Off-Label Inducement

David A. Simon[*]

ABSTRACT: Manufacturers that promote unapproved "off-label" uses of their drugs and devices can cause harm to patients by encouraging providers to prescribe these products unsafely. Examples of this phenomenon are increasingly in the news, as patients injured by off-label uses of drugs like Botox sue manufacturers that promote them. Yet these claims often fail because the current legal framework is ill-equipped to deal with this problem. In some cases, for example, the First Amendment stymies lawsuits by protecting manufacturers' promotional speech. In others, the doctrine of preemption blocks claims because federal law regulating drugs or devices conflicts with state law that imposes liability on manufacturers. The result is problematic: Manufacturers that cause injuries to patients by promoting off-label uses may be immune from liability.

This Article proposes a solution: a new theory of liability—off-label inducement—that makes a manufacturer liable when its promotion induces a provider to negligently prescribe, administer, or use its drug or device off-label. In other words, manufacturers actively encouraging off-label uses that constitute and result in negligent medical care should be liable for the injuries they cause. While tort law supplies the framework for the theory, intellectual property law provides additional support for why it should apply to manufacturers that promote unsafe off-label uses of drugs and devices. Courts have adapted inducement in intellectual property law to address new social problems, such as widespread infringement enabled by file-sharing software. To respond to the harms posed by off-label promotion, courts should do the same with tort law. Manufacturers actively encouraging off-label uses that constitute and result in negligent medical care should be liable for many of the same policy

[*] Associate Professor of Law, Northeastern University School of Law; Co-Director, the Amy J. Reed Collaborative for Medical Device Safety. For comments and suggestions, I thank Daniel Aaron, Tom Baker, Oren Bracha, Anjali Deshmukh, David Fajgenbaum, Janet Freilich, Sara Gerke, Michael Goodyear, Diane Hoffmann, George Horvath, Donald Gifford, Ryan Knox, Mark Lemley, David Schwartz, Shelly Simana, Michael Sinha, Arjun Ramamurti, Chris Robertson, Jake Sherkow, Benjamin Sundholm, Rebecca Tushnet, Michael Ulrich, Liza Vertinsky, Allison Whelan, Ted White, Rebecca Wolitz, Christopher Yoo, as well as the participants at the 2024 Stanford-Penn-Northwestern Junior Faculty Forum for Law & STEM, Stanford Law School's 2023 Biolawlapalooza, and the University of Maryland Carey School of Law Faculty workshop. I thank Kate Armstrong and Olivia Shaw for their research assistance and the editors of the *Iowa Law Review* for their excellent work.

reasons distributors of software are liable for encouraging consumers to infringe intellectual property using their products. After describing the theory, it demonstrates how three different formulations of it could apply to a recent case. The Article then explains how off-label inducement overcomes constitutional and doctrinal obstacles that frustrate traditional attempts to hold manufacturers responsible for harms they cause through off-label promotion. Using this theory to hold manufacturers responsible for the harm they cause by promoting unsafe off-label uses can help to reduce injuries, improve care, and compensate injured patients.

INTRODUCTION

Consider two situations. First, a manufacturer receives federal approval for Cordarone as a drug of last resort for two conditions involving abnormal heart rhythm but aggressively promotes it as a "first-line" therapy for heart rhythm conditions.[1] As a result, a physician prescribes the drug as a first-line therapy and the patient suffers a variety of symptoms,[2] is admitted to the hospital, and eventually dies from complications caused by the drug.[3] Second, a device manufacturer receives federal approval for its bone graft in the lower spine but promotes its use to physicians in the middle and upper spine.[4] Physicians to whom the bone graft was promoted use it in the upper spine, and patients suffer severe injuries.

Should the manufacturers that promoted these unapproved uses—so-called "off-label uses"—be liable for these injuries? In each of these cases, the court said no, but this Article argues that the answer should be yes.[5] What legal theory could make them liable when others have failed? The answer is a new theory of liability: *off-label inducement*. Under this theory, a manufacturer is liable when it induces, through promotion, a provider to negligently prescribe, administer, or use its drug or device off-label.[6]

Off-label inducement is needed because existing law has not kept pace with the harms caused by inappropriate and unsafe off-label promotion. Although federal law regulates how drugs and devices are authorized and

1. Elliott v. Sandoz, Inc., No. 16-CV-00861, 2016 WL 4398407, at *21 (N.D. Ala. Aug. 18, 2016).

2. *Id.* at *1.

3. *Id.* at *2. This case involved a lawsuit against a generic manufacturer, rather than the brand name manufacturer that promoted the use. *Id.* It was barred on preemption grounds. *Id.* at *6; *see* Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 475–76 (2013); Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1672 (2019).

4. A number of cases were filed against the manufacturer. *E.g.*, Wright v. Medtronic, Inc., 81 F. Supp. 3d 600, 605 (W.D. Mich. 2015); Thorn v. Medtronic Sofamor Danek, USA, Inc., 81 F. Supp. 3d 619, 621–22 (W.D. Mich. 2015); Houston v. Medtronic, Inc., 957 F. Supp. 2d 1166, 1171–72 (C.D. Cal. 2013).

5. While the plaintiffs in each case lost, they did so for different reasons.

6. I use the term "provider" because it includes all those persons, including nurse practitioners, who can prescribe, use, and administer drugs and devices. In some cases, this term may include the hospitals and facilities that modulate physician behavior. But it will not do so in every case.

advertised, it does not typically control how physicians use them.[7] Nor does it prevent manufacturers from disseminating truthful, non-misleading information about off-label uses that regulators have yet to review.[8]

While both off-label uses and information about them can be legitimate and even innovative,[9] they can also cause harm. Off-label uses typically are not supported by the same level of evidence as on-label ones.[10] Promoting unsafe or inappropriate off-label uses can increase the chance that a physician causes harm by using the drug or device as promoted. Unfortunately, because off-label sales of drugs and devices increase revenues, manufacturers have a financial incentive to promote inappropriate or unsafe off-label uses.[11] For example, a profit-maximizing manufacturer may try to increase off-label sales by providing physicians with positive information about off-label uses while withholding or minimizing negative information about them.[12] So although information about off-label use can improve provider knowledge, it can also result in inappropriate and unsafe off-label uses that increase costs for insurers and patients by hundreds of millions, perhaps billions, of dollars.[13]

Despite these potential harms, legal tools used to police inappropriate and unsafe off-label promotion are limited in important ways.[14] For example, lawsuits by public regulators[15] that target manufacturer off-label promotion are constrained by resource limitations and First Amendment protections for commercial speech. And private claims under state law often must overcome

---

7. *E.g.*, 21 U.S.C. § 396 (2018). *But see* Patricia J. Zettler, *Pharmaceutical Federalism*, 92 IND. L.J. 845, 857 (2017) (noting that the FDA "*promotes* the public health by . . . mak[ing] sure that the public has the necessary information to properly use those drugs").

8. *See infra* Section III.A.

9. *See generally* David A. Simon, *Off-Label Innovation*, 56 GA. L. REV. 701 (2022); DAVID FAJGENBAUM, CHASING MY CURE: A DOCTOR'S RACE TO TURN HOPE INTO ACTION: A MEMOIR (2019) (describing autobiographical case study of effective off-label use of a drug for rare condition).

10. *E.g.*, David C. Radley, Stan N. Finkelstein & Randall S. Stafford, *Off-Label Prescribing Among Office-Based Physicians*, 166 ARCHIVES INTERNAL MED. 1021, 1021 (2006).

11. They also have countervailing incentives, including reputational and liability costs.

12. David A. Simon, *Off-Label Speech*, 72 EMORY L.J. 549, 551–52 (2023).

13. In one lawsuit, for example, payors claimed billions of dollars in damages. *See generally* Fourth Amended Class Action Complaint, *In re* Neurontin Mktg., Sales Pracs. & Prods. Liab. Litig., No. 04-10981 (D. Mass. Mar. 24, 2011), 2011 WL 11547729 (seeking "to recover billions of dollars they paid to Defendants as a result of Defendants' fraudulent scheme to market and sell the drug Neurontin® ('Neurontin') for a variety of uses for which it is not approved, or medically efficacious"); Settlement Conference at 15, *In re* Neurontin Mktg., Sales Pracs. & Prods. Liab. Litig., No. 04-10981 (D. Mass. July 7, 2014), 2011 WL 11547729.

14. I do not canvas all potential routes of regulation here. Notably, I do not mention antitrust law, which may prohibit or limit how branded drug manufacturers structure payments to generic manufacturers to delay entry of the generic. *E.g.*, Robin Feldman, *The Price Tag of "Pay-for-Delay,"* 23 COLUM. SCI. & TECH. L. REV. 1, 33 (2022).

15. 21 U.S.C. §§ 331(a), 333(a)(2) (misbranding), 355 (new drugs); 31 U.S.C. §§ 3729–3733 (False Claims Act); 42 U.S.C. § 1320a-7a (civil monetary penalties law). Some claims may be initiated by a private party, known as a "Relator." 31 U.S.C. § 3730(b)–(h) (qui tam provisions); *id.* §§ 3729–3733 (False Claims Act).

the additional constitutional obstacle of preemption while contending with doctrinal hurdles in tort and contract.[16]

Although scholars have attempted to address these limitations, they have mainly argued that these legal impediments were either wrongly constructed[17] or should be removed by federal regulation.[18] This Article is different. It attempts to reduce inappropriate and unsafe[19] off-label prescribing by avoiding some of the legal challenges other scholars have tried to correct. Specifically, it contends that this new theory can deter manufacturers from engaging in unsafe off-label promotion by holding them responsible for the negligence they cause—all while evading constitutional and doctrinal torpedoes.[20] Besides deterring harmful manufacturer behavior, imposing liability in this way can improve the quality of information manufacturers provide to physicians. If physicians with more accurate information tend to make better decisions than those with less accurate information, then this theory should also improve the quality of physician decisions to use drugs and devices off-label.

The affirmative case for off-label inducement draws on core tort doctrine. Inducement is a theory of secondary liability that holds an actor liable for another's tortious conduct when the actor intentionally provides substantial encouragement or assistance for the underlying tort.[21] This Article contends that this theory can be applied to drug and device manufacturers that promote unsafe off-label uses to physicians. Specifically, it argues that a manufacturer

16. *See infra* Section III.B.

17. For arguments that the First Amendment has been wrongly interpreted, see Christopher Robertson, *The Tip of the Iceberg: A First Amendment Right to Promote Drugs Off-Label*, 78 OHIO ST. L.J. 1019, 1023–24 (2017); Amy Kapczynski, *The* Lochner*ized First Amendment and the FDA: Toward a More Democratic Political Economy*, 118 COLUM. L. REV. ONLINE 179, 180 (2018); and Aaron S. Kesselheim & Michelle M. Mello, *Prospects for Regulation of Off-Label Drug Promotion in an Era of Expanding Commercial Speech Protection*, 92 N.C. L. REV. 1539, 1543 (2014). For additional discussion, see *infra* Part III. *See also* Nathan Cortez, *The Statutory Case Against Off-Label Promotion*, 83 U. CHI. L. REV. ONLINE 124, 135–36 (2016) (statutory analysis of FDA's prohibition of off-label promotion). For an argument on preemption, see David A. Simon, *Off-Label Preemption*, 2024 WIS. L. REV. 1079, 1123–37. For a comprehensive treatment of issues relating to off-label use, see generally James M. Beck, *Off-Label Use in the Twenty-First Century: Most Myths and Misconceptions Mitigated*, 54 J. MARSHALL L. REV. 1 (2021); and James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71 (1998).

18. On arguments to improve information, see, e.g., George Horvath, *Off-Label Drug Risks: Toward a New FDA Regulatory Approach*, 29 ANNALS HEALTH L. & LIFE SCIS. 101, 126–30 (2020); Ryan Abbott & Ian Ayres, *Evidence and Extrapolation: Mechanisms for Regulating Off-Label Uses of Drugs and Devices*, 64 DUKE L.J. 377, 399 (2014); Fazal Khan & Justin Holloway, *Verify, Then Trust: How to Legalize Off-Label Drug Marketing*, 117 PA. ST. L. REV. 407, 430–38 (2012); and Aaron S. Kesselheim, *Off-Label Drug Use and Promotion: Balancing Public Health Goals and Commercial Speech*, 37 AM. J.L. & MED. 225, 247–50 (2011).

19. One can define "unsafe" in a variety of ways. I use the term "unsafe" interchangeably with "negligent." Later I distinguish unsafe from "inappropriate." *See infra* note 23.

20. *See infra* Part III.

21. *See infra* Section II.B.

should be liable when its promotion induces a provider to negligently prescribe, administer, or use its drug or device off-label.[22]

While tort law supplies the framework for the theory, intellectual property ("IP") law provides additional support for why it should apply to manufacturers that promote unsafe off-label uses of drugs and devices. IP law has adapted inducement to apply to producers that distributed peer-to-peer file sharing software and drug manufacturers that encouraged widespread patent infringement by physicians. Analyzing these adaptations yields three lessons tort can learn from IP. First, courts have adapted existing inducement doctrine to new social problems. Second, courts are willing to stretch doctrinal limitations, such as causation, to overcome practical problems associated with widespread and diffuse conduct that is otherwise impractical to pursue legally. Finally, courts are willing to use inducement to regulate truthful, non-misleading speech that is designed to encourage illegal behavior. Each of these lessons supports applying inducement to manufacturers that encourage unsafe off-label use through promotion.

Despite this support, the analogy to IP is not perfect. But it need not be. What IP provides is a helpful perspective on how and why courts have used inducement to address new social problems. Learning and applying those lessons does not require the new legal domains map on identically to IP. In this respect, IP underscores that tort law should be comfortable adjusting existing doctrine to address new social harms.

This Article proceeds as follows. Part I explains off-label use and promotion. Then it describes the existing laws that target inappropriate and unsafe off-label promotion and use, and explains how they are limited in significant ways.[23] With these limits in view, Part II provides the affirmative case for off-label inducement. It begins by articulating the benefits of the new theory, including shifting legal responsibility to the cheapest-cost avoider and reducing information asymmetries. It then turns to the substantive case for the theory, showing how inducement can apply to manufacturers' promotion of unsafe off-label uses that cause harm to patients. After explaining how IP law adapted inducement to address new social problems, it argues that tort law should do the same for drug and device manufacturers that promote unsafe off-label uses. To show how the theory would work, it applies three formulations of it to a recent case. Part III identifies and responds to the challenges that off-label inducement faces from constitutional law, tort doctrine, and civil procedure—as well as its potential negative effect on innovation. It shows that off-label inducement, although not without challenges, escapes many of the

22. Crucially, it argues that physicians' duty to have adequate knowledge of off-label use includes *a duty to ask* drug manufacturers for information about promoted off-label uses.

23. I use "inappropriate" here to distinguish uses that may not be warranted by evidence from those that are unsafe (i.e., negligent).

problems associated with traditional legal tools that target inappropriate and harmful off-label promotion and acts as an important adjunct to them.

I. OFF-LABEL USE AND LIABILITY

This Part explains off-label promotion, use, and liability. Section I.A describes why manufacturers promote and physicians use drugs and devices off-label. Section I.B highlights the existing tools for regulating harmful off-label uses and discusses their limitations.

A. OFF-LABEL PROMOTION AND USE

Manufacturers promote drugs off-label for a simple reason: money. Drugs and devices are big business. Together they compose more than a $650 billion market in the United States alone.[24] Although new drugs are lucrative for drug companies, they are becoming more expensive to develop[25] and more susceptible to government price regulation.[26] With costs increasing and profits potentially shrinking, drug and device manufacturers may use strategies to generate additional sales to make up the difference.

One method for boosting sales is to promote an approved drug or device for unapproved uses.[27] Although approval from the U.S. Food and Drug Administration ("FDA") licenses the sponsoring manufacturer to market a drug or device only for a particular use, physicians can prescribe an approved drug or device for unapproved uses—so-called "off-label uses." Because each off-label prescription or use results in an additional sale of the drug or device, manufacturers increase revenue when physicians prescribe or use their drug

24. *For U.S. Market Entry, Don't Overlook Abbreviated Applications to FDA for Drugs, Biologics, and Devices*, AM. PHARM. REV. (June 1, 2024), https://www.americanpharmaceuticalreview.com/Featured-Articles/613550-For-U-S-Market-Entry-Don-t-Overlook-Abbreviated-Applications-to-FDA-for-Drugs-Biologics-and-Devices/ [https://perma.cc/PM29-KDJM]. Off-label promotion is typically a problem for new drugs and devices because they are more expensive than older ones. A small number of new drugs, for example, are responsible for the bulk of the government's $421 billion spending on prescription drugs. Thomas J. Hwang, Aaron S. Kesselheim & Benjamin N. Rome, *New Reforms to Prescription Drug Pricing in the US: Opportunities and Challenges*, 328 JAMA 1041, 1041–42 (2022); *see also* Juliette Cubanski & Tricia Neuman, *Relatively Few Drugs Account for a Large Share of Medicare Prescription Drug Spending*, KFF (Apr. 19, 2021), https://www.kff.org/medicare/issue-brief/relatively-few-drugs-account-for-a-large-share-of-medicare-prescription-drug-spending [https://perma.cc/JGW3-TQP4] ("The 250 top-selling drugs in Medicare Part D with one manufacturer and no generic or biosimilar competition (7% of all Part D covered drugs) accounted for 60% of net total Part D spending. The top 50 drugs covered under Medicare Part B (8.5% of all Part B covered drugs) accounted for 80% of total Part B drug spending.").

25. Jack W. Scannell, Alex Blanckley, Helen Boldon & Brian Warrington, *Diagnosing the Decline in Pharmaceutical R&D Efficiency*, 11 NATURE REVS. DRUG DISCOVERY 191, 191 (2012).

26. *See generally* Inflation Reduction Act, Pub. L. No. 117-169, 136 Stat. 1818 (2022) (restructuring Medicare Part D and providing for limited drug price negotiations under Part B).

27. Devices can be approved, cleared, or authorized by FDA. This Article uses the term "approved" to refer all of these categories except where otherwise noted. Although this is not technically correct as applied to "cleared" devices or those granted "de novo authorization," it is more reader-friendly.

or device (on- and) off-label. Manufacturers, therefore, have an incentive to encourage physicians to prescribe or use drugs and devices off-label by providing them with positive information about off-label uses while withholding or minimizing negative information about off-label uses. While this information can improve physician knowledge,[28] it can also result in unnecessary and unsafe uses that increase costs for insurers and patients by hundreds of millions, perhaps billions, of dollars.[29]

Although some manufacturers attempt to generate sales by lavishing physicians with vacations, consultancies, and other benefits,[30] this practice is neither uniform nor universal. And physicians who prescribe or use drugs and devices off-label are not necessarily reacting to manufacturer influence.[31] To the contrary, physicians may prescribe off-label for a variety of medical reasons that are disconnected from promotional efforts. For example, some practice areas, such as pediatrics and oncology, use drugs off-label because on-label treatments are scarce or because off-label uses are the standard of care.[32]

Information about off-label uses in this context can be helpful to physicians in two ways. First, physicians here rely on information about off-label uses to inform prescribing. Information about off-label uses may be published in peer-reviewed journals. But manufacturers—who are likely to have the most complete and comprehensive information—are also a source of information. Sales representatives may provide physicians with written materials or talk with them about off-label uses, sometimes even in the operating room. Information about potential off-label uses in this context may enable surgeons to treat patients more effectively, with fewer side effects and complications.

Physicians also rely on information about off-label use, including information from the manufacturer, to help them innovate. Using their knowledge, physicians discover new off-label uses of drugs to treat diseases without any existing FDA-approved options.[33] Similarly, in the device context, surgeons innovate by using devices off-label when they find the existing use of the

28. *See* Simon, *supra* note 12, at 552.

29. *See supra* note 13 and accompanying text.

30. For a review of these tools, see generally Harindranath R.M. & Bharadhwaj Sivakumaran, *Pharmaceutical Promotion: A Literature Review and Research Agenda*, *in* NEW TECHNIQUES FOR BRAND MANAGEMENT IN THE HEALTHCARE SECTOR 44 (2021).

31. Indeed, information that manufacturers provide to physicians can be beneficial. *See* Simon, *supra* note 12, at 552.

