comment k was designed to shelter some particularly beneficial products from the possibility that excessive liability would drive them off the market.[29] The language of the comment expressly indicates that the rabies vaccine, some other drugs and vaccines that cannot legally be sold except to physicians or under the prescription of a physician, and some new or experimental drugs should be shielded from strict liability.[30] But comment k has been a source of confusion from the time of its adoption by the American Law Institute (ALI) in 1965.[31] As Part II explains, it is not clear that the comment was intended to shield medical devices at all, nor is it clear whether—assuming the shield does extend to devices—it should shield all devices, some categories

27. *See infra* Part I.A.

28. *See infra* Part I.C.

29. *See* Mary J. Davis, *Time for a Fresh Look at Strict Liability for Pharmaceuticals*, 28 CORN. J.L. & PUB. POL'Y 399, 400-01 (2019).

30. *See* RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (A.L.I. 1965).

31. *See* Davis, *supra* note 29, at 409; James A. Henderson, Jr. & Aaron D. Twerski, *Drug Design Liability: Farewell to Comment k*, 67 BAYLOR L. REV. 521, 522 (2015) ("For half a century, Comment k to § 402A of the Restatement, Second, of Torts has caused confusion in prescription drug litigation, seemingly without end." (footnote omitted)); Joseph A. Page, *Generic Product Risks: The Case Against Comment k and for Strict Tort Liability*, 58 N.Y.U. L. REV. 853, 872 (1983) ("Comment k also is vague in that it fails to make clear what kind of special rule it puts in place, what purposes it meets, and to what classes of products it applies.").

of devices, or only individual devices determined on a case-by-case basis. Further, it is not clear which theories of liability are barred.[32]

Over the past quarter-century, courts have increasingly considered whether comment k shields medical device manufacturers from liability. Part III provides empirical evidence that courts have been surprisingly receptive to arguments that comment k does provide such a shield for medical devices.[33] Courts have been willing to exempt entire categories of devices, and in many cases, all medical devices, from strict products liability and sometimes from other legal theories as well.[34] And, as Part IV shows, these judicial decisions have not been required by statute or precedent; rather, courts have been interpreting comment k in ways that obscure the dangers posed by medical devices.[35] As Professor Wendy Wagner has described the approach of manufacturers in the toxic products context, courts in the medical device context are "choosing ignorance,"[36] leaving us all with limited information about the safety of devices on which we may all one day depend. Part IV also presents a set of potential solutions to the problem, focusing on ways to incentivize the production and dissemination of information that reduces the risk uncertainties of all medical devices.[37]

## I. SEEKING A COHERENT REGULATORY SYSTEM FOR MEDICAL DEVICES

This Part presents medical device regulation as the product of two distinct systems: FDA premarket gatekeeping and private products liability litigation. As discussed in Parts I.A and I.B, respectively, each of these systems plays an important information-forcing role, incentivizing manufacturers to produce and disseminate information that reduces risk uncertainty. Ideally, these two systems would complement one another such that when one system fails to force information that reduces risk uncertainty, the other does force the production of that information. Part I.C explains how the Supreme

32. *See infra* Part II.A.3.
33. *See infra* Part III.B.
34. *See infra* Part III.B.
35. *See infra* Part IV.A.
36. *See* Wagner, *supra* note 11, at 774-75.
37. *See infra* Part IV.

Court's decisions in a trio of cases decided between 1996 and 2008 partially achieved this goal. These decisions created the contours of a regulatory system in which FDA premarket gatekeeping and state products liability law complement one another for two important sets of devices but fail to do so for a third important set of devices.

### *A. FDA Premarket Gatekeeping: Regulation Under the Medical Device Amendments*

The Medical Device Amendments of 1976 (MDA, or Act)[38] established the modern federal regime for medical device regulation. The Act charges the FDA with ensuring that before any device enters the U.S. market, there is a "reasonable assurance of ... safety and effectiveness."[39] But "safety," as used in this context, is a shorthand term that comprises at least three important concepts. First, an absolute assurance of safety is not the goal: Whether a device may be marketed in the United States depends on whether the device is "safe enough."[40] Second, whether a device is "safe enough" can be determined only by comparing its risks with its benefits.[41] Third, and central to this project, device "risk" refers to more than just the harms a device can cause (its hazards) and the likelihood and potential severity of those harms occurring (its risks). Any risk-benefit weighing must also consider the unknown hazards and the lack of precision of the estimates of risk for each new device.[42] A primary function of FDA premarket regulation is to reduce the

38. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539.

39. *Id.* at 540; *see* 121 CONG. REC. 1859 (1975) (statement of Sen. Ted Kennedy); S. REP. NO. 94-33, at 6, 7 (1975); *see also* Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1800, 1807 (1996) (noting that the MDA "transformed" the FDA's premarket authority over medical devices and that the Act's architects promised that the MDA "would assure the safety and effectiveness of medical devices").

40. *See* 21 U.S.C. § 360c(a)(1)(A)-(C) (establishing the requirement of a "*reasonable* assurance of the safety and effectiveness" for all devices (emphasis added)).

41. *See* U.S. FOOD & DRUG ADMIN., FDA-2011-D-0577, FACTORS TO CONSIDER WHEN MAKING BENEFIT-RISK DETERMINATIONS IN MEDICAL DEVICE PREMARKET APPROVAL AND DE NOVO CLASSIFICATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 6-7, 9-11 (Aug. 30, 2019) (explaining how the FDA structures its risk-benefit weighing to include consideration of the types and magnitudes of benefits a device may provide, the magnitude and duration of those benefits, serious and nonserious adverse events, and their probability and duration).

42. *Id.* at 11-12.

latter two of these, which I refer to as "risk uncertainty," to an acceptable level.[43] This enables FDA personnel to conduct risk-benefit analyses based on solid information; it also allows other decision makers—physicians who must decide which device to use, patients who must decide if they consent to such usage, and insurers who must decide whether to cover the costs of the device—to make their own risk-benefit determinations.[44]

Every new device presents its own constellation of hazards, risks, and risk uncertainties when it enters the regulatory process. The MDA established a tiered scheme, with each new device assigned to one of three risk classifications based on its generic type.[45] The level of scrutiny a device receives is determined by this classification. The lowest risk (Class I) devices, such as examination gloves and bandages,[46] are those for which only limited FDA regulation is considered necessary to provide a reasonable assurance of safety and effectiveness.[47] Most Class I devices are "exempted" from premarket scrutiny;[48] their manufacturers must comply with the "general controls" that are applicable to all devices, but no premarket approval or clearance by the FDA is necessary.[49] Most intermediate risk (Class II) devices, which range from at-home

43. The FDA includes risk uncertainty in its risk-benefit analysis in premarket evaluations. *Id.*

44. *See id.*

45. The FDA groups devices into roughly 1,700 different generic types. *Classify Your Medical Device*, U.S. FOOD & DRUG ADMIN. (Jan. 15, 2026), https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device [https://perma.cc/6ZBX-KV6T]. A generic device type is "a grouping of devices that do not differ significantly in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness, and for which similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness." 21 C.F.R. § 860.3 (2025).

46. 21 C.F.R. §§ 880.5075, .6250 (2025).

47. *See* 21 U.S.C. § 360c(a)(1)(A). General controls include compliance with good manufacturing practices, registration requirements, and avoidance of misbranding or adulteration. *See* George Horvath, *Empirically Assessing 510(k) Device Safety*, 63 JURIMETRICS 113, 121 (2023).

48. 21 U.S.C. § 360(*l*)(1).

49. *See* 21 U.S.C. § 360c(a)(1)(A). A small number of Class II devices are also exempted from FDA premarket evaluation. *See* 21 U.S.C. § 360(m). The manufacturers of all medical devices, regardless of their risk classification, must comply with general controls such as registering annually with the FDA, ensuring the device labeling comports with FDA regulations, and following published good manufacturing practices. *See* 21 U.S.C. §§ 360c(a)(1)(A)-(C), 360i(f), 360j(f).

pregnancy tests[50] to some knee replacements,[51] are considered to require somewhat more intensive regulatory scrutiny (compliance with both general controls and certain "special controls" that apply to specific types of devices) in order to provide a reasonable assurance of safety.[52] To obtain FDA 510(k) clearance to market such a device, a manufacturer must provide evidence that its new device is "substantially equivalent" to a device of the same risk classification that is already legally marketed in the United States.[53] The highest-risk (Class III) devices, such as implanted pacemakers and deep brain stimulators,[54] are those for which intense regulatory scrutiny is considered necessary to provide an assurance of safety.[55] Class III devices may only be marketed after FDA review and approval of a lengthy and detailed premarket approval (PMA) application.[56]

The standard for marketing a device in the United States is the same for all three risk classes: The FDA must find there to be a "reasonable assurance of the safety and effectiveness of the device."[57] The different levels of regulatory scrutiny are intended to ensure that enough information is provided so that the relevant device hazards have been identified and that the risks of those hazards materializing have been estimated with enough precision—that the risk uncertainty has been reduced enough—to make risk-benefit analysis something more than mere guesswork, regardless of the ex ante risk classification of the device.[58]

The MDA scheme is most effective at reducing the risk uncertainty of new high-risk devices.[59] These Class III devices reach

50. 21 C.F.R. § 862.1155 (2025).

51. *See id.* § 888.3590.

52. 21 U.S.C. § 360c(a)(1)(B). Special controls include performance standards and FDA guidelines. *Id.* For an example of special controls, see 21 C.F.R. § 882.5600 (2025) (providing performance standards and other special controls for neurovascular mechanical thrombectomy devices).

53. *See* 21 U.S.C. §§ 360(k), 360c(f).

54. *See* Jill Jin, *FDA Authorization of Medical Devices*, 311 JAMA 435, 435 (2014).

55. *See* 21 U.S.C. § 360c(a)(1)(C) (defining Class III devices as those which are intended "for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or" which carry "a potential unreasonable risk of illness or injury").

56. *See id.* §§ 360c(a)(1)(C), 360e(c).

57. *See id.* § 360c(a)(1)(A)-(C).

58. Horvath, *supra* note 47, at 118-19.

59. Here, I am distinguishing new Class III devices from those that are modified versions

the market through the PMA pathway. Manufacturers seeking to market a new Class III device must submit a lengthy and detailed "original" PMA application.[60] Applicants are required to submit voluminous information about "the components, ingredients, and properties and of the principle or principles of operation" and "the manufacture, processing, and, when relevant, packing and installation of, such device."[61] The manufacturer must also submit "full reports of all information ... concerning investigations which have been made to show whether or not such device is safe and effective."[62] The FDA's decision whether to approve a PMA application is to be made "on the basis of well-controlled investigations, including 1 or more clinical investigations."[63] The application, typically running several thousand pages, is often reviewed by an independent panel of experts in the field into which the device is classified.[64] Once a Class III device is approved, the manufacturer is required to adhere to the design, manufacturing, and labeling specifications contained in its PMA application.[65] Through these requirements, Congress created a stringent process that serves to reduce the risk uncertainty of PMA devices that reach the market.[66]

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of already-approved devices. Modified versions are marketed under one of the PMA supplement pathways. *See infra* notes 67-78 and accompanying text. One way for a device to be classified as Class III (high-risk) is that "insufficient information exists to determine that the application of general controls ... [and] special controls ... would provide reasonable assurance of its safety and effectiveness." 21 U.S.C. § 360c(a)(1)(C)(i). Other ways are that the device is "purported ... to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or" that may "present[ ] a potential unreasonable risk of illness or injury," *id.* § 360c(a)(1)(C)(ii)(I)-(II), or the device "was not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976," *id.* § 360c(f)(1).

60. *See* 21 U.S.C. §§ 360c(a)(1)(C), 360e(c).

61. *Id.* § 360e(c)(1)(B)-(C); *see also* 21 C.F.R. § 814.20(b) (2025) (providing detailed requirements for PMA applications).

62. 21 U.S.C. § 360e(c)(1)(A).

63. *Id.* § 360c(a)(3)(A). The provision that follows provides some latitude for the optional use of "valid scientific evidence" other than studies conducted in accord with § 360c(a)(3)(A). *Id.* § 360c(a)(3)(B); *accord* 21 U.S.C. §§ 360e(c)(3), 360c(b)(2).

64. *See* 21 U.S.C. §§ 360e(c)(3), 360c(b)(1)-(2).

65. *See* 21 U.S.C. § 360e(d)(5)(A)(i) ("[A] supplemental application shall be required for any change to a device subject to an approved application under this subsection that affects safety or effectiveness."); 21 C.F.R. § 814.80 (2025) ("A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device.").

66. One important limitation to the claim that the original PMA process reduces device

The MDA scheme is less effective at reducing the risk uncertainty of incrementally modified Class III devices. New Class III devices that undergo the original PMA process account for just 2.6 percent of all high-risk devices that reach the U.S. market each year.[67] A vastly larger cohort of Class III devices are modified versions of an already-PMA-approved device.[68] These devices reach the market through one of several "PMA supplement" pathways, which impose a far lower regulatory burden in comparison with the original PMA process. Only panel-track supplements routinely require "substantial clinical data" that demonstrates safety.[69] These are typically used when a manufacturer seeks to change or expand the ways in which an approved device will be used.[70] The other pathway used for significant modifications, 180-day supplements, does not routinely require clinical trials.[71] FDA guidance indicates that the Agency considers 180-day supplements to be appropriate for changes such as the addition of new features, changes to the design or physical

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risk uncertainty should be recognized. The data on which PMA applications have been approved has been vigorously criticized. *See* Sanket S. Dhruva, Lisa A. Bero & Rita F. Redberg, *Strength of Study Evidence Examined by the FDA in Premarket Approval of Cardiovascular Devices*, 302 JAMA 2679, 2683 (2009) (criticizing the studies used to support FDA approval of cardiovascular devices for lacking randomization and blinding, and for using composite and surrogate endpoints); Daniel B. Kramer, Elias Mallis, Bram D. Zuckerman, Barbara A. Zimmerman & William H. Maisel, *Premarket Clinical Evaluation of Novel Cardiovascular Devices: Quality Analysis of Premarket Clinical Studies Submitted to the Food and Drug Administration 2000-2007*, 17 AM. J. THERAPEUTICS 2, 4-7 (2010) (criticizing PMA device studies for their "[p]oorly defined safety and effectiveness end points, absent patient demographics and comorbidities, and poor patient accounting"). Composite endpoints are combinations of individual clinical endpoints, for example, stroke, heart attack, and death, the occurrence of any one of which counts as an endpoint in a clinical trial. U.S. FOOD & DRUG ADMIN., FDA-2016-D-4460, MULTIPLE ENDPOINTS IN CLINICAL TRIALS: GUIDANCE FOR INDUSTRY 10-11 (2022). Surrogate endpoints are markers that are "thought to predict clinical benefit[s] but [that are] not [them]sel[ves] a measure of clinical benefit[s]." U.S. FOOD & DRUG ADMIN., EXPEDITED PROGRAM FOR SERIOUS CONDITIONS—ACCELERATED APPROVAL OF DRUGS AND BIOLOGICS: GUIDANCE FOR INDUSTRY 7 (2024).

67. Based on FDA data for PMA and PMA supplement approvals between June 28, 1976 and July 25, 2025. *PMA Approvals*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/premarket/ftparea/pma.zip (downloaded July 30, 2025) (data on file with author). In that period, the FDA approved 1,400 original PMAs and 53,165 PMA supplements. *See id.*

68. *See id.*

69. U.S. FOOD & DRUG ADMIN., MODIFICATIONS TO DEVICES SUBJECT TO PREMARKET APPROVAL (PMA)—THE PMA SUPPLEMENT DECISION-MAKING PROCESS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 11-12, 11 n.8 (2008) (footnote omitted).

70. *See id.* at 12.

71. *See* 21 U.S.C. § 379i(4)(C).

characteristics of existing features, and alterations to computer hardware and software.[72] Most often, only preclinical testing (for example, bench testing) is required.[73] The remaining PMA supplements, which are intended for less significant modifications, also do not require clinical trial evidence of safety.[74] Overall, less than 1 percent of PMA supplements are panel track, indicating that few modified PMA devices have clinical trial evidence of safety.[75] And even when clinical data is required, the FDA Modernization Act of 1997 and subsequent acts require the FDA to apply the "least burdensome" principle, which obligates the Agency to consider alternatives to premarket clinical trials, such as collecting data in the postmarket period.[76] Under the least burdensome requirements, the FDA's focus is on generating the minimum quantum of information for the clearance or approval of a device.[77] There are no limits to how many times a manufacturer may modify a PMA-approved device through the iterative use of PMA supplements; indeed, most innovation of high-risk devices takes place through dozens or even hundreds of modifications.[78]

The limited clinical trial data required by most PMA supplements, coupled with the extensive iterative modification permitted under them, mean that over time, the risk uncertainty associated

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72. *See* U.S. FOOD & DRUG ADMIN., *supra* note 69, at 15-17.

73. *Id.* at 5, 11-12.

74. "[R]eal-[T]ime [S]upplement[s]" are appropriate for "a minor change to the device, such as a minor change to the design of the device, software, sterilization, or labeling." 21 U.S.C. § 379i(4)(D). Examples of such minor changes include a new sterilization technique for ablation catheters and an expanded range of acceptable temperatures for storing a bone-growth-stimulating protein. *See* U.S. FOOD & DRUG ADMIN., *supra* note 69, at 19.

75. *See infra* note 336 and accompanying text.

76. 21 U.S.C. § 360c(a)(3)(D)(ii) ("The Secretary shall consider, in consultation with the applicant, the least burdensome appropriate means of evaluating device effectiveness."); *id.* § 360c(i)(1)(D)(i) ("[T]he Secretary shall consider the least burdensome means of demonstrating substantial equivalence and request information accordingly."); *id.* § 360e(c)(5)(C) ("[T]he Secretary shall consider the role of postmarket information in determining the least burdensome means of demonstrating a reasonable assurance of device safety and effectiveness.").

77. *See* 21 U.S.C. § 360e(c)(5)(B) ("[T]he term 'necessary' means the minimum required information that would support a determination by the Secretary that an application provides a reasonable assurance of the safety and effectiveness of the device.").

78. *See* George Horvath, *Trading Safety for Innovation and Access: An Empirical Evaluation of the FDA's Premarket Approval Process*, 2017 BYU L. REV. 991, 1030-33 (showing that high-risk devices originally approved after November 1, 2002, had been modified a mean of 12 times, with some having undergone up to 291 modifications).

with some Class III devices can increase dramatically. The original PMA approval, with its extensive data production and disclosure requirements, will have reduced that uncertainty to a low level.[79] One or a few modifications approved through PMA supplements will likely not increase the risk uncertainty by a great amount. But as more and more modifications are made, the risk uncertainty will increase. Quite simply, the more a device with well-characterized hazards and risks is changed, the less certain we can be about the hazards and risks of the resulting devices. Thus, the PMA supplement pathways are less likely to achieve the goal of reducing the risk uncertainty of the largest set of Class III devices.

The MDA framework is least effective at reducing the risk uncertainty of Class II devices. This may seem paradoxical, given that Class II devices are considered to pose an intermediate level of risk. But three features of the 510(k) pathway, through which the vast majority of Class II devices and the plurality of all devices that reach the U.S. market, explain this paradox. First, unlike the FDA's robust authority to require clinical trials for high-risk devices submitted through the original PMA pathway, the Agency has only limited authority to require clinical trial data for 510(k) submissions. The Agency may only require clinical trials when it must determine if the intended use the manufacturer claims is the same as the predicate device, when the subject device has different indications for use, or when the subject device has different technological characteristics from the predicate device.[80] The data must be necessary to establish that the subject device is as safe and effective as the predicate.[81] And the Agency's request must satisfy the requirements imposed by the statutory "least burdensome" principle, which requires the FDA to minimize its data requests and to consider shifting as much of the evaluation as possible to the

79. *See supra* text accompanying notes 59-66.

80. 21 U.S.C. § 360c(i)(1)(A)(ii) (specifying that clinical data may be deemed necessary for devices that have different technological characteristics from their predicates); *id.* § 360c(i)(1)(A) (requiring subject device to "ha[ve] the same intended use as the predicate"); 21 C.F.R. § 807.87(g) (2025) (establishing that 510(k) submissions for devices undergoing a "significant change or modification that could significantly affect the safety or effectiveness of the device ... must include appropriate supporting data" without specifying when clinical data would be appropriate).

81. *See* 21 U.S.C. § 360c(i)(1)(D)(i).

postmarket phase.[82] Given these limitations, the FDA and the Government Accountability Office reported in 2006 that only 10-15 percent of 510(k) submissions included clinical trial data.[83] For devices other than in vitro diagnostic tests, only 8 percent of 510(k) submissions included clinical trial data.[84] As a result, new 510(k) devices are often cleared for the market even though they have a high degree of risk uncertainty.

The second feature of the 510(k) pathway contributing to risk uncertainty is that the assurance of safety comes largely through a statutory requirement for new devices to be similar—"substantially equivalent"—to one or more devices already legally cleared for the U.S. market (so-called "predicate devices").[85] Substantial equivalence does not mean that the new device must be identical to its predicate; in fact, a finding of substantial equivalence may be made even when "there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device."[86]

These two features have a synergistic effect that permits Class II devices to reach the market with a large amount of risk uncertainty: Given the very low percentage of 510(k) devices that have reached the market with clinical trial evidence of safety, the vast majority of predicate devices had never been assessed for risk.[87] In short, there is often a potentially large amount of risk uncertainty for both predicate and subject devices.

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82. The least burdensome provisions were added to the MDA by the Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 205, 111 Stat. 2296, 2337 (codified as amended at 21 U.S.C. § 360c(i)(1)(D)(i)).

