Fair Accountability for Pharmaceutical Companies: It's Time to Discard the Learned Intermediary Doctrine

Steven R. Salbu[*]

For over half a century, pharmaceutical companies have been shielded under the "learned intermediary doctrine" should their products cause harm to patients. Under the doctrine, physicians are considered learned intermediaries who understand drug risks and counsel their patients accordingly, absolving the manufacturer of the duty to warn patients about potential drug risks and dangers. Contemporary medical and commercial practices have fundamentally changed the roles of both physicians and pharmaceutical manufacturers, such that it's time for states to discard the learned intermediary doctrine and hold the drug companies themselves accountable for failure to warn.

I. INTRODUCTION

Pharmaceutical manufacturers have a duty to warn consumers of product risks that the company is aware of at the time of sale.[1] However, under the learned intermediary doctrine,[2] "a warning to an intermediary fulfills a supplier's duty to warn consumers."[3] The idea behind the doctrine is that physicians function as professional conduits between patients and manufacturers, so that if the manufacturer warns doctors of risks, the manufacturer is not obligated to warn patients of those risks.[4] Under the

[*] Cecil B. Day Chair in Business Ethics at the Georgia Institute of Technology Scheller College of Business.

[1] Pustejovsky v. Pliva, Inc., 623 F.3d 271, 276 (5th Cir. 2010) (citing Pavlides v. Galveston Yacht Basin, Inc., 727 F.2d 330, 338 (5th Cir. 1984)). For purposes of explaining the learned intermediary doctrine, the example of Texas law will be referred to here.

[2] Some courts and other authorities refer to the "learned intermediary doctrine" as the "learned intermediary rule," as seen in some of the quotations in this essay. The two phrases refer to the same thing.

[3] Ackermann v. Wyeth Pharmaceuticals, 526 F.3d 203, 207 (5th Cir. 2008) (citing Alm v. Aluminum Co. of Am., 717 S.W.2d 588, 591–92 (Tex. 1986)).

[4] *Id.* (citing Porterfield v. Ethicon, Inc., 183 F.3d 464, 467–68 (5th Cir. 1999)).

doctrine, the physician "understands the propensities and dangers involved in the use of a given drug, and as the prescriber, he stands between this drug and the ultimate consumer."[5] So long as a drug manufacturer provides adequate warning to physicians, it has no duty to ensure that the warning reaches the patient.[6]

The Third Restatement of Torts elaborates on the rationale behind the learned intermediary doctrine.[7] Comment (b) explains, "The rationale supporting this 'learned intermediary' rule is that only health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy."[8]

This essay suggests that, for a variety of reasons, the learned intermediary doctrine is no longer justifiable. All these reasons reflect the same basic underlying dynamic: physicians simply no longer serve the role of learned intermediary to anywhere near the degree necessary to justify the doctrine. First, the proliferation of direct-to-consumer advertising has supplanted the role of physician as the sole, or potentially even the main, source of information and of motivation for patients seeking and using drug treatments.[9] Second, direct-to-patient drug sales means that many patients do not have a meaningful interaction with a physician when they seek and gain prescription drug treatments.[10] Third, fewer patients actually see a doctor for their physical examination, instead being treated by physicians assistants or nurse practitioners authorized under various state law to prescribe.[11] Fourth, when patients do actually go to a doctor's office and are examined by a doctor in person, managed health care limits the allotted time for appointments so severely that the idea that a doctor educates and informs patients of treatment costs and benefits, rather than simply treating them as organisms to be treated as they see fit, is illusory.[12] Finally, because pharmaceutical companies develop close, strong relationships with physicians that often influence their objectivity in dealing with patients, doctors often have a conflict of interest that is directly attributable to the very drug companies that are protected by the doctrine.[13]

---

[5] Wyeth–Ayerst Laboratories Co. v. Medrano, 28 S.W.3d 87, 91 (Tex.App. 2000) (citing Gravis v. Parke–Davis & Co., 502 S.W.2d 863, 870 (Tex.Civ.App. 1973, writ ref'd n.r.e.)).

[6] Stevens v. Parke, Davis & Co., 9 Cal. 3d 51, 65 (1973) (quoting Love v. Wolf, 226 Cal.App.2d 387, 395 (Cal. Dist. Ct. App. 1964) (citing Magee v. Wyeth Laboratories, Inc. 214 Cal.App.2d 340, 350–351 (Cal. Dist. Ct. App. 1963)).