32. *E.g.*, M.M. Saiyed, P.S. Ong & L. Chew, *Off-Label Drug Use in Oncology: A Systematic Review of Literature*, 42 J. CLINICAL PHARMACY & THERAPEUTICS 251, 251, 253 (2017). Off-label prescribing may be advantageous in oncology as it presents evidence-based treatment options to patients who have no alternative options, for example in indications where there were no approved drugs or for patients who have exhausted standard lines of treatment.

33. Simon, *supra* note 9, at 708; FAJGENBAUM, *supra* note 9, at 116–17.

device may be applicable to other conditions or patients.[34] Information about off-label uses, in this way, helps to create better treatment options for patients.

B. LIMITATIONS OF EXISTING LAW

Not all communications about off-label information, however, are beneficial—or legal. To limit the harmful effects of unsupported off-label information, regulators use various legal tools to limit what drug manufacturers say about off-label uses.[35] This Section explains the existing legal tools that public and private actors can use to address inappropriate and unsafe off-label use, as well as their limitations. These include violations of federal drug and device law, federal reimbursement law, and state law.[36]

Consider first a government lawsuit that pursues criminal and civil charges for violating the Federal Food, Drug, and Cosmetic Act ("FDCA") that prohibits misbranding—that is, marketing a drug or device for a use that is not approved.[37] Although this approach can be successful, courts have blunted its force by questioning the extent to which the First Amendment shields truthful, non-misleading off-label promotion from prosecution.[38]

The government can also sue manufacturers that promote off-label under the False Claims Act ("FCA")—a federal law that prohibits causing others to knowingly submit "false claims" for uses the government would not reimburse if it knew they were off-label.[39] This approach can net the government large

34. *E.g.*, Aaron K. Chatterji, Kira R. Fabrizio, Will Mitchell & Kevin A. Schulman, *Physician-Industry Cooperation in the Medical Device Industry*, 27 HEALTH AFFS. 1532, 1535–36 (2008).

35. I do not canvas all potential routes of regulation here. Notably, I do not mention antitrust law, which may prohibit or limit how branded drug manufacturers structure payments to generic manufacturers to delay entry of the generic. *See generally* Feldman, *supra* note 14 (discussing the controversial pay-for-delay agreements between brand and generic pharmaceutical companies).

36. States have counterpart reimbursement and deceptive trade practice laws, in addition to tort and contract. *E.g.*, TEX. HUM. RES. CODE ANN. § 36.002 (West 2019) (false claims). *See generally* TEX. BUS. & COM. CODE ANN. § 17 (West 2021) (deceptive trade practices).

37. *E.g.*, 21 U.S.C. §§ 331(a), 333(a)(2) (misbranding), 355 (new drug).

38. *E.g.*, United States v. Caronia, 703 F.3d 149, 160 (2d Cir. 2012). For an analysis of the case law after *Caronia*, see Sheng Liu, Michelle M. Mello & Aaron S. Kesselheim, *Prospects for Enforcing Prohibitions on Off-Label Drug Promotion After* United States v. Caronia*: An Analysis of Litigated Cases*, 46 J. HEALTH POL. POL'Y & L. 487, 494 (2021) (noting that eighty-one percent of all collected cases involved private lawsuits).

39. False Claims Act, 31 U.S.C. §§ 3729–3733; *see also* 42 U.S.C. § 1320a-7a(a) (creating civil penalties for false claims). Sometimes these claims are based on a violation of another federal statute, the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b. Companion state laws also provide authority for the states' attorneys general to pursue similar claims. *See, e.g.*, MASS. GEN. LAWS ch. 12, § 5A–5O (2024) (false claims). Physicians can be liable under separate statutes, such as the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and the Physician Self-Referral Law (Stark Law), 42 U.S.C. § 1395nn. *See also* Physician Payments Sunshine Act, 42 U.S.C. § 1320a-7h (requiring pharmaceutical companies to report payments to physicians).

settlements and verdicts. For example, Bayer ($40 million in 2021)[40] and Novartis (more than $420 million in 2010) have paid hundreds of millions to settle claims involving off-label promotion.[41] And because the statute authorizing claims allows private parties to initiate them (*qui tam*), FCA lawsuits can leverage the informational advantages of private litigants to burnish enforcement.[42] The lawsuits against Bayer and Novartis, for instance, began when whistleblowers filed private lawsuits under the FCA.[43]

While being quite lucrative and offering important private enforcement mechanisms, the FCA approach has several drawbacks. First, resource constraints influence the type of cases the government pursues.[44] Because the federal law governing false claims applies to *all* claims made to the federal government for reimbursement, the government can pursue only a limited class of cases for off-label promotion. And even within the category of off-label promotion, cases are often clustered around drugs with the most egregious violations, typically focusing on vulnerable populations.[45] While commendable, the lawsuits tend not to target nefarious practices that would yield smaller amounts or require more intensive litigation with less potential material or reputational reward. Second, although there is evidence that FCA settlements have a positive welfare effect and deter antisocial behavior,[46] it is not clear to what extent this extrapolates to all prosecutions and settlements relating to

40. Press Release, U.S. Dep't of Just., Bayer to Pay $40 Million to Resolve the Alleged Use of Kickbacks and False Statements Relating to Three Drugs (Sept. 2, 2022), https://www.justice.gov/opa/pr/bayer-pay-40-million-resolve-alleged-use-kickbacks-and-false-statements-relating-three-drugs [https://perma.cc/P7YX-EWQ7].

41. Press Release, U.S. Dep't of Just., Novartis Pharmaceuticals Corp. to Pay More than $420 Million to Resolve Off-Label Promotion and Kickback Allegations (Sept. 30, 2010), https://www.justice.gov/opa/pr/novartis-pharmaceuticals-corp-pay-more-420-million-resolve-label-promotion-and-kickback [https://perma.cc/7QCS-3Z4H].

42. Other jurisdictions that lack qui tam-style actions rely heavily on competitors to bring claims. Andreas Vilhelmsson, Courtney Davis & Shai Mulinari, *Pharmaceutical Industry Off-Label Promotion and Self-Regulation: A Document Analysis of Off-Label Promotion Rulings by the United Kingdom Prescription Medicines Code of Practice Authority 2003–2012*, PLOS MED. 2 (Jan. 26, 2016), https://journals.plos.org/plosmedicine/article/file?id=10.1371/journal.pmed.1001945&type=printable [https://perma.cc/P9ZG-QWZY].

43. Press Release, U.S. Dep't of Just., *supra* note 40; Press Release, U.S. Dep't of Just., *supra* note 41.

44. *Cf.* David A. Simon, Carmel Shachar & I. Glenn Cohen, *Assessing Public and Private Rights of Action to Police Health Data Sharing*, *in* THE LAW AND ETHICS OF DATA SHARING IN HEALTH SCIENCES 33, 40, 45 (Marcelo Corrales Compagnucci, Timo Minssen, Mark Fenwick, Mateo Aboy & Kathleen Liddell eds., 2024) (discussing resource constraints in the health data sharing context).

45. Maya P. Florence, *DOJ's Evolving Enforcement Approach to Off-Label Promotion*, SKADDEN (Apr. 27, 2021), https://www.skadden.com/insights/publications/2021/04/enforcement-in-life-sciences-series/dojs-evolving-enforcement-approach [https://perma.cc/VG37-C3GN] ("[T]he single biggest factor impacting the terms of a settlement is whether there is a patient safety issue at play, particularly when there is a vulnerable patient population involved.").

46. *See generally* Jetson Leder-Luis, *Can Whistleblowers Root Out Public Expenditure Fraud? Evidence from Medicare*, 107 REV. ECON. & STAT. 1169 (2025) (estimating $1.9 billion in whistleblower settlements specifically deterred $19 billion in false Medicare claims).

off-label promotion.[47] Third, because FCA lawsuits are premised on fraud, claims are subjected to heightened pleading standards.[48] This tends to result in prioritizing claims where extensive information about potential fraud is available before a lawsuit is filed.[49]

Finally, drug and device manufacturers can be liable under tort, contract, and other state laws for defective products that cause injuries to patients.[50] Often, however, these claims fail for two different constitutional reasons.[51] First, courts may find, just as they do in the context of prosecution for misbranding under the FDCA, that the speech itself is protected by the First Amendment. For example, at least one federal appeals court has held that bans on off-label speech are unconstitutional.[52] And although the decision has not been universally followed,[53] defense lawyers have proposed extending it to block tort liability.[54] Second, courts frequently hold that federal law governing drug and device labeling preempts, or precludes, state law claims based on off-label promotion.[55] In other words, courts often hold that federal law requiring FDA approval of label changes conflicts with state law claims that require manufacturers to update their labels to reflect off-label risks. And although the Supreme Court hasn't opined on either issue, the legal ground

47. *See id.* at 1179, 1181 (finding weak deterrent effects with respect to off-label promotion of Botox but noting that may have been attributable to FDA approval of an off-label use around the time of settlement); Aaron S. Kesselheim et al., *False Claims Act Prosecution Did Not Deter Off-Label Drug Use in the Case of Neurontin*, 30 HEALTH AFFS. 2318, 2324 (2011) (finding that prosecution did not lead deter off-label use but noting that off-label prescriptions fell after settlement); *cf.* Bo Wang et al., *The Effect of Federal and State Off-Label Marketing Investigations on Drug Prescribing: The Case of Olanzapine*, PLOS ONE 5–7 (Apr. 7, 2017), https://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0175313&type=printable [https://perma.cc/9TJ6-DH9H] (finding no reduction in off-label prescription of olanzapine after prosecution).

48. FED. R. CIV. P. 9(b).

49. *See infra* Section III.C.3.

50. Firms may also be liable for securities laws violations or civil aiding and abetting, though they face doctrinal obstacles. *See, e.g.*, Press Release, U.S. Dep't of Just., Justice Department Announces Global Resolution of Criminal and Civil Investigations with Opioid Manufacturer Purdue Pharma and Civil Settlement with Members of the Sackler Family (Oct. 21, 2020), https://www.justice.gov/archives/opa/pr/justice-department-announces-global-resolution-criminal-and-civil-investigations-opioid [https://perma.cc/H7RE-3D6H]; Inchen Huang v. Higgins, No. 17-CV-04830, 2019 WL 1245136, at *4–18 (N.D. Cal. March 18, 2022).

51. Contract claims may also fail because of privity requirements or allowable disclaimers. *See, e.g.*, *In re* Allergan Biocell Textured Breast Implant Prods. Liab. Litig., 537 F. Supp. 3d 679, 742 (D.N.J. 2021) (vertical privity required under Arizona law "for asserting UCC-based express warranty claims").

52. United States v. Caronia, 703 F.3d 149, 160, 168–69 (2d Cir. 2012).

53. United States v. Facteau, 89 F.4th 1, 22–24 (1st Cir. 2023) (holding a jury can consider off-label speech in misbranding prosecution). For analysis of cases post-*Caronia*, see Liu et al., *supra* note 38, at 491.

54. Bexis, *How the First Amendment Affects Tort Law*, DRUG & DEVICE L. (Dec. 14, 2012), https://www.druganddevicelawblog.com/2012/12/how-first-amendment-affects-tort-law [https://perma.cc/XA9U-9RKZ].

55. *See* Simon, *supra* note 17, at 1098–1100.

has been shifting toward both positions (protected speech and preemption) over the past thirty years.[56]

Private claims are also typically limited to cases of significant harm, such as permanent paralysis or death. It is far more difficult to bring claims for side effects that are unpleasant and significant, but neither life-threatening nor completely disabling.[57] Private lawsuits for defective products, like those that sound in tort and contract claims, are unlikely to address these harms because they have low value and face significant legal obstacles.

Public lawsuits can play a role in preventing such harms, but they are not primarily directed toward them. The FCA, for example, applies broadly but is designed to police financial harms, not physical ones. Without a federal statute like the Fair and Accurate Credit Transactions Act ("FACTA")—which enables aggregation of millions of small "privacy"-type claims by providing statutory damages—small individual claims that don't fall within the scope of either FCA or FDCA enforcement will go uncompensated and under-deterred.[58]

In summary, the primary challenges for claims based on off-label promotion are resource allocation (especially for public claims); limitations of existing federal law (divergent purposes); low-value claims; and constitutional obstacles (the First Amendment and preemption).

II. THE CASE FOR OFF-LABEL INDUCEMENT

This Part makes the case for off-label inducement. Section II.A briefly introduces the off-label inducement theory and highlights its benefits, including how it fills some liability gaps in current law. Section II.B moves to substantive law, explaining the inducement theory of liability in tort law and how it could apply to drug and device manufacturers. Section II.C describes why and how courts have adapted the doctrine of inducement in copyright and patent law.

---

56. On the First Amendment, see, e.g., *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 557, 579–80 (2011). On preemption, see *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 486–91 (1996); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008); *Wyeth v. Levine*, 555 U.S. 555, 558–59 (2009); *Pliva, Inc. v. Mensing*, 564 U.S. 604, 609 (2011); *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 475–76 (2013); *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672 (2019); Simon, *supra* note 17, at 1098–1100; and David A. Simon, Carmel Shachar & I. Glenn Cohen, *Innovating Preemption or Preempting Innovation?*, 119 NW. U. L. REV. ONLINE 137, 142–46 (2024).

57. Public rights of action, like those under the FCA may be better equipped to address these harms, albeit indirectly, for a somewhat ironic reason: They are not focused on monetary, rather than physical, injury.

58. Fair and Accurate Credit Transactions Act of 2003, 15 U.S.C. §§ 1681–1681x. This avenue may not be available much longer, as the Supreme Court has reinterpreted standing doctrine, and some courts have applied it to preclude some of these claims. TransUnion LLC v. Ramirez, 141 S. Ct. 2190, 2205–07 (2021); Spokeo, Inc. v. Robins, 578 U.S. 330, 338–43 (2016); *see, e.g.*, Thomas v. TOMS King (Ohio), LLC, 997 F.3d 629, 640–43 (6th Cir. 2021) (dismissing lawsuit on the grounds that consumer failed to allege harm sufficient to satisfy the Article III standing requirement where the merchant violated FACTA by including ten digits of the consumer credit card number on the receipt).

Section II.D demonstrates that stitching the lessons of inducement in intellectual property to tort law can fortify a new theory of liability against drug and device manufacturers that promote unsafe off-label uses. Finally, Section II.E previews how three formulations of off-label inducement could work by applying it to a recent case.

A. OFF-LABEL INDUCEMENT AND ITS BENEFITS

This Article proposes to address these challenges by supplementing private enforcement of off-label promotion using a new theory of liability in tort law: off-label inducement.[59] Under this theory, a manufacturer is liable when its promotional activities induce a provider to negligently prescribe, administer, or use a drug or device off-label.

This approach has several benefits. First, by leveraging private litigants to enforce claims against drug and device manufacturers, this theory enables those with the best information about the effects of a drug or device (patients) to bring claims when they are injured by negligent off-label prescribing. It does this, unlike in FCA lawsuits, by identifying off-label promotion that injures physically (the patients) rather than financially (the government). And because there are likely to be far more people injured by off-label promotion than whistleblowers willing to talk about it, the theory provides a relatively large pool of potential claimants from which to glean information.

Second, the theory reduces the information asymmetry between physicians and manufacturers concerning off-label uses. Manufacturers know more than physicians about the risks and benefits of the off-label uses they promote. Imposing liability for inducing negligent off-label use incentivizes manufacturers to provide better-quality information to physicians. And, properly conceived, it incentivizes physicians to obtain more information from manufacturers.[60] Not only does this work to reduce the market failure, it does so under a traditional tort justification by imposing obligations on the cheapest cost avoider—the manufacturer.[61]

---

59. Although fraudulent inducement is already a cause of action in tort, it poses several problems for litigants. *See infra* Section III.C.3.

60. One may argue that it negatively affects providers' incentives to investigate the risks associated with the use. But this misunderstands the nature of the cause of action. For one thing, it is unclear why making the manufacturer liable would worsen existing incentives to investigate risks. In other words, if providers are already relying on manufacturers for risk information, then inducement will improve the type and quality of information manufacturers provide to providers. And, as I argue in Section II.E.2, this will be doubly true if the physician can be negligent for failing to make inquiries of the manufacturer after receiving information from it. A duty of this kind should influence providers to engage in better information-gathering practices. *See infra* Section II.E. At its best, the process should produce a virtuous circle where the liability of both parties incentivizes them to share as much information as possible.

61. GUIDO CALABRESI, THE COST OF ACCIDENTS: A LEGAL AND ECONOMIC ANALYSIS 39–41 (1970). Although off-label inducement may be conceived of as an intentional rather than accidental tort, the cost-avoider analysis still holds.

Third, because many side effects from drugs that harm patients may be of small litigation value, this approach offers a way to monetize claims through class actions and multidistrict litigations ("MDLs") that currently fall outside the scope of most federal enforcement mechanisms. It does this, too, without duplicating FCA actions. While FCA claims and off-label inducement claims may overlap, inducement claims are focused on the behavior of providers and harm to patients. This differentiates them from FCA claims that focus mainly on the behavior of the pharmaceutical company and the financial harm to the government.

Fourth, this approach can avoid two constitutional doctrines that plague the traditional private law causes of action: preemption and the First Amendment. The inducement theory avoids preemption precisely because, unlike traditional tort claims against drug and device manufacturers, it is premised on malpractice and not products liability.[62] And because the conduct promoted by the speech in question constitutes negligence, it is not vulnerable to the same First Amendment attacks that shield manufacturers in off-label promotion cases under either public or private law. Put differently, manufacturers are liable for *the provider's negligence* and not for simply failing to disclose risk information. In fact, because the underlying behavior is negligent, the information provided will not adequately warn of the risk posed by the promoted use of the drug precisely because it should be avoided.[63]

Finally, this theory is consistent with two additional important tort law principles. One is that the innocent injured party (the patient) should not bear the loss caused by the tortious conduct of another (the manufacturer).[64] The other is that individuals wronged by drug and device manufacturers have civil recourse against the wrongdoer.[65]

B. INDUCEMENT IN TORT

This Section explains how inducement currently works in tort law and how it could be extended to drug and device manufacturers that promote off-label uses, creating a new tort: off-label inducement. Inducement stands in contrast to classic tort causes of action, which involve one person directly causing harm to another—for instance, when X fails to stop at a red light and crashes into Y's car. Sometimes, however, the person who is ultimately responsible for a tort is not the person who directly causes it. Under various theories of "secondary" liability, tort law will sometimes hold persons responsible for torts committed by another.

62. *See infra* Section II.B.

63. *See infra* Section III.C.2.

64. *E.g.*, Sepega v. DeLaura, 167 A.3d 916, 920, 932 (Conn. 2017).

65. *E.g.*, JOHN C.P. GOLDBERG & BENJAMIN C. ZIPURSKY, RECOGNIZING WRONGS 25–30 (2020).

Vicarious liability, for example, imputes the actions of the individual committing the tort to another[66] in specific circumstances, such as where a special relationship exists between the tortfeasor and the third party.[67] One well-known example is the doctrine of *respondeat superior*, under which employers are vicariously liable for the torts of their employees committed during the scope of employment or with the employer's chattel.[68] Hospitals, therefore, are liable for the injuries caused by an internist employed by the hospital who commits negligence while treating patients as part of her rounds.[69] In other words, the fact that X has committed a tort is a necessary condition for holding Y liable for it—and Y is liable for X's tort, not her own conduct as such.

This Article is concerned with another situation that can generate secondary liability[70]: when an actor *induces* another to commit a tort. Inducement holds an actor, A, liable for the tortious conduct of another, Y, when X intentionally[71] or sometimes negligently[72] encourages or facilitates Y's culpable conduct.[73]

---

66. RESTATEMENT (THIRD) OF TORTS: APPORTIONMENT OF LIAB. § 13 cmt. c (AM. L. INST. 2020) ("The vicariously liable party has not committed any breach of duty to the plaintiff but is held liable simply as a matter of legal imputation of responsibility for another's tortious acts.").