83. U.S. GOV'T ACCOUNTABILITY OFF., GAO-06-62, MEDICARE DURABLE MEDICAL EQUIPMENT: CLASS III DEVICES DO NOT WARRANT A DISTINCT ANNUAL PAYMENT UPDATE 2-3, 8 (2006).

84. INST. OF MED., MEDICAL DEVICES AND THE PUBLIC'S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS 108 (2011). The Institute of Medicine (IoM) was renamed The National Academy of Medicine. *About the NAM*, NAT'L ACAD. MED., https://nam.edu/about-the-nam/ [https://perma.cc/UF4M-DCKM]. Because the 2011 Report was issued under the IoM name, I refer to the Academy as the Institute or IoM throughout.

85. *See* 21 U.S.C. § 360c(f)(1)(A).

86. *See id.* § 360c(i)(1)(A)-(B).

87. *See* Medtronic, Inc. v. Lohr, 518 U.S. 470, 492-94 (1996) (noting that 510(k) clearance focuses on the equivalence of a new device to its predicate as opposed to focusing on safety); Riegel v. Medtronic, Inc., 552 U.S. 312, 323 (2008) ("[D]evices that enter the market through § 510(k) have 'never been formally reviewed under the MDA for safety or efficacy.'" (quoting *Lohr*, 518 U.S. at 493)).

The third feature of the 510(k) pathway that contributes to the risk uncertainty paradox arises from a process known as "piggybacking."[88] A manufacturer may obtain 510(k) clearance by showing that its new, subject device ($D_1$) is substantially equivalent to an older predicate device ($D_0$); later, a newer device ($D_2$) may cite $D_1$ as its predicate, and later still, $D_3$ may cite $D_2$, and so on, in an endless chain of iterative change.[89] The devices in these chains are not identical. Thus, the 510(k) pathway allows an endless process of iterative change through which the technological features of devices can evolve, often dramatically far from earlier devices. Even if an early ancestor to a new device had been assessed for safety (which is rarely the case),[90] the new device may differ so greatly from that ancestor that little is known about the hazards it poses and their likelihood of occurring. As a result of these features of the FDA regulatory framework, many, or even most, Class II devices reaching market through the 510(k) pathway bring with them a high level of risk uncertainty.

Unfortunately, the two largest cohorts of medical devices subjected to any FDA premarket scrutiny (which account for 99 percent of devices)[91] reach the U.S. market with surprisingly high levels of risk uncertainty. But, as explained in the next section, FDA regulation is not the only system that functions to force the production and dissemination of information that can reduce risk-uncertainty.

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88. *See* INST. OF MED., *supra* note 84, at 252.

89. *See id.* Under the original MDA, manufacturers could cite as predicates only those devices that had been marketed before the MDA's effective date (pre-amendment devices). The Safe Medical Devices Act of 1990 (SMDA), Pub. L. No. 101-629, § 12(a), 104 Stat. 4523, 4523 (codified as amended at 21 U.S.C. § 360c(i)(1)(A)), expanded the definition of legally acceptable predicate devices to include postamendment devices, which had reached the market after the MDA took effect. INST. OF MED., *supra* note 84, at 253.

90. *See supra* text accompanying notes 82-87.

91. Data for 510(k) clearances and De Novo reclassifications were downloaded from the FDA's databases. *510(k) Clearances*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/510k-clearances/downloadable-510k-files (downloaded July 30, 2025) (data on file with author). As of July 25, 2025, the FDA had cleared 172,006 510(k) devices, granted De Novo reclassification to 451 devices, granted 1,400 original PMA approvals, and granted 53,165 PMA supplements. *Id.*

### *B. Products Liability Law*

Characterizing products liability law as a regulatory system is premised on the notion that liability, or even just the threat of litigation, incentivizes manufacturers to make greater efforts to ensure that their devices are safe and effective.[92] In many states, injured consumers can file claims against manufacturers under theories of strict products liability, negligence, breach of the implied warranty of merchantability, breach of the implied warranty of fitness for a particular purpose, and breach of express warranty.[93] Negligence law imposes a duty to "exercis[e] reasonable care in production to avoid unreasonable risk of harm,"[94] and may enable plaintiffs to recover for a broad range of damages.[95] Breach of warranty claims provide a form of strict liability because even innocent breaches are sufficient bases for liability.[96]

However, these actions offer injured consumers only limited avenues for recovery and provide manufacturers with only limited incentives to improve the safety of their products. Proving negligence is difficult,[97] and the reasonableness standard used in negligence cases creates uncertainty for plaintiffs and defendants, as the determination of whether the manufacturer behaved reasonably is informed by risk-benefit analyses, foreseeability, the

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92. *See* Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 521 (1992) ("The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy." (quoting San Diego Bldg. Trades Council v. Garmon, 359 U.S. 236, 247 (1959))).

93. *See* DAVID G. OWEN, PRODUCTS LIABILITY LAW 29-33 (3d ed. 2015). Other potential claims include fraud, fraudulent misrepresentation, negligent misrepresentation, fraudulent concealment, and negligent concealment. *See id.*

94. Fleming James, Jr., *Products Liability*, 34 TEX. L. REV. 44, 49 (1955).

95. *See* Erlich v. Menezes, 981 P.2d 978, 982 (Cal. 1999) ("[T]ort damages are awarded to [fully] compensate the victim for [all] injury suffered." (second and third alterations in original) (quoting Applied Equip. Corp. v. Litton Saudi Arabia Ltd., 869 P.2d 454, 460 (Cal. 1994))). The privity of contract rule that had once limited liability to those with whom an injured consumer had a contractual relationship crumbled during the early to mid-twentieth century, with the beginning of its fall often attributed to Justice Cardozo's decision in *MacPherson v. Buick Motor Co.*, 111 N.E. 1050, 1053 (N.Y. 1916).

96. *See* William L. Prosser, *The Assault upon the Citadel (Strict Liability to the Consumer)*, 69 YALE L.J. 1099, 1126-27, 1134-35 (1960).

97. *See* Escola v. Coca Cola Bottling Co. of Fresno, 150 P.2d 436, 443 (Cal. 1944) (Traynor, J., concurring) ("Manufacturing processes, frequently valuable secrets, are ordinarily either inaccessible to or beyond the ken of the general public.").

experiences of other product users, customs in the industry, expert opinion, and a host of other considerations.[98] Warranty law was developed to control commercial transactions, not to address accidental harms suffered by consumers.[99] Breach of express warranty actions are limited by the requirement that plaintiffs show they relied on some affirmative representation made by the manufacturer about the product, and breach of implied warranty claims depend on proof that the plaintiff had justifiably relied on assumptions about the product's fitness.[100] And recovery in breach of warranty cases may not be available for damages that were not within the purview of the contract.[101]

With the state supreme court's 1963 decision in *Greenman v. Yuba Power Products, Inc.*,[102] California became the first state to recognize a tort claim in strict liability for injuries caused by all products.[103] One year after *Greenman*, the ALI ratified section 402A of the *Restatement (Second) of Torts*, adopting strict liability as a general theory of recovery for injuries resulting from defective products.[104] In the relevant part, section 402A reads:

> One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user

98. *See* Page, *supra* note 31, at 884; James, *supra* note 94, at 70-71.

99. *See* James, *supra* note 94, at 192.

100. *See* Greenman v. Yuba Power Prods., Inc., 377 P.2d 897, 901 (Cal. 1963); *Escola*, 150 P.2d at 441-42 (Traynor, J., concurring).

101. Erlich v. Menezes, 981 P.2d 978, 982 (Cal. 1999) ("Contract damages are generally limited to those within the contemplation of the parties when the contract was entered into or at least reasonably foreseeable by them at that time." (quoting Applied Equip. Corp. v. Litton Saudi Arabia Ltd., 869 P.2d 454, 460 (Cal. 1994))).

102. 377 P.2d at 901. The history of the evolution of strict products liability has been told and retold. For contemporaneous accounts, see, for example, James, *supra* note 94, at 192; Prosser, *supra* note 96, at 1099-1102; William L. Prosser, *The Fall of the Citadel (Strict Liability to the Consumer)*, 50 MINN. L. REV. 791, 791-94 (1966). For later accounts, see, for example, John W. Wade, *Chief Justice Traynor and Strict Tort Liability for Products*, 2 HOFSTRA L. REV. 455 (1974); George L. Priest, *The Invention of Enterprise Liability: A Critical History of the Intellectual Foundations of Modern Tort Law*, 14 J. LEGAL STUD. 461 (1985); Kyle Graham, *Strict Products Liability at 50: Four Histories*, 98 MARQ. L. REV. 555 (2014).

103. *See* Wade, *supra* note 102, at 459.

104. RESTATEMENT (SECOND) OF TORTS § 402A, 402A cmt. a (A.L.I. 1965).

> or consumer ... although ... the seller has exercised all possible care in the preparation and sale of his product.[105]

By the black letter terms of section 402A, manufacturers are liable for harms caused by their defective products, even if they had used reasonable or even extraordinary ("all possible") care, so long as the product is defective.[106] With the requirement of proving negligence eliminated and the possibility of recovery for the full scope of tort damages, strict products liability quickly became the most important legal theory for injured consumers, and thus the most important regulatory input that state common law provides to manufacturers.[107]

The value of products liability litigation as a complement to FDA regulation of drugs and medical devices has been recognized by courts and commentators.[108] In 2008, former FDA Commissioner

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105. *Id.* § 402A.

106. *See id.*

107. *See* David G. Owen, *Design Defects*, 73 MO. L. REV. 291, 293-94 (2008); Richard C. Ausness, *Unavoidably Unsafe Products and Strict Products Liability: What Liability Rule Should Be Applied to the Sellers of Pharmaceutical Products?*, 78 KY. L.J. 705, 709-10 (1990). Strict products liability spread rapidly, with forty-one jurisdictions adopting section 402A within a dozen years of its approval by the ALI. Priest, *supra* note 102, at 518. Relative to a rule of negligence, strict liability might provide stronger incentives for manufacturers, who are in the best position to discover the risks posed by their products, to use greater care in the design, manufacture, and labelling of their products. Page, *supra* note 31, at 884-85. Some early proponents rejected this argument. Prosser, *supra* note 96, at 1119 (rejecting the argument that "strict liability will provide a healthy and highly desirable incentive for producers to make their products safe" when the rule of negligence fails to do so). In addition, requiring manufacturers to internalize something closer to the full costs of the harms created by their products will likely lead to higher prices that more accurately reflect the risks posed by those products. *See* A. Mitchell Polinsky & Steven Shavell, *The Uneasy Case for Product Liability*, 123 HARV. L. REV. 1437, 1459 (2010) (describing but then refuting the price-signaling argument).

108. *See* Larsen v. Pacesetter Sys., Inc., 837 P.2d 1273, 1285 (Haw. 1992) (justifying strict product liability because it "will promote product safety by eliminating the necessity of proving negligence"); Laakmann, *supra* note 20, at 139; Kesselheim & Avorn, *supra* note 22, at 308-09; *see also* Daniel G. Aaron, *Public Health in the Opioid Litigation*, 53 LOY. U. CHI. L.J. 11, 14-15 (2021) (questioning how well private opioid litigation was achieving broad public health goals); Liza Vertinsky & Reuben Guttman, *Public-Private Litigation for Health*, 2021 UTAH L. REV. 1173, 1174 (exploring how litigation can aid public health by supplementing regulatory shortcomings); Rebecca L. Haffajee, *The Public Health Value of Opioid Litigation*, 48 J.L., MED. & ETHICS 279, 279 (2020) (highlighting the "mixed success" of tort litigation in addressing public health harms); Alexander C. Egilman, Aaron S. Kesselheim, Harlan M. Krumholz, Joseph S. Ross, Jeanie Kim & Amy Kapczynski, *Confidentiality Orders and Public Interest in Drug and Medical Device Litigation*, 180 JAMA INTERNAL MED. 292,

David Kessler and David C. Vladeck wrote that during the preceding eight decades the Agency had viewed litigation under failure-to-warn theories as complementing the FDA's premarket evaluation of drugs by "help[ing] uncover and assess risks that are not apparent to the agency during a drug's approval process" and urged that "this 'feedback loop' enabled the agency to better do its job."[109] Kessler and Vladeck thus recognized that many drugs emerge from the FDA regulatory process with significant risk uncertainty. Likewise, many devices that successfully navigate the FDA's premarket processes reach the U.S. market with levels of risk uncertainty that can have tragic consequences.[110] Products liability law can incentivize manufacturers to conduct additional research to ensure the safety of their drugs and devices. Commentors have also argued that litigation has assisted in, or was responsible for, the disclosure of previously hidden risk information about the prescription drugs valdecoxib, paroxetine, olanzapine, cerivastatin, rofecoxib, and others;[111] logically, litigation might be expected to result in the disclosure of information about medical device risks. In essence, many arguments in support of products liability actions against device makers sound in part on the role that such litigation can play as an ex-post regulator.

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292 (2020) (addressing the "prominent role" litigation has played in revealing medical device and drug risk information); Catherine T. Struve, *Greater and Lesser Powers of Tort Reform: The Primary Jurisdiction Doctrine and State-Law Claims Concerning FDA-Approved Products*, 93 CORN. L. REV. 1039, 1040 (2008) (discussing the potential for tort litigation to incentivize increased drug safety monitoring following FDA approval); Catherine T. Struve, *The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation*, 5 YALE J. HEALTH POL'Y, L. & ETHICS 587, 587 (2005) (stating the role of the FDA and the tort system in protecting consumers of medical products); Elizabeth A. Weeks, *Beyond Compensation: Using Torts to Promote Public Health*, 10 J. HEALTH CARE L. & POL'Y 27, 55 (2007) (expressing the advantages of tort litigation as an alternative form of regulation for products that endanger public health).

109. Kessler & Vladeck, *supra* note 23, at 463.

110. *See, e.g.*, Stephen Tower, *Hip Metallosis and Corrosion—A Million Harmed Due to FDA Inaction*, 15 J. PATIENT SAFETY 257, 258 (2019) (defective hip prostheses); David H. Birnie, Ratika Parkash, Derek V. Exner, Vidal Essebag, Jeffrey S. Healey, Atul Verma, Benoit Coutu, Teresa Kus, Iqwal Mangat, Felix Ayala-Paredes, Pablo Nery, George Wells & Andrew D. Krahn, *Clinical Predictors of Fidelis Lead Failure: Report from the Canadian Heart Rhythm Society Device Committee*, 125 CIRCULATION 1217, 1217 (2012) (reporting that over 268,000 potentially defective defibrillator leads had been implanted worldwide); Horvath, *supra* note 20, at 1736 n.235 (collecting cases involving a defective spinal fusion device).

111. *See* Kesselheim & Avorn, *supra* note 22, at 308-09.

### *C. Achieving a Semicoherent Regulatory System: Federal Preemption*

The ability of products liability law to function as a complement to FDA medical device regulation is limited by the fact that the federal regulatory scheme presented in Part I.A may preempt the state products liability claims described in Part I.B.[112] The MDA includes an express preemption provision, 21 U.S.C. § 360k, which provides that: "[N]o State ... may establish or continue in effect with respect to a device ... any requirement ... which is different from, or in addition to, any requirement applicable under this chapter to the device, and ... which relates to the safety or effectiveness of the device."[113]

In *Riegel v. Medtronic, Inc.*, the U.S. Supreme Court held that PMA approval establishes device-specific requirements for design, manufacturing, and labeling with which the manufacturer must comply.[114] This applies to modified devices approved through PMA supplements as well as to new devices approved through original PMA applications.[115] *Riegel* also established that a state law failure-to-warn or design defect action that leads to a damages award would create a state-imposed requirement different from, or in addition to, the requirements established by the PMA.[116] Under *Riegel*, such state law actions against the manufacturers of PMA and PMA supplement devices are thus expressly barred by § 360k.[117] By contrast, in *Medtronic, Inc. v. Lohr*, the Court held that 510(k) clearance does "not 'require' [a cleared device] to take any particular form for any particular reason."[118] Because 510(k) clearance does not

112. *See* Lars Noah, *This Is Your Products Liability Restatement on Drugs*, 74 BROOK. L. REV. 839, 913 (2009) ("[T]he contours of express federal preemption as a defense to tort claims against medical device manufacturers ... may better define those contexts where courts should decline to engage in duplicative design defect review.").

113. 21 U.S.C. § 360k(a) (2018).

114. 552 U.S. 312, 323-24 (2008).

115. *See id.* at 320 (noting that the device in question had been modified and marketed through PMA supplements).

116. *See id.* at 323-24.

117. *See id.* at 330; *see also* Burningham v. Wright Med. Tech., Inc., 2019 UT 56, ¶ 26, 448 P.3d 1283, 1289-90 ("[W]e do not opine on whether PMA-approved medical devices are unavoidably unsafe as a matter of law because they are already exempt from all state product liability claims.").

118. 518 U.S. 470, 493 (1996).

impose device-specific requirements, the MDA's express preemption provision is not triggered.[119]

Even when the requirements imposed by state products liability law are the same as federal requirements imposed by the FDA, products liability claims against device manufacturers may be barred by implied preemption. In *Buckman Co. v. Plaintiffs' Legal Committee*, the Supreme Court held that suits attempting to enforce federal requirements (such as claims alleging fraud by the FDA) stand as obstacles to the Agency's ability to achieve the "delicate balance of statutory objectives" that Congress had assigned to the FDA.[120] This holding potentially subjects all state law claims against PMA devices to preemption. However, in *Riegel*, the Court clarified that certain "parallel" claims may survive preemption analysis.[121] State law claims can avoid preemption only if they impose requirements that arise under state law and are parallel to—not "different from, or in addition to"—the federal requirements.[122] Because some federal courts of appeal have interpreted the scope of the parallel-requirements exception narrowly while others have interpreted it more broadly, in some circuits almost all suits against the manufacturers of PMA-approved devices are barred either by express or by implied preemption, while in other circuits at least some failure-to-warn claims will have a chance of surviving.[123]

Some aspects of the regulatory system that emerged from the Supreme Court's preemption decisions seem to be well calibrated to

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119. *See id.* at 493-94.

120. 531 U.S. 341, 348 (2001).

121. *See Riegel*, 552 U.S. at 330 ("[Section] 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." (quoting *Lohr*, 518 U.S. at 495)).

122. Riley v. Cordis Corp., 625 F. Supp. 2d 769, 776 (D. Minn. 2009) (quoting *Riegel*, 552 U.S. at 322-28); *see also* Jean Macchiaroli Eggen, *Navigating Between Scylla and Charybdis: Preemption of Medical Device "Parallel Claims*," 9 J. HEALTH & BIOMEDICAL L. 159, 161 (2013) (restating the parallel-claims exemption arising from *Riley v. Cordis Corp.*).

123. *Contrast* Stengel v. Medtronic Inc., 704 F.3d 1224, 1233 (9th Cir. 2013) (en banc) (plaintiff successfully pleaded state law complaint that paralleled federal requirements), Hughes v. Bos. Sci. Corp., 631 F.3d 762, 775-76 (5th Cir. 2011) (same), *and* Bausch v. Stryker Corp., 630 F.3d 546, 553 (7th Cir. 2010) (same), *with* Walker v. Medtronic, Inc., 670 F.3d 569, 581 (4th Cir. 2012) (plaintiff failed to plead parallel requirements), Wolicki-Gables v. Arrow Int'l, Inc., 634 F.3d 1296, 1301-02 (11th Cir. 2011) (same), Bryant v. Medtronic, Inc., 623 F.3d 1200, 1205-08 (8th Cir. 2010) (same), *and* Cupek v. Medtronic, Inc., 405 F.3d 421, 424 (6th Cir. 2005) (same).

achieve the production of information that can adequately reduce risk uncertainty.[124] As a rough approximation, products liability claims against the manufacturers of original PMA devices are preempted unless the plaintiff can successfully plead parallel claims. But for these devices, the FDA's premarket scrutiny has forced the production of a robust body of information that has reduced their risk uncertainty. Conversely, for the largest cohort of devices, which are marketed through the 510(k) pathway, products liability claims are not preempted.[125] This seems to be appropriate in view of the serious limitations in the ability of the FDA's premarket evaluation to force the production of information that reduces risk uncertainty.

But the preemption framework also creates a regulatory gap for the second-largest set of devices—modified PMA devices approved through PMA supplements. These devices have a level of risk uncertainty somewhere between PMA devices and 510(k) devices: Because these devices are modified versions of already-PMA-approved devices, the risk uncertainty was reduced through the initial rigorous PMA process, but these devices gradually accumulate risk uncertainty over time through dozens or even hundreds of modifications without clinical trial evidence of safety. For these devices, neither FDA premarket scrutiny nor postmarket private litigation robustly incentivize the production and dissemination of information that can reduce risk uncertainty.

The rest of this Article highlights a further limitation of the ability of medical device regulation to reduce risk uncertainty. As a result of a wave of cases in which courts have limited the role played by state products liability actions based on the hastily drafted and

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124. In previous work, I made a stronger claim that in the broader context of drugs and devices, FDA premarket regulation and state products law postmarket regulation could be conceived of as creating a single, emergent regulatory system under which the information-forcing requirements and incentives were (unintentionally) calibrated to reduce the risk uncertainty of all devices—regardless of whether they reached the market through the PMA or 510(k) pathway—toward similarly low levels. *See* Horvath, *supra* note 20, at 1727. The discussion in this Part does not undercut the conception of FDA premarket scrutiny and postmarket products liability as forming an emergent regulatory system. The discussion does, however, show that the calibration of the emergent system with regard to medical devices is more nuanced when PMA supplement devices are considered.