[7] RESTATEMENT (THIRD) OF TORTS: Prod. Liab. Ch. 1, Topic 2, § 6 (1998) (Mar. 2024 Update). Comment (b).

[8] *Id.*

[9] *See infra* Section II.A.

[10] *See infra* Section II.B.

[11] *See infra* Section II.C.

[12] *See infra* Section II.D.

[13] *See infra* Section II.E.

II. ANALYSIS

A. Direct To Consumer Advertising

In August of 1999, the United States Food and Drug Administration provided guidelines that facilitated direct-to-consumer advertising of prescription drugs by pharmaceutical companies.[14] Direct-to-consumer advertising of prescription drugs then began to proliferate in the United States.[15] These ads frequently include language like "ask your doctor about . . .," or "talk to your doctor about,"[16] placing the drug company in an increasingly influential role in initiating and selling pharmaceutical treatment directly to a whole symptom-class of patients.

Not surprisingly, direct-to-consumer advertising of drugs increases both patient requests to and patient pressure on doctors to prescribe a desired product.[17] Common sense tells us that some doctors will succumb to patient pressure in place of their own best judgment in prescribing drugs,[18] potentially leading to a decline in the net quality of prescription decisions overall. Consistent with this risk, all countries except New Zealand and the United States ban direct-to-consumer drug advertising.[19]

Whether legalized direct-to-consumer advertising is good or bad policy is an interesting subject for another day. In the US today, what is important here is that direct-to-consumer advertising is ubiquitous and it undermines the rationale and the logic behind application of the learned intermediary doctrine. The Supreme Court of New Jersey has recognized this, creating a direct-to consumer advertising exception to the learned intermediary doctrine.[20] The Court reasoned that advertising directly to consumers implies that patients "are active participants in their health care decisions, invalidating the concept

---

[14] Guidance for Industry: Consumer-Directed Broadcast Advertisements, 64 Fed. Reg. 43197 (August 9, 1999).

[15] Jaclyn Carole Hill, *The Learned Intermediary Doctrine and Beyond: Exploring Direct-to-Consumer Drug Advertising Liability in the New Millenium*, 72 DEF. COUNS. J. 362, 362 (2005).

[16] See Monya De, *In a World Full of Drug Ads and Online Advice, 'Talk to Your Doctor' is More Than a Cliché*, USC CTR. FOR HEALTH JOURNALISM (Sept. 18, 2015) https://perma.cc/7Jx7-DS5G ("I wish I had a nickel (well, maybe a quarter — thanks, student loans) for every time I've read or heard the words "Talk to your doctor" on advertisements for medications, supplements, and medical equipment; tucked at the bottoms of blogs or health news articles by non-doctor authors; or as recommendations by my patients' acupuncturists, chiropractors, and therapists.").

[17] David Spurgeon, *Doctors Feel the Pressure From Direct to Consumer Advertising*, 172 WEST J. MED. 60 (Jan. 2000).

[18] Sometimes, doctors don't even "talk" with the patients advised in the ads to talk to their doctors; they simply write the script. *See* Emily Stewart, *The Bizarre Americanness of Prescription Drug Commercials*, VOX (Feb. 9, 2023) https://perma.cc/B7K9-9V6P (noting, "George Porter, a professor at the University of California San Diego, recently came across an ad for Vuity, a prescription eye drop that's supposed to help with blurry vision, and reached out to his ophthalmologist to ask what he thought of it. 'I didn't get a response back from my doctor, I just got a message from CVS that my prescription was ready,' he said.").

[19] Qing Yang & Kevin Parker, *Consult With Your Doctor if Medicines in Those TV Advertisements are Right for you*, STATE J. REG. (Nov. 22, 2021) https://perma.cc/R3DJ-AH9U.