67. RESTATEMENT (SECOND) OF TORTS § 876(c) (AM. L. INST. 1979).

68. *See* RESTATEMENT (SECOND) OF TORTS § 317 (AM. L. INST. 1965). There is another related form of liability, enterprise liability, which holds liable affiliated or similarly-owned companies based on a common agreement or understanding and action in furtherance of it. *See* OLA, LLC v. Builder Homesite, Inc., 661 F. Supp. 2d 668, 672 (E.D. Tex. 2009) (quoting RESTATEMENT (SECOND) OF TORTS § 491 cmt. c (AM. L. INST. 1965)). Neither of these theories is directly relevant to this Article.

69. Strictly speaking, hospitals are not liable for the torts of physicians who are independent contractors. Hospitals may be liable, however, for negligently hiring a physician (even an independent contractor) who is not "competent and careful." RESTATEMENT (SECOND) OF TORTS § 411 (AM. L. INST. 1965). It may also be liable for negligent credentialing. *See* Larson v. Wasemiller, 738 N.W.2d 300, 306 (Minn. 2007) ("At least 27 states recognize the tort of negligent credentialing . . . .").

70. Although vicarious liability is a strict liability tort, not all secondary liability is strict. The employer is strictly liable for the acts of its employees. Secondary liability, however, requires an additional action by the tortfeasor, such as encouraging the underlying tort. A different proposal might be to hold manufacturers vicariously liable for physician negligence. While not impossible, the challenge for this approach is to find something analogous to a "special relationship" that would justify imputing physician negligence liability to manufacturers.

71. Here "intent" means simply that one act with the purpose of causing some result or knowing that a result is substantially certain to follow. But, as discussed below, intent required for inducement tends to be more flexible and capacious than the traditional conceptions of intent required for most intentional torts.

72. Although this theory can sound in negligence, inducement generally requires intentional, rather than unintentional conduct, because the alleged tortfeasor must intend that a third party commit a tort. *But see, e.g.*, Ladner v. AmSouth Bank, 32 So. 3d 99, 101, 105 (Fla. Dist. Ct. App. 2009) (homeowners successfully asserted a claim based on lender's negligent recommendation of builder).

73. RESTATEMENT (SECOND) OF TORTS § 876(b) (AM. L. INST. 1979). There is at least one other theory that directly implicates inducement—and that is where X induces Y to commit a tort by action α with actual or constructive knowledge that, had X performed α, X would be liable in

This general test has been restated to hold X liable for Y's tort when X: (1) knows that Y's conduct is a tort; and (2) provides "substantial assistance or encouragement" for Y's conduct.[74] Inducement holds responsible an actor who played a substantial role in causing the tortious conduct but who themselves did not commit the actual tort.[75]

While the inducer's knowledge of the tort must be actual, circumstantial evidence is sufficient to prove its existence.[76] And sometimes the category of probative circumstantial evidence can be quite inclusive. For example, in certain cases, courts hold that "evidence of a 'general awareness of a role in an improper activity' will satisfy" the knowledge requirement.[77] Other states may require a more demanding test to prove knowledge.[78] In any case, knowledge does not require agreement by the parties to the tort.[79] Nor does it require either that the inducer's actions be independently tortious (i.e., breach some independent duty)[80] or that the inducer knows "whether the tort was accomplished."[81]

---

tort. *See id.* § 877 ("For harm resulting to a third person from the tortious conduct of another, one is subject to liability if he (a) orders or *induces* the conduct, if he knows or should know of circumstances that would make the conduct tortious if it were his own . . . ." (emphasis added)); *see also* RESTATEMENT (SECOND) OF AGENCY § 212 cmt. a (AM. L. INST. 1958) (noting the rule of intending another to violate a duty is not specific to agency "but results from the general rule . . . that one causing and intending an act or result is as responsible as if he had personally performed the act or produced the result" (quoting RESTATEMENT (SECOND) OF TORTS §§ 870, 876, 877 (AM. L. INST. 1979))).

74. RESTATEMENT (SECOND) OF TORTS § 876(b) (AM. L. INST. 1979); Taylor v. Am. Chemistry Council, 576 F.3d 16, 35 (1st Cir. 2009). A similar theory is found in the subsequent section of the Restatement. *See* RESTATEMENT (SECOND) OF TORTS § 877(a) (AM. L. INST. 1979).

75. This cause of action does not require the inducer to breach some other legal duty; the inducer is responsible for the underlying conduct because she encouraged it. *Compare* RESTATEMENT (SECOND) OF TORTS § 876(a), (c) (AM. L. INST. 1979) (committing a tortious act with a third person or helping a third person commit a tortious act while breaching a duty to the third person), *with id.* § 876(b) & cmt. d (encouraging a third person to commit a tortious act). Inducement also should be distinguished from fraudulent inducement or misrepresentation, where the tortfeasor induces another to reasonably rely on a fraudulent statement or misrepresentation. *See infra* Section II.E.2.

76. Aetna Cas. & Sur. Co. v. Leahey Constr. Co., 219 F.3d 519, 539 (6th Cir. 2000).

77. *Id.* at 533 (citing Temporomandibular Joint (TMJ) Implant Recipients v. Dow Chem. Co., 113 F.3d 1484, 1495 (8th Cir. 1997)) (deciding the question on an aiding and abetting theory derived from the RESTATEMENT (SECOND) TORTS § 876(b) (AM. L. INST. 1979)). In IP inducement, by contrast, the Supreme Court has described intent in narrower terms. *See infra* Section II.C.1.

78. *Taylor*, 576 F.3d at 35 ("Unlawful intent comprises two distinct mental states: knowledge that the other's conduct is tortious, and an intent to substantially assist or encourage that conduct."). In Massachusetts, this means that the third party must have the identical intent of the tortfeasor, which poses particular problems for fraud cases. *See id.* at 35 n.21.

79. *E.g.*, *id.*

80. *Compare* RESTATEMENT (SECOND) OF TORTS § 876(b) (AM. L. INST. 1979) (not requiring breach of duty), *with id.* § 876(c) (requiring breach of duty).

81. *Taylor*, 576 F.3d at 37 (though refusing to recognize it under Massachusetts law because it had not been squarely addressed by the state's courts and the argument was not made on appeal).

The other prong of the test, substantial assistance or encouragement, can be advisory or physical. But to qualify as substantial it must not be "slight," such as merely communicating a message as directed by another.[82] Some courts interpret knowledge and substantial assistance as coupled and positively correlated: More knowledge indicates more assistance, while less knowledge indicates less assistance.[83] Courts evaluating this question typically adopt the Restatement's factor-based test, which considers "the nature of the act encouraged, the amount of assistance given by the defendant, his presence or absence at the time of the tort, his relation to the other and his state of mind."[84] Yet even with knowledge and support, X will not be liable for an unforeseeable tort that accompanies a foreseeable one.[85]

This Article argues that the inducement theory should apply to manufacturers' intentional (or negligent) promotion of unsafe off-label uses of drugs and devices that cause physicians to negligently prescribe, administer, or use them for the promoted uses. While "the decision to use [a drug or device off-label] . . . is a medical decision to be made by a patient's [provider] in the best interests of his or her patient,"[86] drug and device manufacturers can substantially influence that decision.[87] And if the underlying decision is malpractice and the drug or device manufacturer induced it, then the drug manufacturer should be responsible for the harms that result. By making the inducer liable for the tortfeasor's conduct, tort law deters conduct that

82. RESTATEMENT (SECOND) OF TORTS § 876 cmt. d, illus. 9 (AM. L. INST. 1979) .

83. Temporomandibular Joint (TMJ) Implants Recipients v. Dow Chem. Co., 113 F.3d 1484, 1495 (8th Cir. 1997).

84. RESTATEMENT (SECOND) OF TORTS § 876 cmt. d (AM. L. INST. 1979).

85. *Id.*

86. Hanohano v. Uppal, No. 257344, 278750, 1997 WL 33426414, at *2 (Cal. Super. Ct. June 3, 1997).

87. *E.g.*, Leila Agha & Dan Zeltzer, *Drug Diffusion Through Peer Networks: The Influence of Industry Payments*, 14 AM. ECON. J., May 2022, at 1, 1–2; Colleen Carey, Ethan M.J. Lieber & Sarah Miller, *Drug Firms' Payments and Physicians' Prescribing Behavior in Medicare Part D*, J. PUB. ECON., Apr. 2021, at 1, 2; Matthew Grennan, Kyle Myers, Ashley Swanson & Aaron Chatterji, Physician-Industry Interactions: Persuasion and Welfare 3–6 (Mar. 12, 2020) (unpublished manuscript) (on file with the *Iowa Law Review*); Adriane Fugh-Berman & Shahram Ahari, *Following the Script: How Drug Reps Make Friends and Influence Doctors*, 4 PLOS MED. 0621, 0622–23 (2007) (discussing the techniques used by pharmaceutical drug reps to influence physicians); Puneet Manchanda & Pradeep K. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 MKTG. LETTERS 129, 131 (2004); *see also* Guy David, Sara Markowitz & Seth Richards-Shubik, *The Effects of Pharmaceutical Marketing and Promotion on Adverse Drug Events and Regulation*, 2 AM. ECON. J., Nov. 2010, at 1, 20–22 (finding that "direct-to-consumer advertising and promotion increase the rate of reported adverse drug reations for certain conditions"). *But see* Anusua Datta & Dhaval Dave, *Effects of Physician-Directed Pharmaceutical Promotion on Prescription Behaviors: Longitudinal Evidence*, 26 HEALTH ECON. 450, 465–66 (2017) (finding effects but explaining that providers most affected already are biased toward prescribing). There is less research examining detailing's effect on off-label prescribing. *See, e.g.*, Bradley T. Shapiro, *Informational Shocks, Off-Label Prescribing, and the Effects of Physician Detailing*, 64 MGMT. SCI. 5925, 5927 (2018).

promotes tortious acts. Critically, however, the inducer is liable for the underlying tortfeasor's act and not for the inducer's actions as such. Thus, although malpractice and products liability are often treated as separate, there are good reasons to join them using inducement.

Under this framework, a drug manufacturer is liable for a provider's off-label use only if the following elements are met:

(1) a manufacturer promotes an off-label use that, if prescribed, used, or administered by a provider, would constitute negligence;

(2) a manufacturer has (or should have[88]) knowledge that the promoted use would constitute negligence if prescribed, used, or administered by a provider;

(3) a manufacturer's promotional activities facilitated or encouraged a physician to use a drug or device off-label as promoted;

(4) the activities in (3) cause a provider to whom the off-label use was promoted to prescribe, administer, or use the drug or device for the use promoted;[89]

(5) by doing (4), the provider is negligent;[90] and

(6) the off-label use by the provider injures a patient.

This theory has several variants, which are explored in Section II.E. For now, however, consider that element (2) allows inducement claims to proceed on a negligence theory in addition to an intentional tort theory. Negligence would not require that the plaintiff show that the manufacturer *actually* knew that the promoted use was malpractice; instead, the plaintiff would need to prove that the manufacturer failed to exercise reasonable care in promoting the use.[91] That is, it was foreseeable that the manufacturer's promotion would lead to the negligent conduct that caused harm, regardless of the manufacturer's intent.

---

88. Constructive knowledge signifies a negligence standard. This standard is explored more in this Section and in Parts II and III.

89. Whitener v. PLIVA, Inc., 606 F. App'x 762, 766 (5th Cir. 2015).

90. In general, the tortfeasor doesn't have to *know his actions are negligent* for the inducer to be liable. Acting on information provided by the inducer is a textbook example. Thus, a physician who is negligent in providing care doesn't need to know that the conduct itself is negligent if the manufacturer supplied the information that induced the conduct. Lack of knowledge can, but need not, result from fraud or negligence. RESTATEMENT (SECOND) OF TORTS § 876 cmt. d, illus. 7–8 (AM. L. INST. 1979). When a physician's negligence results from lack of knowledge as a result of fraud, the claim is for *fraudulent* inducement. Since those claims are covered by existing fraud, I do not discuss them further. I focus only on cases where the physician was negligent, though as I discuss in Section II.E, there are at least two applicable theories of negligence.

91. To be clear, this would represent a new form of inducement in tort. Inducement in IP does not incorporate a negligence standard.

But most tort cases, and especially the ones discussed in the next Section, require intent. Courts are, therefore, more likely to adopt this standard.[92] The standard of proof here is higher because, under element (2), the plaintiff would have to show that the manufacturer actually knew that the suggested use was malpractice, even if it did not know whether the provider would actually prescribe the drug. While this will not be simple, the requirement is blunted somewhat by the law's capacious understanding of "knowledge," which courts ought to embrace. The plaintiff would also need to show under element (3) that the manufacturer's promotional activities constituted substantial assistance or encouragement. Many promotional activities—such as sales reps suggesting or recommending the off-label use to the physician—would satisfy this standard. But each case would depend on the facts and circumstances surrounding the promotional activities. And if courts use the sliding scale described above, then the more likely the manufacturer knew the use was malpractice, the less encouragement would be required—and vice versa. Importantly, however, what matters is whether, given the information available to the manufacturer, it knew the promoted use was malpractice.[93]

Because this theory makes the inducer liable for the underlying malpractice, the plaintiff must show under element (5) that a provider failed to exercise reasonable care in prescribing, using, or administering a drug or device off-label. This responsibility to act reasonably with respect to off-label uses entails at least two duties. One is a duty of *knowledge*. Under general negligence law, the provider has a duty to be "well-informed about the drug or device" for the relevant off-label use.[94] Because, by definition, the use does not appear on the approved drug or device labeling, the provider has an affirmative duty to identify the evidence supporting the use.[95] Liability attaches here when the provider's breach of this duty[96] results in an off-label use that causes harm to

92. The likelihood that courts will accept an inducement claim with an intent standard says nothing about the potential *merits* of a negligence standard. *But see, e.g.*, El Camino Res., Ltd. v. Huntington Nat'l Bank, 722 F.Supp.2d 875, 906 (W.D. Mich. 2010), *aff'd*, 712 F.3d 917 (6th Cir. 2013).

93. For further discussion, see *infra* Part III.

94. Richardson v. Miller, 44 S.W.3d 1, 15 (Tenn. Ct. App. 2000); Worrix v. Medtronic, Inc., No. 13-111, 2013 WL 6834719, at *3–4 (E.D. Ky. Dec. 23, 2013).

95. *Richardson*, 44 S.W.3d at 15.

96. Huss v. Gayden, 571 F.3d 442, 457–58 (5th Cir. 2009) (ordering a new trial on various grounds, including improper exclusion of defendant's expert witness and lack of causation, where the jury found a physician negligent in prescribing a drug off-label that caused cardiomyopathy). Whether the labeling itself constitutes evidence of the standard of care is a separate question. Typically, the labeling is relevant, and most courts will admit it into evidence if accompanied by expert testimony about the standard of care. A smaller number of courts, however, take a burden-shifting approach. Here, a drug label constitutes prima facie evidence of the standard of care, which the defendant can rebut with expert testimony. Arguments over labeling, therefore, will likely reflect the same dynamic as the standard of care generally, with dueling experts reaching opposite conclusions. Thus, while on this latter view, a provider who prescribes off-label

the patient.[97] In Section II.E, I explain two different methods of conceptualizing what this duty entails. To preview, I argue it should entail a duty to ask questions and obtain additional information from the manufacturer about the promoted use. Thus, the duty to know is divisible: It includes a duty to learn from publicly available information *and* a duty to ask for information from a manufacturer who promotes off-label uses.

The second is a duty of *communication*. Under the doctrine of informed consent, the provider treating a patient also has the duty to disclose risks presented by the off-label use that are either (1) customarily disclosed by physicians,[98] or (2) material. Most courts adhere to the latter rule and define material risks as those that affect a reasonable patient's decision to consent.[99] Of the states that follow the materiality standard, most have codified it to include a requirement to provide information about available alternative courses of treatment.[100]

What would influence a reasonable patient's decision to consent is fact-dependent and, hence, a jury question. But most courts take the view that a provider's decision to use a drug or device off-label is not, by itself, material[101]—though the *risks* presented by off-label use may be.[102] This means that physicians generally do not have a duty to disclose the *fact* of off-label use, but they generally do have a duty to inform patients about the *material risks* of the off-label use.[103] Other potentially relevant factors to determine whether a risk is material include the probability of the event in question,[104] the magnitude of the potential harm, and the personal preferences and circumstances of the patient. A physician, therefore, may have perfect knowledge of the promoted use but fail to inform the patient of the use's risks.

Inducement in this context would require showing that the manufacturer caused the physician's failure to disclose risks. Importantly, the claim here is *not* that the manufacturer failed to disclose the risks to the physician, but

---

presumptively breaches her duty, the breach is likely to be resolved by the jury through expert testimony in practice.

97. Some off-label risks appear on the labeling. Simon, *supra* note 17, at 1090–91. But even when they do, they may not reflect the position FDA desires. *Id.*

98. *E.g.*, Roberts v. Young, 119 N.W.2d 627, 630 (Mich. 1963).

99. Shannon v. Fusco, 89 A.3d 1156, 1170 (Md. 2014).

100. Beck & Azari, *supra* note 17, at 88–89.

101. Southard v. Temple Univ. Hosp., 781 A.2d 101, 108–09 (Pa. 2001). To be precise, *Southard* held that, as a matter of law, failure to inform a patient of the FDA regulatory classification did not constitute a breach of informed consent. *Id.*

102. *See* Klein v. Biscup, 673 N.E.2d 225, 231 (Ohio Ct. App. 1996).

103. A central problem here is to what extent should evidence factor into off-label use. At least one court suggested that FDA opinions matter. D.J.C. v. Staten Island Univ. Hosp.-Northwell Health, 157 N.Y.S.3d 667, 673 (Sup. Ct. 2021).

104. Blazoski v. Cook, 787 A.2d 910, 917 (N.J. Super. Ct. App. Div. 2002) ("The medical probability of the risk manifesting in the patient is highly relevant to whether a reasonably prudent patient would consider the risk material or not." (quoting Canesi v. Wilson, 730 A.2d 805, 816 n.5 (N.J. 1999))).

rather that it promoted the use in a way that would *induce the physician to fail to disclose the risks.*[105] Put differently, the physician is liable for failing to disclose the relevant risk and the manufacturer is secondarily liable for causing the physician's failure. Evidence of inducement would focus on the *method and content* of the information provided by the manufacturer to the physician, as well as the information and the method and content by which it is conveyed to the patient.

Under an inducement theory, then, the plaintiff must, as a threshold matter, show that the provider caused injury by breaching the duty of knowledge, the duty to ask, *or* the duty of communication. Although provider malpractice—failure to understand, ask about, or communicate the off-label risks—is a necessary condition for a successful lawsuit, it is not a sufficient one. In other words, a provider must negligently prescribe, use, or administer drugs or devices off-label for the manufacturer to be liable, but the manufacturer will not be liable simply because a provider was negligent. One needs to show that the manufacturer was, in some sense, responsible for the provider's malpractice by encouraging or facilitating it with knowledge of its tortious character. In other words, a key element of the claim is that the manufacturer's action induces the provider to negligently prescribe a drug or device.

To illustrate, suppose a manufacturer of Botox promoted it to a physician off-label for use above the maximum labeled dose, a physician used it as promoted, and injured a patient as a result.[106] If there is publicly available research demonstrating these risks associated with using Botox in high doses, and the physician did not read them and used the drug as promoted, she may be negligent.[107] If there exists no publicly available information about the off-label risks, the physician may still be negligent if she failed to ask the manufacturer about them. The manufacturer is liable for inducing the physician

105. This distinguishes it from a standard failure to warn claim, which requires product manufacturers to inform consumers of the risks posed by the intended use of their product. In states with the learned intermediary doctrine, a drug or device manufacturer can discharge its duty to warn the consumer (patient) by warning the physician. *See* David A. Simon & Aaron S. Kesselheim, *Physician and Device Manufacturer Tort Liability for Remote Patient Monitoring Devices*, *in* DIGITAL HEALTH CARE OUTSIDE OF TRADITIONAL CLINICAL SETTINGS 109, 114–15 (I. Glenn Cohen, Daniel B. Kramer, Julia Adler-Milstein & Carmel Shachar eds., 2024).