125. This is the converse of preemption in prescription drug cases, in which claims against the vast majority of drugs—generic drugs, which account for 85 percent of prescriptions in the United States—are preempted. Davis, *supra* note 29, at 401.

inscrutable comment k to section 402A of the *Restatement (Second) of Torts*, the ability of products liability law to reduce medical device risk uncertainty has been restricted.[126] The impact of this development is greatest on 510(k) devices, which account for three-quarters of all devices that reach the market each year, and which reach the market with a large degree of risk uncertainty.[127] Thus, neither regulatory system may be supplying adequate incentives for manufacturers to produce and disseminate enough information about nearly all medical devices to reduce their risk uncertainty to acceptable levels.

## II. MEDICAL DEVICE REGULATION AND THE LIMITS OF PRODUCTS LIABILITY

The discussion in Part I.B focused on the regulatory benefits offered by private strict products liability litigation. But states' recognition of strict products liability as a basis for recovery can also have detrimental effects. At the time that the ALI approved section 402A, the conception of product defects was largely confined to manufacturing defects, in which individual units of a product deviate from the manufacturer's intended design.[128] Holding manufacturers strictly liable for such isolated and (hopefully) rare events is not a major threat to the survival of the manufacturer or the availability of its product: The amount of liability is limited to the damages suffered by the individual harmed by a single unit.[129] But not long after the ALI adopted section 402A, it became clear that liability for design defects, in which the entire product line is defective, posed a potentially existential threat to manufacturers and the product line, as juries may impose massive damages awards in cases in which tens of thousands of people have been harmed.[130] There is a danger that private litigation might drive socially beneficial products off the market.

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126. *See infra* Part II.A.4 (discussing case-by-case applications of comment k in prescription drug litigation and the impact of those decisions on medical device litigation).

127. *See* U.S. FOOD & DRUG ADMIN., *supra* note 91.

128. *See* Victor E. Schwartz, *Unavoidably Unsafe Products: Clarifying the Meaning and Policy Behind Comment K*, 42 WASH. & LEE L. REV. 1139, 1139 (1985).

129. *See* Owen, *supra* note 107, at 296.

130. *See id.*

Further, as some have argued, the incentives provided by the threat of liability to ensure medical product safety are not certain to materialize, either because liability may turn out to be a weak motivator relative to regulations and market forces, or because manufacturers are insulated by the availability of insurance and their ability to spread the costs of liability across their customer base.[131] Further, it is possible that any benefits that do accrue may be more than completely offset by other effects. As one court noted,

> [t]he potential for strict liability could cause drug manufacturers to refrain from researching and developing beneficial drugs for fear of liability, and the cost of insurance to protect against strict liability could increase the cost of medication beyond the reach of those who need it most.[132]

The same rationale applies to medical devices. There is also a danger that innovation may be hampered by the nonuniformity of products liability rules. In *Erie Railroad Co. v. Tompkins*, the U.S. Supreme Court ruled that there is no general common law that creates a nationwide standard; rather, federal courts sitting in diversity jurisdiction are required to apply "the law of that State existing by the authority of that State."[133] In theory, each state will create and evolve its own products liability regime. Because each state's regime is at least somewhat different from that of other states, the regulatory landscape confronting medical device manufacturers would be expected to be heterogenous in the post-*Erie* world.[134] Such regulatory heterogeneity raises concerns over the potential for stifling the innovation of socially beneficial new technologies.[135]

The excessive liability and regulatory heterogeneity that may arise under common law rules of strict products liability could

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131. *See generally* Polinsky & Shavell, *supra* note 107 (discussing the limited impact of liability vis-à-vis market forces).

132. Garrett v. Howmedica Osteonics Corp., 153 Cal. Rptr. 3d 693, 700 (2013).

133. 304 U.S. 64, 79 (1938).

134. The potential for state law heterogeneity has been cited as the basis for the express preemption provision in § 360k(a). *See* Riegel v. Medtronic, Inc., 552 U.S. 312, 316 (2008).

135. *See Riegel*, 552 U.S. at 326 (describing Congress's concern for "those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations").

disincentivize the development of highly beneficial products and result in higher prices when new products are developed and marketed.[136] The black letter law of section 402A builds several limitations to strict products liability into tort doctrine that partially mitigate these dangers. Plaintiffs are required to prove more than just that the defendant's product caused their injury: They must prove that the product was defective.[137] They must also prove that the product proximately caused their harm.[138] And they must prove that the product was intended to and did reach them "without substantial change in the condition" of the product.[139] Further, only sellers who are "engaged in the business of selling such a product" are subject to strict liability.[140]

These general limitations failed to allay the concerns of many members of the ALI as they were considering the adoption of section 402A in 1964. The floor debate late that year focused on the possibility that excessive liability arising from the new strict liability theory would drive prescription drugs that offered great benefits off the U.S. market.[141] As a result, members sought to add an additional limit on the scope of strict products liability.[142] After initial attempts to add an exemption for prescription drugs in the black letter of section 402A failed, William Prosser, the Reporter for the *Restatement (Second) of Torts*, drafted comment k, which was quickly ratified along with section 402A by the ALI membership.[143]

### *A. Comment k and the Limits of Strict Products Liability*

Comment k to section 402A exempts from strict liability certain products that "in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use,"

136. *See Garrett*, 153 Cal. Rptr. 3d at 700; Mark A. Geistfeld, *A Roadmap for Autonomous Vehicles: State Tort Liability, Automobile Insurance, and Federal Safety Regulation*, 105 CALIF. L. REV. 1611, 1670 (2017).

137. RESTATEMENT (SECOND) OF TORTS § 402A(1) (A.L.I. 1965).

138. *See id.*

139. *Id.* § 402A(1)(b).

140. *Id.* § 402A(1)(a).

141. *See* Henderson & Twerski, *supra* note 31, at 525.

142. *See id.*

143. *See id.*

but which offer important benefits.[144] Such products, according to comment k, are "not defective, nor [are they] *unreasonably* dangerous."[145] Rather, they are "*unavoidably unsafe*," and thus fall outside the black letter definition of defective products subjected to strict liability.[146]

Comment k observes that unavoidably unsafe products "are especially common in the field of drugs."[147] The text provides three examples, only one of which was clearly identified: the Pasteur rabies vaccine.[148] Comment k also refers to "other drugs" that "cannot legally be sold except to physicians, or under the prescription of a physician," and "many new or experimental drugs as to which ... there can be no assurance of safety, or perhaps even of purity of ingredients."[149] For at least some unavoidably unsafe products, comment k states that "[t]he seller ... is not to be held to strict liability for unfortunate consequences attending their use,

144. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (A.L.I. 1965). In full, comment k reads:

> *Unavoidably unsafe products*. 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. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. 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. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

*Id.*

145. *Id.*

146. *Id.*

147. *Id.*

148. *Id.*

149. *Id.*

merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk."[150]

Scholars have long criticized the language of comment k for being inscrutable[151] and the content for being "an ill-conceived jumble of ideas."[152] And courts have long struggled with how to interpret and apply the exemption from liability that the comment provides.[153] For this Article, the lack of clarity around four aspects of comment k are particularly salient to medical device regulation.[154]

### *1. Uncertainty over the Kinds of Products That Are Shielded from Liability*

Comment k can be interpreted as creating an exemption from strict liability solely for the manufacturers of drugs and vaccines. The history of the debates within the ALI that preceded the adoption of section 402A supports such a reading. During the debates, some members strongly advocated for a "blanket exemption of prescription drugs" from strict liability.[155] After a motion for such an exemption failed, William Prosser, the Reporter for the *Restatement (Second) of Torts*, stated that he would "deal with the drug issue in a comment."[156] The text of comment k, which offers only drugs and

150. *Id.*

151. *See* Anita Bernstein, (*Almost*) *No Bad Drugs: Near-Total Products Liability Immunity for Pharmaceuticals Explained*, 77 WASH. & LEE L. REV. 3, 25 (2020) ("The trouble with comment k does not stop with the lack of clarity in it that rises to the level of incoherence."); Henderson & Twerski, *supra* note 31, at 522 ("For half a century, Comment k to § 402A of the Restatement, Second, of Torts has caused confusion in prescription drug litigation, seemingly without end." (citation omitted)); Page, *supra* note 31, at 872 ("Comment k also is vague in that it fails to make clear what kind of special rule it puts in place, what purposes it meets, and to what classes of products it applies."). *But see* Schwartz, *supra* note 128, at 1139-40 (arguing that the language of comment k has "definite meaning").

152. Henderson & Twerski, *supra* note 31, at 522. *But see* Schwartz, *supra* note 128, at 1139-40 (arguing that comment k expresses a clear and coherent policy).

153. Henderson & Twerski, *supra* note 31, at 522.

154. The close textual parsing of comment k that follows may strike some readers as odd, given that comment k itself, and section 402A, are parts of a Restatement with no legally binding effects as opposed to statutes or regulations. But courts have long analyzed them in ways very similar to statutes. *See infra* notes 208-09 and accompanying text.

155. Henderson & Twerski, *supra* note 31, at 525.

156. *Id.*

vaccines as examples, is consistent with this interpretation.[157] One early critic of comment k wrote that "if its examples are taken seriously, comment k reasonably could be read as excluding from section 402A only unavoidably unsafe prescription drugs."[158] Other commentators have found it plausible that comment k is limited to drugs based on their understanding of the policies that support the exemption.[159]

But broader interpretations of the product types to which comment k is addressed are plausible as well. The text begins by stating that "[t]here are some products which ... are quite incapable of being made safe for their intended and ordinary use."[160] The next sentence, "[t]hese are especially common in the field of drugs,"[161] seems to indicate that not all exempted products are drugs. Some commentators have interpreted comment k to exempt medical devices as well as drugs.[162] In addition, the *Restatement (Third) of Torts*' volume on products liability sought to replace section 402A (and thus, comment k) with a new liability rule that largely shields prescription drugs and medical devices from liability.[163]

Comment k has been interpreted even more broadly, as applying to all products that meet the definition of "unavoidably unsafe."[164] Such a reading is consistent with the plain language of the comment, which begins with a reference to products that "are quite incapable of being made safe."[165] As some commentators have pointed out, "[n]ot just *some* products, but *all* products, are categorically dangerous."[166] Thus, in the words of another commentator, "[t]he policy balancing that justifies the immunity in comment k is not necessarily limited to drugs and vaccines."[167]

Unfortunately, as Victor Schwartz has observed, "[w]hile comment k could be read to apply to other products, it does not really

157. *See* RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (A.L.I. 1965).

158. Page, *supra* note 31, at 867.

159. *See* Schwartz, *supra* note 128, at 1140.

160. *See* RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (A.L.I. 1965).

161. *See id.*

162. *See* Henderson & Twerski, *supra* note 31, at 526 (stating that the comment should have clearly specified that it applied to drugs and devices).

163. *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(c) (A.L.I. 1998).

164. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (A.L.I. 1965) (emphasis omitted).

165. *Id.*

166. Henderson & Twerski, *supra* note 31, at 527.

167. Geistfeld, *supra* note 136, at 1670 (emphasis omitted).

give us any examples or suggest other areas in which the policy balancing is precisely the same."[168] Thus, one important question is whether courts should interpret comment k as applying to medical devices at all.

### *2. Uncertainty Whether Comment k Applies to All or to Only Some Products of a Particular Type*

Once it is determined that comment k applies to a general product type, such as drugs, the next question is whether all products of that type are exempted from liability, whether only certain subsets of that product type are exempted, or whether products are exempted on a case-by-case basis.[169] The language of comment k does not provide a clear answer to this question, even for the products—drugs and vaccines—that are explicitly mentioned in its text.

One possible interpretation of comment k is that all drugs are unavoidably unsafe: They pose risks that cannot be eliminated, they offer great social benefits, and their benefit-to-risk ratio is strongly favorable. Under such an interpretation, comment k should apply in blanket fashion, exempting all drugs from strict liability.[170] A more nuanced interpretation is that because a sufficiently large proportion of drugs satisfy these criteria, extending the exemption to all drugs is appropriate.[171] The practical effect of these two interpretations is the same: All drugs would be exempted from liability by the blanket application of comment k. It does not appear that any courts have adopted this broadest possible reading of comment k, which would exempt the manufacturers of prescription as well as over-the-counter drugs from strict liability. Although some commentators have argued in favor of this approach,[172] the few courts that

168. Schwartz, *supra* note 128, at 1141.

169. *See* George W. Conk, *Is There a Design Defect in the* Restatement (Third) of Torts: Products Liability*?*, 109 YALE L.J. 1087, 1095 (2000) (dividing comment k drug cases prior to the year 2000 into those adopting a case-by-case approach and those adopting a blanket approach).

170. *But see id.*

171. *See id.*; OWEN, *supra* note 93, at 1111.

172. *See* Lars Noah, *Treat Yourself: Is Self-Medication the Prescription for What Ails American Health Care?*, 19 HARV. J.L. & TECH. 359, 380 (2006) ("Now that OTC drugs may offer some genuine clinical utility accompanied by non-trivial risks, courts may conclude that these products qualify as 'unavoidably unsafe' and deserve some protection from strict liability claims."); Thomas M. Moore & Scott L. Hengesbach, *Comment k: A Prescription for the Over-*

have confronted the issue have refrained from barring strict liability claims against the manufacturers of over-the-counter drugs.[173]

A second possible interpretation is that comment k exempts only certain categories of drugs. The text of comment k provides the basis for limiting its application to two such categories. The comment notes that many drugs and vaccines are available only "under the prescription of a physician."[174] This is the broadest categorical application of comment k that courts have adopted in the drug cases: All drugs that are available only by prescription are exempted from liability.[175] The second potential categorical application can be found in the reference in comment k to some products that "cannot legally be sold except to physicians,"[176] which would seem to describe a set of drugs distinct from those available by prescription. For example, some drugs can be administered only by a physician.[177] This is a far narrower set of drugs than those available by prescription. However, most courts have ignored this distinction and have considered these categories to be coterminous.[178]

Finally, comment k might be interpreted not to apply in blanket or categorical fashion. Rather, the exemption may be available only to specific drugs on a case-by-case basis. Under this approach, it would be necessary first to determine whether a particular drug satisfied the comment k definition of an unavoidably unsafe product.[179] The same determination would need to be made for other products of a type to which comment k applies. Hence, (assuming that comment k applies to medical devices) it is unclear whether

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*the-Counter Drug Industry*, 22 PAC. L.J. 43, 44 (1990) ("[S]ince OTC products provide enormous social and economic benefits by encouraging self-medication, these products should be exempt from strict liability.").

173. *See, e.g.*, Larkin v. Pfizer, Inc., 153 S.W.3d 758, 761-63 (Ky. 2004) (rejecting the application of the comment k exemption to over-the-counter drugs).

174. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (A.L.I. 1965).

175. *Id.*

176. *Id.*

177. While most prescription drugs are self-administered, a small subset are administered only by physicians. *See, e.g.*, *In re* Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d 20, 29-30 (D. Mass. 2007) (distinguishing physician-administered drugs, such as the cancer drugs Zoladex and Taxol, from self-administered drugs, such as the asthma drug albuterol).

178. *See, e.g.*, Hahn v. Richter, 673 A.2d 888, 889-90 (Pa. 1996) (applying comment k to all prescription drugs); Brown v. Superior Ct., 751 P.2d 470, 477 (Cal. 1988) (same).

179. *See* Grundberg v. Upjohn Co., 813 P.2d 89, 93-94 (Utah 1991) (describing the split between courts applying comment k broadly or on a case-by-case basis).

comment k should exempt all devices, only certain categories of devices, or only individual devices based on a case-by-case analysis.

*3. Uncertainty over Which Legal Theories Are Barred*

Comment k does not specify the theories of liability from which manufacturers are exempted. Clearly, the comment exempts manufacturers from at least some strict liability theories. The comment is addressed to section 402A, which sets out the rule of strict products liability.[180] In the first example discussed, comment k states that, despite the serious risks it poses, the Pasteur rabies vaccine "is not defective, nor is it *unreasonably* dangerous,"[181] which echoes the definition of a product defect for strict liability claims under section 402A.

At a more granular level, comment k clearly exempts manufacturers from strict liability claims for design defects.[182] The comment discusses the risk of "serious and damaging consequences" arising from the use of the rabies vaccine.[183] These consequences are intrinsic to the vaccine—that is, they are a risk posed by every dose of the vaccine as opposed to a risk arising from a contaminant or some other isolated manufacturing flaw.[184] Courts and commentators widely agree that comment k bars strict liability claims that a product was defectively designed.[185]

Some courts and commentators have argued that comment k bars *only* strict liability design defect claims.[186] But others have

180. *See* RESTATEMENT (SECOND) OF TORTS § 402A (A.L.I. 1965).

181. *Id.*

182. *See Grundberg*, 813 P.2d at 92.

183. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (A.L.I. 1965).

184. *See* Page, *supra* note 31, at 873 (referring to "risks that are designed into a product as well as to those naturally and unavoidably present"); CAL. DEP'T PUB. HEALTH, FACTS ABOUT RABIES VACCINATION FOR COMPANION ANIMALS 2 (July 2014), https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/FactsAboutRabiesVaccinationForCompanionAnimals.pdf [https://perma.cc/CYE4-DK5J].

185. Henderson & Twerski, *supra* note 31, at 529-30 (explaining that courts, for a time, interpreted comment k to totally bar strict liability design defect claims involving prescription drugs); Page, *supra* note 31, at 855-57 (discussing how courts have limited the imposition of strict liability and instead applied negligence-like tests to design defect claims); Schwartz, *supra* note 128, at 1144-46 ("[C]omment k deals with liability for design of ... products." (emphasis omitted)).

186. *See* Moss v. Wyeth Inc., 872 F. Supp. 2d 162, 167 (D. Conn. 2012) ("[C]omment k does not exempt products from strict liability for manufacturing defects or warning defects. Rather,

interpreted comment k to exempt manufacturers from a broader set of legal theories. Because a product is considered to be defective if it is not accompanied by adequate warnings about nonobvious risks,[187] comment k has sometimes been interpreted as barring strict liability claims for warning defects.[188] And in its discussion of new or experimental drugs, comment k notes that in some circumstances a lack of time or experience may prevent an assurance "perhaps even of purity of ingredients,"[189] leading some courts to interpret comment k as barring strict liability claims for manufacturing defects.[190] Some courts have even held that comment k bars *all* strict products liability claims for all prescription drugs or all unavoidably unsafe products.[191]

Some courts have gone even further. A small but sizable number, noting that products liability claims arising from breaches of implied or express warranties sound in strict liability, have found that comment k exempts manufacturers from liability arising from these claims as well.[192] And a small number of courts have gone so far as to hold that comment k bars even negligence claims.[193]

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the exemption from strict liability applies only to allegations of defective design."); Toner v. Lederle Lab'ys, 732 P.2d 297, 308 (Idaho 1987) ("[C]omment k immunizes certain products from strict liability claims based on an alleged defective design, though not from strict liability claims based on alleged defective manufacture or inadequate warning."); *see also* Schwartz, *supra* note 128, at 1139, 1144-46 (noting that the *Restatement* authors intended strict liability only for manufacturing defects and "comment k deals with liability for *design* of, and not the warning about, products"). Professor Schwartz argued that other parts of the *Second Restatement* provided that the standard for design and warning defects is negligence. *See id.* at 1139-40 (arguing that section 389 provided a negligence standard for design defect and that section 402A comment j provided a negligence standard for warning defects).

187. *See* Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 490 (2013) (finding that state design-defect theories "place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling").

188. *See, e.g.*, Kaspers v. Howmedica Osteonics Corp., No. C15-0053, 2015 WL 12085853, at *8 (W.D. Wash. Oct. 23, 2015).

189. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (A.L.I. 1965).

190. *See* Lance v. Wyeth, 85 A.3d 434, 453 (Pa. 2014) ("[F]or policy reasons this Court has declined to extend strict liability into the prescription drug arena.").

191. *Id.*; *see* Aaron v. Medtronic, Inc., 209 F. Supp. 3d 994, 1013-14 (S.D. Ohio 2016) (interpreting Ohio law to apply comment k to bar all strict products liability claims against unavoidably unsafe products).

192. *See* Makripodis *ex rel.* Makripodis v. Merrell-Dow Pharms., Inc., 523 A.2d 374, 377 (Pa. Super. Ct. 1987) ("[T]he very nature of prescription drugs themselves precludes the imposition of a warranty of fitness for 'ordinary purposes.'").

193. *See* Barcal v. EMD Serono, Inc., No. 14-cv-01709, 2016 WL 1086028, at *3 (N.D. Ala. Mar. 21, 2016) (interpreting Alabama law to apply comment k to bar negligent design defect

*4. Uncertainty over Which Product-Specific Conditions Must Be Satisfied for Comment k to Apply*

The text of comment k can be interpreted as requiring certain conditions to be satisfied in order for a manufacturer to benefit from the exemption from liability, regardless of whether the exemption is available to all drugs, to a certain category of drugs, or only on a case-by-case basis. Two of these conditions are not directly related to the design of the product but rather to the preparation of and the warnings provided with the product. Regarding the rabies vaccine and other products, the comment specifies that only if they are "properly prepared, and accompanied by proper directions and warning," are such products "not defective, nor ... unreasonably dangerous."[194] And regarding new and experimental drugs, the manufacturer's exemption is available "with the qualification that they are properly prepared and marketed."[195] Many courts have described these allusions to proper preparation and warning as "caveats" to the application of the exemption.[196] Some courts consider one or both of these to be necessary conditions for the exemption from strict liability to apply, while others, even those that recognize this as a plain-language reading of comment k, do not.[197]

Comment k also describes four other conditions that concern the design and generic risks of the product, the satisfaction of which might be necessary for the exemption to apply. Comment k describes the products it covers as being "incapable of being made safe," noting the example of the "serious and damaging consequences" that may attend the administration of the rabies vaccine.[198] One interpretation of this language is that if there were a way to make the product safer, the comment k exemption would not be available. Comment k also notes that the use of products it covers "not uncommonly leads to very serious and damaging

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claims); *see also* Davis, *supra* note 29, at 409 ("Virtual blanket immunity from liability for pharmaceutical design is one response, influential, in part, due to its support by California courts.").

194. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (A.L.I. 1965) (emphasis omitted).

195. *Id.*

196. *See, e.g.*, Parkinson v. Guidant Corp., 315 F. Supp. 2d 741, 747 (W.D. Pa. 2004).

197. *See id.*

198. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (A.L.I. 1965).

consequences" and that there is a "high degree of risk which they involve."[199] Thus, carrying serious risks might be seen as a necessary condition to be eligible for the comment k exemption. Further, comment k notes that at least some of these risky products are "apparently useful and desirable" to the public or, in other words, that they offer a substantial benefit.[200] This could be interpreted to mean that only some products are sufficiently beneficial as to warrant an exemption from liability. Finally, comment k suggests that its exemption is based on a favorable risk-benefit ratio.[201] As the rabies vaccine illustrates, the risk presented by a drug is, in isolation, likely an insufficient consideration to remove a drug from the ambit of strict liability under section 402A.[202] Thus, the more risky the product, the more salient the benefits become. Having a favorable risk-benefit ratio might be a necessary condition in order to benefit from the exemption to liability.[203]

* * *

The confusion bred by the language of comment k has resulted in decades of frustration; as Professors James Henderson and Aaron Twerski, the Reporters to the Products Liability volume of the *Restatement (Third) of Torts*, have urged, "[b]idding farewell to Comment k is both justifiable and overdue."[204] But the application of comment k to drugs has been litigated extensively and has been the subject of a great deal of scholarly attention, offering some limited clarity in this context. Expert consensus appears to be that a majority of courts have taken a case-by-case approach to the application of comment k in prescription drug cases.[205] Based on my review of state court holdings in cases involving drugs, vaccines, and blood products, nearly 60 percent of the state high courts that have

199. *Id.*
200. *Id.*
201. *See id.*
202. *See id.*
203. *See* Kearl *ex. rel.* v. Lederle Lab'ys, 218 Cal. Rptr. 453, 464 (Ct. App. 1985), *overruled by*, Brown v. Superior Ct., 751 P.2d 470, 477 (Cal. 1988).
204. Henderson & Twerski, *supra* note 31, at 522.
205. *See id.* at 530-31; Davis, *supra* note 29, at 409; OWEN, *supra* note 93, at 1109-10; Conk, *supra* note 169, at 1094.

ruled on the issue have either held that comment k applies only on a case-by-case basis or not at all.[206]

Until recently, the role of comment k in strict products liability claims against the manufacturers of medical devices had not been widely litigated.[207] Further, little scholarly attention has focused on this issue despite a rapidly growing number of cases that have examined this issue. This lack of attention is unfortunate because, as discussed in Part I.C, the FDA's premarket assessment of the vast majority of devices (those that reach the market through the PMA supplement and 510(k) pathways) has not reduced their risk uncertainty. Private litigation under state products liability law would ideally serve as a complementary regulatory input. But without knowing how broadly courts are interpreting comment k to

206. In fifteen drug cases, a state high court adopted a case-by-case approach or held that comment k did not apply at all. *See* Shanks v. Upjohn Co., 835 P.2d 1189, 1197 (Alaska 1992) (does-not-apply); West v. Searle & Co., 806 S.W.2d 608, 612 (Ark. 1991) (case-by-case); Ortho Pharm. Corp. v. Heath, 722 P.2d 410, 415 (Colo. 1986) (case-by-case); Am. Home Prods. v. Ferrari, 668 S.E.2d 236, 239 (Ga. 2008) (case-by-case); Toner v. Lederle Lab'ys, 732 P.2d 297, 308 (Idaho 1987) (case-by-case); Savina v. Sterling Drug, Inc., 795 P.2d 915, 925-26 (Kan. 1990) (case-by-case); McMichael v. Am. Red Cross, 532 S.W.2d 7, 9, 11 (Ky. 1975) (case-by-case); Bennett v. Madakasira, 1999-CA-00266-SCT (¶57), 821 So. 2d 794, 809 (Miss. 2002) (case-by-case); Freeman v. Hoffman-La Roche, Inc., 618 N.W.2d 827, 840 (Neb. 2000) (case-by-case); Allison v. Merck & Co., 878 P.2d 948, 953-56 (Nev. 1994) (does-not-apply); Feldman v. Lederle Lab'ys, 479 A.2d 374, 383 (N.J. 1984) (case-by-case); White v. Wyeth Lab'ys, 533 N.E.2d 748, 752 (Ohio 1988) (case-by-case); Senn v. Merrell-Dow Pharms., Inc., 751 P.2d 215, 218 n.4 (Or. 1988) (case-by-case); Castrignano v. E.R. Squibb & Sons, Inc., 546 A.2d 775, 780-81 (R.I. 1988) (case-by-case); Collins v. Eli Lilly Co., 342 N.W.2d 37, 51-52 (Wis. 1984) (does-not-apply). In addition, at least one state high court has strongly implied that it would apply a case-by-case approach. *See* Madison v. Am. Home Prods. Corp., 595 S.E.2d 493, 496 n.3 (S.C. 2004) (noting that because the case was decided on other grounds, "we need not determine whether Effexor would be considered an 'unavoidably unsafe' product"). In eleven drug cases, a state high court adopted a blanket or categorical application. *See* Stone v. Smith, Kline & French Lab'ys, 447 So. 2d 1301, 1304 (Ala. 1984) (categorical); *Brown*, 751 P.2d at 482-83, 482 n.11 (categorical); Vitanza v. Upjohn Co., 778 A.2d 829, 832, 837, 845 (Conn. 2001) (categorical); Fisher v. Sibley Mem'l Hosp., 403 A.2d 1130, 1134 (D.C. 1979) (categorical); Miles Lab'ys, Inc. Cutter Lab'ys Div. v. Doe, 556 A.2d 1107, 1121 (Md. 1989) (categorical exemption for blood and blood products); Payton v. Abbott Labs, 437 N.E.2d 171, 189-90 (Mass. 1982) (blanket or categorical); Wolfgruber v. Upjohn Co., 423 N.Y.S.2d 95, 97 (App. Div. 1979) (categorical); McKee v. Moore, 648 P.2d 21, 23-25 (Okla. 1982) (categorical); Hahn v. Richter, 673 A.2d 888, 891 (Pa. 1996) (categorical); Grundberg v. Upjohn Co., 813 P.2d 89, 90 (Utah 1991) (categorical); Young v. Key Pharms., Inc., 922 P.2d 59, 63-64 (Wash. 1996) (categorical).

207. *See infra* Figure 1 for the increase in medical device cases over time, demonstrating that these cases were uncommon prior to the year 2000.

shield device manufacturers, it is impossible to know if private litigation is serving this role.

### *B. Why Courts Should Be Less Inclined to Apply Comment k to Medical Devices*

There are strong reasons to expect that courts would be less inclined to interpret comment k as exempting medical devices from liability to the same extent they have in cases involving drugs. In fact, it is reasonable to expect that courts would find that comment k does not apply to medical devices at all. Further, when they do find that comment k applies, it is reasonable to expect that courts will apply comment k narrowly—that is, on a case-by-case basis, to exempt fewer devices than drugs. The reasons for this are set out here.

#### *1. The Text of Comment k*

Although comment k and section 402A are restatements of the law, and thus, lack any binding effect until they are formally adopted into state law, they have, according to many, "achieved the status of sacred scripture" or a "holy writ" that has come to "dominate judicial thinking"[208] and have been "accepted uncritically as divine."[209] Indeed, reading some of the judicial interpretations of comment k can give the sense that courts are engaging in statutory interpretation.[210] Nothing in the text of comment k explicitly mandates its application to medical devices.[211] While not a model of clarity, the comment does explicitly mention drugs and vaccines; however, the comment is silent as to whether the exemption from

208. James A. Henderson, Jr. & Aaron D. Twerski, *A Proposed Revision of Section 402A of the* Restatement (Second) of Torts, 77 CORN. L. REV. 1512, 1512-13 (1992).

209. David G. Owen, *Design Defect Ghosts,* 74 BROOK. L. REV. 927, 935 (2009) ("With a gusto unmatched in the annals of the *Restatements of the Law*, courts and legislatures across the land embraced section 402A .... If ever a Restatement reformulation of the law were accepted uncritically as divine, surely it was section 402A of the *Restatement (Second) of Torts*.").

210. *See* Tansy v. Dacomed Corp., 890 P.2d 881, 885-86 (Okla. 1994) (analyzing the language and policies of comment k at length); Larsen v. Pacesetter Sys., Inc., 837 P.2d 1273, 1285-86 (Haw. 1992) (parsing the language of comment k to determine the scope of its applicability).

211. *See supra* Part II.A.1.

strict liability was intended to extend to medical devices.[212] Considering that the adoption of strict products liability was a hard-won victory for proponents who had advocated on its behalf for decades,[213] it might seem unlikely that courts would abandon it in circumstances not expressly called for in the language of the comment.

*2. The Poor Policy Fit*

It is not clear that the policy concerns that motived William Prosser to draft and the ALI membership to ratify comment k extend to medical devices. During the preratification deliberations, some called for the blanket exemption of prescription drugs from strict liability.[214] But, as one court recently noted, "whether the rationale supporting the application of comment k to drugs necessarily carries through to devices ... is not intuitively clear."[215] If the comment's rationale was that drugs (or at least some category of drugs) should be exempted from liability because a sufficiently large proportion offered critically important benefits,[216] the same calculus might not apply to devices.[217] Devices comprise a broad and heterogeneous set of products, many fewer of which are likely to offer the kind of lifesaving benefits conferred by the rabies vaccine or the experimental drugs to which comment k refers.[218] And if the rationale was that a sufficiently large proportion of drugs were incapable of being made safe, the same calculus might not apply to devices.

212. *See* RESTATEMENT (SECOND) OF TORTS § 402A cmt. k. (A.L.I. 1965).

213. *See, e.g.*, Escola v. Coca Cola Bottling Co. of Fresno, 150 P.2d 436, 440-41 (Cal. 1944) (Traynor, J., concurring). *See generally* Prosser, *supra* note 96 (describing the centuries-long process of expanding the application of strict liability from food and drink to all products).

214. Henderson & Twerski, *supra* note 31, at 525.

215. Spear v. Atrium Med. Corp., 621 F. Supp. 3d 553, 556 (E.D. Pa. 2022).

216. *See* Conk, *supra* note 169, at 1093.

217. *See Spear*, 621 F. Supp. 3d at 556-57.

218. For example, Class I devices, which comprise roughly half of all devices, U.S. FOOD & DRUG ADMIN., MEDICAL DEVICE SAFETY ACTION PLAN: PROTECTING PATIENTS, PROMOTING PUBLIC HEALTH 3 (2021), https://www.fda.gov/about-fda/cdrh-reports/medical-device-safety-action-plan-protecting-patients-promoting-public-health [https://perma.cc/B9HE-5JMU], by definition do not provide such lifesaving benefits. *See* 21 U.S.C. § 360c(a)(1)(A)(ii)(I) (defining Class I devices as not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health).

Compared to drugs, medical devices are more often amenable to design changes that can make them safer.[219] Drugs are characterized by a specific molecular structure.[220] If that structure is redesigned—changed—the manufacturer has created a new drug.[221] As a legal matter, drugs cannot be redesigned to be more safe; they can only be replaced by safer new drugs.[222] Devices, however, can be redesigned.[223] Devices approved through the PMA process cannot be changed without FDA approval, but various supplemental PMA pathways afford manufacturers the option of modifying their devices without needing to submit the full set of data required for an initial approval.[224] Legally, the result is a modified version of the same device. Devices cleared through the 510(k) pathway can be altered, and the altered version can be cleared by the FDA based on substantial equivalence.[225] Thus, too small a portion of medical devices would fit the definition of unavoidably unsafe products to justify a liability shield to ensure their availability. As a result, courts might be expected to find the policies underlying comment k will not apply to medical devices.

If, however, courts were to decide that comment k does apply to at least some medical devices, then—just as in the drug cases—they would have to grapple with the question of whether the exemption from strict liability applies in blanket fashion to all devices, only certain categories of devices, or only individual devices on a case-by-case basis. As just discussed, because fewer devices meet the definition of unavoidably unsafe products, it would seem likely that blanket applications should be rare.[226] The same considerations would suggest that if courts were to apply comment k on a case-by-case basis to medical devices, the result would be that few devices would be found to be exempt from strict liability. Because it is more common for devices to be capable of being made more safe and

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219. *See* Noah, *supra* note 112, at 914.

220. *See id.*

221. *See* Henderson & Twerski, *supra* note 31, at 544-45.

222. *See* James A. Henderson, Jr. & Aaron D. Twerski, *Drug Designs* Are *Different*, 111 YALE L.J. 151, 163-64 (2001).

223. *See* Noah, *supra* note 112, at 914.

224. *See* 21 C.F.R. § 814.39(c)(1) (2025).

225. *See* 21 U.S.C. § 360c(i)(1)(A).

226. *But see* Allen v. Mentor Corp., No. 04CV642, 2006 WL 861007, at *7 (D. Conn. Mar. 31, 2006) (holding that comment k applies to "[m]edical products").

because risk-benefit weighing may be, or may seem to be, more simple in the device context,[227] it would seem reasonable that courts adopting a case-by-case approach to the application of comment k to medical devices would only infrequently shield manufacturers from liability based on comment k.

*3. The Preemption Framework*

Changes in the legal environment might alter courts' approaches to the application of comment k to medical devices. The Supreme Court established the preemption framework for prescription drugs in a series of three decisions issued between 2009 and 2013.[228] However, the majority of cases on the application of comment k to drugs had been decided well before these decisions.[229] Thus, when the comment k drug cases were being decided, the external limits to the role of state products liability law had not been established, leaving the concerns about excessive liability particularly salient. By contrast, the three major Supreme Court cases on preemption in the medical device context were decided between 1996 and 2008.[230] Fewer than one-quarter of the cases in the data set of medical device comment k cases presented in Part III had been decided by the time the last of these device preemption cases was decided.[231] Thus, most of the case law on the application of comment k to devices has emerged within a well-defined preemption framework.

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227. The regulatory frameworks for drugs and devices embody the view that risk-benefit analyses are more difficult for drugs than devices. All new drugs, even those quite similar to already-approved drugs, must navigate the rigorous new drug application process. *See* 21 U.S.C. § 355(a). Only drugs whose active ingredient is the same as an approved drug are eligible for the less-burdensome abbreviated new drug application for generics. *Id.* § 355(j)(2)(A)(ii). By contrast, new devices that are similar to existing devices, even if there are significant technological differences, are eligible for the less-burdensome 510(k) pathway. *See supra* text accompanying notes 85-86; *see also* Noah, *supra* note 112, at 914 ("[D]evices generally should not present the same unpredictable (and variable) responses encountered with metabolized drugs.").

228. *See* Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 490 (2013); PLIVA, Inc. v. Mensing, 564 U.S. 604, 611-13 (2011); Wyeth v. Levine, 555 U.S. 555, 570-73 (2009).

229. *See supra* text accompanying note 206.

230. *See* Riegel v. Medtronic, Inc., 552 U.S. 312, 330 (2008); Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 347-48 (2001); Medtronic, Inc. v. Lohr, 518 U.S. 470, 484-86 (1996).

231. In the data set presented in Part III, 45 of 188 cases (23.9 percent) had been decided prior to the U.S. Supreme Court's decision in *Riegel v. Medtronic, Inc. See infra* Part III.A.

As discussed in Part I.C, there would be little need to adopt comment k in cases involving devices marketed under original PMAs and PMA supplements, because most products liability claims would already be preempted by *Riegel* and *Buckman*.[232]

By contrast, for 510(k) devices, the policy concerns point in the opposite direction. Under *Lohr*, state law claims against devices marketed through 510(k) clearance remain largely viable.[233] This could raise concerns about excessive liability and about the potential for nonuniformity under the products liability law of fifty-one jurisdictions, which could jeopardize innovation.

One potential response would be for courts to apply comment k categorically to 510(k) devices, while not applying comment k at all to PMA and PMA supplement devices. This may be complicated by the court system in which a case is decided. Concerns about excessive liability and regulatory heterogeneity might be less important to state courts, whose focus is directed more toward protecting the health and safety of in-state residents, compared with federal courts' interest in promoting national uniformity.[234] Thus, the issue of which courts (state or federal) are deciding the application of comment k might have particular salience for 510(k) devices.[235]

*4. The Adoption of the Risk-Utility Test*

Changes in state products liability law might be expected to render the exemption from strict liability offered by comment k moot. Under the consumer expectation test that was set out in comment g to section 402A and that was adopted by most states early on, a manufacturer could be held strictly liable where the risks presented by a device were not within the risks contemplated by an ordinary consumer.[236] A design defect could be found regardless of

232. *See supra* Part I.C.

233. *See Lohr*, 518 U.S. at 487-89.

234. *See* Diego A. Zambrano, *Federal Expansion and the Decay of State Courts*, 86 U. CHI. L. REV. 2101, 2103-04 (2019) ("[W]hile federal courts have embraced prodefendant procedural rules ... circumscribing access to court in the process—state courts have remained relatively pro-plaintiff and have ensured broader access to court.").

235. *See Lohr*, 518 U.S. at 478-79, 485.

236. RESTATEMENT (SECOND) OF TORTS § 402A & cmt. g, i (A.L.I. 1965); *see* Aaron D. Twerski & James A. Henderson, Jr., *Manufacturers' Liability for Defective Product Designs:*

how much care a manufacturer had used in designing its device, and regardless of whether the socially beneficial aspects of the device far outweighed the risks.[237] Thus, strict liability was built into the structure of section 402A through the adoption of the consumer expectation test.[238] In this environment, comment k served an important function by exempting some product manufacturers from this rule.[239] But the majority of states now use a risk-utility test, which renders the boundary between negligence and strict liability less distinct.[240] The risk-utility test contemplates factors typically associated with negligence analyses, including the utility of the product, gravity and likelihood of injury, availability and cost of a substitute product, manufacturer's ability to make changes to the product to make it safer, and impairment of the product's utility that such changes would cause.[241] Indeed, some courts have written that there is no difference between the reasonableness standard in negligence actions and the risk-utility standard in strict liability actions.[242] Courts that find the two standards synonymous might have less incentive to apply comment k broadly, if at all, because the result is the same: If plaintiffs' strict liability design defect claims are barred by comment k, only negligence claims will be available,[243] and if those claims are not barred, they will be decided under the negligence-like rules of the risk-utility test.

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*The Triumph of Risk-Utility*, 74 BROOK. L. REV. 1061, 1066-67 (2009).

237. Twerski & Henderson, *supra* note 236, at 1066 ("[T]he drafters [of § 402A] justified their new rule of strict liability by pointing to the disappointment of consumer expectations that defect-caused product failures cause."). The black letter rule of section 402A states that a seller is liable even if it had "exercised all possible care in the preparation and sale of his product," RESTATEMENT (SECOND) OF TORTS § 402A(2)(a) (A.L.I. 1965), confirming the strict liability nature of the consumer expectations test.

238. *See* Twerski & Henderson, *supra* note 236, at 1066.

239. *See* Mullins v. Ethicon, Inc., 117 F. Supp. 3d 810, 817 (S.D. W. Va. 2015).

240. *See id.* ("[T]he risk-utility test in strict product liability bears a striking resemblance to the principles of negligence.").

241. *See* Adams v. Bos. Sci. Corp., 177 F. Supp. 3d 959, 964-65 (S.D. W. Va. 2016) (citing Am. Tobacco Co. v. Grinnell, 951 S.W.2d 420, 432 (Tex. 1997)).

242. Prentis v. Yale Mfg. Co., 365 N.W.2d 176, 184 (Mich. 1984) (distinction between risk-utility and negligence tests is "nothing more than semantic").

243. *See* Woodard v. Stryker Corp., No. 11-CV-36-F, 2012 WL 12860868, at *7 (D. Wyo. Feb. 9, 2012) (noting that the Minnesota Supreme Court had stated "that the policies behind comment K are 'implicitly reflected in the negligence-based "reasonable care" standard adopted by the Minnesota Supreme Court in strict liability design defect cases.'" (quoting Kociemba v. G.D. Searle & Co., 695 F. Supp. 432, 433 (D. Minn. 1988))).

*5. The Risk of Chaos*

As Professor Mary Davis has observed, "[d]ebate over the meaning of comment *k* began immediately and continued for the next four decades."[244] After more than five decades of litigation in the context of prescription drugs, courts' interpretations of comment k and the resulting role of products liability law to prescription drugs reveal doctrinal confusion, or, in the words of Professors Henderson and Twerski, "[c]onceptual [c]haos."[245]

In the medical device context, there is an even greater risk of chaos: If courts adopt a categorical approach in medical device cases, there are more possible categories of devices that could be defined. For drugs, the main categorical approach was to apply comment k to all prescription drugs; courts largely considered the other potential category of drugs—those that "cannot legally be sold except to physicians"[246]—to be coterminous with prescription drugs. Courts in device cases might adopt either term to distinguish these devices from over-the-counter devices,[247] although some have expressed uncertainty over whether the two categories were truly coterminous.[248]

But devices can also be categorized in other ways. One such category is that of "implanted medical device[s]."[249] This is by far the narrowest of the categorical approaches: All implanted devices are available only through the services of a physician, but not all devices available through a physician are implanted.[250] Courts might

244. Davis, *supra* note 29, at 409.

245. Henderson & Twerski, *supra* note 31, at 542.

246. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (A.L.I. 1965); *see, e.g.*, Smith v. Angiodynamics, Inc., 731 F. Supp. 3d 1262, 1267-68 (M.D. Ala. 2024) (interpreting comment k and its applicability to both categories of drugs).

