
The Trouble with the Curve: Manufacturer and Surgeon Liability for “Learning Curves” Associated with Unreliably-Screened Implantable Medical Devices

Frank Griffin, M.D., J.D.*

I. INTRODUCTION

Implantable medical devices have a considerable effect on the health and finances of Americans. The United States consumes about half of the worldwide market for implantable medical devices.¹ Every year, surgeons perform approximately seven million procedures implanting devices from eye lenses to hip replacements, with each procedure ranging in price from \$800 to \$45,000.² Publicly traded device manufacturers alone generate nearly \$200 billion in revenue per year, with most of the revenue being produced by just thirty companies.³

The rate of success of the implantation of the medical device depends upon device design and physician experience. New devices are often associated with an increased rate of complications during the first few years the device is on the market as doctors learn how to better implant the device and as

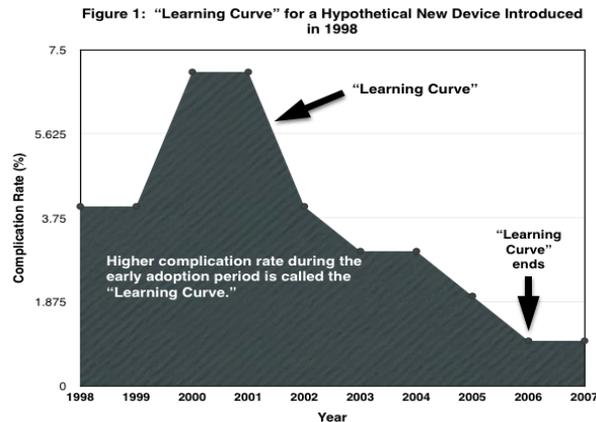
* The author thanks Professor Rob Leflar, Professor Amanda Hurst, Michael Goswami, and Micah Goodwin for their feedback and assistance with this article. The author is an orthopedic surgeon.

1. INST. OF MED., *MEDICAL DEVICES AND THE PUBLIC’S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS* 173 (2011) [hereinafter IOM REPORT], <http://www.nap.edu/catalog/13150/medical-devices-and-the-publics-health-the-fda-510k-clearance> [https://perma.cc/78VZ-UX7B].

2. Douglas A. McIntyre, *The Eleven Most Implanted Medical Devices in America*, 24/7 WALL ST. (July 18, 2011), <http://247wallst.com/healthcare-economy/2011/07/18/the-eleven-most-implanted-medical-devices-in-america/print/> [https://perma.cc/FWC8-RM5D].

3. *Id.*; see also IOM REPORT, *supra* note 1, at 169-70 (noting revenues of almost \$190 billion in 2008).

device companies make modifications to the device.⁴ On a graph depicting complication rates of devices, a distinct elevation can be seen during this initial phase as the device is being introduced for public use. This phenomenon is known as the “learning curve”⁵ and is shown for a hypothetical implant in Figure 1.⁶



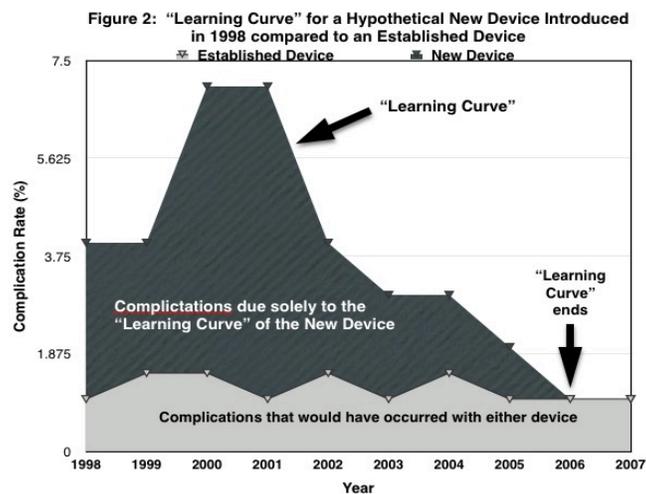
4. See, e.g., Aaron J. Johnson et al., *Is There a New Learning Curve with Transition to a New Resurfacing System?*, 69 BULL. N.Y.U. HOSP. JOINT DISEASES S16, S16 (2011) (noting a “substantial learning curve” when surgeons first switched to hip resurfacing implants from other procedures); Brahmajee K. Nallamothu et al., *Operator Experience and Carotid Stenting Outcomes in Medicare Beneficiaries*, 306 JAMA 1338, 1342 (2011) (finding higher mortality rates associated with early operator experience); Mikko Peltola et al., *Learning Curve for New Technology? A Nationwide Register-Based Study of 46,363 Total Knee Arthroplasties*, 95 J. BONE & JOINT SURGERY 2097, 2102 (2013) (finding a learning curve effect and early revision risks in knee implants, and further suggesting that the manufacturers consider the learning effect when designing new implants); Aartik Sarma, *The Learning Curve for Medical Devices: Experience with Vascular Closure Devices in Massachusetts*, 61 J. AM. COLL. CARDIOL. 10_S (2013) (finding the rate and magnitude of the learning curve differed between two different vascular closure devices); Kesavapillai Subramonian, *Acquiring Surgical Skills: A Comparative Study of Open Versus Laparoscopic Surgery*, 45 EUR. UROLOGY 346 (2004) (finding differences in the learning curve for open versus laparoscopic surgery).