106. The facts are modified from *Drake v. Allergan, Inc.*, 63 F. Supp. 3d 382 (D. Vt. 2014). Examples like *Drake* are not perfect for a number of reasons. For one thing, the inducement cause of action is not alleged, making application to existing cases difficult because frequently many of the relevant facts are not reported. For another, cases frequently lack features that might be present if an inducement theory had been available, such as the conduct of the prescribing physician. *E.g.*, Markland v. Insys Therapeutics, Inc., 270 F. Supp. 3d 1318, 1330 (M.D. Fla. 2017), *aff'd*, 758 F. App'x 777 (11th Cir. 2018) (holding as preempted a claim of "negligent marketing" of short-term pain medication for off-label treatment of chronic pain). Finally, some factual situations, like that in *Drake*, enable plaintiffs to survive a motion for summary judgment on traditional theories like failure to warn. But in many other cases, the issue of liability is not reached because plaintiffs' claims are dismissed on other grounds, such as preemption. *See id.*

107. She will be negligent only if the use is unreasonable.

to use Botox negligently by promoting it to the physician directly, through office visits, promotional material, and other enticements like consulting and trips, with knowledge that it is unsafe.

Finally, the physician may be negligent if she had knowledge of the risks associated with using Botox above the maximum dose but failed to disclose them to the patient. The manufacturer induces the physician to fail to disclose risks when they downplay or overshadow the risks in their promotional activities. This could occur, for instance, if the manufacturer discloses the risks in voluminous literature but in other promotional activities excludes, downplays, or overshadows them. Providing material benefits to physicians, such as trips or consulting fees is also likely to influence how the physician will comprehend and convey the risks to patients. To emphasize, this is not the claim that the manufacturer failed to disclose the risks to the physician; rather, it is the claim that the manufacturer disclosed the risks in a way that induced physicians not to disclose them.[108]

C. INDUCEMENT IN IP

Although the application of inducement to off-label promotion is straightforward, it has never been litigated.[109] Manufacturers are likely to argue that the law shouldn't be stretched to cover this new situation because inducement in tort is a narrow doctrine where "the leading cases applying [it] are statutory securities cases, with the common-law precedents 'largely confined to isolated acts of adolescents in rural society.'"[110] For example, tort inducement cases are often referred to as "civil aiding and abetting" and can involve questions about whether an alleged bank knew, for example, of its customer's fraudulent activities.[111] Manufacturers are likely to argue promotional activities are not analogous to civil aiding and abetting and, therefore, the doctrine should not cover manufacturer off-label promotion.[112]

To show why this argument is wrong, this Section uses the application of inducement in copyright and patent law to make three points. First, both legal

---

108. For a further discussion, see *infra* Sections II.B, III.C.2.

109. A similar line of reasoning can be found in overpromotion cases. *E.g.*, Stevens v. Parke, Davis & Co., 507 P.2d 653, 663 (Cal. 1973) (noting a genuine issue of material fact existed in part because "plaintiff introduced expert testimony by a physician that the advertising and promotion of the drug 'played a role' in inducing physicians to prescribe it when it was not sound practice to do so"). And sometimes straight product liability and tort claims based on off-label promotion may survive summary judgment. *E.g.*, *Drake*, 63 F. Supp. 3d at 394.

110. El Camino Res., Ltd. v. Huntington Nat'l Bank, 722 F. Supp. 2d 875, 902 (W.D. Mich. 2010), *aff'd*, 712 F.3d 917 (6th Cir. 2013) (quoting Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A., 511 U.S. 164, 181 (1994)).

111. *Id.* at 908. Some states may not have such causes of action. *E.g.*, Zafarana v. Pfizer, Inc., 724 F. Supp. 2d 545, 559 (E.D. Pa. 2010) (discussing New Jersey law).

112. Or they may argue that these are really conspiracy claims, which should be dismissed. *E.g.*, *Zafarana*, 724 F. Supp. 2d at 559 (dismissing conspiracy claim for lack of underlying cause of action).

regimes have adapted inducement to address new social problems, such as peer-to-peer file sharing and drug advertising. Second, many of the same reasons that led copyright and patent to develop an inducement jurisprudence in the contexts of peer-to-peer file sharing and drug advertising apply equally to the off-label promotion context. Third, the type of action that constitutes "inducement" is quite broad and can include truthful statements and promotional activities, making its application to off-label promotion consistent with legal doctrine.

1. Inducement in Copyright

Copyright law provides limited rights to "authors" of "writings"[113] that constitute "original works of authorship fixed in any tangible medium of expression,"[114] such as sound recordings, musical compositions, and movies (audiovisual works).[115] Authors have exclusive rights to copy, display, reproduce, and perform the protected work. Copyright infringement is frequently described as a strict liability tort—violating one of these exclusive rights infringes them, regardless of the actor's fault—though it can also be described, at least in some cases, as fault-based.[116]

Like in tort, in copyright one can be secondarily liable for another's tortious conduct. Inducement received renewed attention in the early 2000s when novel technologies allowed users to share digital copies of songs using an internet connection and computer software like Napster, Limewire, and Gnutella. With millions of individuals sharing, copying, and downloading copyrighted songs and movies,[117] the recording industry immediately identified copyright infringement as an existential threat to its booming business selling compact discs and digital video discs.[118]

Although the recording industry filed individual lawsuits against individual infringers, the strategy proved costly and a public relations nightmare. Attempts to deter infringement backfired, with publicity around sympathetic defendants

113. U.S. CONST. art. I, § 8, cl. 8.

114. 17 U.S.C. § 102(a).

115. *Id.*

116. For an argument that the tort is actually not strict liability, see Patrick R. Goold, *Is Copyright Infringement a Strict Liability Tort?*, 30 BERKELEY TECH. L.J. 305, 338 (2015). Jules Coleman made this point about tort generally. *See* JULES L. COLEMAN, RISKS AND WRONGS 212–24 (Oxford Univ. Press 2002) (1992).

117. Users were also sharing other works that may not have been copyright infringement.

118. *See* Don Clark, *Recording Industry Group Sues Napster, Alleging Copyright Infringement on Net*, WALL ST. J. (Dec. 9, 1999, 12:01 AM), https://www.wsj.com/articles/SB944711263509285168 (on file with the *Iowa Law Review*).

that included a twelve-year-old girl,[119] a sixty-six-year-old grandmother,[120] and an eighty-three-year-old great-grandmother who died by the time the suit was filed.[121] Without a strong deterrent effect, the recording industry would have to pursue individual lawsuits against millions of individual defendants, which was cost-prohibitive.

The recording industry responded by adopting a new legal strategy: sue the software companies that produced and distributed the product used by consumers to infringe. Relying on an inducement theory of secondary liability,[122] it argued that the software companies had encouraged infringement with knowledge that the conduct was infringing. Although IP had long incorporated the tort principle of secondary liability, it had not yet been applied in this context.

In 2005, the Supreme Court held in *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, that software producers could be held liable for inducing infringement by users of its software.[123] A successful inducement claim, according to the Supreme Court, required a plaintiff to show that: (1) the defendant intentionally induced or encouraged infringement that; (2) caused; (3) a third party to directly infringe the plaintiff's copyright.[124] At bottom, then, the tort of secondary liability requires the plaintiff to make two showings: that direct infringement occurred (with all that requires),[125] and that the defendant caused this direct infringement by encouraging it.

Direct infringement was not hard to prove in *Grokster*—users were uploading, sharing, and downloading copyrighted works.[126] What the decision hinged on instead was the plaintiff's ability to show that the software companies possessed the necessary intent.[127] In a previous decision involving the video

119. John Borland, *RIAA Settles with 12-Year-Old Girl*, CNET (Sept. 9, 2003, 4:05 PM), https://www.cnet.com/tech/home-entertainment/riaa-settles-with-12-year-old-girl [https://perma.cc/9BXK-QHWQ].

120. *Grandmother Piracy Lawsuit Dropped*, BBC NEWS (Sept. 25, 2003, 4:07 PM), http://news.bbc.co.uk/2/hi/entertainment/3140160.stm [https://perma.cc/AXL9-2A6F].

121. Nate Mook, *RIAA Sues Deceased Grandmother*, BETANEWS (Feb. 4, 2025), https://betanews.com/2005/02/04/riaa-sues-deceased-grandmother [https://perma.cc/2SEM-JYVP].

122. Although there were two theories at issue, this Article focuses on only one.

123. Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd., 545 U.S. 913, 941 (2005). The Supreme Court has recognized both contributory and vicarious liability. Grokster described the inducement theory as a subset of the contributory liability theory. *Id.* at 930. But there is also the "material contribution" theory of infringement. Hunter Killer Prods., Inc. v. AKA Wireless, Inc., No. 19-00323, 2020 WL 4043317, at *5–6 (D. Haw. July 17, 2020). The theory of vicarious infringement is not pursued here because it is inapt: It requires a right and ability to control the conduct of infringing users. *Grokster*, 545 U.S. at 930; *see* Perfect 10, Inc. v. Giganews, Inc., 847 F.3d 657, 673 (9th Cir. 2017).

124. *Grokster*, 545 U.S. at 930–34. Some subsequent courts have read in a fourth element—namely, that (4) the tortfeasor must distribute the product that is used to infringe. *E.g.*, *Perfect 10, Inc.*, 847 F.3d at 672.

125. This requires a valid copyright, ownership, and violation of one of the rights in 17 U.S.C. § 106.

126. *Grokster*, 545 U.S. at 923.

127. *Id.* at 936–37.

cassette recorder ("VCR"), *Sony Corp. of America v. Universal City Studios, Inc.*,[128] the Supreme Court established an important rule that limited secondary infringement: distributing a product that was capable of "substantial noninfringing uses," even ones the distributor knew would occur, did not subject the distributor to liability.[129] But this did not mean courts could "ignore evidence of intent if" it existed.[130] And, traditionally, intent could be inferred from advertising an infringing use or "instructing how to engage" in one.[131] In either case, the intent of a tortfeasor's communication was to encourage users to infringe.

Both distributors in *Grokster* did this through different means. Grokster distributed a newsletter that encouraged downloading copyrighted works; StreamCast advertised its program as a replacement for Napster,[132] which the Court apparently took to mean another infringing file-sharing service. Each acted to encourage others to infringe with the knowledge that the encouraged acts constituted infringement.[133]

A focus on intent is important in IP inducement because it signals culpability: Acting with intent to encourage infringement is blameworthy conduct. Grokster was blameworthy because it was trying to stimulate others to do actions it knew were illegal. Intent also links the culpable action to the underlying tort—the blameworthy action is not the software producer's speech as such, but rather its attempt to encourage others to infringe copyrighted works using its software with the knowledge that the encouraged action is infringement. In other words, while advertising the product for infringing uses is not praiseworthy, what makes the conduct worth punishing is that the underlying tort (here infringement) generates harm.[134]

While the culpability analysis is important for liability to attach, there is another more practical reason for secondary liability to apply to file-sharing software: Suing all direct infringers was unfeasible, but curbing infringement was an important social goal.[135] Inducement, here called contributory liability, enabled the owner of the copyrighted work to sue the person facilitating

128. *See generally* Sony Corp. of Am. v. Universal City Studios, Inc., 464 U.S. 417 (1984).

129. *Id.* at 442; *Grokster*, 545 U.S. at 931–33.

130. *Grokster*, 545 U.S. at 934–35.

131. *Id.* at 936.

132. *Id.* at 938.

133. *Id.* at 939.

134. The harm here may be different.

135. *Grokster*, 545 U.S. at 930–36. Of course, suing *some* direct infringers was possible—the recording industry had been doing it repeatedly to deter individuals from downloading copyrighted works without authorization. But it turned out not to be a particularly effective deterrent, and one that had bad optics. A similar problem exists with new uses of existing drugs. Pharmaceutical companies would have to sue physicians directly for prescribing generic drugs in a manner that infringed new use patents. Simon, *supra* note 9 at 726–33; Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL'Y L. & ETHICS 717, 724 (2005).

infringement, rather than millions of users who infringed. The practicality of this approach also made it more efficient.[136]

2. Inducement in Patent

While copyright provides exclusive rights to the authors of original writings, patent provides exclusive rights to inventors of new, useful, and nonobvious inventions. Inventors who receive a patent grant from the government obtain the exclusive rights to prevent others from making, selling, or using the invention.[137] Because anyone who infringes these rights is liable regardless of fault, patent infringement is a strict liability tort.

Secondary liability can also apply in patent law. Although inducement in patent, unlike copyright, was eventually codified in a federal statute,[138] the general legal test is the same in both domains. The defendant must take action to encourage infringement with knowledge that the encouraged conduct constitutes infringement.[139] Just as in copyright, these two general requirements both ground inducement's culpability and enable it to apply flexibly to new, unanticipated situations.

While the doctrine has been applied in a number of contexts,[140] recent lawsuits involving generic prescription drugs are instructive. Under a federal law enacted in 1984 referred to as "Hatch–Waxman," generic drug manufacturers can quickly enter the market when the patent covering a marketed drug compound expires.[141] Because the brand manufacturer often owns patents covering uses and formulations of the drug in addition to the compound, the generic manufacturer must "carve out" the patented uses from labeling—a practice used to both ensure non-infringement and comply with FDA's requirement that generic and brand labels be identical.[142] For example, assume a manufacturer has obtained an approved drug label with indications for psoriasis (autoimmune disease) and angina

136. William Landes & Douglas Lichtman, *Indirect Liability for Copyright Infringement: Napster and Beyond*, 17 J. ECON. PERSPS. 113, 123 (2003).

137. 35 U.S.C. § 154(a)(1).

138. *Id.* § 271(b); Glob.-Tech Appliances, Inc. v. SEB S.A., 563 U.S. 754, 763–64 (2011) (explaining 1952 codification of common law contributory infringement).

139. GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 7 F.4th 1320, 1327 (Fed. Cir. 2021).

140. *See, e.g.*, *Glob.-Tech Appliances, Inc.*, 563 U.S. at 770 (cool-touch deep fryer design); TecSec, Inc. v. Adobe Inc., 978 F.3d 1278, 1297 (Fed. Cir. 2020) (system for flexibly restricting access to computer data); Berkeley*IEOR v. Teradata Operations, Inc., 719 F.Supp.3d 842, 858–60 (N.D. Ill. 2024) (software tool); *In re* Bill of Lading Transmission & Processing Sys. Pat. Litig., 681 F.3d 1323, 1339–46 (Fed. Cir. 2012) (method of transferring shipping documentation).

141. 21 U.S.C. § 355(j).

142. *Id.*; 21 C.F.R. § 314.93 (2025); *see* U.S. FOOD & DRUG ADMIN., ACCEPTABILITY OF DRAFT LABELING TO SUPPORT ANDA APPROVAL: GUIDANCE FOR INDUSTRY 3 (2015), https://www.fda.gov/files/drugs/published/Acceptability-of-Draft-Labeling-to-Support-Abbreviated-New-Drug-Application-Approval—Guidance-for-Industry.pdf [https://perma.cc/CCL2-4MWW]; *see also* 21 C.F.R. § 314.70 (requiring brand drug manufacturers submit supplements for labeling changes); *id.* § 601.12 (requiring the same for biologics).

(chest pain). Assume also that the manufacturer owns an expired patent covering the drug compound and a current patent covering the method of using the drug to treat angina. If a generic manufacturer receives approval, its label must "carve out" or omit the indication for angina because it is still covered by a patent.

Despite the carve-outs, generic entry can threaten the profits earned from these patented uses because it is difficult for brand name manufacturers to identify and sue the infringers—either the doctors prescribing or the patients using the drugs.[143] Like the copyright holder in *Grokster*, the patentee of a brand name drug finds itself with enforcement problems because there are too many infringers to sue and suing the infringers would be a public relations disaster.[144]

Like courts in the copyright context, courts in the Hatch–Waxman context have used inducement here to help solve the diffuse infringement problem in the same way. By suing the central actor that facilitates patent infringement, rather than the direct infringer, the patentee can efficiently prevent the infringement at scale. Consider *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.* ("*GSK*"),[145] where the generic manufacturer of an off-patent drug compound truthfully advertised its generic drug as AB-rated—or therapeutically equivalent to the brand drug as determined by FDA.[146] The brand name drug manufacturer, which held a patent on several methods of using the drug, alleged that this advertisement induced physicians to infringe these method-of-use patents.[147] It claimed that by advertising the drug as AB-rated, the generic manufacturer encouraged physicians to prescribe drugs for *all uses*, including the patented ones that had been carved out of the label.[148]

The court found that, in advertising the drug as AB-rated, the generic manufacturer knew both that physicians would prescribe the drug for the patented use and that such use infringed the patent.[149] This was true even

143. *See* Eisenberg, *supra* note 135, at 724–25.

144. *Id.*

145. *See generally* GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 7 F.4th 1320 (Fed. Cir. 2021). For a more recent case, see generally *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, 104 F.4th 1370 (Fed. Cir. 2024) (denying a motion to dismiss a complaint where generic manufacturer's public statements referred to drug as "generic equivalent" to brand name).

146. *GlaxoSmithKline LLC*, 7 F.4th at 1324 & n.2. The case is complicated by drug regulation, which allows generic drug manufacturers to enter the market quickly after patent expiration by relying on the brand name manufacturer's data. *See* 21 U.S.C. § 355(j). Approval, however, requires identity between brand and generic labeling. *See supra* note 142 and accompanying text. For the labeling to be nonidentical for a generic, the generic manufacturer must specifically request the change in the Abbreviated New Drug Application, and FDA must approve it. 21 U.S.C. § 355(j); 21 C.F.R. § 314.93(b). When manufacturers "carve out" patented uses on the generic label, their labels lose weight and become "skinny." *See GlaxoSmithKline LLC*, 7 F.4th at 1341 (Prost, J., dissenting); 21 U.S.C. § 355(j)(2)(A)(viii).

147. *GlaxoSmithKline LLC*, 7 F.4th at 1325 (majority opinion).

148. *Id.* at 1323, 1325.

149. *Id.* at 1339.

though the generic manufacturer had "carved out" the potentially infringing use from its label.[150]

GSK reinforces the points made by *Grokster*. For one thing, it shows that inducement can be adapted to help solve practical problems with suing tortfeasors *en masse*. Suing physicians that use a generic drug for a patented use is impractical. It is costly both in monetary and reputational terms, and it is exceedingly difficult to identify infringing physicians.[151] Inducement allows brand name manufacturers to pursue the generic manufacturer encouraging the tortious conduct—which is less costly and more effective than suing individual direct infringers (doctors and patients).

For another, it focuses on the knowledge of the inducer. Here, however, it provides added context by highlighting the effect of the promotional behavior of drug manufacturers. Although the original *GSK* opinion was subsequently withdrawn, both it and the opinion issued after rehearing confirmed that advertising was crucial to the finding of induced infringement.[152] The original opinion found that the generic manufacturer's "intent in issuing a press release telling the world it could use [generic] tablets as a substitute for [the brand's] tablets to treat congestive heart failure was to encourage that [infringing] use."[153] In so doing, it credited the brand's expert, who "testified that the [generic manufacturer's] 2007 press release's use of 'cardiovascular agent' indicated to doctors they could use Teva's carvedilol 'for all indications,' including heart failure."[154]

The focus on truthful advertising and its effects has two important implications for inducement in the off-label promotion context. First, promotional activities can be a legal cause of the underlying tort, even if the promotion is not explicit about what it wants the infringer to do.[155] Second, it highlights that what is problematic is *the underlying behavior* the speech encourages, rather than the speech itself. In *GSK*, the promotion was truthful commercial speech—it accurately described the generic as "therapeutically

150. *Id.* at 1342 (Prost, J., dissenting). If the patented use had been included on the label, then that could be sufficient to find inducement. Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp., 785 F.3d 625, 631 (Fed. Cir. 2015).

151. Benjamin N. Roin, Solving the Problem of New Uses 31 (Oct. 1, 2013) (unpublished manuscript) (on file with the *Iowa Law Review*).

152. The reissued opinion placed more emphasis on the drug's label, which it claimed could induce physicians to infringe a patent if prescribed according to it. *Compare* GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 976 F.3d 1347, 1353 (Fed. Cir. 2020), *with* GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 7 F.4th 1320, 1333 (Fed. Cir. 2021).

153. *GlaxoSmithKline LLC*, 7 F.4th at 1336.

154. *Id.* (quoting McCullough – Direct at *94, *195, GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 313 F.Supp.3d 582 (D. Del. 2018), 2017 WL 10794781).