247. *See* Taylor v. Danek Med., Inc., No. 95-7232, 1998 WL 962062, at *7 (E.D. Pa. Dec. 29, 1998) (predicting Pennsylvania Supreme Court would apply comment k to all prescription medical devices); 21 C.F.R. § 801.109 (2025) (exempting devices from the requirement of labelling that included "adequate directions for use" that would be understandable by laymen provided the device is labelled as "Rx only" and "[i]s to be sold only to or on the prescription or other order" of a practitioner).

248. *See* Artiglio v. Superior Ct., 27 Cal. Rptr. 2d 589, 593 (Ct. App. 1994) ("Since the device is provided directly by the physician, it is not strictly speaking within the category of a 'prescribed' product.").

249. *See, e.g.*, Hufft v. Horowitz, 5 Cal. Rptr. 2d 377, 378 (Ct. App. 1992).

250. *See, e.g.*, Taylor v. Intuitive Surgical, Inc., 389 P.3d 517, 520 (Wash. 2017) (involving a robotic surgical device used in laparoscopic surgery); Payne v. Paugh, 360 P.3d 39, 41

also apply comment k to devices that reached the market through a specific pathway, either the 510(k) pathway or the PMA pathway.[251] And courts might combine categories—for example, applying comment k to prescription implanted devices.[252]

* * *

How courts should apply comment k in cases involving medical devices is far from clear as an *a priori* matter. Until recently, courts had not addressed the application of comment k in cases involving medical devices. How courts apply comment k in device cases could have dramatic—or minimal—effects on the ability of private products liability litigation to incentivize information bearing on device risk. The empirical study presented in Part III was designed, in part, to provide an understanding of the impact of these decisions.

## III. EMPIRICAL STUDY: COMMENT K IN MEDICAL DEVICE CASES

The findings presented in this Part are derived from a study of court decisions in cases in which plaintiffs alleged they had been harmed by defective medical devices and in which courts confronted the question of whether any of the claims were barred by comment k. In addition to this Article's goal of understanding how the decisions in these cases impacted the regulatory system that emerges from FDA premarket regulation and private products liability litigation, the study also sought to document and explain the survival of comment k in the face of attempts to develop new liability rules for drugs and medical devices and to use this set of cases to add to our understanding of the increasing federalization of the common law. These issues will be explored elsewhere. Part III.A presents an overview of the study methodology. Part III.B then presents the findings of the study that are relevant to this Article.

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(Wash. Ct. App. 2015) (involving endotracheal tubes that are used during throat surgery).

251. *See, e.g.*, Burningham v. Wright Med. Tech., Inc., 2019 UT 56, ¶31, 448 P.3d 1283, 1290 (applying comment k only to certain devices cleared through the 510(k) pathway).

252. *See, e.g.*, *Hufft*, 5 Cal. Rptr. 2d at 378, 383 (explaining the public policy rationale for extending application to prescription implanted devices).

### *A. Overview and Methodology*

Court decisions through June 30, 2024, that addressed the application of comment k in cases alleging that a medical device had harmed the plaintiff were identified through multiple searches of the Westlaw and LEXIS databases. The searches identified decisions in state and federal courts through the use of a variety of search terms and Boolean connectors.[253] Each case that the searches identified was initially screened, and those that did not involve a medical device; were purely procedural or duplicative; were ratified in a subsequent, reasoned decision; or neither discussed nor applied comment k were removed to a separate file that was not used in the analysis.[254]

The searches identified 402 unique decisions. Based on the initial screening, 196 cases were excluded.[255] This process resulted in a data set containing 206 judicial decisions issued between April 27, 1978, and June 26, 2024.[256] Detailed information was then extracted from each remaining case using well-established quantitative, systematic, content-analytic methodologies.[257] A full description of the methodology and the raw data is provided in the Appendix.[258] In brief, a coding form and a coding manual were developed in an incremental fashion based on the language of comment k, the

253. The Westlaw Edge and LEXIS search engines were queried using two sets of terms. The first set was "comment k," "cmt. k," "unavoidably unsafe," and "unavoidable." The second set of terms was "device" and "medical device." The queries were thus "comment k" AND "device," "unavoidably unsafe" AND "medical device," and all remaining permutations. The Westlaw search engine was also queried using the West Key Number System codes 313Ak113 (Strict Liability) and 313Ak223 (Health Care and Medical Products), with results filtered for cases containing the terms "comment k," "cmt. k," or "unavoidable."

254. *See infra* Appendix Part A. These cases were analyzed and recorded in a separate data set for possible future use.

255. Most of the excluded cases involved litigation over other products such as drugs, vaccines, tobacco, and asbestos (n=114) or an absence of an analysis of comment k (n=61). Other cases were excluded because they were addressed by subsequent cases (n=11), were only case filings (n=6), or were duplicates with different reporter (Westlaw, Lexis) designations (n=4).

256. *See infra* Appendix Part A.

257. For a background on examples of the methodologies used in quantitative content analysis in legal scholarship, see Mark A. Hall & Ronald F. Wright, *Systematic Content Analysis of Judicial Opinions*, 96 CALIF. L. REV. 63, 67, 79, 107 (2008) (explaining the role of content analysis and the processes of case selection and coding).

258. *See infra* Appendix Part A.

analysis presented in Part II of this paper, and an initial coding of a subset of the device cases.[259] Using the finalized coding form and manual, forty-six data points were coded by the author for each case.[260] Approximately half of the cases were also independently coded by two additional readers (law student research assistants) in order to assess interobserver variability in coding. All of the cases were also coded a second time by the author for an assessment of intraobserver variability.[261]

### *B. Findings*

#### *1. A Growing Wave of Cases*

Litigation over the role of comment k in cases involving allegedly defective medical devices trailed the analogous litigation in drug cases by several decades.[262] By the year 2000, twenty-two state high courts had ruled on the application of comment k in cases involving drugs, vaccines, and blood products; the total now stands at twenty-six states.[263] By contrast, cases involving comment k in the medical device context were uncommon prior to the year 2000; in no single year prior to that date were there more than five decisions, and in many years there were none.[264] Since the year 2000, decisions on the application of comment k to medical devices have been rendered with increasing frequency, as Figure 1 illustrates. In total, 206 cases were identified, with just under 61 percent issued in the past decade.

259. *See infra* Appendix Part D.

260. *See infra* Appendix Part C.

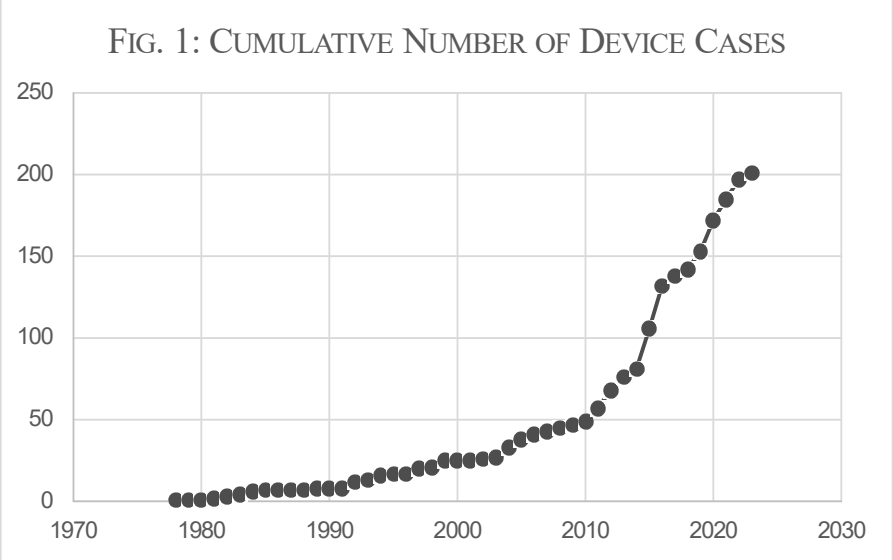
261. The coded data used in this study are available at https://www.uclawsf.edu/academics/centers/consortium-2/initiatives/medical-device-safety-innovation-and-law/ [https://perma.cc/26WU-FRPG].

262. *Cf.* Henderson & Twerski, *supra* note 208, at 1543 nn.64-65 (collecting and synthesizing comment k drug cases decided largely during the 1980s).

263. *See supra* note 206 and accompanying text.

264. *See infra* Appendix Part A.

Figure 1. Cumulative Number of Device Cases




The absolute number of decisions, while large and still growing, does not reflect the extent of harm suffered by the plaintiffs in these cases or the broader impact of the comment k decisions on injured patients' ability to seek compensation; nor does it reflect the impact that one or a small number of judicial decisions can have on the ability of products liability law to incentivize manufacturers' production and dissemination of information that can reduce medical device risk uncertainty. Although the majority of cases in the data set involved a single plaintiff (60 percent of all cases) or a small number of plaintiffs in a consolidated action (7 percent), involvement in multidistrict litigation (MDL) was commonplace, with 33 percent of cases decided within or having been transferred from an MDL. After an early peak in 2003 resulting from cases involving orthopedic bone screws,[265] the proportion of decisions that arose from MDLs declined for several years, but since 2016, the proportion has remained over 25 percent of all decisions. Some of the

265. The fraud on the FDA claims in these cases culminated in the U.S. Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Committee*, which did not, however, address comment k. 531 U.S. 341, 341, 346 (2001).

MDLs have involved tens of thousands of individual claims.[266] Many of the MDL decisions were rendered by a single district court judge who was overseeing seven MDLs involving over seventy thousand surgical mesh cases.[267] This illustrates the potential for any one judge (in these cases, a federal court judge) to determine whether products liability law can serve as an incentive for manufacturers to produce safer products.[268]

A wide variety of devices caused the harm suffered by plaintiffs in these cases. However, two generic device types accounted for more than half of all cases: surgical mesh devices that are used in hernia repairs[269] and pelvic resuspension surgeries (n=73),[270] and prosthetic hip joint replacements (n=31).[271] Most of the cases involved implanted devices.[272] A smaller number involved devices that are used during surgery but are not implanted, such as robotic surgery devices (n=4),[273] endotracheal tubes (n=1),[274] and surgical drapes (n=1).[275] Others involved devices that are used after surgery, such as infusion pumps that deliver medications to surgical sites to

266. *See, e.g.*, Sederholm v. Bos. Sci. Corp., No. 13-cv-12510, 2015 WL 5842796, at *1 (S.D. W. Va. Oct. 6, 2015) (noting that seven MDLs involving surgical mesh comprised nearly seventy thousand individual cases).

267. *See, e.g.*, Fowler v. Bos. Sci. Corp., No. 13-cv-03932, 2016 WL 1317410, at *1 (S.D. W. Va. Apr. 1, 2016) (decided by Judge Joseph R. Goodwin); Stidham v. Bos. Sci. Corp., No. 2:12-cv-06759, 2015 WL 2452984, at *1 (S.D. W. Va. May 22, 2015) (same).

268. *See Stidham*, 2015 WL 2452984, at *4 (also decided by Judge Joseph R. Goodwin).

269. *See, e.g.*, Carson v. Atrium Med. Corp., 191 F. Supp. 3d 473, 475 (W.D. Pa. 2016) (illustrating one surgical mesh case in which the patient experienced severe abdominal and leg pain postprocedure).

270. *See, e.g.*, Huskey v. Ethicon, Inc., 848 F.3d 151, 155 (4th Cir. 2017) (involving a pelvic resuspension case in which the plaintiff experienced severe pelvic pain from mesh erosion).

271. *See, e.g.*, Johnson v. Zimmer, Inc., No. 02-1328, 2004 WL 742038, at *2 (D. Minn. 2004) (illustrating a plaintiff's case against a hip stem manufacturer for premature loosening, requiring surgical revision).

272. Other implanted devices that appear frequently in the data set include inferior vena cava filters (n=17) and spinal fusion devices (n=14). *See, e.g.*, Tillman v. C.R. Bard, Inc., 96 F. Supp. 3d 1307, 1314 (M.D. Fla. 2015) (IVC filter); Byrnes v. Small, 60 F. Supp. 3d 1289, 1292 (M.D. Fla. 2015) (spinal fusion bone graft device).

273. *See, e.g.*, Taylor v. Intuitive Surgical, Inc., 389 P.3d 517, 520 (Wash. 2017) (robotic laproscopic surgery device).

274. *See, e.g.*, Payne v. Paugh, 360 P.3d 39, 40 (Wash. Ct. App. 2015) (involving an endotracheal tube that caught fire, burning the patient).

275. *See, e.g.*, Racer v. Utterman, 629 S.W.2d 387, 391 (Mo. Ct. App. 1981) (involving a surgical drape that caught fire, burning the patient).

alleviate pain (n=11).[276] No cases involved in vitro diagnostic tests or over-the-counter devices.

Most of the injuries reported in the decisions appear to have been serious, although in many cases the procedural posture of the case dictated that the court accept the plaintiff's account of the severity of the injury.[277] Thus, the amount of harm caused by device defects cannot be quantified. One data point that is less manipulable is the need for surgery to correct or remove a device or to treat the harm that the device caused. In over half of the cases (56 percent), at least one surgery was reportedly necessary to treat the harm caused by the device defect.

For the first twenty years of the data set (1978-1997), relatively few device cases were decided (n=20); during this time, a majority of decisions (55 percent) were made by state courts. In 1999, the cumulative federal share of cases exceeded the state share for the first time, and the cumulative proportion has increasingly favored the federal courts—remaining over 80 percent of all decisions since 2015. In the twenty-year period between 2004 and 2023, 91 percent of decisions were made by federal courts—the vast majority by federal district courts sitting in diversity jurisdiction.

*2. Broadly Barring Liability*

Expert consensus about comment k cases involving prescription drugs is that the majority of courts have taken a case-by-case approach.[278] My review of state high court decisions on the application of comment k in cases of allegedly defective drugs, vaccines, and blood products supports this consensus, finding that of the twenty-six state high courts that have issued holdings, 58 percent applied comment k narrowly; twelve applied comment k on a case-by-case basis,[279] and three held that comment k did not apply at all.[280] Eleven state high courts (41 percent) applied comment k

276. *See, e.g.*, Prather v. Abbott Lab'ys, 960 F. Supp. 2d 700, 703, 707 (W.D. Ky. 2013) (postoperative implantable pain management device).

277. *See, e.g.*, *id.* at 705.

278. *See* Davis, *supra* note 29, at 409; OWEN, *supra* note 93, at 1109-10; Conk, *supra* note 169, at 1094.

279. *See supra* note 206 and accompanying text.

280. *See supra* note 206 and accompanying text.

broadly, categorically exempting the manufacturers of all prescription drugs.[281]

In the medical device cases, courts appear to be applying comment k more broadly.[282] Whether the court applied comment k to all medical devices (Blanket), to only some category of devices (Categorical), to devices on a case-by-case basis (Case-by-Case), or not at all (Does-Not-Apply) could be at least partially determined in 197 of the cases (96 percent) in the data set.[283] As discussed in Part II.B, courts have strong reasons to find that comment k has no application in medical device cases, and thus to adopt the Does-Not-Apply approach. Surprisingly, this was not found: Only six cases (3 percent) were coded as explicitly holding that comment k did not apply. Including cases in which the court might have been adopting a Does-Not-Apply approach,[284] the maximum portion of cases that might have taken this approach was just 14.2 percent. Thus, courts overwhelmingly continued to find at least some role for comment k as a liability shield in medical device cases.

Also surprising was how broadly courts applied comment k. In 49.5 percent of the cases (n=97), courts exempted device makers in either a blanket or a categorical fashion. A total of twenty-five cases (12.8 percent) were coded as applying comment k in a blanket fashion, and sixty-seven cases (34.2 percent) were coded as taking a categorical approach. There were five cases (2.5 percent) that were

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281. *See supra* note 206 and accompanying text. One of these decisions may have intended a blanket application to all drugs, including over-the-counter drugs. *See* Payton v. Abbott Labs, 437 N.E.2d 171, 189-90 (Mass. 1982).

282. The comparison between the drug and device cases presented here is admittedly imperfect. Unlike the drug cases, in which binding precedent had been established by more than half of all state high courts, only five state high courts have established binding precedent on the application of comment k in the device cases. As a result, the comparison presented here is between state high court decisions in drug cases and all decisions (state and federal, all levels) in the device cases.

283. For some cases that were coded as Cannot Be Determined (CBD), both Blanket and Categorical could be excluded, meaning that comment k would either apply on a Case-by-Case basis or not at all (Does-Not-Apply, DNA); these cases were considered to apply comment k narrowly and were coded as CBD/DNA. Cases that were coded as Cannot Be Determined, but for which both Case-by-Case and Does-Not-Apply could be excluded (viz, comment k would either apply in blanket or categorical fashion) were considered to apply comment k broadly and were coded as B/C. All of these cases were considered to be partially determined.

284. That is, cases that were coded as Cannot Be Determined, but in which Blanket and Categorical applications could be excluded, thus leaving either Case-by-Case or Does-Not-Apply as possible determinations.

coded as adopting either a blanket or categorical approach. Thus, the cases were divided nearly equally between broad and narrow applications of comment k, with 50.5 percent adopting a narrow approach.

Table 1: Breadth of Comment k Liability Shield

| Application | Number (% of total fully or partially determined outcomes) |
|---|---|
| Broad Liability Shield | |
| Blanket | 25 (12.8%) |
| Categorical | 67 (34.2%) |
| Blanket or Categorical | 5 (2.5%) |
| Narrow or No Liability Shield | |
| Case-by-Case | 72 (36.5%) |
| Does-Not-Apply | 6 (3.0%) |
| Case-by-Case or Does-Not-Apply (but cannot be determined which) | 22 (11.2%) |

A further surprise was the scope of the liability theories that courts have found to be barred by comment k. By its explicit terms, comment k appears to shield some products from strict products liability claims alleging a design defect.[285] Thus, it was not surprising that a large majority of the decisions (85 percent) included an analysis of whether comment k barred design defect claims. But courts have also held that comment k may bar strict liability manufacturing defect claims in just under 18 percent of decisions and strict liability failure-to-warn claims in nearly 29 percent of decisions. In 13.6 percent of the decisions, courts ruled that comment k may bar all three bases of strict liability, leaving plaintiffs dependent on legal theories that are either more difficult to prevail on (negligence) or that provide compensation for a very limited set of harms (breach of warranty). Because not all decisions addressed strict liability manufacturing defect and failure-to-warn claims, these percentages almost certainly underestimate the number of courts that would extend the comment k exemption beyond design defect claims and would potentially bar all forms of strict liability.

285. *See supra* notes 183-85 and accompanying text.

Some decisions extended the comment k exemption even further. In 14.6 percent of decisions, courts held that comment k barred at least one type of breach of warranty claim (typically breach of implied warranty of merchantability). All but two of these decisions arose under Pennsylvania law. And in one jurisdiction, comment k was held to bar even negligence claims for design defects.[286] Thus, in the years since 2000, courts have been fashioning a surprisingly broad role for comment k in medical device cases, shielding manufacturers from a wide range of products liability claims.

The decision of whether to apply comment k broadly or narrowly had a decisive effect on the outcome of strict liability design defect claims. There were 170 cases in which both the application of comment k and the outcome of a strict liability design defect claim could be coded. When courts applied comment k broadly (n=78), the plaintiff's strict liability design defect claim failed 91 percent of the time; by contrast, when courts applied comment k narrowly, strict liability design defect claims survived 92 percent of the time ($X^2$ (1, N=170) = 118.2926, $p < 0.001$). Clearly, the incentives to produce information that reduces risk uncertainty are largely eliminated by broad applications of comment k.

The decision to apply comment k broadly or narrowly also had important implications for the ability of products liability law to force manufacturers to disclose information about device hazards and risks. Strict liability design defect claims failed earlier in the litigation process when courts applied comment k broadly as opposed to narrowly, with 61 percent of dismissals in cases adopting a broad application coming at the pleading stage, compared to 29 percent in cases adopting a narrow application.[287] Examining all cases in which courts made a comment k decision at the pleading stage, when they applied comment k broadly (n=48), just two (4 percent) survived; by contrast, when courts applied comment k narrowly (n=19), nearly all (17, or 89 percent) survived ($X^2$ (1, N=67) = 48.7578, $p < 0.001$). The majority of pleading stage dismissals (69 percent) were for 510(k) devices. Dismissing plaintiffs' claims at the

286. *See* Smith v. Angiodynamics, Inc., 731 F. Supp. 3d 1262, 1271 (M.D. Ala. 2024) (citing with approval Barcal v. EMD Serono, Inc., No. 14-cv-01709, 2016 WL 1086028 (N.D. Ala. Mar. 21, 2016)).

287. Because there were so few failures under narrow applications (n=7), this difference was not statistically significant ($X^2$ p=0.10).

pleading stage means that the plaintiffs in these cases likely had limited opportunity to conduct discovery. Thus, broad judicial interpretations of comment k reduce the incentives for manufacturers to disclose information about the hazards and risks associated with their devices, particularly those of 510(k) devices for which FDA premarket regulation is least effective at forcing this information.