5. See Brian Aros et al., *Is a Sliding Hip Screw or IM Nail the Preferred Implant for Intertrochanteric Fracture Fixation?*, 466 CLINICAL ORTHOPAEDICS & RELATED RES. 2827, 2830 (2008).

6. The learning curve is defined as “[t]he time taken and/or the number of procedures an average surgeon needs to be able to perform a procedure independently with a reasonable outcome.” K. Subramonian & G. Muir, *The ‘Learning Curve’ in Surgery: What Is It, How Do We Measure It and Can We Influence It?*, 93 BJU INT’L 1173, 1173 (2004).

For medical devices, the learning curve refers to the early period of device adoption when the device company and surgeons are developing the knowledge needed to implant the device reliably in a manner that minimizes the risk of harm to the patient.⁷ Many medical devices exhibit learning curves associated with serious complications—including death in some cases.⁸

During the learning curve period, the complication rate for the new device is often higher than for the established device being replaced.⁹ In those instances, patients suffer unnecessary complications because the doctor could have used the



established device to avoid the added risk. Figure 2¹⁰ demonstrates this scenario where the older device is much safer during the learning curve period:

7. *See id.*

8. Nallamothe et al., *supra* note 4, at 1342.

9. *See infra* notes 10-12 and accompanying text.

10. *See* Subramonian & Muir, *supra* note 6, at 1174 (“The slope of a learning curve depends on the nature of the procedure. It has been postulated that the learning curve for minimally invasive procedures is longer than that for open surgical procedures.”).

For the hypothetical implant in Figure 2, note that the complication rate was higher for the new device from 1998 through 2005.¹¹ The expertise of subspecialty surgeons, who were early adopters of the new device, may have elicited lower complication rates for the first couple of years (1998-1999 in Fig. 2). This was followed by higher complication rates as the more average surgeons adopted the device (2000-2001 in Fig. 2).¹² In some cases, a new device may be so broadly adopted that it becomes the standard of care at the peak of the learning curve even though its complication rate is substantially higher than the replaced device. This is likely due to a rush by surgeons to adopt the latest and greatest technology.¹³ Finally in 2006, in the hypothetical implant example depicted in Figure 2, after surgeon self-education and implant company modifications to the new device, the complication rate for the new device eventually equaled that of the established device.¹⁴ In reality, after the learning curve is complete, the complication rate for the new device could remain higher than, equal to, or, ideally, lower than the established device.

11. See Subramonian & Muir, *supra* notes 6, 9 and accompanying text.

12. See *id.*

13. Jeffrey O. Anglen & James N. Weinstein, *Nail or Plate Fixation of Intertrochanteric Hip Fractures: Changing Pattern of Practice: A Review of the American Board of Orthopaedic Surgery Database*, 90 J. BONE & JOINT SURGERY AM. 700, 706 (2008).

14. See *supra* Figure 2.

One device that demonstrated a substantial learning curve was a special type of intramedullary nail (Nail) used to treat hip fractures. Around 1997, the Nail began to replace an older device known as the compression hip screw (Screw).¹⁵ Figure 3 depicts the Nail's learning curve for the bone fractures resulting from complications¹⁶ (e.g., an additional fracture that occurred during or after the device was implanted to treat a broken hip) and is taken from an article comparing the results of the Nail to the Screw.¹⁷

Figure 3¹⁸

For a copy of the graph, please contact the Managing Editor of the *Arkansas Law Review* at arkansaslawreview@gmail.com.

(Reprinted with permission of *The Journal of Bone and Joint Surgery*)

15. Anglen & Weinstein, *supra* note 12, at 705.

16. *Id.* at 704.

17. *Id.*

18. Jeffrey O. Anglen & James N. Weinstein, *Nail or Plate Fixation of Intertrochanteric Hip Fractures: Changing Pattern of Practice: A Review of the American Board of Orthopaedic Surgery Database*, 90 J. BONE & JOINT SURG. AM., no. 4. 700, 704 (2008). Graph reprinted with permission.

The bars on the right of each pair demonstrate the rate of bone fracture for the Nail, and the bars on the left of each pair demonstrate the rate of bone fracture for the Screw.¹⁹ From 1999 through 2004, the Nail had a substantially higher risk of causing bone fracture than the Screw, forming a clear learning curve similar to that depicted in Figure 2.²⁰ Finally in 2005, the risk of bone fracture with the Nail was similar to the risk associated with the Screw.²¹

When the results of the two devices are compared, implantation of the Nail placed patients at an increased risk of bone fracture from 1999 through 2005, which coincides with the learning curve for the Nail.²² Several of those patients suffered unnecessary bone fracture—a serious injury.²³ Given the thirty-eight percent death rate among elderly patients with such bone fractures (i.e., femur fractures) and that the average age of the Nail/Screw patients was 77.9,²⁴ it is likely some patients died due to the Nail’s learning curve.²⁵ In addition, the financial costs associated with adoption of the Nail were likely significant considering that hip fractures of the type treated with the Nail and the Screw are a “major source of morbidity and financial burden” in the United States.²⁶

Risk-utility balancing can be used to determine whether or not the manufacturer (or surgeon) acted negligently by releasing (or using) the device with a learning curve.²⁷ For a risk to be acceptable, there must be enough benefit associated with

19. *Id.*

20. *See id.*

21. Anglen & Weinstein, *supra* note 12, at 704.

22. *See id.*

23. *See id.* at 704-05.