[20] Perez v. Wyeth Laboratories Inc., 161 N.J. 1, 21 (1999).

that it is the doctor, not the patient, who decides whether a drug or device should be used."[21] The Court also observes, "consumer-directed advertising rebuts the notion that prescription drugs and devices and their potential adverse effects are too complex to be effectively communicated to lay consumers."[22] To date, New Jersey is the only state that has created a direct-to-consumer advertising exception to the learned intermediary doctrine.[23]

It's speculative to suggest that pharmaceutical industry lobbying and pressure have contributed to the resilience of the learned intermediary doctrine despite contemporary realities. It's also not unreasonable to hypothesize the existence and potential effectiveness of such pressure.

B. Direct-to-Patient Drug Sales

In early 2024, Eli Lilly was the first major pharmaceutical company to announce a foray into direct-to-consumer channels for sales of their prescription drugs.[24] The platform, called LillyDirect, will "eliminate[] the need for a patient to visit the doctor's office to get a prescription and, in some cases, for a pharmacy to fill it."[25]

Deloitte consultants Flaherty and Lou explain the concept of a typical direct-to-patient sales scenario from the customer's view.[26] Without consulting their doctor, patients go to a website, create an account, enter a payment method, and answer medical history questions.[27] Shortly after, a doctor calls patients to ask them some questions.[28] Patients receive their prescription medicine by mail a few days later without being examined by, or even meeting with, a physician.[29]

Direct-to-Patient drug sales have several benefits. They reflect contemporary realities around how people interact with manufacturers in the era of e-commerce; they facilitate the path between patients and treatments they might need; and they enhance what has been called "freedom not to see a

---

[21] *Id.* at 19 (quoting Susan A. Casey, Comment, *Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine*, 19 WM. MITCHELL L. REV. 931, 956 (1993)).

[22] *Id.*

[23] *See* Michelle Yeary, *No DTC Advertising Exception to Learned Intermediary Rule in Washington*, DRUG & DEVICE L. BLOG (June 7, 2022) https://perma.cc/MDX8-2J2Y ("It has been 23 years since New Jersey adopted a direct-to-consumer advertising exception to the learned intermediary rule. And, as of last week it remains the only state to have done so.").

[24] Annika Kim Constantino, *Eli Lilly's Direct Drug Sales Alone may not Upend the Industry, but Others Could Follow Suit*, CNBC HEALTH & SCI. (Jan. 5, 2024) https://perma.cc/QC7R-XXED.

[25] *Id.*

[26] Michael Flaherty & Richie Lou, *Direct-to Patient (DTP) Sales Channels Might be the Next Frontier for Pharmaceutical Companies,* DELOITTE HEALTH FORWARD BLOG, Oct. 1, 2020, https://www2.deloitte.com/us/en/blog/health-care-blog/2020/direct-to-patient-sales-channels-might-be-the-next-frontier-for-pharmaceutical-companies.html.

[27] *Id.*

[28] *Id.*

[29] *Id.*

doctor" in the current political abortion environment.[30] Moreover, direct-to-patient drug sales remove the retailer from the transaction, potentially reducing the cost of the prescription to the patient.[31]

Much like direct-to-consumer advertising, direct-to-patient drug sales have implications for the learned intermediary doctrine. These sales further attenuate the relationship between doctors and patients. The patient needn't see a physician at all, answering a cursory checklist of questions posed by a doctor remotely over the phone.[32] This new doctor-patient dynamic diminishes the role of the physician and the physician's contact and relationship with the patient. It likely also at least sometimes detracts from the quality and thoroughness of the interaction between doctor and patient. Given these realities, any justification for shifting responsibility for drug warnings from the manufacturer to the physician is also substantially diminished.

C. More Patient Appointments are Now with Physician Assistants and Nurse Practitioners Rather than with Doctors

The learned intermediary doctrine, adopted in the mid-20th century,[33] is predicated on an assumption that prescriptions are written by medical doctors.[34] In *Reyes v. Wyeth Labs.,* Fifth Circuit Judge Wisdom (using an anachronistic generic male voice that was common at the time) explained the rationale behind the doctrine in 1974: "As a medical expert, the prescribing *physician* [emphasis added] can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes

---

[30] Grossman recently coined the term "freedom not to see a doctor" in response to state laws limiting or prohibiting abortion in the wake of the *Dobbs* decision. Lewis A. Grossman, *Freedom Not to See a Doctor: The Path Toward Over-the-Counter Abortion Pills*, 2023 WISC. L. REV. 1041 (2023). He does recognize importance of prescription when a doctor's supervision is needed to ensure safety and efficacy. *Id.* at 1045. He suggests, however, that the FDA might reasonably remove the prescription requirement for abortion pills mifepristone and misoprostol if it finds "sufficient evidence that people can take the abortion medication regimen safely and effectively without a health care professional's supervision." *Id.* at 1048. Removing the requirement for learned intermediary intervention by classifying mifepristone and misoprostol as over-the-counter medications would remove several obstacles that might prevent a patient from receiving the drugs within the relatively short timeframe in which they can be used. *Id.* at 1045. These obstacles include making an appointment with a health care provider, taking time off work, accessing and traveling to a medical provider in rural areas, and paying for a medical provider without health insurance. *Id.*

[31] *See* Cathy Tie, *The New Era of Pharma is Direct-to-Consumer Healthcare*, NASDAQ BIOTECH (Jan. 18, 2024) https://perma.cc/Y73V-7NDV (observing that direct-to-consumer delivery of pharmaceuticals increases affordability to patients). This potential cost benefit to patients presumes that elimination of the retailer will pass on cost savings to the consumer, and not simply add to and increase the profits of the manufacturer. This assumption is suspect, given the natural profit orientation of business. If consumers are sufficiently attracted to direct-to-patient sales by the other benefits already discussed in this Section, *see supra* notes 26-30 and accompanying text, the manufacturer has little or no incentive to pass any of the savings from shortening the supply chain on to the patient.

[32] *See supra* note 28 and accompanying text.

[33] The learned intermediary doctrine dates to the mid-1960s. *See* Sterling Drug v. Cornish, 370 F.2d 82, 85 (8th Cir. 1966).

[34] Reyes v. Wyeth Labs., 498 F.2d 1264, 1276 (5th Cir. 1974).

is an informed one, an individual medical judgment bottomed on a knowledge of both patient and palliative."[35] Judge Wisdom declined to apply the learned intermediary doctrine in this case, wherein the vaccination in question was not administered by a physician, but rather by a public health nurse.[36]

Indeed, when the Learned Intermediary Doctrine was created in 1966,[37] medical examinations were conducted exclusively by licensed physicians, as the first very small class of Physician Assistants did not graduate from the first PA program until a year later,[38] and nurse practitioners as a category of health care providers date back only to 1965.[39] Today, many patients are not treated by physicians at all—rather, they see physician assistants or nurse practitioners, who also prescribe medications as they deem appropriate.[40] Harris notes, "the proportion of health care visits delivered by nurse practitioners (NPs) and physician assistants (PAs) has increased quickly in the US, according to data collected from about 276 million visits. By 2019, the proportion of visits that NPs and PAs provided had risen to nearly 26%, an increase from 14% in 2013."[41]

It's not my intent in any way to diminish either the valuable role or the strong qualifications of these two very important groups of medical practitioners. In an era of rising healthcare costs and physician shortages, the augmented role of physician assistants and nurse practitioners in 2024 is prudent public policy. Rather, the point here is that this trend is one of the five trends discussed in this essay that, taken together, undermine the strength of the rationale behind the learned intermediary doctrine.

Post baccalaureate, physicians attend four years of medical school plus several years of residency and sometimes an additional fellowship prior to full practice.[42] In contrast, PA programs are typically two-year masters programs following the baccalaureate,[43] and nurse practitioner programs are generally

---

[35] *Id.*

[36] *Id.* at 1277.

[37] *See Sterling Drug,* 370 F.2d at 85.

[38] *See Nurse Practitioners and Physician Assistants,* APPLIED POL'Y (Oct. 5, 2022) https://perma.cc/443T-EWXF (noting that Duke University created the first Physician Assistant Program, which graduated three Physician Assistants in 1967).

[39] *See* Theresa Granger, *Nurse Practitioners: A Look Back and Moving Forward*, USC SUZANNE DWORAK-PECK SCH. OF SOC. WORK (Nov. 10, 2017) https://perma.cc/E6M7-KWR3 ("The first nurse practitioner (NP) program in the nation was created in 1965 by Loretta Ford and Henry Silver from the University of Colorado. At the time, there was a need for health care among underserved populations. Nurses wanted a way to meet this need and saw expanding their role as the best way to accomplish this.").