155. This point is also made in *Grokster* when the court interprets equivalence claims to Napster to be encouraging infringement. Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd., 545 U.S. 913, 937–38 (2005).

equivalent to the brand product."[156] But the court held that in so doing, it implied that physicians *should* prescribe it for all uses, including the patented ones.[157] Even though it was truthful, the advertising could be prohibited because it encouraged tortious behavior.[158]

D. WHAT TORT CAN LEARN FROM IP

IP's use of tort principles provides three lessons for claims alleging inducement liability for manufacturers that promote off-label uses that constitute negligence. First, courts' use of inducement in IP demonstrates how the doctrine can be adapted to new situations but still remain rooted in basic tort law principles of compensating those harmed and deterring undesirable social behavior. A principal example of this is the Court's willingness to recognize inducement in the context of *Grokster* where the case was strong but refusing to do so in other contexts where the case was weak, such as in *Sony* with the VCR.

GSK is also illustrative. Although the correctness of the ruling is contested, the court was concerned with the possible infringement that would result from the generic manufacturer's efforts to promote its drug. Widespread advertising might undercut the method-of-use patents on the unprotected compound—undermining both the patent owner's profits and the incentive to invent and invest in new uses. And underpinning both of these decisions was the impracticality of suing diffuse and numerous individual infringers to further the policy goals of copyright and patent law. Both cases, then, demonstrate how courts can adapt inducement to changing social contexts.

Off-label promotion is just another new situation to which inducement should adapt—there is nothing strange or unwieldy about applying the doctrine to a new social practice that causes harm. If off-label promotion induces physicians to prescribe unsafe off-label uses, then a novel fact pattern should not be a barrier to applying inducement theory. This is doubly true if applying the theory serves tort's goals of deterring harmful conduct (negligent prescribing) and compensating victims (injuries from negligent off-label prescribing). Courts, therefore, should not be shy about using inducement to hold drug manufacturers liable for encouraging physicians to prescribe off-label uses that constitute negligence.

Second, it shows that practical considerations drive courts to adapt inducement to new contexts.[159] A central problem for copyright and patent owners in *Grokster* and *GSK* was that suing direct infringers was costly and impractical. In *Grokster*, copyright infringers numbered in the millions, and lawsuits were ineffective and a public relations disaster. Likewise, in *GSK*,

156. *GlaxoSmithKline LLC*, 7 F.4th at 1335.

157. *Id.* at 1339–40.

158. *E.g.*, United States v. Facteau, 89 F.4th 1, 26 (1st Cir. 2023).

159. This point is distinct from the first, which focused on the *possibility* of adaptation. The point here is that practical considerations motivate this adaptation.

infringing physicians were both too numerous and too sympathetic to sue. And with physicians, there was another factor that made suing them impractical: It was often impossible for drug companies to determine when a prescribed use was infringing.

Similar considerations apply to plaintiffs who are injured by off-label uses promoted by manufacturers. Each claim against a provider based on a promoted off-label use is analogous to suing individual infringers—one-off claims may spark more one-off lawsuits, but there is no way to efficiently reach the entity responsible for the provider's action: drug manufacturers. If provider behavior is caused by manufacturers, then it is inefficient to try to deter all physicians by suing them individually—the most effective solution is to sue the manufacturers that promote unsafe off-label uses.

Another practical problem here is a variation of *Grokster* and *GSK*: In some cases, the plaintiff cannot recover from the individual provider, in part, because the value of the claims may be too low. This is particularly true where the effects of the drug are not life-threatening. A million patients who suffer temporary paralysis or weeks of vomiting may be injured but have trouble finding a lawyer willing to take their case. Allowing plaintiffs to join their claims through an inducement action could capture a variety of low-value claims that otherwise would never be brought against individual physicians. And while the plaintiff must prove the underlying tortious conduct for inducement in IP, it needn't prove every single direct infringement.[160] Likewise, the plaintiff in an off-label inducement claim would need to prove some underlying negligence, but would not need to prove each and every off-label use was negligent.[161]

Finally, the IP inducement cases emphasize that the action facilitating tortious conduct can take a number of forms, including truthful advertising. For example, advertising a generic drug as therapeutically equivalent to the brand name, while true, was sufficient to induce physicians to use the drug for patented uses. What creates culpability for a particular product is the inducer's action and knowledge in relation to what it encourages. Peer-to-peer file-sharing software can be used for a variety of purposes that do not infringe copyright. Prescription drugs and devices, too, can be prescribed for uses that are unpatented or off-patent. Putting either on the market is not, by itself, sufficient to generate inducement. Some further action is needed, such as instructing users on how to share copyrighted works or advertising a drug as therapeutically equivalent, with knowledge that some doctors were likely to prescribe a generic for a patented use.

This is important to the off-label context because a principal defense of manufacturers is likely to be that the promoted speech is protected by the First Amendment.[162] In the criminal context, some courts have held truthful

160. *See infra* Section III.C.5.

161. *See infra* Section III.C.5.

162. *See infra* Section III.A.

non-misleading off-label promotion to be protected commercial speech, limiting government prosecutions and potential tort claims.[163] *GSK* highlights that the First Amendment argument is out of place in the inducement context. Because inducement is not focused on speech as such, but rather on the underlying conduct the speech encourages, the First Amendment will be of limited help to manufacturers who promote unsafe off-label uses, even if they do so truthfully. Because the conduct they are encouraging is tortious, they cannot defend on the grounds that it is truthful.

These three lessons underscore why inducement can and should apply to off-label promotional activity that causes physicians to use drugs or devices negligently. Inducement as a doctrine is designed flexibly to accommodate new situations like off-label promotion. Indeed, its flexibility is precisely why it is used to respond to new social problems. The doctrine fits particularly well where, as in the case of off-label injuries, claimants and tortfeasors are diffuse but the behavior that causes the tortious conduct is centralized. By enabling claims against the actor that encourages the tortious behavior, inducement solves the practical problem of suing thousands of individual physicians who cause harm by negligently prescribing off-label. And because promotion, even truthful off-label speech, can and is intended to affect provider behavior, inducement's focus on the knowledge and encouragement seems to directly target the conduct causing the underlying harm.

While important, these lessons do not universally support the conception of inducement described in Part II. For example, inducement in IP defines intent more narrowly than the one proposed in this Article. Put differently, intent in cases like *Grokster* means knowledge that the encouraged act was infringement; generalized awareness is not enough. If IP has lessons to teach tort, why isn't this one?

The answer is that the lessons we draw from IP and carry over to tort depend on the social function and nature of the tort. Neither supports a narrow understanding of intent for off-label inducement. For IP, the underlying tort is strict liability, making the key question whether the inducer encouraged copying. But for off-label inducement, the underlying tort is negligence, which is more difficult to establish. Construing the intent standard too strictly would undermine the purpose of the tort.

E. APPLICATION

This Section shows how off-label inducement could work by applying three formulations of the theory to a recent case. First, it discusses how off-label inducement works when the physician breaches the duty of knowledge by failing either to consult publicly available information about off-label uses or to inform the patient of known risks. Second, it describes how the clinician

163. *See, e.g.*, United States v. Caronia, 703 F.3d 149, 168–69 (2d Cir. 2012); Simon, *supra* note 12, at 553–54.

may breach the duty of care in a different way: by failing to ask the manufacturer for additional information about the drug's effects. Finally, it explains how this new tort would work if physicians were strictly liable for engaging in certain off-label uses.

1. Case 1: Inducing Malpractice and the Physician's Duty to Know

In a variety of lawsuits, plaintiffs have alleged tort claims against Medtronic based on its off-label promotion of its Infuse Bone Graft device. In one case, for example, a plaintiff alleged that "Medtronic knew a number of studies showed that off-label use of Infuse often produced severe side effects . . . [and] tried to conceal these risks by funding biased studies and articles by opinion leaders in key medical journals that showed a lower incidence of off-label adverse effects."[164] The complaint also alleges that the surgeon was "unaware" of the risks.[165] But the plaintiff's misrepresentation claim was based on literature that identified the same increased risk of complications.[166]

Under an inducement theory, the plaintiff would meet the six elements described in Section II.B. First, the plaintiff must establish that the promoted use was negligent. In other words, the plaintiff would need to show that a reasonable physician would not prescribe, administer, or use the promoted use.[167] This is different from a case that proceeds on a failure to warn theory, which argues that the physician would not have prescribed the drug if the manufacturer had adequately disclosed the risks associated with its use. Here the argument is that the physician was negligent by prescribing the use. Negligence consists of failing to consult medical journals and other published literature explaining the risks or investigating them further. In short, the physician breached her duty to know.

Providers may also be liable for breaching their duty to inform patients, in addition to their duty to know. Consider another case against Allergan based on off-label promotion. The plaintiff claimed that the physician had deliberately exceeded the maximum dose of Botox as determined by the manufacturer and stated on the drug fact sheet.[168] At the same time, however, the manufacturer had promoted dosages of Botox that exceeded the maximum dose.[169] Despite having the relevant information about the product, the prescribing physician never informed the plaintiff's parents that his use

164. Ramirez v. Medtronic Inc., 961 F. Supp. 2d 977, 982 (D. Ariz. 2013).

165. *Id.* at 983; *see* Complaint for Damages at 8, *Ramirez*, 961 F. Supp. 2d 977 (No. 13-CV-00512) (D. Ariz. 2013), 2013 WL 1089587.

166. Complaint for Damages, *supra* note 165, at 19–26.

167. For ease, I refer to "prescribing, use, or administration" of a drug or device off-label as "use."

168. Drake v. Allergan, Inc., 63 F. Supp. 3d 382, 390 (D. Vt. 2014).

169. *Id.* at 392.

exceeded the maximum dose.[170] Here the physician could have been negligent for breaching both her duty to know and her duty to inform. She breached the former by failing to consult the literature on maximum dosage and administering the medication in spite of it. She breached the latter by failing to inform the patient (or the legal guardian) of the risks of prescribing the drug above the maximum dosage.

Second, after proving provider negligence, the plaintiff must show that the manufacturer had knowledge that the use constituted negligence. In both cases mentioned above, the manufacturer had information that directly contradicted its promoted use. There was evidence, dating back many years, that Medtronic had known of the severe bone overgrowth and adverse outcomes associated with it.[171] There was also evidence that they concealed the information that suggested the off-label use was unsafe, which is evidence that they knew the risks were material to physicians.[172] Concealment may be used to demonstrate the manufacturer's knowledge that the use was negligent.[173] Likewise, because of the documented evidence of injury, Allergan knew that prescribing above the maximum dose could result in serious harm. And it promoted the practice to a physician who ultimately did so. The claim here is not that Allergan failed to disclose risks to the physician. Rather, it is that Allergan promoted the use in a way that would *induce the physician to fail to disclose them* to the patient. In other words, Allergan induced the physician to breach its duty of informed consent.[174]

Third, the manufacturer's off-label promotional activity would need to encourage the use that injures the patient. In most cases, as in the cases mentioned above, this element will be relatively straightforward. Although manufacturers are likely to argue that their activities did not "promote or encourage" but rather "informed," the distinction is a flimsy one. Under the line of cases in patent and copyright, advertising a use or instructing others how to perform the negligent use is sufficient. It appears that in this case, and most cases, this is precisely what Medtronic and Allergan did.

The fourth, fifth, and sixth elements—that the promotion causes the physician to negligently prescribe, administer, or uses the drug or device for the use promoted, and the use injures a patient—elements can be met in most cases, including the case described above.

---

170. Plaintiffs' Statement of Facts and Memorandum of Law in Opposition to Defendant's Motion for Partial Summary Judgment at 8–9, *Drake*, 63 F. Supp. 3d 382 (No. 13-CV-234).

171. Complaint for Damages, *supra* note 165, at 18–19.

172. *Id.* at 26–29.

173. In a failure to warn claim, concealment may be used to show whether the provider with access to the concealed information would have used the drug or device.

174. In a different case, Eli Lilly "told its sales representatives to play down [the risks of taking its drug] in conversations with doctors." Alex Berenson, *Eli Lilly Said to Play Down Risk of Top Pill*, N.Y. TIMES (Dec. 17, 2006), https://www.nytimes.com/2006/12/17/business/17drug.html (on file with the *Iowa Law Review*). Even if the risks were disclosed, the manufacturer's actions could induce *physicians* to prescribe the drug without adequately disclosing the risks.

2. Case 2: Inducing Malpractice and the Physician's Duty to Ask

While the application to the cases above seems straightforward, it may be difficult to prove that a physician was negligent if the manufacturer misrepresented, concealed, or partially disclosed information. In such cases, the physician will not have the relevant information. An inducement claim can't help an injured plaintiff if it requires the provider to know of data the manufacturer has not provided. That leaves plaintiffs with two bad options: standard failure to warn claims, which face significant constitutional obstacles of preemption and the First Amendment,[175] or fraud claims, which have difficult-to-meet heightened pleading requirements.[176] In short, the window for claims is narrowed significantly.

To avoid dismissal, a plaintiff should plead that the provider breached her duty to know, which required her to inquire about the risks and benefits associated with the use, including comprehensive, if not complete, information about it. If the physician failed to make the necessary requests and acted on incomplete information, then she breached this duty. In other words, here the plaintiff is claiming that the provider's reliance on the manufacturer and their sales representatives was unreasonable. What constitutes the appropriate amount of information to enable the provider to make a reasonable decision to use a drug or device is fact-dependent and will be developed by courts. At a minimum, however, failing to ask for information and receiving none will likely be negligent and asking for and receiving complete information will not necessarily immunize the physician from liability.[177] One possibility, for example, is to create a rule and vary it using burden-shifting mechanisms.[178]

In the cases described above, there is no evidence that providers followed up with drug representatives or sent letters asking about the studies, including how they were conducted or the data relied on to publish them. Nor was there any evidence the physicians independently tried to identify risks and benefits associated with the use by searching for information on PubMed or other publicly available databases. Instead, the evidence showed that the physicians relied almost exclusively and unquestioningly on the information provided by

175. *See infra* Sections III.A–.B.

176. *See infra* Section III.C.3.

177. A physician that receives complete information, however, may be negligent if they prescribe, administer, or use the drug or device in a way that no reasonable physician with such information would. The manufacturer would then be liable for inducement if the promoted use was negligent.

178. One could imagine a burden-shifting rule: A physician's failure to ask for any additional information is negligence, which the physician can rebut by providing evidence that additional information from the manufacturer would not have altered her decision. Importantly, however, the manufacturer, on this view, must be under a duty to provide complete and accurate information to the physician. Otherwise, the physician can argue, circularly, that the manufacturer would not have provided the precise information that would have altered her decision.

the manufacturer. Although more facts are needed, this should be enough to allege breach of both knowledge and informed consent.

In another case against a manufacturer for failure to warn, a physician testified that "she relied on the manufacturers to supply accurate information and to inform her if the information available to doctors about the drug was no longer accurate."[179] Such reliance, without additional questions or inquiries, should be able to form the basis for a negligence action in some cases.

If the provider did not even attempt to obtain more complete information from salespeople, then a plaintiff can argue that they failed to reasonably determine whether the use was indicated for the patient. Additionally, without the knowledge sufficient to inform the patient of the risks and benefits, the provider *per se* breached a duty of informed consent.

If the provider does make the appropriate requests but the manufacturer provides false or misleading information, then the suit against the provider fails. However, this opens the door to fraudulent misrepresentation claims, which many courts hold to escape the principal obstacles (e.g., First Amendment and preemption) faced by failure to warn claims. This is helpful because the plaintiff is in a position to identify specific information from the provider about potential fraud. And the provider has an incentive to cooperate: The more information the provider offers, the less likely the provider is liable for malpractice. It also shores up the duty of the manufacturer to provide complete and accurate information. Providers must ask for information, and if the manufacturer doesn't provide it, conceals it, or misrepresents it, the plaintiff can sue on a fraud/misrepresentation theory.

3. Case 3: Inducing Malpractice Using Strict Liability

To avoid the challenges off-label inducement may face when based on underlying negligence, it may be preferable to base the action on strict liability. Using strict liability is straightforward because it relieves the plaintiff of proving malpractice and instead concentrates the inquiry on the manufacturer's knowledge and activities that encouraged the prohibited conduct.[180]

But the application is straightforward only once strict liability is assumed. One still has to make the case that it is possible and desirable that certain off-label prescribing should subject the provider to strict liability. This Section therefore is devoted to explaining how off-label use could be a strict liability tort, the concerns it raises, and how to respond to them.

---

179. Kellogg v. Wyeth, 762 F. Supp. 2d 694, 698 (D. Vt. 2010).

180. Legislatures have used prescribing as a means to regulate other conduct. For example, shortly after ratification of the Eighteenth Amendment, Congress enacted criminal statutes that prohibited physicians from prescribing certain amounts of alcohol. *See, e.g.*, Lewis A. Grossman, *Criminalizing Transgender Care*, 110 IOWA L. REV. 281, 336–37 (2024).

i. Creating Strict Liability

Either the courts or the legislature could make providers strictly liable for certain off-label uses. Courts could interpret certain kinds of conduct as an "abnormally dangerous activity"[181] typically covered by strict liability. However, this approach suffers from two problems. First, the kind of activities that fall within the "abnormally dangerous" category are traditionally activities carried out on land that pose risks to others,[182] not "typical activities" that occur between two parties.[183] And strict liability for use of products is typically reserved for the manufacturer. This objection is not fatal, however, since nothing *requires* a possessor of land to engage in abnormally dangerous activities for them to be the subject of strict liability. And there may be good policy reasons for holding someone strictly liable when engaging in an activity, particularly where there exists a power asymmetry that subjects one party to virtually all of the physical risk. For example, a provider is significantly more powerful than the patient, often dictating or at least substantially influencing the terms and options of treatment.[184] This power commands deference, and is in part caused by the provider's informational advantage: By knowing more than the patient, the provider is both in a position of power and commands deference because of it.

Second, courts are weak agents for this change—in part because they may be skeptical of this argument, and in part because courts are unlikely to consistently adopt this rule. One can answer this objection by pointing to courts striking out on new liability ground in a variety of areas, including intentional infliction of emotional distress,[185] invasion of privacy,[186] and modified alternative liability.[187] Nevertheless, given that courts are conservative institutions, a variant of this argument is that we ought not to rely on them to make bold adaptations of law—at least not in a widespread manner.

Given these limitations, the legislative route to strict liability may be more probable. And for several other reasons, it may be preferable to judicial action. One reason in favor of the legislative route is that it engages a deliberative body and a congeries of interests. Stakeholders are likely to shape the scope and application of the rule. Additionally, legislatures already have familiarity with amending laws in response to off-label use. For example, most states have

181. RESTATEMENT (SECOND) OF TORTS § 519 (AM. L. INST. 1977).

182. *See id.* reporter's note (collecting examples).

183. *Id.* reporter's note on subsection (1).

184. Effects of this asymmetry may be felt strongly by those with limited income or education. For example, a person on public health insurance may not have the ability to "shop around" for treatment. Likewise, individuals working multiple jobs with no paid time off may lack the time and resources to look for second opinions.

185. *E.g.*, Craft v. Rice, 671 S.W.2d 247, 251 (Ky. 1984).

186. *See, e.g.*, RESTATEMENT (SECOND) OF TORTS § 652 cmt. a (AM. L. INST. 1977); Samuel D. Warren & Louis D. Brandeis, *The Right to Privacy*, 4 HARV. L. REV. 193, 193 (1890).

187. Sindell v. Abbott Lab'ys, 607 P.2d 924, 936–38 (Cal. 1980).

written certain off-label uses of oncology drugs into their reimbursement laws.[188] These laws rely on private sources of information to tie coverage to forms of evidence. And several states have proposed or passed laws immunizing providers for certain kinds of off-label uses. For example, a bill introduced into the Texas Senate would have immunized providers who prescribed drugs off-label to treat patients that were exposed to or diagnosed with COVID-19.[189] And in Kansas, the House introduced a bill that would have relieved physicians from liability for prescribing off-label when the patient signs a waiver.[190] Mississippi also has a law prohibiting off-label use of certain weight-loss medications,[191] though a House Representative recently introduced a bill that would prohibit the physician and nursing licensing boards from restricting off-label prescribing.[192] Each of these activities constitutes the regulation of the practice of medicine, which is within the state's traditional health and welfare powers.

ii. Defining the Conduct

To create inducement liability—and indeed to discourage physicians from engaging in the problematic behavior—the legislature could simply make physicians strictly liable for engaging in certain kinds of off-label prescribing. At a minimum, this statute would need to identify: (1) prohibited conduct; (2) remedies; and (3) defenses.