24. Philipp N. Streubel et al., *Mortality After Distal Femur Fractures in Elderly Patients*, 469 CLINICAL ORTHOPAEDICS & RELATED RES. 1188, 1190 (2011). The thirty-eight percent death rate is at a maximum follow up of 9.8 years. *Id.*

25. Anglen & Weinstein, *supra* note 12, at 705.

26. Eric Swart et al., *Cost-Effectiveness Analysis of Fixation Options for Intertrochanteric Hip Fractures*, 96 J. BONE & JOINT SURGERY AM. 1612, 1612 (2014) (stating hip fractures account for seven percent of osteoporotic fractures and approximately \$6 billion annually).

27. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. d (AM. LAW INST. 1998).

the device to more than offset the risks of the learning curve.²⁸ In the case of the Nail, recent studies have failed to demonstrate any clear benefit to individual patients, or to society as a whole, when the Nail replaced the Screw for the vast majority of hip fracture patients.²⁹ In fact, a research committee within the American Board of Orthopedic Surgeons (ABOS) concluded that “the consensus from the orthopaedic literature is that . . . nail fixation is associated with a higher complication rate and no better outcomes”³⁰ when directly compared to the Screw, noting that the Nail was associated with “higher implant costs and surgeon fees.”³¹

It is inherently unreasonable for patients to be subjected to a learning curve for a device that promises worse and more expensive outcomes than an established device. Under simple risk-benefit analysis for both the individual patient and society as a whole, where an unreliably-screened, implantable, medical device (USIMD)³² offers no proven benefit, no additional risk over an established device should be accepted. Patients injured

28. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. f.

29. Swart et al., *supra* note 24, at 1618.

30. Anglen & Weinstein, *supra* note 12, at 705.

31. *Id.* at 706.

32. For the purposes of this paper, an unreliably-screened, implantable, medical device (USIMD) is one that reached the market without undergoing reliable premarket screening of safety and effectiveness by the FDA. In 2011, the Institute of Medicine concluded that the FDA’s 510(k) screening process (which uses “substantial equivalence” as the standard for clearance) “lacks the legal basis to be a reliable premarket screen of the safety and effectiveness of moderate-risk devices.” IOM REPORT, *supra* note 1, at 2. Therefore, for purposes of this paper, the phrase “unreliably-screened” applies to any device cleared through the 510(k) process or any other FDA path using “substantial equivalence” as the standard. USIMDs for this article are specifically limited to those that are susceptible to state law defective design claims because their FDA approval is based upon substantial equivalency, and thus, are not subject to federal pre-emption afforded Class III devices approved through the Premarket Approval (PMA) process of the Medical Device Amendments of 1976. See Gregory J. Scandaglia & Therese L. Tully, *Express Preemption and Premarket Approval Under the Medical Device Amendments*, 59 Food & Drug L.J. 245, 246-55 (2004) (explaining common law claims were not expressly preempted “when the device was cleared under the [less stringent section 501(k)] process.”). But see *Gomez v. St. Jude Med. Daig. Div. Inc.*, 442 F.3d 919, 930, 933 (5th Cir. 2006) (finding state law claims alleging defective design of devices cleared by federal PMA process are preempted by Medical Device Amendment). “The § 510(k) notification process is by no means comparable to the PMA process [T]he § 510(k) review is completed in an average of only 20 hours” whereas “1200 hours [is] necessary to complete a PMA review.” *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478-79 (1996).

during the learning curve for a USIMD have at least two potential routes to recovery under current law: (1) defective design under products liability law, and (2) informed consent doctrine under medical malpractice law.³³

II. PRODUCT LIABILITY: DEFECTIVE DESIGN³⁴

A learning curve for a USIMD³⁵ associated with significant patient injury is prima facie evidence of a defective design because the risks of the learning curve are not offset by any proven benefit.³⁶ This results from the fact the USIMD “lacks the legal basis” of any “reliable premarket screen of its safety and effectiveness.”³⁷ The World Health Organization (WHO) noted that a slow learning curve resulting in poor performance is indicative of a poorly-designed device.³⁸ Federal law does not preempt state-law defective design claims against manufacturers of USIMDs.³⁹

A plaintiff that can demonstrate the presence of a learning curve for a USIMD has a prima facie case for defective design, and the burden shifts to the device manufacturer to prove that the USIMD’s benefits outweigh its risks.⁴⁰ Absent such proof, the injured plaintiff should prevail in a lawsuit against the manufacturer of a USIMD with a learning curve. A failure-to-

33. See Theodore R. LeBlang, *Informed Consent and Disclosure in the Physician-Patient Relationship: Expanding Obligations for Physicians in the United States*, 14 MED. & L. 429, 429-30 (1995) (noting that a doctor’s duty to inform a patient of material information in regards to medical care and treatment is heightened where innovative techniques or research activities are involved); see also Mary Beth Neraas, *Medical Device Preemption After Medtronic, Inc. v. Lohr*, 51 FOOD & DRUG L.J. 619, 623 (1996) (noting that defective design claim could be brought for devices cleared under 510(k) process).

34. This section addresses state tort law, not FDA standards.

35. See *supra* note 30.

36. See *Quintana-Ruiz v. Hyundai Motor Corp.*, 303 F.3d 62, 71 (1st Cir. 2002).

37. IOM REPORT, *supra* note 1, at 2.

38. WORLD HEALTH ORG., MEDICAL DEVICES: MANAGING THE MISMATCH: INCREASING COMPLEXITY OF MEDICAL TECHNOLOGY AND CONSEQUENCES FOR TRAINING AND OUTCOME OF CARE 7 (2010) [hereinafter WHO PAPER], http://whqlibdoc.who.int/hq/2010/WHO_HSS_EHT_DIM_10.4_eng.pdf.