*3. Creating Chaos*

Not only are the decisions in the comment k cases creating a broader-than-expected liability shield for medical devices, but they are also creating a chaotic liability landscape. This is evident in the finding of a nearly 50:50 split between courts applying comment k broadly and narrowly.[288] Clearly, there is no consensus position that is emerging. And these numbers do not capture the full extent of the comment k chaos: A majority of the cases that were coded as categorical and for which a category could be determined (n=66) held that comment k exempted the manufacturers of prescription devices. However, as Table 2 shows, courts have applied comment k to at least nine different categories of devices.

Table 2: Categories of Devices to Which Comment k Was Applied

| Category of Device | Number of Cases |
|---|---|
| Prescription | 41 |
| Prescription implanted | 11 |
| Implanted | 6 |
| Implanted and available only through MD | 2 |
| Available only through MD | 2 |
| Implanted and become integral parts of the body | 1 |
| Prescription or Implanted | 1 |
| PMA | 1 |
| Class III | 1 |

288. *See supra* Table 1.

Further, courts' approaches to the caveats—which require that the product have been properly prepared and accompanied by adequate warnings in order for comment k to apply[289]—were also quite heterogeneous. Of the cases that were coded as adopting a case-by-case approach (n=72), 43 percent required that the device had been properly prepared and 50 percent required adequate warning for comment k to apply.[290] Requiring satisfaction of the caveats was less common in the categorical decisions. Of the sixty-seven categorical decisions, 24 percent required the product to have been properly prepared and 27 percent required the product to have been accompanied by adequate warnings. Not surprisingly, courts adopting a blanket approach infrequently required either caveat to be satisfied—only 16 percent (4 of 25) of decisions required proper preparation and only 12 percent required adequate warnings.

The chaotic nature of the comment k decisions is further underscored by the unsettled nature of this area of the common law. The cases in the data set were decided under the laws of twenty-five different states, with the number of decisions under each state's law ranging from one to fifty-four. Despite this large volume of litigation, very little binding precedent has been created. Just 13 percent of all decisions were rendered by state courts, and a mere seven cases (3.4 percent) were from the highest courts of five states (Connecticut, Hawai'i, Oklahoma (2), Utah, and Washington (2)). In three states (Hawai'i, Oklahoma, and Utah), the high court held that comment k is applied on a case-by-case basis, while two other states held that it is applied categorically. In California, although the state high court has not decided a case raising this issue, the state's intermediate courts of appeal have repeatedly held that a categorical approach is used.[291] In most other states, the law has not been settled; there is little to no case law with binding precedential value.[292]

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289. *See supra* Part II.A.4.

290. All of the cases that required proper preparation also required adequate warning.

291. *See* Garrett v. Howmedica Osteonics Corp., 153 Cal. Rptr. 3d 693, 701 (Ct. App. 2013); Warner v. Breg, Inc., No. D040124, 2004 WL 68757, at *5 (Cal. Ct. App. Jan. 16, 2004); Artiglio v. Superior Ct., 27 Cal. Rptr. 2d 589, 592-93 (1994); Hufft v. Horowitz, 5 Cal. Rptr. 2d 377, 384 (Ct. App. 1992).

292. An example is provided by the cases arising under Pennsylvania law, which comprise the largest set of cases (n=68) in the data set. Only two of these were decided by Pennsylvania state courts (one in common pleas and one in superior court), with the remaining decided by

Arguably, this aspect of the comment k chaos is a feature, not a flaw, of an area of common law—each state is free to pursue its own policy goals through its own liability rules.[293] But medical devices are subjected to federal regulation, in large part, because of concerns that state-by-state heterogeneity will suppress innovation.[294] By creating a single, nationwide, regulatory framework in the MDA, Congress sought to strike an optimal regulatory balance between ensuring device safety and allowing innovation to flourish.[295] In the comment k context, nearly sixty years have elapsed since the liability shield was first adopted by the ALI, yet we remain far from any national uniformity.

* * *

This study shows that courts have been increasingly shielding medical device manufacturers from various forms of products liability in spite of strong reasons not to do so. Part IV shows how these judicial decisions keep us ignorant of the hazards and risks the medical devices pose, and suggests ways that we might be able

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federal district courts. In the absence of a state high court ruling, federal courts predicted that the high court would apply comment k broadly in 75 percent of cases, but a sizeable minority (25 percent) predicted a narrow application. Because Pennsylvania law allows for certified questions to the state supreme court only from federal courts of appeal or the U.S. Supreme Court, 210 PA. CODE Rule 3341 (2025), only a single case has been certified by the Third Circuit; this case, however, was dismissed prior to a decision by the high court. *See* Ebert v. C.R. Bard, Inc., No. 20-2139, 2021 WL 9950511, at *1 (3d Cir. Nov. 10, 2021) (dismissing appeal); Solano v. Bos. Sci. Corp., No. 23-12366, 2024 WL 1675692, at *2 (D. Mass. Apr. 5, 2024) (explaining the dismissal based on settlement prior to state supreme court ruling). Thus, as in most other states, and despite a very high volume of litigation, the law on comment k remains unsettled in Pennsylvania.

293. *See* Erie R.R. Co. v. Tompkins, 304 U.S. 64, 78-79 (1938).

294. In the years leading up to the MDA, a quarter of the states had implemented their own premarket approval systems for medical devices, threatening to create a hodge-podge of regulatory requirements that would soon stifle innovation. *See* Robert B. Leflar & Robert S. Adler, *The Preemption Pentad: Federal Preemption of Products Liability Claims After Medtronic*, 64 TENN. L. REV. 691, 703 & n.66 (1997); *see also* Susan Bartlett Foote, *Loops and Loopholes: Hazardous Device Regulation Under the 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act*, 7 ECOLOGY L.Q. 101, 128 & n.134 (1978) (illustrating preemption questions between the federal regulatory framework and California's device regulation under the state Sherman Act).

295. *See* Riegel v. Medtronic, Inc., 552 U.S. 312, 326 (2008) (interpreting congressional intent from the statute's plain text).

to stimulate the production and dissemination of information that can reduce risk uncertainty in this area.

## IV. CHOOSING AND COMBATING IGNORANCE FOR MEDICAL DEVICE DANGERS

At the outset, this Article posited that FDA premarket gatekeeping and private litigation under products liability theories should form a coherent regulatory system that functions to reduce medical device risk uncertainty to such an extent that decision makers could engage in meaningful risk-benefit analyses. This idea is not new: Before a sudden change in perspective within the FDA in 2007, the Agency espoused the view that private litigation served as a valuable complement to the FDA's effort to ensure device and drug safety.[296] And commentors have urged that private litigation had forced the disclosure of information about the hazards and risks of devices and drugs—including Halcion, Zomax, ultra-absorbent tampons, ephedra, Paxil, and silicone breast implants[297]—making it likely that litigation can serve the same role in the device context. My position here is more nuanced: I propose that the intensity of FDA premarket scrutiny and the availability of legal theories to support private litigation should be calibrated so that where one falls short of the goal of reducing risk uncertainty, the other functions robustly.

Unfortunately, as shown in Part I.C, the Supreme Court's preemption decisions in the medical device cases have only partially achieved this goal while leaving a significant regulatory gap. For the second-largest set of devices—those that reach the market through the PMA supplement pathways—the FDA's premarket evaluation rarely requires the production and dissemination of clinical trial evidence,[298] and yet private litigation is largely foreclosed under the preemption framework established in *Buckman* and *Riegel*.[299]

And as the findings of the empirical study presented in Part III show, courts' decisions over the past quarter-century have been creating a second regulatory gap. Despite strong reasons for expecting

296. *See* Kessler & Vladeck, *supra* note 23, at 463.
297. *Id.* at 493-94.
298. *See supra* Part I.A.
299. *See supra* Part I.C.

courts not to interpret comment k as exempting medical device makers from strict liability,[300] the decisions in the data set have overwhelmingly found at least some role for comment k to shield device makers.[301] And, contrary to expectations, courts have interpreted this shield quite broadly.[302] In California, for example, comment k has been interpreted in the majority of cases as categorically exempting all prescription devices from strict liability for design defects regardless of whether the caveats (proper preparation and adequate warnings) are satisfied.[303] And many courts applying Pennsylvania law have held that comment k shields manufacturers not only from strict products liability claims but also from breach of warranty claims.[304] Courts applying Alabama law have even found that comment k bars negligence claims.[305] And where courts have applied comment k broadly, design defect claims almost never survived (4 percent) a motion to dismiss at the pleading stage,[306] likely foreclosing plaintiffs from engaging in discovery, which could have unearthed information that could reduce risk uncertainties. The predominant impact has been on 510(k) devices: The majority of pleading-stage dismissals in the data set (69 percent) were for 510(k) devices.[307] Because of these decisions, the role of private products liability litigation is being constrained, its information-forcing function limited where it is most needed.

This is to say that the combination of federal preemption and comment k is creating a regulatory mess: For the two largest sets of medical devices—those Class II devices that reach the market through the 510(k) pathway and those Class III devices that reach the market through the PMA supplement pathways—neither the

300. *See supra* Part II.B.

301. *See supra* Part III.B.

302. *See supra* Part III.B.

303. *See, e.g.*, Artiglio v. Superior Ct., 27 Cal. Rptr. 2d 589, 593-94 (Ct. App. 1994) (holding that the only factual determination needed to apply comment k was whether the device was "physician-directed and physician-applied").

304. *See, e.g.*, Soufflas v. Zimmer, Inc., 474 F. Supp. 2d 737, 751-52 (E.D. Pa. 2007) (holding that prescription medical devices were not subject to actions based on implied warranty of merchantability and implied warranty of fitness for a particular purpose).

305. *See, e.g.*, Smith v. Angiodynamics, Inc., 731 F. Supp. 3d 1262, 1271 (M.D. Ala. 2024) (citing with approval Barcal v. EMD Serono, Inc., No. 14-cv-01709, 2016 WL 1086028, at *3 (N.D. Ala. Mar. 21, 2016)).

306. *See supra* Part III.B.2.

307. *See supra* Part III.B.2.

FDA's premarket scrutiny nor private litigation under products liability theories are serving to force the production and dissemination of information that reduces medical device risk uncertainty. In the process, patients, physicians, insurers, courts, and others are being forced to make critical risk-benefit decisions under conditions of needlessly heightened risk uncertainty.

This Part discusses two issues. First, it highlights the fact that this situation is a matter of judicial choice, not of necessity dictated by statute or precedent. Second, it begins the discussion of possible ways that medical device risk uncertainty can be reduced.

### *A. The Medical Device Regulatory Mess: A Choice, Not a Necessity*

There is an inescapable irony at the heart of this regulatory mess: It is in large part the result of judicial choices that are mandated neither by the language of nor the rationales that animated comment k, nor by existing state statutory law, nor by existing state common law precedent. Rather, courts—almost exclusively federal district courts—have been choosing to interpret comment k in ways that will increase medical device risk uncertainty.[308]

As discussed earlier, there is little textual support for the proposition that the ALI intended comment k to shield medical device manufacturers.[309] The plain language of the comment makes clear that the products shielded from liability include the rabies vaccine, "many other drugs, vaccines, and the like ... [that] cannot legally be sold except to physicians" and "many new or experimental drugs."[310] Indeed, these are the only products for which comment k provides clarity; medical devices are never explicitly mentioned, even though by the time of the ALI's adoption of comment k, lifesaving devices such as dialysis machines and permanent pacemakers, and life-improving devices like hip and knee replacements, were already in use.[311] It seems reasonable that, had the ALI intended devices to be

308. *See supra* Part III.B.1.

309. *See supra* Part II.B.1.

310. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (A.L.I. 1965).

311. *See* Hamid Rabb, Kyungho Lee & Chirag R. Parikh, *Beyond Kidney Dialysis and Transplantation: What's on the Horizon?*, J. CLINICAL INVESTIGATION, Apr. 1, 2022, at 1 (describing the first successful human hemodialysis machine used in 1943); William H. Harris & Clement B. Sledge, *Total Hip and Total Knee Replacement*, 323 NEJM 725, 725 (1990) (citing the first modern artificial hip joint implanted in 1962); David A. Sonstegard, Larry S.

exempted from its new rule of strict products liability, comment k would have stated this explicitly. Also, the policy concerns that motivated William Prosser to draft, and the ALI members to adopt, comment k do not clearly translate from the drug to the device context.[312] During the debates on section 402A, members appeared to be concerned with exempting prescription drugs from strict liability because drugs were seen as conferring lifesaving benefits and yet could not be made safer.[313] But the nature of devices makes them, as a product type, a poor fit with the kinds of unavoidably unsafe products that are defined and shielded from liability by comment k: Many devices provide benefits that are far from lifesaving and most can be redesigned to make them safer.[314]

Further, courts' broad applications of comment k have not been mandated by state statutes. Many states have codified their product liability law.[315] Some have established specific standards or legal theories for device and drug cases.[316] And some have expressly adopted the strict liability regime created by section 402A for all products.[317] Some state statutes use portions of the terminology in comment k, expressly excluding from their general definitions of

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Matthews & Herbert Kaufer, *The Surgical Replacement of the Human Knee Joint*, 238 SCI. AM. 44, 45 (1978) (noting that artificial knee joints were first developed in the 1950s); Hiroko Beck, William E. Boden, Sushmitha Patibandla, Dmitriy Kireyev, Vipul Gupta, Franklin Campagna, Michael E. Cain & Joseph E. Marine, *50th Anniversary of the First Successful Permanent Pacemaker Implantation in the United States: Historical Review and Future Directions*, 106 AM. J. CARDIOLOGY 810, 810 (2010) (describing the first pacemaker implanted in 1960).

312. *See supra* Part II.B.2.

313. *See* Henderson & Twerski, *supra* note 31, at 525.

314. *See generally* George Horvath, *Incremental Innovation*, 28 SMU SCI. & TECH. L. REV. 131, 132 (2025) (describing how medical devices of all risk classes undergo extensive incremental innovation that can improve (or decrease) their safety).

315. *See* STUART M. SPEISER, CHARLES F. KRAUSE & ALFRED W. GANS, 5 AMERICAN LAW OF TORTS § 18:10 (2025). Although many states have codified only limited aspects of their products liability law, such as defenses and procedural issues, others have engaged in extensive codification. *Id.*

316. *See, e.g.*, Taupier v. Davol, Inc., 490 F. Supp. 3d 430, 437, 439, 448 (D. Mass. 2020) (holding that, under Massachusetts law, strict products liability claims are only available under breach of implied warranty theories); IND. CODE § 34-20-2-1 (2025) (stating that products liability actions under Indiana law are governed by a negligence-based reasonable foreseeability standard).

317. *See, e.g.*, ARK. CODE ANN. § 16-116-101; Taylor v. Intuitive Surgical, Inc., 389 P.3d 517, 523 (Wash. 2017) (noting that the Washington Product Liability Act "closely mirrors" section 402A).

defective products those that cannot be made safe[318] or that are considered unavoidably unsafe.[319] At least one state exempts medical devices that are unavoidably unsafe from the definition of defective products.[320] But none provide any indication as to whether comment k applies to medical devices or whether it should apply in a categorical or case-by-case basis.

Finally, state common law precedent at the time of the decisions in the data set provides little support for extending a broad liability shield to device makers. Only two state high courts—Connecticut[321] and Washington[322]—have ruled that comment k applies categorically to prescription-implanted devices and devices only available through the services of a physician, respectively. In California, although the high court has not ruled in a medical device case, five intermediate appellate court decisions have applied the state's broad drug exemption to medical devices.[323] By contrast, three state high courts (Hawai'i,[324] Oklahoma,[325] and Utah[326]) have ruled that comment k is applied on a case-by-case basis. In all other states, there is no high court decision that mandates how a federal court should rule. In most cases, this has left federal courts in the position of relying on a small number of state lower court decisions on medical devices or state high court decisions on other products. For example, in Pennsylvania, courts have based broad applications of comment k on state supreme court decisions in cases involving

318. *See, e.g.*, IND. CODE § 34-20-4-4 (2025).

319. *See* N.J. STAT. ANN. § 2A:58C-3 (2025).

320. *See* OHIO REV. CODE ANN. § 2307.75(D) (West 2025).

321. *See* Hurley v. Heart Physicians, P.C., 898 A.2d 777, 784 (Conn. 2006).

322. *See* Taylor v. Intuitive Surgical, Inc., 389 P.3d 517, 526 (Wash. 2017); Terhune v. A.H. Robbins Co., 577 P.2d 975, 977-80 (Wash. 1978).

323. *See* Garrett v. Howmedica Osteonics Corp., 153 Cal. Rptr. 3d 693, 696, 699-701 (Ct. App. 2013); Warner v. Breg, Inc., No. D040124, 2004 WL 68757, at *5 (Ct. App., Jan. 16, 2004); Artiglio v. Superior Ct., 27 Cal. Rptr. 2d 589, 593-94 (Ct. App. 1994); Plenger v. Alza Corp., 13 Cal. Rptr. 2d 811, 818 (Ct. App. 1992); Hufft v. Horowitz, 5 Cal. Rptr. 2d 377, 378 (Ct. App. 1992). Although the drug cases have at least some probative value for how the state high court would likely rule in a device case, the Utah Supreme Court adopted a case-by-case approach for devices, Burningham v. Wright Med. Tech., Inc., 2019 UT 56, ¶2, 448 P.3d 1283, 1285, despite its earlier categorical application for prescription drugs, Schaerrer v. Stewart's Plaza Pharmacy, Inc., 2003 UT 43, ¶¶1, 16-18, 79 P.3d 922, 927-28; Grundberg v. Upjohn Co., 813 P.2d 89, 90, 92 (Utah 1991).

324. Larsen v. Pacesetter Sys., Inc., 837 P.2d 1273, 1285-86 (Haw. 1992).

325. Tansy v. Dacomed Corp., 890 P.2d 881, 886 (Okla. 1994).

326. *Burningham*, 2019 UT 56, ¶42, 448 P.3d at 1293.

drugs[327] and steel tubing for construction,[328] and on one superior court case that analyzed comment k in a single paragraph.[329]

Courts that have chosen to extend the comment k liability shield in blanket or categorical fashion to cover 510(k) devices have made troubling choices. Through their broad interpretations of comment k, they have largely eliminated an important, albeit secondary, regulatory input that could incentivize device makers to produce and disclose information that could reduce the risk uncertainties of their devices. The effect of these decisions extends to every individual and every entity that must engage in a risk-benefit analysis about a medical device.

### *B. Strengthening the Regulatory System's Ability to Reduce Risk Uncertainty*

The problem that the study in Part III identified is that courts' broad application of comment k is limiting the ability of private litigation under products liability theories to incentivize the production and dissemination of information that can reduce risk uncertainty, predominantly for 510(k) devices. And, as discussed in Part I.C, the Supreme Court's medical device preemption framework limits the availability of products liability actions for PMA supplement devices.[330] For both sets of devices, which together account for 99 percent of all devices, the FDA's premarket evaluation also produces limited information that can reduce risk uncertainty.[331] Thus, an ideal solution would address the regulatory gaps that exist for 510(k) and PMA supplement devices.

The most straightforward solution would be to enhance the FDA's role in reducing the risk uncertainty of all devices. As discussed above, only about 8 percent of 510(k) devices, other than in vitro

327. *See, e.g.*, Lance v. Wyeth, 85 A.3d 434, 437-38, 451-52 (Pa. 2014); Hahn v. Richter, 673 A.2d 888, 889 (Pa. 1996); Incollingo v. Ewing, 282 A.2d 206, 219-20 (Pa. 1971).

328. Tincher v. Omega Flex, Inc., 104 A.3d 328, 335 (Pa. 2014).

329. Creazzo v. Medtronic, Inc., 2006 PA Super. 152, ¶16, 903 A.2d 24, 31.

330. As discussed in Part I, the Court's preemption cases also bar most state products liability actions in cases involving original PMA devices; however, the FDA's relatively rigorous premarket scrutiny serves to lower the risk uncertainty for these devices. *See supra* Part I.C.

331. *See supra* note 91 and accompanying text.

diagnostic tests, are cleared with clinical trial evidence of safety.[332] This paucity of data has several contributors: the limited circumstances in which the FDA is statutorily authorized to require such data,[333] the Agency's reticence to use the authority it does possess,[334] and the least burdensome principle that the FDA is statutorily required to implement.[335] Also, less than 1 percent of PMA supplement devices reach the market through a pathway that regularly requires clinical trial evidence of safety.[336] Ideally, Congress would enhance the FDA's authority to require additional evidence of device safety and roll back the least burdensome principle's push to shift information production to the postmarket period. Were this to occur, courts' broad applications of comment k to shield device makers would become less salient because devices would reach the market with already-lowered levels of risk uncertainty.

Enhancing the FDA's authority to require clinical trials raises concerns over the possibility of stifling innovation; after all, clinical trials are costly and time-consuming.[337] To mitigate this concern, it would be reasonable to impose certain threshold conditions that would limit the situations in which the FDA could require clinical trials. In one threshold approach, the FDA's authority to require new clinical trials could be triggered when a device model has caused documented harm. If a device has a Class I recall,[338] subsequent modifications of that device would need to be supported by clinical trial evidence of safety.[339] A related approach would focus on

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332. *See supra* text accompanying notes 80-84.

333. *See supra* text accompanying note 80.

334. *See* W. Nicholson Price II, Rachel E. Sachs & Rebecca S. Eisenberg, *New Innovation Models in Medical AI*, 99 WASH. U. L. REV. 1121, 1147-48 (2022) (discussing FDA's exercise of enforcement discretion in various contexts).

335. *See supra* text accompanying note 82.