In defining prohibited conduct, the statute should be narrowly crafted to achieve two goals simultaneously: limit harmful off-label prescribing, while not deterring physicians from writing appropriate off-label prescriptions.[193] A third goal, at least in the United States, is also a requirement: It must satisfy the First Amendment. Any inclination that the law is designed to disfavor certain speakers will raise constitutional problems. For this reason, the first two goals must cede to the third by making the law content-neutral.[194]

---

188. *E.g.*, 28 TEX. ADMIN. CODE § 21.3011 (2025); *see* David A. Simon, *Gatekeeping Drugs*, 57 ARIZ. ST. L.J. 289, 306 (2025).

189. S. 426, 88th Leg., Reg. Sess. (Tex. 2023) (immunizing providers for off-label uses to treat exposure to or infection of COVID-19).

190. H.R. 2280, 2021 Leg., Reg. Sess. (Kan. 2021).

191. 2640-1 MISS. CODE R. § 1.5 (LexisNexis 2024) (citing MISS. CODE ANN. § 73-43-11 (1972)).

192. H.B. 1601, 2024 Leg., Reg. Sess. (Miss. 2024).

193. Because the conduct at issue is the physician's, this is *not* a products liability action, which avoids any conflict with state products liability statutes. *E.g.*, N.J. STAT. ANN. § 2A:58C-2 (West 2014 & West Supp. 2025) (defining liability of manufacturers in products liability actions); *id.* § 2A:58C-3 (exceptions); *id.* § 2A:58C-4 (warning and compliance defense); *id.* § 2A:58C-5 (limitations on punitive damages).

194. *See* Sorrell v. IMS Health Inc., 564 U.S. 552, 572 (2011). Commercial speech restrictions are subject to a less demanding test ("intermediate scrutiny") than noncommercial speech restrictions ("strict scrutiny"): "[T]he statute directly advances a substantial governmental interest and that the measure is drawn to achieve that interest." *Id.* at 566–67, 572.

Avoiding constitutional scrutiny, however, is relatively straightforward because the law would regulate the conduct of prescribing rather than the speech promoting it. Unless the Supreme Court defines speech to include prescribing drugs, this move should insulate the law from First Amendment challenges.[195]

Achieving the other two goals requires focusing on drugs that are likely to cause the most harm: new drugs that command large reimbursement amounts and/or may have a narrow indication.[196] Manufacturers are likely to promote these uses off-label because the revenues generated "count" the same as the use of the drug on-label. Drugs not subject to regulatory protection, such as patents or exclusivities, on the other hand, are usually available as generics—and the profit margins are typically too thin for generic manufacturers to engage in off-label promotion.[197] With respect to these latter drugs, allowing physicians wide latitude to prescribe off-label is probably less risky and more advantageous to patients.

New drugs, however, may have beneficial off-label uses, and prohibiting all off-label uses of new drugs may constrain physicians from prescribing needed medications, particularly in certain domains. It is important, then, to carve out certain kinds of off-label prescriptions from liability—or potentially make defenses available—where off-label use is a necessary component of the standard of care. For example, many drugs are not indicated for children, but, without off-label use, children would not have access to them. Certain practice areas may rely on off-label uses, even of new drugs, to treat patients who otherwise would go without treatment. Exceptions for these types of off-label uses, therefore, should be written into the law.[198] For certain areas that have a high incidence of off-label use, liability could even be associated with reimbursement criteria.[199] Likewise, physicians should continue to be able to prescribe off-label as part of an Institutional Review Board-compliant research program that evaluates the safety and efficacy of the off-label use.

Next, the statute might specify the evidentiary standard for injury required to recover. How the injury standard is set should be based on an analysis of firm behavior and proper off-label prescribing habits, as well as the particular state's risk tolerance. While this Article does not undertake this analysis, it is worth noting how one sets the bar will influence the type and quantity of claims.

---

195. There may be other constitutional challenges, which Professor Lewis Grossman has detailed. Grossman, *supra* note 180, at 301–05.

196. The same is generally true for devices as well, though the situation is more complicated because there are no "generic" devices. The specifics of device reimbursement are beyond the scope of this Article.

197. *Cf.* Kesselheim et al., *supra* note 47, at 2324 (describing brand name manufacturer reaping significant profits from off-label promotion).

198. Introducing exceptions, however, raises the specter of powerful interests that may expand it to swallow the rule.

199. *See* Simon, *supra* note 9, at 724–25 n.97, 726 n.101.

A low bar will encourage more claims, which will generate significantly more costs (at least at first) but potentially better regulate manufacturers. A high bar, conversely, will reduce the number of claims but will be less effective at regulating manufacturer behavior. Spelling out these issues in precise detail is beyond the scope of the Article. However, the bar should be low enough to encourage claim aggregation. In any case, the primary evidentiary bar will not be set for proving violations of the statute, but rather for proving that the manufacturer caused a violation of the statute.

iii. Costs of Strict Liability

Although the strict liability approach provides more bite, it also could have negative effects. First, physicians may become afraid to prescribe off-label, and patients may go without potential treatments. Second, malpractice insurance rates may increase, as physicians now have new liability exposure. Third, legislatures may make erroneous determinations about off-label uses that are political rather than evidence-based, as some have done with gender-affirming care, abortion, and COVID-19.[200] Finally, liability may chill innovation if physicians are afraid to try new off-label treatments.

Although each of these concerns is real, their effects can be mitigated. First, fear of off-label prescribing comes only from either ignorance of the law or a law that does not clearly describe the prohibited conduct. To prevent this, legislators should provide clear categories that prohibit or allow off-label use or otherwise delegate the task to state administrative agencies. Medical associations and societies can then work to distribute relevant information to their members about the new laws.

Second, it is not clear that malpractice liability insurance would necessarily increase. If it did, the increase is likely to reflect the learning curve of physicians[201] (and hence decrease over time) and the practice areas where inappropriate off-label use is highest.[202] Insurance premium increases are also likely to be correlated with the breadth and specificity of the statute, making the legislative drafting process key to reducing these costs.

Third, although legislatures may make determinations that do not reflect the medical evidence regarding off-label use, that is not a good reason to prevent them from any decision that requires evaluation of evidence.[203] To drive home the point, consider several examples. A bill introduced into the Kansas legislature would have immunized physicians from lawsuits based on

200. *See infra* notes 204–05 and accompanying text. For a catalog of bans on specific off-label prescribing, see Grossman, *supra* note 180, at 326–34.

201. *See* Alberto Galasso & Hong Luo, *Tort Reform and Innovation*, 60 J.L. & ECON. 385, 386–87 (2017).

202. Given that off-label promotion's effect seems to be sticky, this may be highly desirable. *See* David et al., *supra* note 87, at 22.

203. More generally, legislatures make poor decisions routinely, but that is hardly a reason to prevent them from making decisions.

using drugs off-label to treat COVID-19.[204] In other states like Texas and Arkansas, legislatures have banned evidence-based standard-of-care treatments for gender-affirming care.[205] In both circumstances, lawmakers acted in ways that were contrary to public health and evidence. These examples show that the legislature may not always correctly identify the types of off-label uses that warrant liability.

None of these examples show, however, that the legislature is the wrong body to make decisions about off-label prescribing—or even that it is incapable of making evidence-based decisions. All they show is that legislatures in some states have some made bad decisions—a result endemic to the political process. And if legislatures are already making poor decisions, there is little sense in preventing them from making good ones. In other words, while the risk of bad decisions cannot be ignored, neither can the benefit of good ones. The right course of action is to attempt to improve the existing legislative decision-making processes. Given the freedom and deliberation a thoughtful legislative body can provide, the best option is to use the decision-making process to encourage medically supported decisions while discouraging unsupported ones.

Finally, physicians will certainly be less likely to prescribe for prohibited uses—but that is the goal. Whether this significantly affects innovation depends on the scope of the law. But if properly drafted, it is not unreasonable to expect this to *increase* innovation by forcing proper study of the potential off-label uses—either by drug manufacturers who want to promote them or by physicians who want to evaluate them using a proper research method. And, indeed, since the law will apply to new drugs, we should not expect a decrease in innovation for new uses of older drugs and devices. In such cases patients will be protected and innovation preserved by the traditional malpractice standard.

One final benefit of using strict liability: It makes class action and MDL simpler because the precise method of prescribing and the nature of the use are not important—all that matters is that the injury occurred as a result of the use. The cost, of course, is that areas with low malpractice risks, such as psychiatry, may increase.[206]

III. CHALLENGES

Off-label inducement is not foolproof. If used, it will face several significant challenges. This Part reviews these challenges and how the inducement theory can meet or overcome them. Section III.A explains why traditional tort claims

204. S.B. 381, 2022 Leg., Reg. Sess. (Kan. 2022). In North Dakota, the legislature prohibited medical boards from taking action against physicians who prescribed ivermectin for treatment or prevention of COVID-19. N.D. CENT. CODE § 43-17-31.2 (2024); *see* MO. ANN. STAT. § 334.100(8) (Supp. 2024); TENN. CODE ANN. § 63-10-224(e) (2023). The legislature in Texas introduced a similar bill with more expansive scope, but it died in 2003. H.B. 4341, 88th Leg. Sess. (Tex. 2023).

205. ARK. CODE ANN. § 20-9-1503(a) (West 2024); TEX. HEALTH & SAFETY CODE ANN. § 62.151(g) (West Supp. 2024).

206. *See, e.g.*, Galasso & Luo, *supra* note 201, at 405.

sometimes fail because the First Amendment protects manufacturer speech and why the inducement theory sidesteps this constitutional pitfall. Section III.B identifies another potential roadblock for tort claims—preemption—and argues that off-label inducement bypasses it. Section III.C describes the doctrinal challenges internal to tort law that the inducement theory is likely to face and argues that the theory can overcome them. Section III.D briefly describes some potential procedural issues confronting off-label inducement and explains how they may be addressed. Section III.E describes how fault allocations between the manufacturers and physicians could facilitate or undermine the goals of inducement. Finally, Section III.F evaluates whether off-label inducement will chill innovation by increasing liability. It contends that the new theory's effect on innovation is likely to be positive or minimally negative.

A. THE PROBLEM OF THE FIRST AMENDMENT

Manufacturers sued for injuries caused by off-label promotion can assert a powerful defense: Their speech is protected by the First Amendment. Most of the caselaw on point comes from federal criminal prosecutions under the FDCA, not state law liability claims. The most famous case, *United States v. Caronia*, held that government restrictions on truthful off-label promotion were subject to, and failed, intermediate scrutiny.[207] *Caronia* is also part of a larger trend in the courts, including the Supreme Court that has rolled back speech restrictions, particularly in the context of FDA-regulated drugs and devices.[208]

Recently, however, courts like the First Circuit have distinguished *Caronia* by trying to limit its holding, claiming that *Caronia* struck down government restrictions that purported to punish salespeople for violations of the FDCA based on only their speech.[209] That is, where there is evidence of a manufacturer's objective intent to misbrand beyond only its speech, the case can proceed on the theory that speech alone is not what is being regulated.[210]

Whatever the merits of this position,[211] the inducement theory avoids the questions it raises for two reasons. First, the theory is one of *secondary* liability—

207. United States v. Caronia, 703 F.3d 149, 168–69 (2d Cir. 2012). For an example of a court following *Caronia*, see, e.g., *Amarin Pharma, Inc. v. U.S. Food & Drug Administration*, 119 F. Supp. 3d 196, 237 (S.D.N.Y. 2015). For other relevant cases concerning commercial speech, see generally *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976); and *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980).

208. Kapczynski, *supra* note 17, at 191–94.

209. United States v. Facteau, 89 F.4th 1, 35–38 (1st Cir. 2023).

210. Violations are based on the introduction of a drug or device into commerce. 21 U.S.C. § 331.

211. Recently, Professors Abraham and White have proposed that the First Amendment should not reach much of the speech that tort law regulates. *See generally* Kenneth S. Abraham & G. Edward White, *First Amendment Imperialism and the Constitutionalization of Tort Liability*, 98 TEX. L. REV. 813 (2020). Notably, however, their analysis of product defects involves failure to warn, fraud, and misrepresentation. *Id.* at 846–54. While their analysis is sound, the inducement theory

recall that we are holding the manufacturer liable *for the actions of another*. What causes the action is the speech, but the speech itself is not the only thing that generates liability. Second, the nature of the speech that makes a person liable is already disfavored because the underlying conduct the inducer encourages is tortious.[212] Under the First Amendment, disfavoring speech that encourages people to commit murder, steal cars, or overthrow the government is unproblematic because the speech itself is promoting behavior the law already sanctions. This is true in IP, where the law is unconcerned with holding inducers liable for their speech encouraging infringement because infringement is illegal. Similarly, if promotion induces malpractice, then the speech in question should be disfavored because it encourages tortious conduct.[213]

B. THE PROBLEM OF PREEMPTION

Although state law claims based on off-label promotion are not uncommon, they are often blocked by the defense that federal law preempts them.[214] Preemption is a complex doctrine and has several types.[215] But the relevant part of the doctrine holds that state law must give way to federal law when the two conflict.[216] For claims based on off-label promotion, the gist of the problem is this: State law claims seem to impose on manufacturers a duty to update their labeling to include promoted off-label uses, but federal law prohibits label changes without FDA permission.[217] Because updating the label with information related to off-label use is prohibited by federal law, manufacturers argue, the FDCA conflicts with, and therefore preempts, state law claims that contend manufacturers should have provided additional warnings.[218]

Inducement claims, however, do not have to fend off preemption because they are based on a theory of secondary liability. The relevant tortious conduct

---

does not rely on it because the new tort is not premised on failure to warn, fraud, or misrepresentation.

212. Fraudulent inducement claims likewise can avoid constitutional challenges because false or misleading speech is not protected under the First Amendment. Illinois *ex rel.* Madigan v. Telemarketing Assocs., Inc., 538 U.S. 600, 612 (2003). But, as noted in Section III.C.3, these claims face pleading challenges.

213. Additionally, speech can be used to show intent. *E.g.*, Wisconsin v. Mitchell, 508 U.S. 476, 489 (1993) (criminal case). Since inducement hinges on showing the manufacturer intended the use, its speech suggesting the off-label use is fair game.

214. This doctrine is derived from the Supremacy Clause of the U.S. Constitution. U.S. CONST. art. VI, cl. 2; *see* Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 516 (1992).

215. These cases are reviewed in detail in Simon, *supra* note 17, at 1115–22.

216. *E.g.*, Wyeth v. Levine, 555 U.S. 555, 573 (2009); Hines v. Davidowitz, 312 U.S. 52, 67 (1941).

217. *See* 21 C.F.R. § 314.70(b) (2025) (prior approval supplement); 21 U.S.C. § 355(o) (codification of FDA-initiated proposed change under 2007 amendments). The exception is the "changes being effected" regulation, which permits a manufacturer to update its label and then submit the update to the FDA for approval. *See* 21 C.F.R. § 314.70(c)(6)(iii)(A), (C).

218. For an argument as to why this is wrong, see Simon, *supra* note 17, at 1130–35.

is the provider's negligence, not the manufacturer's failure to warn of risks. In other words, by encouraging physicians to commit malpractice, manufacturers are responsible for the malpractice they encouraged. This makes inducement claims categorically and doctrinally distinct from failure to warn claims. The latter may be barred by preemption because the manufacturer cannot update the label to comply with state law without violating federal law. But the former will not because they do not involve tortious conduct premised on or in conflict with federal law. The underlying conduct is the provider's negligence in prescribing, using, or administering a drug or device off-label—activities that fall within the state-regulated practice of medicine.[219] Because there is no conflict between federal law governing drug labeling and state law regulating their use, preemption will not bar inducement claims based on off-label promotion.

C. *THE PROBLEMS OF TORT LAW*

Several doctrinal features of tort law make applying inducement to claims centered on off-label promotion potentially challenging. First, it is not clear that the problem of off-label promotion fits within tort law's traditional domain. Although there are some similarities between the situations involving IP inducement and off-label promotion, IP and tort concern fundamentally different harms. Second, tort law typically allows manufacturers to discharge their duty to inform by issuing adequate warnings to physicians. An inducement cause of action seems to upend this traditional doctrine by holding the manufacturer liable even when it gives adequate warnings. Third, tort law already has a cause of action for fraud in the inducement or misrepresentation, potentially making inducement duplicative. Fourth, because a plaintiff must prove the manufacturer intended to induce the tortious conduct, successfully litigating off-label inducement claims may be exceedingly difficult. Fifth, inducement seems to gut tort law's causation requirement, allowing plaintiffs to sue without having to prove causation in a way typical in most tort actions. Sixth, the requirement that the plaintiff proves the underlying conduct is negligent could derail off-label inducement claims because physicians' actions may be reasonable given the information to which they had access. In other words, physicians may not have the information needed to determine that the off-label use is inappropriate. The following subsections respond to these concerns and argue they are misplaced.

1. The Problem of Fit

Tort law may seem like an odd place to resuscitate inducement given the doctrine's limited application. To ask whether the theory can fit within the doctrine is not necessarily the wrong question, but it is also far from the most

219. Federal law, of course, affects the practice of medicine in a variety of ways. Sometimes this effect is direct, as with FDA regulation of stem cells. *See generally* 21 U.S.C. § 356g; 21 C.F.R. pt. 1271.

important one.[220] And, as shown in Sections I.B and I.C, there are good reasons to extend the doctrine to cover manufacturer off-label promotion.

Still, there are two potential problems with applying inducement this way. Both involve poking holes in the analogy to IP Section II.C used to make the case for inducement's application to drug manufacturers that promote unsafe off-label uses. First, IP and tort concern different types of costs. Tort law tries to reduce accident costs while IP is designed to stimulate the creation of new works and inventions.[221] Thus, while the social cost in tort is harm to persons or things, the social cost in IP is "foregone benefit" of works that are not created (or perhaps disseminated).[222]

Second, IP infringement is a strict liability cause of action. But malpractice is a negligence cause of action. Knowledge of copyright or patent infringement requires only that the rightsholder knows an infringing act took place, not that a person violated some standard of conduct. Knowledge of malpractice, however, requires knowing both what the standard of conduct is and that the encouraged action is likely to violate it.[223]

Each problem has a relatively straightforward response. As to the difference in harm, it is not clear why it should matter. The fact that copyright and patent conceive of the social cost of infringement as reduction in incentives seems irrelevant to whether the inducement doctrine ought to apply to discourage the offending behavior. Additionally, reduced incentives are *a* harm, but they are not the only harm—the author also is harmed economically when their work is used without compensation. Therefore, while the type of harm in tort may be different from IP, the fact of harm, rather than the specific type of harm, is what matters.

With respect to the difference in fault, the answer is threefold. First, the fact that IP is strict liability and malpractice is negligence makes no material difference to whether the theory ought to apply. Indeed, inducement has been applied in the negligence context.[224] While this makes the theory more challenging to prove, it does not speak to whether there is a good reason to

220. *See* Harold J. Laski, *The Basis of Vicarious Liability*, 26 YALE L.J. 105, 129 (1916).

221. This is an overgeneralization. Both tort and IP may have other purposes, which commentators have debated at length.

222. Goold, *supra* note 116, at 342. This is not mortally certain. If one thinks IP's role is to protect property rights based on Lockean labor theory or other rights based on personality theory, then one might assert harm beyond "lost works."

223. In some sense, inducement in IP also requires knowledge of conduct insofar as the inducer must know the act is infringing. But in the easy case, the inducer typically does not need to engage in substantive analysis of whether the act in question met some *other* standard of conduct. For example, if an actor induces another to share a copy of a copyrighted work, the inducer must only know that sharing the work is infringement. They need not engage in further substantive analysis about *whether and how* the sharing occurred (i.e., was it shared carefully?); the act alone is enough. The same may not be true for inducing what may be considered "fair use." 17 U.S.C. § 107.