39. *Medtronic*, 518 U.S. at 492-94 (holding that devices cleared through § 510(k) process are subject to state suit for defective design).

40. *Barker v. Lull Eng’g Co.*, 573 P.2d 443, 455 (Cal. 1978) (shifting burden to defendant to prove device was not defective based on risk-benefit theory); see *supra* note 33-34 and accompanying text.

warn claim is likely to be unsuccessful for plaintiffs against device manufacturers due to the affirmative defense in some jurisdictions provided by the Learned Intermediary Doctrine—except in cases where the device manufacturer failed to properly warn the surgeon.⁴¹

A. “Learning Curve” as a Prima Facie Case of Defective Design

By definition, a product is “defective in design when the *foreseeable risks* of harm posed by the product could have been reduced or avoided by the adoption of a *reasonable alternative design* . . . and the omission of the alternative design renders the product *not reasonably safe*.”⁴²

Many states hold the seller liable for products using the “unreasonably dangerous” standard in contrast to the “not reasonably safe” standard.⁴³

1. *Foreseeable Risks*

The risks associated with a USIMD’s learning curve are *foreseeable* where the medical literature documents numerous implants with learning curves,⁴⁴ where the device manufacturer is an expert in the field with knowledge of such medical literature,⁴⁵ and/or where the experts writing the literature are

41. See *Phelps v. Sherwood Med. Indus.*, 836 F.2d 296, 299-303 (7th Cir. 1987) (applying the learned intermediary doctrine to medical devices and stating that the doctor has the duty to warn patient—not the device manufacturer); see also *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1231-32 (4th Cir. 1984) (finding that the manufacturer does not have a duty to warn the patient after adequately notifying the physician of risks).

42. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2(b) (AM. LAW INST. 1998) (emphasis added).

43. RESTATEMENT (SECOND) OF TORTS § 402A cmt. i (AM. LAW INST. 1965) (“Unreasonably dangerous” is defined as “dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics.”); see *Voss v. Black & Decker Mfg. Co.*, 450 N.E.2d 204, 208 (N.Y. 1983) (stating that the “not reasonably safe” standard is the test to be applied in defective design cases); see also *Horst v. Deere & Co.*, 752 N.W.2d 406, 410 (Wis. Ct. App. 2008) (applying the “unreasonably dangerous” standard to products liability law).

44. See *supra* note 4.

45. *Huggins v. Stryker Corp.*, 932 F. Supp. 2d 972, 987-88 (D. Minn. 2013).

often agents of the device companies.⁴⁶ The risks must be *foreseeable* for a product to be defective such that “[o]nce the plaintiff establishes that the product was put to a reasonably foreseeable use, physical risks of injury are generally known or *reasonably knowable by experts in the field*. It is not unfair to charge a manufacturer with knowledge of such generally known or knowable risks.”⁴⁷

Medical device manufacturers are required to be as knowledgeable as experts in the field for which they create devices.⁴⁸ The expert surgeons and scientists who author medical literature acknowledging the presence of learning curves are often paid consultants for the manufacturer of the USIMDs.⁴⁹ Therefore, as agents of their principal manufacturer, their knowledge can be properly imputed to the device manufacturer.⁵⁰

2. Reasonable Alternative Design

A product is defective if the risk of harm could have been reduced by adopting a *reasonable alternative design* and “the omission of the alternative design renders the product not reasonably safe.”⁵¹ The established device with the lower complication rate that forms the floor of a USIMD’s learning curve (Figure 2) is an obvious reasonable alternative design

46. See *id.* at 987-990; see also Mustafa H. Kahn et al., *The Surgeon as a Consultant for Medical Device Manufacturers: What Do Our Patients Think?*, 32 SPINE 2616, 2617 (2007) (discussing the role of orthopedic surgeons as consultants for device manufacturers).

47. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. m (AM. LAW INST. 1998) (emphasis added).

48. See *Curtis, Collins & Holbrook Co. v. United States*, 262 U.S. 215, 222 (1923) (“The general rule is that a principal is charged with the knowledge of the agent acquired by the agent in the course of the principal’s business.”); RESTATEMENT (THIRD) OF AGENCY § 5.03 (AM. LAW INST. 2006); RESTATEMENT (SECOND) OF AGENCY § 271 (AM. LAW INST. 1958); RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. m (AM. LAW INST. 1998); A. G. S., Annotation, *Duty of Manufacturer or Seller to Warn of Latent Dangers Incident to Article as a Class, as Distinguished from Duty with Respect to Defects in Particular Article*, 86 A.L.R. 947, 949 (1933).

49. See Kahn et al., *supra* note 44, at 2616-17.

50. See, e.g., *Curtis, Collins & Holbrook Co.*, 262 U.S. at 224 (finding that knowledge was still imputed to the principal despite adverse interests between agent and principal).

51. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(b).

since it is used for the same type of injury with a lower baseline complication rate.⁵² Therefore, the Screw is a reasonable alternative design to the Nail.⁵³

The risk-utility test will always find the established device a more favorable alternative regardless of whether it considers risk-utility from the standpoint of the individual patient at risk of direct harm of the USIMD or the standpoint of society who will be responsible for the expenses resulting from USIMD complications. The USIMD by definition has no proven safety and effectiveness benefit over the established device and, therefore, the established device will be considered the reasonable, alternative design wherever risk-utility balancing is required.⁵⁴

Some states explicitly require proof of a reasonable, alternative design, while others do not.⁵⁵ Whether a state requires the reasonable, alternative design may depend upon how it applies risk utility balancing principles. Some states use the “Consumer Expectations Test”⁵⁶ which requires that the device sold “must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer.”⁵⁷ In a

52. *See* Genie Indus., Inc. v. Matak, 462 S.W.3d 1, 7 (Tex. 2015); *see also supra* Figure 2.

53. Anglen & Weinstein, *supra* note 12, at 705; Swart et al., *supra* note 24, at 1618.

54. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. a (AM. LAW INST. 1998).

55. *See, e.g.*, LA. STAT. ANN. § 9:2800.56(1) (2016) (codifying the requirement of plaintiff to prove “[t]here existed an alternative design for the product that was capable of preventing the claimant’s damage”); Gen. Motors Corp. v. Edwards, 482 So. 2d 1176, 1189 (Ala. 1985) (requiring that reasonable alternative design be shown); Nacci v. Volkswagen of Am., Inc., 325 A.2d 617, 620 (Del. Super. Ct. 1974) (requiring a reasonable alternative design). *But see* French v. Grove Mfg. Co., 656 F.2d 295, 298 (8th Cir. 1981) (stating that the requirement of a reasonable alternative design is not necessary under Arkansas law); Lee v. Volkswagen of Am., Inc., 688 P.2d 1283, 1288 (Okla. 1984) (stating that the ordinary consumer expectations of unreasonably dangerous be used instead of proof of a reasonable alternative design).

56. Aaron D. Twerski, *From Risk-Utility to Consumer Expectations: Enhancing the Role of Judicial Screening in Product Liability Litigation*, 11 HOFSTRA L. REV. 861, 901 (1983).

57. *Aller v. Rodgers Mach. Mfg. Co.*, 268 N.W.2d 830, 834 (Iowa 1978). “[T]he injured plaintiff must prove the product is dangerous and that it was unreasonable for such a danger to exist. Proof of unreasonableness involves a balancing process. On one side of the scale is the utility of the product and on the other is the risk of its use.” *Id.* at 835. *See also* Seattle-First Nat’l Bank v. Tabert, 542 P.2d 774, 779 (Wash. 1975) (noting that “the

USIMD case, a jury could find that the ordinary consumer would reasonably expect the medical device to be reliably screened for safety and efficacy.⁵⁸ An ordinary consumer might also reasonably expect that the device would not be marketed to supplant an established device where there is knowledge of a harmful learning curve and no reliable evidence that the USIMD is superior to the established device. Therefore, in any jurisdiction, the reasonable alternative design requirement should be easily met when the USIMD with a proven learning curve is being used in place of an established device.

3. Not Reasonably Safe

USIMDs with learning curves are not reasonably safe where they expose patients to increased risks of harm without any proven benefit to offset that risk.⁵⁹ To be defective, the jury must determine that the USIMD is not reasonably safe.⁶⁰ The language for this requirement varies between states and includes phrases like “not reasonably safe,” “unreasonably dangerous” or “fails to meet reasonable consumer expectations.”⁶¹ The reasonable, alternative design concept typically becomes relevant in proving whether a device is not reasonably safe where many states require proof that it was technologically (and in some states, economically) feasible to produce the product in a safer manner.⁶² In cases where a USIMD replaces an established device, the established device already proves both technologic and economic feasibility.

cost and feasibility of eliminating or minimizing the risk may be relevant in a particular case”).

58. See Romualdo P. Eclavea, Annotation, *Products Liability in Connection with Prosthesis or Other Product Designed to be Surgically Implanted in Patient's Body*, 1 A.L.R.4th 921 (1980) (citing *Hopkins v. Dow Corning, Corp.*, 33 F.3d 1116 (9th Cir. 1994)).

59. *Tincher v. Omega Flex, Inc.*, 104 A.3d 328, 398 (Pa. 2014).

60. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. d (AM. LAW INST. 1998).

61. *Id.*; ARK. CODE ANN. § 16-116-102(7)(A) (West 2006).

62. See *Voss v. Black & Decker Mfg. Co.*, 450 N.E.2d 204 (N.Y.1983). The court imposed the requirement of a reasonable alternative design stating that “[t]he plaintiff, of course, is under an obligation to present evidence that the product, as designed, was not reasonably safe because there was substantial likelihood of harm and it was feasible to design the product in a safer manner.” *Id.* at 208.

Reasonableness with regard to negligence claims is often evaluated by using risk-utility balancing where the risks and benefits are compared, as memorialized by Judge Learned Hand in *United States v. Carroll Towing Co.*⁶³ Professor John Wade has identified seven factors that have been used by many jurisdictions in performing risk-utility evaluations.⁶⁴ Risk-utility balancing with Wade's factors makes it apparent that USIMDs' learning curves are not reasonably safe because Wade's factors reveal the lack of adequate benefit to offset the associated risks. This is true both for the individual patient and for society as a whole.

First, a USMID with a proven learning curve fails to satisfy the test of Wade's first factor, "usefulness and desirability of the product—its utility to the user and to the public as a whole."⁶⁵ "Utility to the individual user" requires a proven benefit over an established device,⁶⁶ and utility to the public as a whole requires either a lower cost or another benefit to society.⁶⁷ A USIMD offers no proven benefit, only theoretical advantages that have often failed to pan out with prior generations of comparable USIMDs.⁶⁸ In fact, USIMDs

63. 159 F.2d 169, 173 (2d Cir. 1947); RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. d (AM. LAW INST. 1998).