[40] Emily Harris, *Increasing Proportion of Visits Delivered by NPs, PAs*, 330 J. OF AM. MED. ASS'N 1516, 1516 (2023).

[41] *Id.*

[42] *See* Sarah Wood, *How Long is Medical School and What is it Like?,* U.S. NEWS & WORLD REP. (Jan. 12, 2024) https://www.usnews.com/education/best-graduate-schools/top-medical-schools/articles/how-long-is-medical-school-and-what-is-it-like ("For a medical student who subsequently completes a residency and fellowship, training to become a physician may add up to a decade or longer.").

[43] *See Our Programs*, PHYSICIAN ASSISTANT EDUC. ASSOC., https://perma.cc/XHF4-SHK6 (resource page for individual schools' PA program requirements).

two to three years of post-baccalaureate study.[44] This is a significant difference in the required training toward the "learned" part of learned intermediary. The replacement of doctors with these two classes of healthcare professionals must at least weaken the argument in favor of the learned intermediary doctrine.

D. Inadequate Doctors Appointment Times

In 2016, The Physicians Foundation surveyed U.S. physicians and the public about their experience with doctors' appointments, finding that only 11 percent of patients and 14 percent of doctors said their appointments actually provided the amount of time they needed together.[45] This highly disturbing phenomenon isn't limited to the United States, as a 2019 survey in the United Kingdom revealed:

> A staggering 94% of NHS doctors surveyed said short appointment times put patients at risk, with GP's reporting that they felt the minimum 'safe' timeframe would be 16 to 20 minutes. Four in five said they don't always have time to properly diagnose patients, with 55% fearing they have missed serious health issues . . . and 37% believing they have prescribed the wrong course of treatment. Half of the GP's surveyed said they are expected to keep appointment times to less than ten minutes. Others were pressured to reduce this further depending on patient demand for attention.[46]

Linzer et al. identify some costs of the system where short physician visits are inadequate to the amount of work to be done: "Increased work during short (<20 min) visits means appointments in which fewer health care issues are addressed and the depth of understanding is diminished. Time-consuming psychosocial determinants of health are left unaddressed. These consequences translate to decreased patient satisfaction, excess emergency room usage and non-adherence to treatment plans." [47]

Needless to say, these abbreviated doctor visits and the resulting concerns expressed by doctors[48] are very troubling from the standpoint of quality healthcare delivery, particularly regarding increased incidence of misdiagnosis and inappropriate prescription.[49] For the purposes of this essay, rushed patient

---

[44] *See* Leona Werezak, *How Long Does It Take To Become a Nurse Practitioner?*, NURSE.ORG (Jan. 12, 2023) https://perma.cc/M2RP-H7H2.

[45] *Physician-Patient Relationship Remains Strong but Cost May Challenge Its Future*, BUSINESSWIRE (Oct. 4, 2017) https://www.businesswire.com/news/home/20171004005025/en/Physician-Patient-Relationship-Remains-Strong-Cost-Challenge-Future.

[46] *Doctors Admit Short Appointment Times are Putting Patients at Risk,* OPEN ACCESS NEWS (July 25, 2019) https://perma.cc/D3XG-PSYY.

[47] Mark Linzer et al., *The End of the 15-20 Minute Primary Care Visit*, 30 J. GEN. INTERN. MED. 1584 (2015).

[48] *See supra* note 46 and accompanying text.

[49] *Id.*

appointment times and increased incidence of inappropriate prescription[50] should place the learned intermediary rule in serious doubt and under very careful scrutiny. When doctors spend so little time with patients, thereby increasingly making prescription errors,[51] the legal and social justifications for the learned intermediary rule become untenable.