336. From the FDA databases discussed in note 67, I obtained data on the supplement type for 44,881 approved PMA supplements since January 1, 2000. There were 366 panel track supplements, accounting for 0.8 percent of all supplements approved. It is possible that other modifications were supported by clinical trial data evaluating safety and effectiveness, but this finding strongly indicates the paucity of such information.

337. Eli Y. Adashi, Katina M. Robison & I. Glenn Cohen, *Deadly Legacy—The 510(k) Path to Medical Device Clearance*, 157 JAMA SURGERY 185, 186 (2022).

338. Class I recalls are a standard marker of serious device flaws that are used in empirical studies. Horvath, *supra* note 78, at 1020.

339. *Cf. id.* at 1038-39 (reporting empirical evidence that was equivocal as to whether a Class I recall for a specific PMA or PMA supplement device was predictive of a subsequent Class I recall); Horvath, *supra* note 47, at 166 (providing empirical evidence from a small

generic product types: If a certain number of Class I recalls is exceeded for a generic device type, this would trigger the Agency's enhanced authority to require clinical trials and would put the least burdensome principle requirements in abeyance. It would, of course, be important to permit manufacturers to respond rapidly to safety problems.

Both of these approaches have the disadvantage of waiting for problems to emerge—of waiting for enough patients to suffer harm—before the generation of data on risk would even begin to be required. A different, more proactive, threshold approach would be based on the rate of modification or innovation of generic product types. This approach would focus on the dangers that the process of incremental and iterative innovation can pose in 510(k) and PMA supplement devices. When a threshold number of 510(k) clearances or PMA supplements are granted for a device type over a specified period of time, the FDA's enhanced authority to require clinical trial evidence would be triggered.[340] A third approach would be based on purely temporal considerations: As others have suggested, the FDA could be empowered to require clinical trial evidence for 510(k) devices or generic device types every so many years.[341]

Proposals that would increase the requirements placed on manufacturers to produce information bearing on device safety face serious obstacles under any circumstances. And a long-term political economy that disfavors increased obligations to conduct clinical trials, coupled with an administration that is exhibiting little serious interest in ensuring device and drug safety, makes such

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cohort of 510(k) devices that a Class I recall in a predicate showed a trend toward an increased likelihood of Class I recall in modified versions of that predicate). Further empirical study is warranted.

340. *See* Horvath, *supra* note 78, at 1046-47 (advocating such an approach for cardiovascular devices based on empirical data).

341. *See* Benjamin N. Rome, Daniel B. Kramer & Aaron S. Kesselheim, *FDA Approval of Cardiac Implantable Electronic Devices via Original and Supplement Premarket Approval Pathways, 1979-2012*, 311 JAMA 385, 390 (2014).

expansions and use of the FDA's authority highly unlikely.[342] Thus, it is important to consider other avenues.

One such avenue would be to reduce or eliminate the limitations on the role of private litigation in reducing the risk uncertainty of all devices. That is, courts could stop applying comment k in blanket or categorical fashion. The reasons for interpreting comment k narrowly in the medical device context have been catalogued above.[343] This is not to argue that no medical devices should ever be shielded from strict and even negligence liability; rather, the argument is that such shielding should be done on a case-by-case basis. An initial determination as to whether the device in question is unavoidably unsafe would be made by the court, based on the considerations discussed in comment k: whether the device offered a significant benefit to at least some patients, whether the device was incapable of being made safe, and whether the risks posed by the device to all patients was sufficiently outweighed by the benefits provided.

Two states' high court precedents would preclude this approach (Connecticut and Washington, whose high courts have ruled that comment k broadly shields device manufacturers) and in at least one other state (California) a large number of intermediate appellate court decisions that have applied comment k broadly would do the same.[344] But for the small number of decisions made by state courts in other jurisdictions, given the absence of binding precedent, courts could interpret comment k narrowly. And for the majority of cases, which are decided in federal courts, predictions about the

342. In February 2025, the Center for Devices and Radiologic Health, responsible for medical device regulation, lost 230 to 240 employees (out of a total of about 2230), although some were apparently rehired. *See* Elise Reuter, *Device Industry Scrambles amid Concern FDA Layoffs Will Cause Delays*, BIOPHARMADIVE (Feb. 20, 2025), https://www.biopharmadive.com/news/fda-cdrh-cuts-device-industry-impact/740535/ [https://perma.cc/887H-6DSP]. The FDA's budget proposal for fiscal year 2026 would cut an additional 260 full-time equivalents. DEP'T OF HEALTH & HUM. SERVS., FOOD & DRUG ADMIN., FDA FISCAL YEAR 2026 JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES (2025), https://www.fda.gov/media/186732/download?attachment [https://perma.cc/J3Q7-V868]. The FDA Commissioner's recent statement of priorities emphasized speeding new products to the market, suggested that AI systems would be used to assist in this goal, and postulated that big data approaches would improve postmarket information gathering. *See* Martin A. Makary & Vinay Prasad, *Priorities for a New FDA*, 334 JAMA 565, 565 (2025). The details have yet to be seen.

343. *See supra* Part II.B.

344. *See supra* notes 321-23 and accompanying text.

scope of comment k's applicability are not bound by existing state law or binding precedent, making narrow interpretations possible.[345]

A more ambitious private law approach would be to formulate a new set of liability rules for devices, and perhaps for drugs and biologics as well. There are several potential ways in which new liability rules might be fashioned. State courts could develop new doctrines in classic common law fashion that move away from the comment k framework. But this seems unlikely, considering that state courts are hearing a vanishingly small number of cases in this area. It might, however, be possible for federal courts more frequently to certify questions about its application.[346] Alternatively, state legislatures could establish liability rules; indeed, many state legislatures already have experience in this area.[347] And unlike courts, legislatures can involve a wide range of stakeholders in the process of formulating new liability rules.

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345. The reasons why the vast majority of device cases, whose legal theories are based on state common law, are being litigated in federal courts are not clear. A project using the data set described in Part III to understand these reasons is under way.

346. In Utah, although earlier state high court precedent had applied comment k in categorical fashion to prescription drugs, *see* Grundberg v. Upjohn Co., 813 P.2d 89, 95 (Utah 1991), the high court later held that comment k applied in case-by-case fashion to medical devices. Burningham v. Wright Med. Tech., Inc., 2019 UT 56, 448 P.3d 1283. Thus, forum may matter, although interestingly nine of the ten federal district court decisions rendered after *Grundberg* but before *Burningham* predicted that the Utah high court would adopt, as it did, the case-by-case approach for devices. Christiansen v. Wright Med. Tech. Inc., 127 F. Supp. 3d 1306, 1357 (N.D. Ga. 2015) (interpreting Utah law as requiring proof that device "was made as safe as it could be made" for comment k to apply); Hoffman v. Bos. Sci. Corp., No. 12-cv-04433, 2015 WL 5842785, at *4 (S.D. W. Va. Oct. 6, 2015) (applying Utah law and predicting that comment k would apply to medical devices but that determination of whether a device was unavoidably unsafe needs to be made on a case-by-case basis); Stewart v. Bos. Sci. Corp., No. 12-cv-03686, 2015 WL 5842762, at *5 (S.D. W. Va. Oct. 6, 2015) (same); Sederholm v. Bos. Sci. Corp., No. 13-cv-12510, 2015 WL 5842796, at *4 (S.D. W. Va. Oct. 6, 2015) (same); Flandro v. Bos. Sci. Corp., No. 13-cv-17027, 2015 WL 5842823, at *4 (S.D. W. Va. Oct. 6, 2015) (same); Cook v. Bos. Sci. Corp., No. 2:12-cv-01089, 2015 WL 5842744, at *4 (S.D. W. Va. Oct. 6, 2015) (same); Robbins v. Bos. Sci. Corp., No. 12-cv-01413, 2015 WL 5842753, at *4 (S.D. W. Va. Oct. 6, 2015) (same); Christiansen v. Wright Med. Tech. Inc., No. 13-cv-297, 2015 WL 12090063, at *4 (N.D. Ga. Nov. 18, 2015) (predicting that Utah courts would require proof that device was as safe as permitted by available testing and research); Christiansen v. Wright Med. Tech. Inc., 178 F. Supp. 3d 1321, 1353-55 (N.D. Ga. 2016) (predicting that Utah courts would require proof that adequate warning and proper preparation were required in order for comment k to apply to medical devices). In *Creech v. Stryker Corp.*, the district court predicted that comment k would not apply to medical devices. No. 07CV22, 2012 WL 33360, at *5 n.6 (D. Utah Jan. 6, 2012).

347. *See supra* notes 315-20 and accompanying text.

Additionally, the ALI could try again to formulate a liability rule for medical products. Responding to decades of frustration with the chaos arising from comment k and to the movement from strict liability back toward negligence in design defect and failure-to-warn cases,[348] the ALI attempted such a step in the Products Liability volume of the *Restatement (Third) of Torts*. There, the Institute adopted a negligence-based risk-utility test for product defectiveness for all products.[349] But for drugs and devices, the Products Liability volume adopted a different, physician-centric rule for defining product defect: A device design defect exists only if "reasonable health-care providers, knowing of [the] foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients."[350] This standard has been criticized because of its extremely broad shielding effect and its physician-centered nature.[351] Section 6(c) has not been widely adopted in the decades since its publication in 1998.[352] So perhaps the time has come for a new products liability volume.

Unfortunately, approaches that focus on enhancing the role of products liability law face a significant limitation: They would not have much impact on PMA supplement devices, given existing preemption jurisprudence. But we should not completely discount the value of solutions that would reduce the risk uncertainty of

348. *See supra* notes 241-42 and accompanying text.

349. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(b) (A.L.I. 1998) (defining design defect as existing where "the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design").

350. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(c) (A.L.I. 1998). Like the *Second Restatement*'s section 402A, the rule set out in section 6(c) was a de novo creation as opposed to a restatement of existing common law. *See* Noah, *supra* note 112, at 843-44 (noting that the Reporters for the *Third Restatement* had declared that "[c]ase law that is unintelligible cannot be intelligently restated"); Conk, *supra* note 169, at 1102-07 (same).

351. *See* Mele v. Howmedica, Inc., 808 N.E.2d 1026, 1038-39 (Ill. App. 2004); Davis, *supra* note 29, at 410-11, 411 n.63 (cataloguing criticisms of § 6(c)); Conk, *supra* note 169, at 1102-07 (criticizing § 6(c) for abandoning a reasonable alternative design approach for a single product category). *But see* Noah, *supra* note 112, at 848-88 (providing a balanced defense of the liability rule in § 6(c)).

352. *See, e.g.*, *Mele*, 808 N.E.2d at 1039 (rejecting § 6(c) for Illinois); Dunn v. Zimmer, Inc., No. 00CV1306, 2005 WL 756533, at *7-8 (D. Conn. 2005); *see also* Noah, *supra* note 112, at 914-15 (noting that as of 2009, few courts had considered § 6(c) and those that had were not favorable).

510(k) devices, which comprise the single largest set of devices that reach the market and for which the risk uncertainty is the largest.[353]

In contrast to these "stick" type approaches, incentive-based "carrot" type approaches are also possible.[354] A rich literature has explored the potential role for incentive-based approaches to stimulating desired forms of innovation in the drug and biologic product context.[355] Patents and FDA-conferred regulatory exclusivity periods are examples of prizes (in the form of market exclusivity periods) that are awarded to successful innovators.[356] Other forms of prizes that have been discussed in the pharmaceutical context include competitions, which are often government operated,[357] and adjustments to insurance-based reimbursements for prescription drugs.[358] Similarly, the role of priority review vouchers[359] in stimulating pharmaceutical innovation has been widely discussed.[360] In the device context, prizes, insurance-based incentives, and priority review vouchers might be offered in exchange for the production and dissemination of information that diminishes risk uncertainty, even where requiring manufacturers to do so would be beyond the FDA's legal authority.[361]

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353. *See* INST. OF MED., *supra* note 84, at 3-4.

354. Rachel E. Sachs, *Regulating Intermediate Technologies*, 37 YALE. J. ON REGUL. 219, 225 & nn. 10-17 (2020) (cataloguing the incentives that have been considered for stimulating innovation).

355. *See* Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Institutions and the Opioid Crisis*, 7 J.L. & BIOSCIENCES 1, 36-39 (2020); Michael S. Sinha, Nina Jain, Thomas Hwang & Aaron S. Kesselheim, *Expansion of the Priority Review Voucher Program Under the 21st Century Cures Act: Implications for Innovation and Public Health*, 44 AM. J.L. & MED. 293, 333-35 (2018); Jordan Paradise, *Cultivating Innovation in Precision Medicine Through Regulatory Flexibility at the FDA*, 11 NYU J.L. & LIBERTY 672, 683-84 (2017); Rachel E. Sachs, *Prizing Insurance: Prescription Drug Insurance as Innovation Incentive*, 30 HARV. J.L. & TECH. 153, 201-02 (2016); Amy Kapczynski & Talha Syed, *The Continuum of Excludability and the Limits of Patents*, 122 YALE L.J. 1900, 1942-44 (2013).

356. *See* Sachs, *supra* note 355, at 158.

357. *See* Hemel & Ouellette, *supra* note 355, at 40-41.

358. *See* Sachs, *supra* note 355, at 158.

359. Priority review vouchers are offered for the development of agents to treat certain tropical diseases, 21 U.S.C. § 360n, qualified infectious diseases, 21 U.S.C. § 360n-1, and pediatric diseases, 21 U.S.C. § 360ff. A voucher entitles the bearer to FDA action on a new drug application in less than six months, 21 U.S.C. § 360n(a)(1); the voucher may be sold, 21 U.S.C. § 360n(b)(2), thus allowing vouchers to serve as general-purpose innovation accelerators. *See* Sinha et al., *supra* note 355, at 339-41.

360. *See, e.g.*, Sinha et al., *supra* note 355, at 339; Paradise, *supra* note 355, at 690.

361. *See* Sachs, *supra* note 355, at 157-58.

At least three other private approaches to the problem of risk-uncertainty may be considered. Professors W. Nicholson Price II, Rachel Sachs, and Rebecca Eisenberg have argued that insurers, with access to vast amounts of information about their subscribers' health care, could develop databases that fill in missing information about medical product safety and effectiveness.[362] Because of the large numbers of patients and continuous follow-up that would be available as insurers log each and every claim, it might be possible to identify previously unrecognized hazards and to narrow the confidence intervals of known hazards beyond what is possible in clinical trials of limited size.[363]

Another proposal has been for insurers to leverage their power in making coverage decisions to demand the production of information on device risk. Professors Wendy Netter Epstein, David Hyman, and Charles Silver have argued that private insurers should use contracts that condition future reimbursement for drugs and devices that have been approved through accelerated pathways on the completion of postmarket trials that establish safety and effectiveness.[364] Extending this idea to a broader set of devices has its appeal. Insurers, whose coverage determinations rely in part on risk-benefit analyses, should have incentives to explore this option.

A third approach would increase the reporting requirements for the harms caused by medical devices. At present, device manufacturers are required to report to the FDA information about deaths, serious injuries, and malfunctions likely to result in death or serious injury within thirty days.[365] Facilities, such as hospitals and ambulatory surgery centers, must submit reports about device-related deaths to the FDA and the manufacturers, and about serious injuries to the FDA or the manufacturer.[366] However, physicians, who are also well placed to learn about device-related harms, are not required to report them.[367] Requiring physicians to report harms

362. Price II, Sachs & Eisenberg, *supra* note 334, at 1137-39.

363. *See supra* notes 12-13 and accompanying text.

364. *See generally* Wendy Netter Epstein, David A. Hyman & Charles Silver, *Better Drugs and Devices Through Private Contracts*, 59 U.C. DAVIS L. REV. (forthcoming 2026) (proposing mechanisms through which private insurers can incentivize drug and device manufacturers to complete postmarket trials).

365. 21 C.F.R. §§ 803.10(c), 803.3(k) (2025).

366. *Id.* § 803.10(a).

367. *See id.* § 803.10 (setting out reporting requirements with no inclusion of physicians).

caused by devices could help to add to our knowledge about device hazards and risks, and thus to reduce risk uncertainty.

One problem with this approach—and others—that depend on information about device hazards and risks that emerge in the postmarket period is that such information often emerges only over a long period of time. Sometimes this is because the risk of very serious hazards is low: There is always the possibility that even the best-designed and -executed clinical trials will lack sufficient power to detect devastating but uncommon harms. And sometimes this is because harms only occur after prolonged exposure to a device. Unfortunately, this means that by the time a problem is recognized, large numbers of patients may have been placed at risk. For example, by the time that the occurrence of metallosis, which can cause heart failure, cancer, and other devastating illnesses, was recognized as a hazard of metal-on-metal knee and hip replacements, tens of thousands of patients had been implanted with these devices.[368]

Thus, it would be useful to consider ways to slow the adoption of new medical devices into clinical practice. It has become common for physicians to rapidly adopt 510(k) and PMA supplement devices into their clinical practices. Examples include some new models of hip replacements and implantable defibrillator leads[369]: Physicians have implanted tens or even hundreds of thousands of these new devices within a few years of their reaching the market; in some cases, these devices caused harms that were not previously recognized or had a much greater likelihood of causing those harms than anticipated.[370] In short, many new devices that are rapidly adopted into clinical practice turn out to have high levels of risk uncertainty. Slowing the adoption of new devices would allow time for safety signals to emerge and could avoid the widespread harms that have occurred in hip replacement and defibrillator lead cases.

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368. *See* Tower, *supra* note 110, at 258. Other metal-on-metal hip prostheses also caused similar problems. *See* Christiansen v. Wright Med. Tech., Inc., 851 F.3d 1203, 1205 (11th Cir. 2017).

369. *See* Horvath, *supra* note 314, at 135-37 (discussing a new metal-on-metal hip prosthesis and a new defibrillator that were implanted into roughly 50,000 and 300,000 patients, respectively, within a few years of reaching the market).

370. *Id.* Neither the hip replacement nor the defibrillator lead had undergone clinical trials that assessed safety and effectiveness.

One way to avoid widespread harm and to allow time for the collection of data that can reduce risk uncertainty would be for the FDA to limit the rate at which new devices can be released. At present, the Agency has limited authority to restrict the sales of PMA devices.[371] Expanding the FDA's authority by allowing it to limit the number of new devices, including 510(k) devices, that can be sold during some initial period, could—if done judiciously—allow for the collection of postmarket data that would refine the risk-benefit calculations in which the Agency, physicians, and others need to engage.

A distinct and, I believe, more promising approach would be to encourage physicians to be more judicious in their adoption of new devices. Physicians have many incentives to adopt new technologies into their practices, including the appeal of offering their patients new benefits and the desire to be, and to be seen as, practicing at the cutting edge of medicine (which might increase referrals).[372] But with the limitations on FDA premarket scrutiny and on private litigation acting synergistically to minimize manufacturers' incentives to invest in clinical trials, slowing physicians' adoption of new technologies may be a useful temporizing measure. Indeed, as regulators increasingly turn their focus away from ensuring device safety, slowing adoption of new technology might become a long-term necessity.

Of course, attorneys and legal scholars have little to contribute to the individual decisions that doctors and patients make, but they can provide valuable insights about the current state of medical device risk uncertainty and its underlying causes that clinicians may lack. Finding ways to engage constructively with the medical community and with medical educators would be a reasonable first step.

One advantage of the physician-based (as opposed to the FDA-based) approach is that risk-benefit determinations would be made on a case-by-case basis: In each case, the patient and physician would decide which, if any, device to use. By contrast, the FDA-based approach would be far blunter, making individual tailoring

371. 21 U.S.C. §§ 360e(d)(1)(B)(ii), 360j(e); 21 C.F.R. § 814.82(a) (2025).

372. My own experience in the course of fifteen years of cardiology practice supports these observations.

more difficult. Either approach would, however, allow clinicians and manufacturers to gain understanding about the safety and effectiveness of new devices, which could help to sustain innovation.[373]

## CONCLUSION

We are entering an era in which federal agencies' ability, or even intent, to protect us from dangerous products will be more constrained than at any time within living memory. Thus, it is more important than ever to understand regulation in a broader context, in order to identify other avenues for ensuring safety. For medical devices, private lawsuits under state products liability theories offer one such avenue. Unfortunately, the combined effects of the Supreme Court's preemption decisions and more recent lower court decisions that have shielded device manufacturers from products liability through their broad interpretations of comment k to section 402A of the *Restatement (Second) of Torts* have led to private litigation also becoming less effective at reducing medical device risk uncertainty. As a result, all of us—patients, physicians, regulators, insurers, courts, and juries—are at a needless disadvantage as we try to figure out whether to have surgery or to approve a new device or to use a device. Our regulatory system—broadly conceived—owes us all quite a bit more. In the absence of a response, we owe it to ourselves to find other ways of protecting ourselves.

373. *See* CTR. FOR DEVICES & RADIOLOGICAL HEALTH, CDRH INNOVATION INITIATIVE 1, 5-6 (Feb. 2011), https://web.archive.org/web/20110211051948/http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHInnovation/default.html [https://perma.cc/YT2H-454K] (describing device innovation as cyclical and iterative, and illustrating how clinical experience can feedback to early stages of the next cycle of innovation of a medical device).

## APPENDIX

### *A. Methodology*

A deliberately overinclusive data set of cases was assembled through multiple searches of the Westlaw and LEXIS databases. The searches covered decisions in state and federal courts, including published and unpublished decisions, using all combinations of two sets of search terms. The first set sought to identify all decisions in which a court addressed comment k, whether by name or by reference, and used the terms "comment k," "cmt. k," "unavoidably unsafe," and "unavoidabl!". The second set sought to identify all decisions in which a court addressed medical devices, and used the terms "device" and "medical device." To limit the results to decisions addressing the application of comment k to medical devices, the Boolean connector "AND" was used; queries were thus "comment k" AND "device," "unavoidably unsafe" AND "medical device," and all remaining permutations. The Westlaw search engine was also queried using the West Key Number system codes 313Ak113 (Strict Liability) and 313Ak223 (Health Care and Medical Products), with results filtered for cases containing the terms "comment k," "cmt. k," or "unvoidabl!".