64. John W. Wade, *On the Nature of Strict Tort Liability for Products*, 44 MISS. L.J. 825, 837–38 (1973). Professor Wade's factors have been adopted by many jurisdictions. See, e.g., *LaBelle v. Philip Morris, Inc.*, 243 F. Supp. 2d 508, 515 n.4 (D.S.C. 2001); *Dart v. Wiebe Mfg., Inc.*, 709 P.2d 876, 879–80 (Ariz. 1985); *Armentrout v. FMC Corp.*, 842 P.2d 175, 184 n.10 (Colo. 1992); *Potter v. Chi. Pneumatic Tool Co.*, 694 A.2d 1319, 1330 n.10 (Conn. 1997); *Tabieros v. Clark Equip. Co.*, 944 P.2d 1279, 1309 (Haw. 1997); *Banks v. Iron Hustler Corp.*, 475 A.2d 1243, 1251–52 (Md. Ct. Spec. App. 1984); *Nunnally v. R.J. Reynolds Tobacco Co.*, 869 So. 2d 373, 379–80 (Miss. 2004); *Duke v. Gulf & W. Mfg. Co.*, 660 S.W.2d 404, 411–12 (Mo. Ct. App. 1983); *Johansen v. Makita U.S.A., Inc.*, 607 A.2d 637, 642–43 (N.J. 1992); *Duran v. Gen. Motors Corp.*, 688 P.2d 779, 784 (N.M. Ct. App. 1983); *Roach v. Kononen*, 525 P.2d 125, 128–29 (Or. 1974); *Phatak v. United Chair Co.*, 756 A.2d 690, 694 (Pa. Super. Ct. 2000).

65. Wade, *supra* note 62, at 837.

66. See *Shetterly v. Crown Controls Corp.*, 719 F. Supp. 385, 399 (W.D. Pa. 1989) (noting the utility to the individual user, from the use of the pallet trucks, as increased productivity and monetary savings).

67. See *id.* (noting the utility to the public as lower grocery prices).

68. Marc J. Nieuwenhuijse et al., *Appraisal of Evidence Base for Introduction of New Implants in Hip and Knee Replacement: A Systematic Review of Five Widely Used Device Technologies*, 349 *BMJ* g5133, at 5 (2014) (finding "no clinically relevant improved benefits for these devices compared with older and established alternative implants"); see also Swart et al., *supra* note 24, at 1613.

are often found to be worse than the device they replaced resulting in harm to the patient at a more expensive price.⁶⁹ Where a device produces equal or worse outcomes for the individual patient and is more expensive to the payer system in terms of cost of the individual cases plus complications—there is simply no benefit to offset the risks of the learning curve. Therefore, the first factor heavily favors declaring these USIMDs not reasonably safe.

Second, USIMDs with learning curves fail to pass Wade’s second test which involves assessment of the “safety aspects of the product,” including the likelihood of resulting injury and the seriousness of any injury because USIMD injuries are often serious and occur without underlying reliable safety testing.⁷⁰ Significant patient injuries are often associated with USIMD learning curves.⁷¹ Complications from implantable medical device procedures may be serious causing further surgeries, disability, and/or death. The company’s decision to forego reliable safety and effectiveness screening results in a lack of information upon which to base reliable benefit assessments of the USIMD. Instead, safety and efficacy testing is basically completed during the learning curve period which is perilously close to human experimentation—and is, at an absolute minimum, unreasonable where patients’ lives and livelihoods are placed at risk unnecessarily due to the learning curve.

Wade’s third factor is the “availability of a substitute product” to meet the “same need and not be as unsafe.”⁷² USIMDs with learning curves will fail the third factor. The majority of USIMDs are released with a goal of replacing some other device that is already serving the same need and has a proven track record.⁷³ If the proven track record of the established device is poor or if there is no established device,

69. Nieuwenhuijse et al., *supra* note 67.

70. Wade, *supra* note 62, at 837.

71. See *supra* note 4 and accompanying text.

72. Wade, *supra* note 62, at 837.

73. See Nieuwenhuijse et al., *supra* note 67 (finding that several recently introduced devices were not safer nor were they more effective than established devices).

then the hurdle for the USIMD is low.⁷⁴ But if the established device has a satisfactory track record, the USIMD should offer some type of benefit before subjecting patients to the increased risks. For learning curve USIMDs that replace an established device, unless the USIMD has evidence to support that it is safer than the established device, analysis of USIMDs using Wade's third factor also leads to the conclusion that use of the USIMD is not reasonably safe.

USIMDs with learning curves also fail Wade's fourth factor, which evaluates whether the manufacturer can eliminate the device's unsafe character without making it too expensive to maintain its utility.⁷⁵ The manufacturer has a duty to determine whether or not the device has an unsafe character.⁷⁶ A manufacturer cannot assess the expenses involved in eliminating learning curve risks unless reliable premarket screening is first performed to identify those risks. Further, where no utility or benefit over an established device has been scientifically proven, there is no utility to maintain since the user can simply use the established device instead.