E. Aggressive Manufacturer Relationships with Physicians

Pharmaceutical manufacturers are increasing their budgets for the marketing of their products to physicians.[52] Sales representatives (sales reps) meet frequently with target doctors to develop strong relationships aimed at increasing sales of their products.[53] Activities in this realm include hosting lunches in doctors' offices to discuss the company's products,[54] general education of the doctors regarding the company's products,[55] inviting doctors to give paid presentations to their peers in company hosted speaker series dinners,[56] and inviting audience doctors to attend these complimentary dinners at fine-dining venues.[57] Some states, concerned about manufacturer influence of health care provision decisions, have begun to regulate interactions between sales reps and physicians, although these fall short of banning such access.[58] Some healthcare systems, however, now prohibit sales rep visits to their doctors.[59]

---

[50] *Id.*

[51] *Id.*

[52] *See* J. G. Navarro, *Mean Marketing Budgets of Healthcare Companies in the United States From 2019 to 2023, by Type*, STATISTA (Apr. 25, 2024) https://perma.cc/Q4NM-JNJG (reporting survey revealing that "47.2 percent of healthcare-related marketers surveyed between late 2023 and early 2024 reported plans to increase marketing budget to patients in the latter year.").

[53] *See* Adriane Fugh-Berman & Shahram Ahari, *Following the Script: How Drug Reps Make Friends and Influence Doctors*, 4 PUB. LIBR. OF SCI. MED. e150 (2007).

[54] *See* Joe Graedon, *Who Pays for Doctors' Free Lunches?*, THE PEOPLE'S PHARMACY (Aug. 5, 2023) https://perma.cc/NV93-MKUE ("Pharmaceutical drug representatives bring pizza, tacos or other goodies to hospitals, clinics or offices. This allows them to nurture relationships with important gate-keepers like receptionists or nurses. The reps' reward? They get to talk to a busy doctor for a few minutes.").

[55] *See* Roy Moynihan, *The Invisible Influence*, 336 BRIT. MED. J. 416, 416 (Feb. 2008), https://perma.cc/2Y89-G3RF (discussing pharmaceutical sponsorship of educational seminars, medical symposiums, and scientific conferences).

[56] *See* Charles Ornstein et al., *We Found Over 700 Doctors Who Were Paid More Than a Million Dollars by Drug and Medical Device Companies*, PROPUBLICA (Oct. 17, 2019) https://perma.cc/WGG6-NAXF (finding that hundreds of physicians each have been paid hundreds of thousands of dollars for giving promotional talks and consulting about pharmaceutical company products).

[57] *See* Charles Ornstein, *Doctors Dine on Drug Companies' Dime*, PROPUBLICA (Sept. 7, 2011) https://perma.cc/FDM2-L8J8 ("Hundreds of thousands of doctors have accepted free meals from pharmaceutical companies that invite them to scientific or educational sessions. At least 20 physicians accepted more than $2,000 worth of meals from one company last year, ProPublica's Dollars for Docs database shows.").

[58] Jacob Vazquez, *State Laws Seek to Regulate Sales Rep & Physician Interactions*, P360 BLOG (Jan. 17, 2020) https://perma.cc/TFJ4-WWLM.

[59] *Id.*

These activities are neither exclusively beneficial nor exclusively harmful. They can provide doctors with accurate, up-to-date, valuable information about the products the company offers, to the benefit of both the doctors and their patients.[60] On the negative side, these activities can be tarnished by the relationship's conflict of interest, as companies have incentives to err on the side of increased sales rather than balanced informational accuracy.[61] Likewise, the doctors have incentives to prescribe a company's products to encourage perquisites that the companies can provide to them in the future.[62]

I've already addressed these ethical conundrums in my previous work.[63] For the purposes of this essay, the critical point is that drug companies play an oversized role in formulating and communicating the information that doctors rely on regarding pharmaceutical products. Pharmaceutical companies have voluntarily undertaken this substantial function in the education of physicians in regard to drugs, their purported efficacy, and their risks.[64] As profit-seeking businesses, they do this not out of altruism, but rather to increase the sales of their own products by incorporating this educational function into the sales function of their representatives.

A reasonable implication of this dynamic is that responsibility to warn patients of drug risks should be charged to the pharmaceutical companies themselves. The learned intermediary doctrine that historically has shielded manufacturers from much liability was adopted at a time before drug companies undertook todays' enormous, aggressive educational and sales functions.[65] Back when the role of physicians' continuing education about drugs was more of a personal responsibility and less of a manufacturer undertaking, it made some sense to place greater responsibility on the doctors themselves. But in the 21st century, the drug companies' increasingly powerful and influential role in shaping physician behavior further justifies movement away from the learned intermediary doctrine.