The identified cases were first screened for duplicates, which were removed. A total of 402 unique decisions were identified. Each of these decisions was read by the author to identify cases that did not involve an allegedly defective medical device or did not discuss comment k to section 402A of the *Restatement (Second) of Torts* for exclusion. Based on the initial screening, 196 cases were excluded, comprising cases involving litigation over other products such as drugs, vaccines, tobacco, and asbestos (n=114) or an absence of an analysis of comment k (n=61). Other cases were excluded because they were addressed by subsequent cases (n=11), were only case filings (n=6), or were duplicates with different reporter (Westlaw, LEXIS) designations (n=4).

This process resulted in a data set containing 206 judicial decisions, which were issued between April 27, 1978, and June 26, 2024. Data from each case was then coded. Some information, such as the court in which the case was decided and the date of the

decision, was downloaded from the Westlaw and LEXIS search engines directly into the database. Other information, such as the procedural posture of the decision, was clearly stated in most cases.

The data needed to address questions concerning how courts applied comment k were collected through the use of well-established quantitative, systematic content-analytic methodologies.[374] For this, a coding form and a coding manual were developed in incremental fashion based on the language of comment k, the analysis presented in Part II of this paper, and an initial reading of a subset of the device cases. An overarching goal was to minimize the impact of subjectivity, and thus, to maximize the reproducibility of the findings. To the greatest extent possible, subjectivity was limited by carefully framing the data to be coded into yes or no questions. The data points collected are listed in Part C and the coding book instructions are presented in Part D. Of note, many of the data points were not relevant to the present Article, but will be used in future works.

Using the finalized coding form and manual, data points were coded by the author for each case. Additionally, eighty-three (40 percent) of the cases were also independently coded by two additional readers (two law student research assistants), in order to assess interobserver variability in coding. All of the cases were also coded a second time by the author for an assessment of intraobserver variability.

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374. For a background on examples of the methodologies used in quantitative content analysis in legal scholarship, see generally Hall & Wright, *supra* note 257, at 65-66 (cataloging the use of the technique and attempting to establish a set of best practices); William Baude, Adam S. Chilton & Anup Malani, *Making Doctrinal Work More Rigorous: Lessons from Systematic Reviews*, 84 U. CHI. L. REV. 37, 37 (2017) (describing and applying a four-step process "that could be used whenever someone is trying to make objective claims about the state of legal doctrine" (emphasis omitted)); Samuel Issacharoff & Florencia Marotta-Wurgler, *The Hollowed-Out Common Law*, 67 UCLA L. REV. 600, 608-09, 628-30 (2020) (employing quantitative content analysis to derive a model of how and where state common law in cases involving clickwrap, shrinkwrap, and browsewrap contracts); Oren Bar-Gill, Omri Ben-Shahar & Florencia Marotta-Wurgler, *Searching for the Common Law: The Quantitative Approach of the Restatement of Consumer Contracts*, 84 U. CHI. L. REV. 7, 8 (2017) (employing quantitative content analysis in their role as Reporters for a new Restatement of Contracts "to answer the question of what rules the majority of courts and jurisdictions follow"); William M. Landes, Lawrence Lessig & Michael E. Solimine, *Judicial Influence: A Citation Analysis of Federal Courts of Appeals Judges*, 27 J. LEGAL STUD. 271, 271 (1998) (using quantitative analysis of judicial decisions to study the influence of individual judges).

Statistical analyses were performed using Minitab Statistical Software version 21.1.0.0.

### *B. Interobserver and Intraobserver Variability*

Interobserver and intraobserver variability in coding was assessed using the Kappa statistic test. The Kappa statistic is calculated as:

$$\kappa = \frac{P(A) - P(E)}{1 - P(E)}$$

where P(A) is the proportion of times in which the observers agreed and P(E) is the proportion of agreement expected by random chance alone.[375] For the interobserver variability analysis, which was conducted by three coders, each data point generated three pairings (coders A and B, A and C, B and C). Kappa statistics of 0.8 and higher were considered to reflect a strong level of agreement, while statistics from 0.6 to 0.79 were considered to reflect a moderate level of agreement, and statistics from 0.4 to 0.59 were considered to reflect a weak level of agreement.[376]

#### *1. Interobserver Variability*

A maximum of 249 observations were possible for each variable, based on single observations by three observers in eighty-three cases. Because of missing data points, typically when one or more observers did not enter a coded value, the number of observations is often less than 249.

| Data Point (Possible Responses) | Kappa Statistic | Number of Observations | Strength of Agreement |
|---|---|---|---|
| Decision Within MDL/Class Action/Consolidated (MDL, Class Action, Consolidated, No) | .96 | 245 | Strong |

375. *See* Mary L. McHugh, *Interrater Reliability: The Kappa Statistic*, 22 BIOCHEMIA MEDICA 276, 280 (2012).

376. *Id.* at 279 tbl. 3.

| | | | |
|---|---|---|---|
| Case Was Ever Part of MDL/Class Action/Consolidated (Yes, No) | .84 | 245 | Strong |
| Procedural Posture (Pleading, Motion for Summary Judgment, Post-Trial, Other) | .92 | 249 | Strong |
| Outcome of Strict Liability Design Defect Claim (Survived, Failed, No SL Design Defect Claim) | .72 | 239 | Moderate |
| Blanket Application (Yes, No) | .66 | 174 | Moderate |
| Categorical (Yes, No) | .61 | 212 | Moderate |
| Case-by-Case (Yes, No) | .54 | 191 | Weak |
| Does-Not-Apply (Yes, No) | .91 | 175 | Strong |
| Cannot Be Determined (Yes, No) | .47 | 191 | Weak |
| Broad Application (Blanket or Categorical) or Narrow Application (Case-by-Case or Does-Not-Apply) | .73 | 191 | Moderate |
| Comment k Applies Only if Properly Prepared (Yes, No, Cannot Be Determined) | .43 | 241 | Weak |
| Applies Only if Adequate Warning Provided (Yes, No, Cannot Be Determined) | .43 | 241 | Weak |
| Applies Only if Cannot Be Made More Safe (Yes, No, Cannot Be Determined) | .23 | 237 | Minimal |
| Applies Only if Favorable Risk-Benefit Ratio Demonstrated (Yes, No, Cannot Be Determined) | .33 | 239 | Minimal |
| Comment k Bars/Could Bar SL Manufacturing Defect (Yes, No, Cannot Be Determined) | .52 | 248 | Weak |
| Comment k Bars/Could Bar SL Failure to Warn | .49 | 245 | Weak |
| Bars/Could Bar All Forms of SL (Yes, No, Cannot Be Determined) | .52 | 247 | Weak |

| | | | |
|---|---|---|---|
| Bars Warranty Claims (Yes, No, Cannot Be Determined) | .74 | 243 | Moderate |
| Bars Other Claims, e.g., Negligence (Yes, No, Cannot Be Determined) | .91 | 243 | Strong |

*2. Intraobserver Variability*

The author initially coded the available cases in October-November 2021. The cases were recoded by the author and two research assistants in 2023-2024. In total, the author coded 180 cases twice, allowing for an assessment of intraobserver variability at an interval of two years.

| Data Point (Possible Responses) | Kappa Statistic | Number of Observations | Strength of Agreement |
|---|---|---|---|
| Decision Within or Ever Part of MDL/Class Action/Consolidated | .94 | 180 | Strong |
| Procedural Posture: Pleading, MSJ, Post-Trial, Other | .95 | 180 | Strong |
| Outcome of SL Design Defect Claim: Survived, Failed, No SL Design Defect Claim | .83 | 180 | Strong |
| Blanket Application (Yes, No) | .82 | 163 | Strong |
| Categorical: Yes, No | .41 | 160 | Weak |
| Case-by-Case: Yes, No | .75 | 145 | Moderate |
| Does-Not-Apply: (Yes, No) | .96 | 142 | Strong |
| Cannot Be Determined (Yes, No) | .56 | 166 | Moderate |
| Broad Application (Blanket or Categorical) or Narrow Application (Case-By-Case or Does-Not-Apply) | .64 | 162 | Moderate |
| Comment k Applies Only if Properly Prepared (Yes, No/Unstated) | .71 | 180 | Moderate |
| Applies Only if Adequate Warning Provided (Yes, No/Unstated) | .68 | 180 | Moderate |
| Applies Only if Cannot Be Made More Safe (Yes, No/Unstated) | .78 | 180 | Moderate |

| | | | |
|---|---|---|---|
| Applies Only if Favorable Risk-Benefit Ratio Demonstrated (Yes, No/Unstated) | .71 | 180 | Moderate |
| Comment k Bars/Could Bar SL Manufacturing Defect (Yes, No/Unstated) | .89 | 180 | Strong |
| Comment k Bars/Could Bar SL Failure to Warn (Yes, No/Unstated) | .76 | 180 | Moderate |
| Bars/Could Bar All Forms of SL (Yes, No/Unstated) | .90 | 180 | Strong |
| Bars Warranty Claims (Yes, No/Unstated) | .89 | 180 | Strong |

### *C. Data Points Collected*

| |
|---|
| Case Name |
| Citation |
| Date Filed |
| Court |
| Court System (Federal or State) |
| Court Hierarchy (Trial, Intermediate Appellate, High Court) |
| Labelled Nonprecedential (Yes, No) |
| Removed from State Court (Yes, No) |
| State Law Applied |
| Decision Within MDL/Class Action/Consolidated (Yes (Whether MDL, Class Action, or Consolidated), No) |
| Case Was Ever Part of MDL/Class Action/Consolidated (Yes, No) |
| Procedural Posture (Pleading (e.g., demurrer, (12(b)(6)), Motion for Summary Judgment, Post-Trial, Certified Question to State High Court) |
| Outcome of SL Design Defect Claim (Survived Instant Decision, Failed (was dismissed), No SL Design Defect Claim) |
| Based on Actual or Predicted State Law (federal court cases only) |
| Comment k Text Discussed in Decision (Yes, No) |
| Relevant State Products Liability Statute in Comment k Discussion (Yes, No) |
| Policy-based Analysis Supporting Court's Decision |
| |

| **For State Court Decisions, in the Comment k Discussion, Court Cited:** |
|---|
| Precedent by In-State High Court (case name(s)) |
| Decisions by In-State Lower Courts (case name(s)) |
| Decisions by Out-of-State State Courts (case name(s)) |
| Decisions by Federal Courts Applying In-State Law (case name(s)) |
| Decisions by Federal Courts Applying Out-of-State Law (case name(s)) |
| Antiprecedent (case name(s) of precedent expressly rejected in instant decision) |
| |
| **For Federal Court Decisions, in the Comment k Discussion, Court Cited:** |
| Precedent by In-State High Court (case name(s)) |
| Decisions by In-State Lower Courts (case name(s)) |
| Decisions by State Courts of Other States (case name(s)) |
| Precedent by Same-Circuit Federal Court of Appeals (case name(s)) |
| Decisions by Other Federal Courts (case name(s)) |
| Antiprecedent (case name(s) of precedent expressly rejected in instant decision) |
| |
| **Scope of Comment k Exemption:** |
| Blanket (all devices: Yes, No) |
| Categorical (only certain set or sets of devices: Yes, No) |
| Case-by-Case (application determined Case-by-Case, based on whether device was capable of being made more safe, whether a favorable risk-benefit ratio supported marketing of the device: Yes, No) |
| Does-Not-Apply (application of comment k to medical devices rejected: Yes, No) |
| Cannot Be Determined (scope cannot be determined: Yes, No) |
| |
| **Role of Comment k Caveats:** |
| Applies Only if Properly Prepared (Yes, No, Cannot Be Determined) |
| Applies Only if Adequate Warning Provided (Yes, No, Cannot Be Determined) |
| Applies Only if Cannot Be Made More Safe (Yes, No, Cannot Be Determined) |
| Applies Only if Favorable Risk-Benefit Ratio Demonstrated (Yes, No, Cannot Be Determined) |

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|---|
| Proper Warning Sufficient to Bar SL Design Defect (Yes, No, Cannot Be Determined) |
| Comment k Used to Support State's Learned Intermediary Doctrine (Yes, No, Cannot Be Determined) |
| |
| **Liability Theories Barred in Part or in Total by Comment k:** |
| Comment k Bars/Could Bar SL Manufacturing Defect (Yes, No, Cannot Be Determined) |
| Comment k Bars/Could Bar SL Failure to Warn |
| Bars/Could Bar All Forms of SL (Yes, No, Cannot Be Determined) |
| Bars Warranty Claims (Yes, No, Cannot Be Determined) |
| Bars Other Claims (e.g., negligence: Yes, No, Cannot Be Determined) |

### *D. Coding Book*

| Heading | Coding Instructions |
|---|---|
| Case Name | Prepopulated |
| Citation | Prepopulated |
| Date Filed | Prepopulated |
| Court | Prepopulated |
| Court System | Select federal or state |
| Court Hierarchy | Select level of deciding court (note that some states' highest court are not named their "supreme court") |
| Labelled Non-precedential | Yes: Decision labelled nonprecedential;<br>No: Decision not labelled nonprecedential |
| Removed from State Court | Yes: Decision states case was removed from state court;<br>No: Decision states case was originated in federal court;<br>Not Applicable: State court decision;<br>Cannot Be Determined: Select if no other response applies |
| State Law Applied | Enter name of state whose law is applied |
| MDL/Class Action/ Consolidated | Concerning the instant decision:<br>No: Single case<br>MDL: Decision made within a multidistrict litigation<br>Class Action: Decision as part of an established class action<br>Consolidated: Any other action involving two or more separate actions |

| | |
|---|---|
| Case Was Ever Part of MDL/ Class Action/ Consolidated | Was this case ever part of an MDL, Class Action, or other consolidated action:<br>Yes: e.g., Case was sent to deciding court from an MDL court<br>No: Case was never part of MDL/Class Action<br>Cannot Be Determined: If cannot be determined from opinion |
| Procedural Posture | Pleading: 12(b)(6), demurrer, failure to state a claim<br>MSJ: Motion for summary judgement<br>Post-Trial: JMOL, JNOV, other jury stage<br>Certified Question: Certified question to state supreme court<br>Other: Any other action |
| Outcome of SL Design Defect Claim | Survives: SL Design Defect claim is part of care and was not dismissed in current decision<br>Fails: SL Design Defect claim dismissed<br>Deferred: SL Design Defect claim challenged but not decided<br>No SL Design Defect claim at issue |
| Actual or Predicted State Law (federal court cases only) | State Court Case: Case was decided by a state court<br>Actual: Court says that state law is settled and refers to state high court decision<br>Stated Actual but No State High Court Decision: Court says state law is settled but does not refer to high court decision in device case<br>Stated Predicted but State High Court Opinion: Court says it is predicting state law but state high court had already decided role of comment k in device case involving the same issue<br>Predicted: Court predicting state high court ruling |
| Comment k Text | Quoted: Part or all of comment k is quoted but is not discussed or analyzed<br>Discussed: Court discusses or analyzes comment k beyond mere quotation<br>Not Quoted or Discussed: Court neither quotes nor discusses/analyzes Comment k |
| Relevant State Statute | Yes: Decision refers to relevant state products liability statute<br>No: Decision does not refer to a state products liability statute |

| | |
|---|---|
| Policy Discussion | Yes: Decision includes discussion of policy regarding comment k<br>No: Decision does not include discussion of policy regarding comment k |
| State Court Decisions | |
| Precedent by In-State High Court | Enter caption of any cited in-state high court/supreme court decision involving application of comment k |
| Decisions by In-State Lower Courts | Enter caption of any cited in-state trial level or intermediate appellate court decision involving application of comment k in a device case |
| Decisions by Out-of-State State Courts | Enter caption of any cited out-of-state state court decision involving application of comment k in a device case |
| Decisions by Federal Courts Applying In-State Law | Enter caption of any cited federal court decision applying in-state law that involved the application of comment k in a device case |
| Decisions by Federal Courts Applying Out-of-State Law | Enter caption of any cited federal court decision applying law of another state that involved the application of comment k in a device case |
| Antiprecedent | Enter caption of any cited decision the holding of which is rejected by deciding court |
| Federal Court Decisions | |
| Precedent by In-State High Court | Enter caption of any cited in-state high court/supreme court decision involving application of comment k |
| Decisions by In-State Lower Courts | Enter caption of any cited in-state trial level or intermediate appellate court decision involving application of comment k in a device case |
| Decisions by State Courts of Other States | Enter caption of any cited out-of-state state court decision involving application of comment k in a device case |
| Precedent by Same-Circuit Federal Court of Appeals | Enter caption of any cited decisions by federal district court's supervising appellate court |

| | |
|---|---|
| Decisions by Other Federal Courts | Enter caption of any cited decisions by any other federal courts |
| Antiprecedent | Enter caption of any cited decision the holding of which is rejected by deciding court |
| Device Categories | |
| Blanket | Yes: Comment k exempts all devices from strict liability, if any relevant caveats are satisfied<br>No: Blanket application can be excluded |
| Categorical | Yes: Comment k exempts a specific category or categories of devices, if any relevant caveats are satisfied. Examples of device categories include prescription devices, devices available only through a physician, implanted devices, devices approved through a specific pathway;<br>No: Categorical application can be excluded |
| Case-by-Case | Yes: Comment k exempts only devices determined on a case-by-case basis<br>No: Case-by-case application can be excluded |
| Does-Not-Apply | Yes: Comment k exempts no devices<br>No: Comment k applies to one or more devices under blanket, categorical, or case-by-case approach |
| Cannot Be Determined | Cannot determine specific role of comment k, including cases in which it can be determined that comment k applies to at least one category of device but cannot determine if it applies to other categories or in blanket fashion |
| Caveats and Conditions Necessary for Comment k to Apply | |
| Applies Only If Properly Prepared | Yes: Court states that comment k defense available only if device is properly prepared or if there is no manufacturing defect<br>Unstated: Whether proper preparation/absence of manufacturing defect is required cannot be determined<br>No: Court states that proper preparation/absence of manufacturing defect is not needed for comment k defense to be available |

| | |
|---|---|
| Applies Only if Adequate Warning Provided | Yes: Court states that comment k defense available only if device is accompanied by adequate warnings/no failure to warn<br>Unstated: Whether proper warning/absence of failure to warn is required cannot be required<br>No: Court states that adequate warning not required for comment k defense to be available |
| Applies Only if Cannot Be Made More Safe | Yes: Court states that comment k defense available only if device cannot be made more safe<br>Unstated: Whether device incapable of being made more safe is required for comment k to apply cannot be applied<br>No: Court states that device being incapable of being made more safe not required for comment k defense to be available |
| Applies Only if Favorable Risk-Benefit Ratio | Yes: Court states that comment k defense available only if favorable risk-benefit ratio if present<br>Unstated: Whether a favorable risk-benefit ratio is present is required cannot be determined<br>No: Court states that favorable risk-benefit ratio not required for comment k defense to be available |
| Proper Warning Sufficient to Bar SL Design Defect | Yes: Court states that provision of an adequate warning bars SL Design Defect claim<br>Unstated: Whether provision of adequate warning bars SL Design Defect claim not addressed<br>No: Court states that provision of adequate warning does not bar SL Design defect claim |
| Learned Intermediary Doctrine | Yes: Comment k arises from or is based on the Learned Intermediary doctrine<br>Unstated: Relationship of comment k to Learned Intermediary Doctrine not stated<br>No: Court holds that comment k is unrelated to Learned Intermediary Doctrine |
| Effect of Comment k on Other Legal Theories | |

| | |
|---|---|
| Comment k Bars/Could Bar SL Manufacturing Defect | Yes: Comment k barred plaintiff's claim of SL Manufacturing Defect in this case or court indicated that comment k could bar SL Manufacturing Defect claims in other cases<br>Unstated: Effect of comment k on SL Manufacturing Defect cannot be determined<br>No: Court stated that comment k does not bar claims of SL Manufacturing Defect |
| Comment k Bars/Could Bar SL Failure to Warn | Yes: Comment k barred plaintiff's claim of SL Failure to Warn in this case or court indicated that comment k could bar SL Failure to Warn claims in other cases<br>Unstated: Effect of comment k on SL Failure to Warn claims cannot be determined<br>No: Court stated that comment k does not bar claims of SL Failure to Warn |
| Bars/Could Bar All Forms of SL | Yes: Comment k bar SL Manufacturing, Design, *and* Failure to Warn claims in this case, or court indicated that comment k could bar SL Manufacturing, Design, *and* Failure to Warn claims in other cases<br>Unstated: Whether comment k bars all SL claims cannot be determined<br>No: Court states that comment k does not bar all three types of SL claims |
| Bars Warranty Claims | Yes: Comment k held to bar at least some Breach of Warranty claims<br>Unstated: Whether comment k bars any Breach of Warranty claim cannot be determined<br>No: Comment k held not to bar Breach of Warranty claims or court permits any Breach of Warranty claim |
| Bars Other Claims | Yes: Comment k held to bar any claims other than SL or Breach of Warranty<br>Unstated: Cannot be determined if comment k bars claims other than SL or Breach of Warranty<br>No: Comment k held not to bar claims other than SL or Breach of Warranty or court allows other claims |
| Any Case Citations Were in Footnotes | Yes: Any cases listed on coding form were included only in footnotes<br>No: Cases were only from body of opinion |