224. *See supra* note 72 and accompanying text.

apply it. Second, even if the first point falls, it is not clear that there is as much difference between the two as supposed. At least with respect to copyright infringement, the tort may actually be closer to negligence than strict liability because it requires the plaintiff to show both that the plaintiff copied a work and that the use was unfair.[225] This is different from traditional strict liability, which requires showing only that the defendant engaged in the prohibited conduct.[226] Finally, it is possible to craft new theories of negligence to accommodate the tort, or to advocate that the legislature makes certain kinds of malpractice strict liability.[227]

One critical concluding point: These arguments and responses mistakenly assume that the IP analogy is necessary to off-label inducement. It is not. Off-label inducement can stand and fall on its own merits. What IP provides is a helpful perspective on how and why courts have used inducement to address new social problems. Learning and applying those lessons does not require the new legal domains map on identically to IP.

2. The Problem of Warnings

Tort law has traditionally allowed drug and device manufacturers to avoid liability for risks posed by their products if they provide adequate warnings to providers who prescribe them.[228] Under this learned intermediary doctrine, manufacturers should not be responsible for harms that result from off-label promotion that adequately warns providers of the risks associated with the use. Manufacturers, then, are likely to argue that they cannot be liable for off-label promotion because they adequately warned providers of the risks associated with the promoted use.

Under the inducement theory, however, manufacturers are *not* being held liable because they failed to give adequate warnings. They are held liable because they are promoting off-label uses for which warnings are irrelevant.[229]

---

225. Goold, *supra* note 116 at 338–41. In other places copyright law uses fault under different names. For example, for conduct to be "volitional" the actor must in some sense be aware of the prohibited conduct. *E.g.*, Tom Hussey Photography, LLC v. BDG Media, Inc., No. 20-404, 2020 WL 7481770, at *2 (D. Del. Dec. 18, 2020); *see* SoClean, Inc. v. RespLabs Med. USA, Inc., 21-CV-03422, 2024 WL 669621, at *2 (N.D. Ill. Feb. 19, 2024).

226. Strict liability, too, exhibits these characteristics if comparative negligence is allowed as a defense. *See* COLEMAN, *supra* note 116, at 228.

227. *See supra* Section II.E.3; *infra* Section III.C.6.

228. This rule is called the learned intermediary doctrine, which supplants the manufacturer's traditional duty to warn the consumer with a duty to warn the physician treating the consumer. *E.g.*, Wolicki-Gables v. Arrow Int'l, Inc., 641 F. Supp. 2d 1270, 1286–87 (M.D. Fla. 2009), *aff'd*, 634 F.3d 1296 (11th Cir. 2011) (addressing adequacy of warning a question of law when "the warning is accurate, clear and unambiguous").

229. This is different from claiming that warnings are insufficient to trigger the learned intermediary doctrine or failure to warn claims. Hansen v. Baxter Healthcare Corp., 764 N.E.2d 35, 43 (Ill. 2002). Likewise it is not the same thing as "overpromotion" that negates or dilutes a warning. Stevens v. Parke, Davis & Co., 507 P.2d 653, 661 (Cal. 1973). Even in cases where there

In other words, if the underlying use is malpractice, then it would be irrelevant whether the manufacturer warned a provider of the risks of the off-label use because the decision to prescribe is unreasonable *even with this information*. This is similar to advertising to consumers a product for a use that is likely to cause harm to them, but then disclosing to the consumer the risks of using it in the advertised manner.[230] In both cases, the warning is ineffective because the warning is meaningless.[231] In a world where providers are pressed for time and face high patient demand, it is also unreasonable to expect that a warning in such situations would have any effect. Yet in some cases this is precisely what manufacturers argue.[232]

3. The Problem of Fraud or Misrepresentation

Another challenge for the inducement theory is that causes of action already exist for inducement in tort—fraudulent or negligent misrepresentation—and plaintiffs have brought them.[233] This tort has five basic elements, though they vary by jurisdiction.[234] First, the speaker must make a fraudulent misrepresentation of fact, opinion, intention, or law. Second, the speaker must have knowledge of the statement's falsity. Third, the speaker must intend to induce reliance on the statement. Fourth, there must be a justifiable

---

is a warning, the physician is liable for failing to disclose the risks associated with the off-label use. The manufacturer, in such cases, is liable for the provider's negligence if it *induced* the physician not to warn by promoting it in a certain manner.

230. *E.g.*, Chellman v. Saab-Scania AB, 637 A.2d 148, 150 (N.H. 1993).

231. The same would have been true if Grokster had warned users not to infringe copyright law. And the same is true of products often marketed as devices while simultaneously warning they are not. David A. Simon, Carmel Shachar & I. Glenn Cohen, *Skating the Line Between General Wellness Products and Regulated Devices: Strategies and Implications*, 9 J.L. & BIOSCIS. 4 (2022), https://academic.oup.com/jlb/article/9/2/lsac015/6637474 [https://perma.cc/Q5MM-JRXG]; David A. Simon, Carmel Shachar & I. Glenn Cohen, *At-Home Diagnostics and Diagnostic Excellence: Devices vs General Wellness Products*, 327 JAMA 523, 523 (2022).

232. Memorandum of Law in Support of Defendant Allergan, Inc.'s Motion for Partial Summary Judgment at *8, Drake v. Allergen, Inc., No. 13-CV-234 (D. Vt. Sept. 5, 2014) ("The evidence unmistakably establishes that even if Allergan had provided the warnings plaintiffs contend were necessary, Dr. Benjamin still would have treated J.D. with a dose of 12 u/kg of BOTOX® on May 24, 2012. Plaintiffs' negligence claim premised on Allergan's promotion of BOTOX® for off label use also fails for lack of proximate causation because there is no evidence that any promotion influenced Dr. Benjamin's treatment decisions."); *id.* ("But the evidence unmistakably establishes that Dr. Benjamin would have used the same 12 u/kg dose of BOTOX® to treat J.D. *even if* Allergan had told him that the maximum recommended or maximum safe dose was 8 u/kg."). This was a serious point of contention during the briefing.

233. These claims can escape preemption. *E.g.*, Alton v. Medtronic, Inc., 970 F. Supp. 2d 1069, 1097–98 (D. Or. 2013); Houston v. Medtronic, Inc., 957 F. Supp. 2d 1166, 1179 (C.D. Cal. 2013).

234. RESTATEMENT (SECOND) OF TORTS §§ 525, 557, 557A (AM. L. INST. 1977); *see* Ramirez v. Medtronic Inc., 961 F. Supp. 2d 977, 996 (D. Ariz. 2013) (stating nine elements).

reliance on the misrepresentation. Fifth, there must be an injury proximately caused by the justifiable reliance on the misrepresentation.[235]

When these claims involve off-label promotion, a plaintiff must allege that the manufacturer promotes an off-label use as having properties or characteristics it knows the use does not have. She must also allege that, in making these fraudulent misrepresentations, the manufacturer intended to induce providers to rely on it when making prescribing decisions. A manufacturer will be liable if the plaintiff can show that the provider's justifiable reliance on this information caused the provider to use a drug or device off-label, injuring the plaintiff. In other words, when manufacturers promoting off-label uses to providers hide or lie about their risks, they can be liable for the harms that result when the provider, relying on this bad information, injures a patient by using a drug or device off-label.

Fraudulent misrepresentation claims against manufacturers for off-label promotion pose two problems for plaintiffs bringing them. First, claims involving fraud require heightened pleading standards. The plaintiff must plead fraud "with particularity,"[236] which often includes "'the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby.'"[237] But plaintiffs in off-label promotion cases often do not have access to this information prior to discovery.[238] Second, the reliance on the statement must be justifiable. But manufacturers may argue that the physicians to whom statements were not justified in relying on them alone. Physicians have an independent duty to learn and understand the risks of a particular drug. If physicians did not fulfill that duty, manufacturers may be successful in defending the claim.[239]

Plaintiffs bringing off-label inducement claims avoid these difficulties. Because the plaintiff does not need to allege either fraud or misrepresentation, the requirement to plead claims with particularity is inapplicable. Without a misrepresentation to anchor the claim, the plaintiff also need not worry about whether the provider's reliance on the manufacturer's statement was justifiable. Instead, the plaintiff must prove only that the provider was negligent, and that the manufacturer induced the negligence. Just as truthful statements about the uses of generic drugs may induce infringement, statements about off-label

235. When the misrepresentation is negligently made, rather than fraudulently made, the injured party can bring a claim provided they were not negligent in relying on the misrepresentation. RESTATEMENT (SECOND) OF TORTS § 552A (AM. L. INST. 1977).

236. *E.g.*, FED. R. CIV. P. 9(b).

237. Angeles v. Medtronic, Inc., 863 N.W.2d 404, 422 (Minn. Ct. App. 2015) (quoting Baker v. Best Buy Stores, LP, 812 N.W.2d 177, 184 (Minn. Ct. App. 2012)); *Ramirez*, 961 F. Supp. 2d at 984.

238. *See generally Ramirez*, 961 F. Supp. 2d 977.

239. As noted below, however, the manufacturer induced the doctor to breach its duty. And it should be held responsible for that. The manufacturer cannot have it both ways—promote a use it knows to be negligent and then defend on the grounds that the physician was unreasonable in relying on the information.

uses may not be false or misleading but still generate liability if they encourage the provider to commit malpractice. And, as noted below, if the provider's reliance on the manufacturer's statement was unreasonable because she failed to ask about the risks, *that* can supply the basis for a negligence action (even though it undermines the misrepresentation claim).

4. The Problem of Intent

Inducement requires intent, which suggests a fairly high burden. In tort, intent traditionally means that one acts with the purpose of causing some result or acts knowing that the result is substantially certain to occur.[240] Applying this standard to off-label promotion means that the plaintiff must show that the manufacturer acted with the purpose of causing the provider to commit malpractice or knowing malpractice was substantially certain to occur. That is a high bar to pass.

This is not, however, the test for inducement. This Article has argued that, at least in tort, intent for inducement purposes requires knowledge that the encouraged act is tortious coupled with encouragement—not that the manufacturer acted with the purpose of causing malpractice or acted knowing to a substantial certainty malpractice would occur. The upshot is that the plaintiff must show that the manufacturer knew that the promoted use constituted malpractice and encouraged it.

Even on this understanding of intent, however, the plaintiff seems to have a high bar—she must prove the manufacturer *knew* the use was malpractice. While this is certainly not a low bar, it is not as high as it seems. Inducement does not require one to have only direct evidence of intent or knowledge. Of course, as in *Grokster*, direct evidence of both is helpful, but it is not required. Promoting a negligent use, as in *GSK*, can supply the requisite intent as well.[241] Indeed, as described in Section II.B, inducement in tort evaluates knowledge and intent based on a variety of factors, and circumstantial evidence is the norm. Direct evidence of intent may come from internal memoranda, salespeople, or staff. Circumstantial evidence may include the manufacturer's marketing strategy and research, and projected sales numbers. Particularly in class actions or mass tort cases, plaintiffs may introduce evidence showing the effects of pharmaceutical detailing on provider behavior.[242] Other relevant evidence that could provide the basis for finding a manufacturer possessed the requisite knowledge include the fact that the use was not approved;

240. *See* RESTATEMENT (SECOND) OF TORTS § 8A (AM. L. INST. 1965). The Restatement speaks of *belief* that a result is substantially certain to occur, but the comments characterize this as knowledge. *Id.*

241. Likewise, in claims under the FCA, the plaintiff must show that the manufacturer *knowingly* caused a physician to make a false claim. 31 U.S.C. § 3729. Manufacturers must therefore know that the use they promote will not be reimbursed by the federal government.

242. *See* Ani B. Satz & Liza Vertinsky, *Customary Corruption*, 66 WM. & MARY L. REV. 693, 701–02 (2025).

manufacturer studies showing that the drug or device was not safe and effective or very likely to have negative side effects that outweigh its potential benefits; and manufacturer concealment of negative information that would have influenced providers *not* to use the drug or device for the promoted use.

5. The Problem of Causation

Another bedrock principle of tort law is causation, which ties the harm directly to the tortfeasor's conduct by requiring the latter cause the former. If the defendant did not cause the plaintiff's injury, it is unclear why they ought to be held responsible for it. Off-label inducement could fracture this bedrock principle by putting pressure on the concept of causation. Consider that, ordinarily, inducement would require the plaintiff to prove each instance of malpractice by a particular provider and that the manufacturer proximately caused each provider's behavior. While this could be done, a strict causal requirement frustrates inducement if one of the doctrine's purposes in this context is to collate and organize a variety of claims. To ensure that small and diffuse claims are organized and pursued, inducement would work best by taking a page from IP and allowing claims without showing each and every instance of tortious conduct. Doing so, however, seems to break the causal bedrock that supports culpability and, hence, liability.

There are three responses here. The first is to point out that IP relaxes the causal requirement for inducement precisely because of the practical difficulties in pursuing individual claims. Put differently, if one purpose of inducement is to overcome the practical difficulties in suing diffuse tortfeasors, it makes little sense to require minitrials of each potential individual tortfeasor.[243] That reasoning applies equally to malpractice claims.

The second response is to note that tort law has historically adapted elements of causation to fit new circumstances, just as it has adapted traditional causes of action like nuisance.[244] Consider market share liability, which is a judicially created doctrine designed to overcome the limitations of the causation analysis.[245] Market share liability operates when an individual is injured by a

---

243. In IP, courts take two views of damage awards for indirect infringement: Some measure how much damages the plaintiff suffered while others calculate damages based on the number of direct infringements. *See generally* Dmitry Karshtedt, *Damages for Indirect Patent Infringement*, 91 WASH. U. L. REV. 911 (2013) (addressing the two approaches).

244. Public nuisance was used as a theory of liability against opioid manufacturer Purdue Pharma for their marketing and sale of prescription painkillers. *See, e.g.*, State v. Purdue Pharma LP, No. CJ-2017-816, 2019 WL 4019929, at *1 (Okla. Dist. Ct. Aug. 26, 2019); Commonwealth v. Purdue Pharma, L.P., No. 1884CV01808, 2019 WL 5495716, at *2 (Mass. Super. Ct. Oct. 8, 2019). Even the opioid litigation showed causation can be relaxed in certain circumstances. *In re* Nat'l Prescription Opiate Litig., 589 F. Supp. 3d 790, 808 (N.D. Ohio 2022) (rejecting the argument that failure to provide evidence of specific prescriptions was necessary to show causation and that simultaneous increase in prescriptions and opioid addiction sufficient to show causation).

245. *See* Sindell v. Abbott Lab'ys, 607 P.2d 924, 937–38 (Cal. 1980).

product, typically a drug; a number of defendants manufactured the product in question; the plaintiff lacks information, through no fault of her own, about which firm manufactured the product that injured her; and not all of the firms that manufactured the product can be joined to the suit.[246] If the plaintiff is successful in her claim, the defendant is responsible for the amount of damages in equal proportion to its share of the market.

Off-label inducement represents less of a departure from traditional causation principles than market share liability. While market share liability does not require showing that the manufacturer in fact caused the harm in question, inducement does require showing that at least some tortious behavior was the legal cause of the harm. Being the legal cause, of course, is a policy judgment, but it is one that is made as to particular tortious conduct. That differentiates it from traditional tort claims and ties it more closely to causation than something like market share liability.

The third response is to reinforce the first two by showing that law has flexed and bent causation in similar ways and for similar reasons but under a different regime: the False Claims Act.[247] Under the FCA, the plaintiff must prove that someone "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."[248] Off-label promotion can cause a physician to make a false claim for reimbursement without being the *sole* reason for the physician doing so. What it does require is showing facts that would allow a factfinder to infer that the off-label promotion was *a substantially strong* reason[249] for submitting false claims.[250] This may require showing a specific instance or instances where the false statements by the drug manufacturer could have influenced provider behavior,[251] but it does not require the plaintiff to make

246. *Id.* at 931–32, 936.

247. FCA cases, however, also require a heighted pleading standard under Federal Rule of Civil Procedure 9(b). *In re* Pharm. Indus. Average Wholesale Price Litig., 478 F. Supp. 2d 164, 171–72 (D. Mass. 2007). But because they incentivize individuals inside a company to bring claims, this information is more readily available than in other cases. In malpractice or off-label promotion lawsuits, for example, the patient has virtually no information about a manufacturer's marketing practices.

248. 31 U.S.C. § 3729(a)(1)(A)–(B). This is also true of FCA state law counterparts. *In re Pharm. Indus. Average Wholesale Price Litig.*, 478 F. Supp. 2d at 172.

249. "Causation" never means the "only" reason. And even when the but-for analysis may fail, courts have been willing to alter the causation standard in a variety of contexts. *See, e.g.*, Nesbitt v. Candler County, 945 F.3d 1355, 1359–60 (11th Cir. 2020) (discussing causation in the antiretaliation provision of the FCA).

250. United States *ex rel.* Duxbury v. Ortho Biotech Prod., L.P., 579 F.3d 13, 31 (1st Cir. 2009). Of course, FCA claims based on off-label promotion must satisfy the pleading standards for fraud.

251. *Id.* at 30–31.

this showing in each and every case.[252] Nor could it. Like with induced infringement, it would be impossible to pursue the bulk of claims if the law required the plaintiff to prove each and every violation. And while FCA claims are creatures of statute and not common law, the keystone causation analysis is the same in both contexts.

6. The Problem of Negligence

Lawsuits against physicians for negligent off-label use are relatively infrequent.[253] This may suggest that malpractice for off-label use—and by extension off-label inducement—is an unattractive legal theory, particularly if customary practice is to prescribe off-label.[254] But that conclusion is too quick. Claims are not necessarily constrained by the law; they may (also) be constrained by the circumstances that provide an incentive to bring them. Circumstances, rather than law itself, may constrain lawsuits against providers for negligent off-label use because providers have incentives to protect the profession, manufacturers influence standards of care,[255] or lawyers find claims against individual providers less attractive than the those against manufacturers.[256] Inducement can make lawsuits against providers for negligent off-label use more attractive in limited circumstances, either by comparison to or in complement with, some claims against manufacturers. By adding liability of the manufacturer, off-label inducement makes a case against a provider into one or more claims against a manufacturer—an area that plaintiffs' attorneys seem to value more than individual claims against only providers for negligent off-label use.

Even if claims against physicians become more frequent, off-label inducement must confront doctrinal issues relating to negligence. For example, an inducement theory based on a negligent act is limited by the information available to providers. Because the theory requires underlying malpractice, providers must have access to information that could alert them to the risks

252. *Id.* ("[The plaintiff] has alleged facts that false claims were in fact filed by the medical providers he identified, which further supports a strong inference that such claims were also filed nationwide.").

253. My search of Westlaw produced fewer than 50 cases alleging negligent off-label use against a physician.

254. In certain cases, this may be a limiting factor in suits against physicians.

255. Satz & Vertinsky, *supra* note 242, at 702, 722–56. One hope is that this theory of liability will overcome some of the issues identified by Professors Satz and Vertinsky.

256. One should remember that lawyers evaluate claims relative to other potential claims. Lawyers may also lack an adequate theory that includes physicians in a relevant way. For example, claims against manufacturers based on *fraudulent* inducement require a showing that the physician didn't have the relevant knowledge because of the manufacturer's fraudulent conduct. *See supra* notes 233–39 and accompanying text.

posed by the promoted off-label use.[257] Studies or case reports identifying the risks or even data from online sources could suffice, depending on the standard courts use to evaluate provider knowledge. In some cases, however, the information will not exist—because no studies were done, or because manufacturers will have withheld the information or misrepresented it in some way. Thus, inducement claims will be difficult to prove based on underlying provider negligence where manufacturers failed to provide complete information or withheld information about off-label risks.[258]

But the claim is not completely dead. Plaintiffs could pursue off-label inducement on the theory that the provider was negligent *in relying on the manufacturer's statements* without further inquiry. Framed affirmatively, the physician has a duty to ask manufacturers about the information received from them. Plaintiffs could argue that manufacturers' goal is to increase sales, and they have done this by failing to provide objective information to physicians. Here, existing evidence on the influence of drug manufacturers is important.[259] Plaintiffs would then have to show that it was unreasonable for the provider to rely substantially on the sales representation for objective, complete information about the safety and efficacy of a drug or device.[260] This is the flip side of a fraud claim where a manufacturer may try to defend on the ground that the provider's reliance was unreasonable. But if it was unreasonable and the manufacturer is the reason the physician committed malpractice, then the manufacturer has induced the tort; it can't turn around and defend based on the breach of duty it relied on in promoting the off-label use.