---

[60] *See* Veronica Salib, *Can Pharmaceutical Companies Ethically Sponsor Medical Education?*, PHARMANEWS INTELLIGENCE (Sept. 19, 2023) https://perma.cc/5LKM-HD94 (discussing both benefits and costs of drug company involvement in medical education, noting the benefits to include access to information and less expensive education).

[61] *See* Moynihan, *supra* note 55, at 416-417 (discussing conflict of interest in the relationship between pharmaceutical companies and physicians).

[62] *Id. See also* Hannah Fresques, Ryann Grochowski Jones & Charles Ornstein, H*ow We Analyzed Doctors' Pharma Industry Ties and Medicare Prescribing*, PROPUBLICA (Dec. 20, 2019) https://perma.cc/3DS8-LD8Q (identifying correlation, but not proving causation, between physician product prescribing and physician contact with the company's pharmaceutical representatives).

[63] Steven R. Salbu, *Professional Medical Judgment and Pharmaceutical Marketing: Drawing Legal and Ethical Lines Around Conflict of Interest*, 12 WM. & MARY BUS. L. REV. 23 (2020).

[64] *See supra* note 60 and accompanying text.

[65] *See supra* note 33 and accompanying text. *See also* Lisa M. Schwartz & Steven Woloshin, *Medical Marketing in the United States, 1997-2016*, 321 J. OF AM. MED. ASS'N 80 (2019).

III. CONCLUSION

The Third Restatement of Torts actually opened the door to placing one small, narrow limitation on learned intermediary doctrine. It suggests that manufacturers should have an obligation to warn patients directly "when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings."[66] This exception is illogical and makes no sense. In what way is the doctor's ability to reduce risks of harm relevant to whether the manufacturer has an obligation to warn the patient of those risks? The reasoning here seems pointless and sloppy.

If we stretch our imaginations to try to deduce a point in the Restatement's exception, it's a troubling one. The exception implies that the function of the learned intermediary physician is, paternalistically, to "fix" the patient, who therefore implicitly lacks agency and need not worry their head over the risks—risks exclusively for the doctor to weigh and assess in ordering a treatment. This model of the doctor-patient relationship, upon which much of the learned intermediary doctrine is predicated, is outdated. Moreover, it's offensive to what should be important goals in the medical profession of patient autonomy and self-determination in making major health care decisions.

The question then becomes, exactly why do we have the learned intermediary doctrine? Is it because the doctor has the duty to warn the decision-making patient of drug risks, or because the doctor is the one who assesses those risks and makes all treatment decisions based on professional expertise? In 2024, we should have advanced to the stage where patient rights and agency demand that they themselves be informed of risks and benefits of proposed treatments, and that they themselves be the ultimate decision-makers regarding their treatment, of course within the bounds of FDA regulation of specific drugs.

The Third Restatement gets it wrong. A small exception to the learned intermediary rule for when doctors can't manage risks is authoritarian and it fails to address changes in medical care that have made the entire concept of "learned intermediary" farcical. The real point in evaluating the learned intermediary doctrine should be whether physicians still play a strong, meaningful, consistently substantial role of a learned intermediary between drug companies and patients. As we have seen, there are many reasons why this role has become highly attenuated in today's healthcare environment. Unlike when the learned intermediary doctrine was adopted, drug companies now advertise their products directly to consumers.[67] And going forward, they won't just advertise the drugs directly to consumers—they also will sell them

[66] *See* RESTATEMENT (THIRD) OF TORTS, *supra* note 7, § 6(d)(2).
[67] *See supra* Section II.A.

directly to consumers.[68] It is rare these days for patients to have a substantial amount of time with their doctors to learn about drug risks. They get brief appointment times, often remotely and without the opportunity for an actual physical examination, and often with a prescribing nurse practitioner or a physician assistant rather than a physician.[69] Making matters worse, drug companies cultivate relationships with doctors as part of their sales strategy, creating a conflict of interest that undermines the physician's supposed role of a learned intermediary who protects the patient against product risks.[70] For all these reasons, the learned intermediary doctrine has become functionally obsolete and indefensible in the contemporary health care environment. The shield it has historically created for drug companies to hide behind can no longer be justified, and states should discard the doctrine either by statute or through developing case law.

[68] *See supra* Section II.B.
[69] *See supra* Sections II.C & II.D.
[70] *See supra* Section II.E.