Wade's fifth factor—"the user's ability to avoid danger by the exercise of care in the use of the product"—may or may not be met depending upon whether the user referred to by Wade is the surgeon or the patient.⁷⁷ If the user is the surgeon, then the USIMD fails this factor because the surgeon is unlikely to be able to circumvent the learning curve since the learning curve phenomenon occurs in spite of the surgeon's extensive training and care in implanting a new USIMD.⁷⁸ An argument

74. See, e.g., *Surace v. Caterpillar, Inc.*, 111 F.3d 1039, 1053 (3d Cir. 1997); *Sansom v. Crown Equip. Corp.*, 880 F. Supp. 2d 648, 663 (W.D. Pa. 2012).

75. Wade, *supra* note 62, at 837.

76. *Hopkins v. Dow Coming Corp.*, 33 F.3d 1116, 1126 (9th Cir. 1994). The court found that punitive damages were justified where the manufacturer, in a rush to develop and market implants, "failed to adequately test the implants" and ignored knowledge of adverse health consequences associated with implants where "no research concerning the long-term health effects [of product] had been conducted." *Id.* at 1119. Furthermore, the manufacturer "knew long-term studies of implants' safety were needed . . ." *Id.* at 1127.

77. Wade, *supra* note 62, at 837.

78. *Phelps v. Sherwood Med. Indus.*, 836 F.2d 296, 301-02 (7th Cir. 1987) (debating whether surgeon should be considered a user of medical device); see also *Cutshall v. Photo Medic Equip., Inc.*, No. CIV.A.1:CV98-297, 2000 WL 1028548, at *5 (M.D. Pa. July 11, 2000) (stating that Wade's fifth factor refers to the user as the ordinary consumer).

may be made that USIMDs are “unavoidably unsafe” products,⁷⁹ but this argument fails where an established device already has a safe track record since the danger can be avoided simply by using the established device instead.

If the user is the patient, the patient should be informed of the learning curve in order to have the opportunity to avoid the danger. The manufacturer may claim that it has no duty to inform the patient under the Learned Intermediary Doctrine and that it is up to the surgeon to obtain informed consent.⁸⁰ To eliminate the manufacturer’s duty to the patient, the manufacturer must properly inform the learned intermediary (surgeon) that the USIMD has not been reliably tested for safety and efficacy.⁸¹ Arguably, the manufacturer may also be required to inform the surgeon that the USIMD has not been proven to be superior to the established device, or at least, not mislead the surgeon into believing otherwise.⁸²

Once the surgeon is properly informed by the manufacturer, the surgeon then has a duty under the Informed Consent Doctrine to properly apprise the patient of the risks so that the patient can make an informed decision about his or her own health care when choosing between the unproven promise of the USIMD and the established device.⁸³ Where the implant company has failed to notify the surgeon of the USIMD’s approval path and lack of safety and efficacy testing, such knowledge cannot be imputed to the surgeon where the surgeon is not an expert in implant design and the approval process—so the responsibility still lies with the manufacturer.⁸⁴ Without disclosure, the surgeon may not have the opportunity to properly inform the patient and avoid the danger of the learning curve where the manufacturer’s marketing materials promote

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

80. See *infra* Section II.C.

81. Diane Schmauder Kane, Annotation, *Construction and Application of Learned-Intermediary Doctrine*, 57 A.L.R.5th 26 (1998).

82. See *id.* at 34-35; *Schenebeck v. Sterling Drug, Inc.*, 423 F.2d 919, 922 (8th Cir. 1970).

83. See *Kowalski v. Rose Drugs of Dardanelle, Inc.*, 2011 Ark. 44, at 17, 378 S.W.3d 109, 120 (stating physicians are in the best position to inform patients of risks of treatment).

84. See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. d (AM. LAW INST. 1998).

advantages that the surgeon may reasonably assume have a solid scientific basis. Likewise, the surgeon and patient may have reasonably assumed that safety and efficacy testing are a part of the approval process.

Wade's sixth factor is "[t]he user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions."⁸⁵ USIMDs with learning curves fail Wade's sixth factor because there is little public knowledge of the learning curve and its associated dangers for new USIMDs. Presumably much of the public (including physicians) assumes safety and efficacy testing is a required part of the approval process by the FDA. However, it is unlikely that the public or physicians are generally aware of shortcuts such as the "substantial equivalence" test.⁸⁶

Wade's final factor is "[t]he feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance."⁸⁷ The medical device industry is very profitable making it feasible for the manufacturer to carry liability insurance. Where a small percentage of users suffer unnecessary complications during the learning curve period of a theoretically advantageous new USIMD, it is not unreasonable to require the device manufacturer to spread the loss sustained by those individuals to all users of the device and to the manufacturer themselves by either purchasing liability insurance or by self-insuring. The device manufacturer can eliminate its liability by conducting reliable safety and efficacy testing or by undergoing the Premarket Approval process, which may result in federal preemption.⁸⁸

85. Wade, *supra* note 62, at 837.

86. See Nicholas Bakalar, *Medical Procedures May Be Useless, or Worse*, N.Y. TIMES: WELL (July 26, 2013, 2:30 PM), <http://well.blogs.nytimes.com/2013/07/26/medical-procedures-may-be-useless-or-worse> [<https://perma.cc/3U7R-FEKV>] ("We usually assume that new medical procedures and drugs are adopted because they are better.").

87. Wade, *supra* note 62, at 838.

88. 21 U.S.C. § 360e(d)(2) (2012); see *Medtronic, Inc., v. Lohr*, 518 U.S. 470, 477, 503 (1996).

Thus, Wade's risk-utility analysis clarifies that a USIMD with a learning curve is not reasonably safe if it causes significant patient injuries.