This approach could improve the information to which physicians get access, and potentially buttress fraud claims. For example, imposing a duty on providers to request additional details about the information provided by sales representatives could improve the quality of information manufacturers provide to physicians. If a provider asks for the entire study on which the information is based, a manufacturer that misrepresents the results or provides falsified information opens itself to a fraud or misrepresentation

257. Inducement will not cover failure to warn or fraud claims. This is expected, of course, because those claims cover a different type of conduct—manufacturer conduct that causes innocent physician conduct.

258. Some risks associated with off-label uses actually do appear on the label. *See* 21 C.F.R. § 201.57(c)(9)(iv)(E)–(F) (2025); *id.* § 201.57(c)(9)(v)(D); *id.* § 201.80(f)(9)(v)(vi); *id.* § 201.80(f)(10)(iv).

259. For an example of how economic analysis can be used to show the aggregate effect of off-label marketing, see *In re Neurontin Marketing & Sales Practices Litigation*, 712 F.3d 21, 29 (1st Cir. 2013).

260. This is standard analysis under the Restatement's explanation of inducement. It explains that the party committing the tort need not know the conduct is tortious. RESTATEMENT (SECOND) OF TORTS § 876 cmt. on cl. b (AM. L. INST. 1979). They can be negligent in their actions *in relation to the inducer. See id.* § 876 illus. 8.

claim, which is unlikely to be preempted or stymied by the First Amendment.[261] And litigation over the physician's negligence is likely to produce information about *how* manufacturers promoted a drug or device and whether they did so fraudulently. This is an improvement compared to existing fraud and misrepresentation claims that die upon pleading because the plaintiff does not have this information.

If, on the other hand, manufacturers do provide information that demonstrate the risks but providers do not adequately study this information, then the provider is liable for negligence. The manufacturer may still be on the hook for inducement, however, if its *promotion* encouraged the negligent conduct. The reason is because, as discussed above, the lack of warning is not the issue; the issue is the encouragement of illegal conduct regardless of any warning. If Napster had encouraged users to infringe but also put a disclaimer on materials that users shouldn't infringe copyright, it would still have been liable for inducing infringement. Thus, the physician's negligence in not thoroughly reviewing the information forms the basis of a negligent off-label inducement claim. But the manufacturer is still on the hook for that liability because it encouraged a negligent use, even if it provided the information that should dampen one's desire to commit negligence.

This is important because it is a mutually reinforcing system. It encourages providers to ask for information and potentially ward off harmful off-label prescriptions, but it leaves the manufacturer on the hook precisely because "warning" is not enough. If the manufacturer is promoting a use that would constitute negligence regardless of the disclosure, then the manufacturer is liable despite providing the information.

Manufacturers are likely to argue that this upends the central tenet of the learned intermediary doctrine. Under this doctrine, a manufacturer is not liable for risks it adequately discloses to the provider.[262] A provider, of course, can still be liable for negligence even when the manufacturer makes an adequate disclosure if the provider breaches her duty of knowledge or informed consent. Manufacturers are likely to argue that this new test is an end run around the learned intermediary doctrine because it makes the manufacturer liable *no matter what they disclose*.

But this is not correct. Manufacturers are liable for inducing malpractice. Risk information does not discharge *all* duties. If manufacturers are promoting a drug or device for a use *they know is malpractice*, then they should be liable for the inducement, regardless of what risks they disclose.

But even if these arguments are not convincing, there is another way to overcome the problems negligence poses. State legislatures could pass laws

261. Commercial speech that is false or misleading is not protected under *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557, 564 (1980). *See also supra* Sections III.A–.B.

262. *E.g.*, Riley v. Am. Honda Motor Co., 856 P.2d 196, 199 (Mont. 1993); Campbell v. Am. Crane Corp., 60 F.3d 1329, 1331 (8th Cir. 1995).

that make providers strictly liable for prescribing certain drugs off-label.[263] Moving from negligence to strict liability for provider misconduct is not a new idea.[264] But it could make sense in this context for several reasons. First, we are not as concerned with the information generation function *about the malpractice* as we are about the *off-label promotion*. Thus, one principal criticism of strict liability—that it fails to produce detailed information about practices—applies far less forcefully to this context compared to provider misconduct claims generally. Second, imposing strict liability makes the off-label inducement claims even more like the IP inducement actions described in Section II.B. That would further support its application in this context. Third, the states—which bear the costs of physical harm from harmful off-label promotion (through health care, litigation, and administrative costs)—are legally the proper actors to regulate provider behavior. Finally, the strict liability law could be tailored to address the goals relating to off-label promotion specifically—and it could do this without raising important First Amendment concerns by penalizing particular speakers or types of speech.[265]

D. THE PROBLEMS OF PROCEDURE

A new cause of action raises procedural issues that courts must resolve for plaintiffs to plead and prove a successful claim. Although a complete treatment of every issue this raises is too complex to deal with fully, this Section briefly examines several pertinent ones, including pleading, class certification, and MDL requirements.

The underlying tort of malpractice is required for secondary liability. This suggests that in every case of inducement, the plaintiff must also plead and prove the underlying malpractice. In other words, the plaintiff must sue both the physician and the manufacturer, pleading and proving malpractice of an individual physician and the manufacturer's inducement of that malpractice.[266]

There are two potential ways to construct this requirement. The first is straightforward and requires each individual plaintiff to prove an underlying act of malpractice. In such cases, the plaintiff would join both the physician and the manufacturer in a single lawsuit and pursue them separately under two different theories: malpractice and inducement.

---

263. State legislatures have already done the opposite by making some off-label uses exempt from liability. *See supra* Section II.E.

264. *See generally* Assaf Jacob & Roy Shapira, *An Information-Production Theory of Liability Rules*, 89 U. CHI. L. REV. 1113 (2022).

265. *See supra* Section II.E.

266. *E.g.*, Williams v. Nidek Co., No. D050753, 2009 WL 226024, at *9–10 (Cal. Ct. App. Feb. 2, 2009) (denying class certification on vicarious liability because of diverse and distinct factual issues would require 17 to 70 "mini-trials" to address misrepresentation questions, because those mini-trials would need to be subdivided further to explore informed consent, and because plaintiffs lacked evidence of coordination or conspiracy among physicians and the manufacturer). Notably, off-label inducement does not require physicians to conspire or coordinate with one another or with the manufacturer.

The second draws on inducement in IP, which recognizes that suing diverse infringers is practically difficult. Thus, in certain cases, IP does not require proving individual acts of infringement where it is widespread. This approach would not require the plaintiff to plead and prove each individual provider committed malpractice that was proximately caused by the manufacturer's conduct. Instead, it would be enough to show that the use in question was unreasonable and that providers prescribed it. Thus, widespread use and promotion could form the basis of the lawsuit even without the plaintiff being required to prove that each individual off-label prescription or use was the result of promotional activity.[267] Courts will likely require individual providers to be joined to the suit. They could, however, avoid a requirement to join all providers based on evidence that promotional efforts had effects on prescribing behavior, in much the same way courts allow epidemiological evidence to prove causation in toxic tort cases.[268]

Because manufacturers promote drugs and devices in different markets, injured plaintiffs will likely bring claims in several states. If there are common factual or legal issues involved in each case, they may be resolved through MDL or class actions.[269] Claims across states with high to moderate value but that are dispersed across states are likely to wind up in MDL. When used, MDL consolidates lawsuits that have one or more common questions of fact by transferring them to a special panel that determines that MDL "will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions."[270] Common factual issues are centrally litigated pretrial, with the findings then applicable to all discrete cases that proceed to trial. MDL, however, will not be used where the claims are small in number and there are discrete factual issues.[271]

Claims that are low value or that involve a large common set of claims, by contrast, may be better suited for class action lawsuits. Class action lawsuits, which may be initiated at the state or federal level,[272] require large numbers of plaintiffs that are impractical to sue, common questions of law or fact, common defenses, and fair and adequate protection of class interests by representatives.[273] They also require a court to find that prosecuting claims

267. Whether and how tort law recognizes malpractice is also state-specific. This distinguishes it in principle from copyright infringement actions, which are federal and, in theory, uniform across states. Of course, while copyright infringement is theoretically a uniform cause of action, courts do not always apply the test for infringement uniformly.

268. *E.g.*, *In re* Silicone Gel Breast Implants Prods. Liab. Litig., 318 F. Supp. 2d 879, 892–93 (C.D. Cal. 2004).

269. The machinations of either MDLs or class actions are beyond the scope of this Article.

270. 28 U.S.C. § 1407(a).

271. Hasman v. G.D. Searle & Co., 106 F.R.D. 459, 460 (E.D. Mich. 1985).

272. FED. R. CIV. P. 23 governs federal class actions. Individual states may have their own class action rules. *See, e.g.*, FLA. R. CIV. P. 1.220 (West 2020); 735 ILL. COMP. STAT. ANN. § 5/2-801 (West 2003 & Supp. 2025).

273. FED. R. CIV. P. 23(a).

separately would "create the risk of . . . inconsistent . . . standards of conduct for the party opposing the class," decisions with respect to one potential class member that would determine the outcome of another potential class member's lawsuit, or that the common questions of law or fact are the most important questions and the class action is the best method of resolving the dispute.[274]

However, courts have obstructed this avenue for mass tort claims since the 1990s.[275] Assuming lawyers can find a way to open class actions to mass tort claims, this procedural device could aggregate low-value claims, centralize litigation costs, incentivize lawyers to take cases, and serve the tort's deterrence and compensation functions. In short, it would deter manufacturers from engaging in off-label promotion of uses that are likely to be both lucrative and unsafe but of low litigation value.

The limitations of MDLs and class actions may blunt the ability of off-label inducement to consolidate claims. However, recent litigation suggests that requirements for both will not be a complete barrier. The renewed interest in class actions for mass tort cases could gain traction, particularly in cases of off-label promotion that involve minor side effects and center mainly on promotional activities.[276] In any case, MDL will remain an avenue to resolve these cases. For example, claims against Medtronic for its off-label promotion of the InFuse Bone Graft were part of MDL, as were other lawsuits centered on off-label promotion.[277] Although there will be some factual and legal differences, the common factual issues—manufacturer promotional activities and their effects on physician prescribing patterns—are likely to predominate.

E. THE PROBLEM OF FAULT

While inducement liability may deter wrongful conduct, how successfully it does so may depend in part on who bears the cost of damages. Inducement requires allocating damages between two tortfeasors: the physician and the manufacturer. If the standard tort principles are applied, then the factfinder will allocate responsibility among them in proportion to their culpability.[278] In this scenario, the parties have two different incentives. First, they have the opposite incentive with respect to the substantial assistance or encouragement element of inducement. Under this element, the manufacturer's responsibility depends on the reason for the physician's actions. If the physician prescribed

274. FED. R. CIV. P. 23(b).

275. *See, e.g.*, Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 597 (1997); Ortiz v. Fireboard Corp., 527 U.S. 815, 821 (1999); *In re* Rhone-Poulenc Rorer, Inc., 51 F.3d 1293, 1303–04 (7th Cir. 1995).

276. *See* Myriam Gilles & Gary Friedman, *Rediscovering the Issue Class in Mass Tort MDLs*, 53 GA. L. REV. 1305, 1308–09 (2019).

277. For a class action, see *In re Neurontin Marketing & Sales Practices Litigation*, 712 F.3d 21, 29 (1st Cir. 2013).

278. RESTATEMENT (SECOND) OF TORTS § 881 (AM. L. INST. 1979). Even in states with joint and several liability, the defendants typically have a right of contribution. *See id.* § 886A.

because of the manufacturer's promotion, both parties are liable. But if the physician prescribed based on her independent judgment, then the physician is liable, not the manufacturer. Therefore, the parties have incentives to blame each other for the off-label use. The physician is likely to argue that the manufacturer overpowered her with promotion; the manufacturer is likely to argue the physician negligently exercised her own skill and judgment. Because this incentive structure pits the parties against one another, it does not pose a challenge to inducement—and may make it more effective.

However, there is a second incentive—on the question of malpractice—that does create a potential stumbling block: The physician and the manufacturer have the same incentive to argue that the off-label use does not breach the standard of care. Since malpractice is an essential element of the tort, the parties can defeat the inducement claim by showing the off-label use is the standard of care. In other words, the parties have an incentive to cooperate.

Cooperation of this type creates a challenge absent from traditional lawsuits against drug manufacturers only. Consider a failure to warn claim against a manufacturer. To succeed, a plaintiff must show that the manufacturer did not adequately warn the physician of the risks associated with the off-label use. Because the physician has no stake in the outcome, the physician lacks an obvious disincentive to cooperate with the plaintiff. A physician, therefore, could be willing to testify about the content, nature, and effect of the manufacturer's promotion without significant fear of liability of her own.

For inducement, however, the physician and the manufacturer are both liable for the negligence.[279] They want to show that the off-label use is not malpractice. The physician, therefore, is unlikely to cooperate with the plaintiff absent a change to this incentive, such as a settlement.

Potential for cooperation between defendants has several implications for off-label inducement. First, expert testimony will be crucial in establishing the standard of care. While it is always important in a malpractice case, the nature of off-label use will make even more relevant the issue of how the law sets the standard of care.[280] Second, the type and quantity of evidence supporting the off-label use will also play a key role in determining whether the off-use was negligent—something missing from standard lawsuits against manufacturers. Third, settlement strategy will be important for plaintiffs. Settlements with the

279. Of course, the liability could be apportioned to militate against this incentive. Because this is likely to be fact-dependent issue, however, it is not discussed further here.

280. Besides the issue of custom versus reasonableness, plaintiffs may have to show that the standard of care deviated from the one in her particular locality. *E.g.*, Katy v. Capriola, 742 S.E.2d 247, 251 (N.C. Ct. App. 2013) (requiring familiarity with standard of care in community or resources available in community bearing on standard of care); Pitts v. Nash Day Hosp., Inc., 605 S.E.2d 154, 156 (N.C. Ct. App. 2004) (similar).

physician may allow them to testify as a non-party at fault.[281] If treating physicians testify as to the manufacturer behavior (i.e., cooperate), plaintiffs' claims are more likely to be successful. Given litigation history, however, defendants may seek to admit a non-party physician's prior statements about his own malpractice, which are unlikely to help plaintiffs. Nevertheless, plaintiffs may develop settlement strategies with defendant physicians that can mitigate this problem by encouraging cooperation early in a case.

Finally, the defendants' incentive to cooperate has another implication: It underscores the importance of the plaintiff asserting complementary claims, such as those based on a duty to ask.[282] If courts recognize this duty, for instance, it will provide a counterweight to the physician's incentive to cooperate with the manufacturer. To defend such a claim, the physician will argue that she asked relevant questions of the manufacturer, but the manufacturer did not provide sufficient information, or otherwise concealed it—opening the manufacturer to traditional misrepresentation and concealment claims. In other words, by pleading commentary theories of liability, plaintiffs may induce physicians to cooperate with plaintiffs to avoid liability on the most damaging claim.

F. THE PROBLEM OF INNOVATION

Increasing liability may also decrease physician innovation. If we define innovation in this context roughly as *finding* new effective uses of legally marketed drugs and devices, then the reduction could take two forms. First, physicians may be more reluctant to innovate with new off-label uses if they are subject to increased malpractice liability. Second, physicians may be less likely to discover new uses because firms react to liability by providing less information about off-label uses. If innovation also includes *using* new off-label uses, the reduced information flow between manufacturers and physicians could also negatively affect innovation.[283] With less information about off-label uses, physicians may be unlikely to know about—and hence less likely to use—them. Both types of innovation declines could harm patients by depriving them of treatments that could alleviate symptoms of their disease or condition.

Although off-label inducement could reduce innovation, its effect may be neither significant nor negative. It may not be significant because if inducement is properly calibrated, it should reduce the number of harmful

281. Two or more defendants may be contributorily liable, but one or more defendants may settle prior to trial. When this happens, in some states the non-settling party may attempt to shift liability onto the settling party to reduce their proportionate share of damages. *E.g.*, GA. CODE ANN. § 51-12-33(c)–(d) (West 2024); CertainTeed Corp. v. Dexter, 330 S.W.3d 64, 74 (Ky. 2010). To apportion liability, the parties may in some cases introduce statements or testimony of the settling party. *E.g.*, Rowe v. Bell & Gossett Co., 218 A.3d 784, 801 (N.J. 2019).

282. *See supra* Section II.B.

283. *See, e.g.*, Simon, *supra* note 9, at 722–26.

off-label uses and communication about them. Because the tort would target uses that constitute negligence, reducing off-label uses should affect only harmful off-label uses. Manufacturers could still provide information on uses that are not negligent. Indeed, as explained in Section II.E.3, off-label inducement may incentivize manufacturers to bring their off-label uses on-label by seeking FDA review. Moreover, physicians are unlikely to be liable for merely prescribing off-label given that the crux of the cause of action will center on the physician's duty to know *and ask* manufacturers for additional information on the off-label uses they promote. Given that manufacturer speech does not cause a large portion of off-label use, it is unlikely that physicians will be held liable simply for using drugs and devices off-label.

Risk to innovation is also likely to be limited to a small subset of drugs —new drugs with unexpired patents. The reason is that virtually all drug promotion—including off-label promotion—is performed by brand name manufacturers for drugs with unexpired patents. In other words, inducement actions will apply only to uses promoted by brand name manufacturers, relatively close in time to the original approval.[284] To the extent that physicians are innovating *sui generis*, inducement has little to say. Indeed, physicians that innovate and prescribe off-label are still free to do so. And they, along with researchers, are free to publish any case reports, observational data, or clinical trials in journals. In other words, inducement addresses the problematic behavior (e.g., brand name manufacturer off-label promotion of on-patent drugs) without touching wide swaths of off-label prescribing (e.g., off-label use of generics).

Nevertheless, there is still a risk that more expansive liability will chill innovative behavior and speech about innovative uses for new drugs beyond those that are negligent. Even if this risk materializes, however, it is probably a cost worth bearing. Manufacturers currently have incentives to selectively provide information to providers, and providers do not have significant constraints on prescribing off-label.

Additionally, the increased cost may be offset by the gains from stimulating firms to seek additional authorization from the FDA for off-label uses. If the risk of liability for promoting off-label uses increases, then firms will have additional incentive to bring those uses on-label. This is important because, as noted above, virtually all off-label promotion is for new, on-patent drugs. And these are precisely the uses that should undergo testing to ensure they are safe and effective before marketing to physicians and health systems.[285] To the extent that medical products reflect the additional cost of authorization, it is probably good value for the money.

---

284. Any negative effects on innovation must also consider that newer drugs prescribed off-label are associated with higher adverse event rates than older drugs prescribed off-label as standard practice. *See* Tewodros Eguale et al., *Association of Off-Label Drug Use and Adverse Drug Events in an Adult Population*, 176 JAMA INTERNAL MED. 55, 59 tbl. 2 (2016).

285. Firms currently do pursue drug applications for some new uses of on-patent drugs. To the extent that this is already happening, a new liability rule should not have any effect in either direction.

CONCLUSION

This Article argued for off-label inducement, a new legal theory that makes a manufacturer liable when its promotion induces a provider to negligently prescribe, administer, or use its drug or device off-label. It argued that the theory was needed because the existing legal tools to address inappropriate and unsafe off-label promotion leave liability gaps. Sometimes, for example, laws and regulations designed to limit inappropriate off-label promotion focus on other problems, such as reimbursement and labeling, rather than patient injury. In other cases, the preemption and First Amendment law frustrate them, which restrict claims by injured patients and the government alike. Off-label inducement, this Article contended, avoids these problems and provides a means for injured patients to recover in ways that appropriately balance the risks and benefits of constraining informational transmission by manufacturers. Future work should closely analyze procedural mechanisms that enable lawyers to bring and aggregate these claims to ensure they adequately compensate victims and deter manufacturers from promoting unsafe uses.