B. Burden Shift: The Device Manufacturer Should Be Required to Prove Benefit Once the Plaintiff Establishes "Learning Curve" Risks

After proving a USIMD is associated with a learning curve, a plaintiff will have made a prima facie case of defective design because the plaintiff will have shown foreseeability of risk, reasonable alternative design, and a presumptive risk-utility balance that supports a finding of lack of reasonable safety.⁸⁹ If the patient can demonstrate with expert testimony that his or her physician was on the learning curve, then the burden shifts to the device manufacturer to demonstrate benefits to offset the risks associated with the learning curve because the manufacturer has the means and the motivation to prove that its devices are beneficial, if such proof can be found.⁹⁰ It is unreasonable to require a plaintiff to prove *Defectiveness* by scientific standards where the manufacturer has never shown *Effectiveness*. Once the manufacturer has presented its case for benefit versus the plaintiff's case for risk, the question becomes one of fact for the jury to consider in light of risk-utility balancing considerations.

The manufacturer is in the best position to prove the benefits of its implants. The USIMD manufacturer has access to: the means to manufacture and alter the device; the designing surgeons who are implanting and evaluating the device; and patient follow-up information during the product development period. This makes it feasible for the company to monitor the outcomes of early patients and encourage their affiliated surgeons to produce research proving safety, efficacy, and beneficial use. Research will benefit the company's financial bottom line if it can prove that a device is effective. The company can then market those findings to other surgeons. Thus, the device manufacturer has the means and the motivating

89. See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(b) (AM. LAW INST. 1998).

90. See *Barker v. Lull Eng'g Co.*, 573 P.2d 443, 455 (Cal. 1978).

factors to provide proof of beneficial use and effectiveness, if such proof exists. If reliable established devices are available and the company cannot prove beneficial use of the USIMD, then no learning curve risk should be tolerated based on simple risk-to-benefit analysis.

Conversely, a plaintiff patient—with access only to clinical studies outside information available from the manufacturer through discovery—would not be able to produce reliable scientific studies proving defectiveness. The plaintiff is unlikely to have the means to secure expert testimony adverse to wealthy manufacturers from implant designers who hope to continue to work in this \$200 billion per year industry.⁹¹ This generally leaves hired guns as the only feasible alternatives to testify on behalf of the plaintiff,⁹² and at a very high financial cost and limited credibility under *Daubert* standards.⁹³ From a practical standpoint for the plaintiff, the barriers imposed by *Daubert* are usually insurmountable for learning curve USIMDs due to the costs involved and the limited ability of anyone outside the industry to produce such devices and test them in patient care circumstances.

Therefore, the plaintiff should only be required to put forth *Daubert*-level evidence proving that the risks outweigh the benefits, if the device manufacturer can scientifically prove sufficient benefit. If the device manufacturer is unable to prove any benefit over an established device that is safe, then the plaintiff should prevail when he/she was injured during a learning curve.

C. Other Design Defect Considerations: Failure to Warn and the Learned Intermediary Doctrine

91. See IOM REPORT, *supra* note 1, at 169-70; see also McIntyre, *supra* note 2.

92. See Scott E. Sundby, *The Jury as Critic: An Empirical Look at How Capital Juries Perceive Expert and Lay Testimony*, 83 VA. L. REV. 1109, 1126-30 (1997).

93. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). *Daubert* places limits on the admissibility of scientific evidence by applying a reliability standard that requires that testimony be grounded in scientific methods and procedures. *Id.* at 592-93. The judge is to consider whether the theory can be tested, whether it has been subjected to peer review and publication, whether it has a known error rate, whether standards control its operation and whether it is widely accepted in the scientific community. *Id.* at 593-94. The focus is on the principles and methodology. *Id.* at 595.

Device manufacturers may be liable for defective design for failure to warn of the harms associated with the learning curve for USIMDs, but the Learned Intermediary Doctrine's affirmative defense makes this approach difficult for the plaintiff.

[A product] is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe.⁹⁴

However, in some states, the device manufacturer may assert an affirmative defense under the Learned Intermediary Doctrine that it reasonably relied upon the physician to convey relevant warnings to the patient.⁹⁵ In the vast majority of medical implant cases, the device manufacturer has no direct contact with the plaintiff prior to the surgical procedure, and imposing a duty on the manufacturer to intervene in the doctor-patient relationship is generally disfavored.⁹⁶ Therefore, the Learned Intermediary Doctrine would apply to most medical device cases.

On the other hand, the plaintiff may still have an argument for failure to warn because the device manufacturer has a duty to warn the surgeon of the product's dangerous propensities and may have failed to do so.⁹⁷ To assert the Learned Intermediary defense as a shield against liability, the device company for the USIMD must provide adequate warnings to the prescribing surgeon.⁹⁸ Some courts have ruled

94. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(c) (AM. LAW INST. 1998).

95. See *Hill v. Searle Labs.*, 884 F.2d 1064, 1070 (8th Cir. 1989) (applying Arkansas law); Kane, *supra* note 80, at 73-74 (1998 & Supp. 2016) (noting that courts in fourteen states allowed the Learned Intermediary Doctrine to relieve the manufacturer of the duty to warn the patient directly).

96. *West v. Searle & Co.*, 305 Ark. 33, 42, 806 S.W.2d 608, 613 (1991); *Craft v. Peebles*, 893 P.2d 138, 155 (Haw. 1995); see Kane, *supra* note 80, at 73-77 (1998 & Supp. 2016).

97. See *Hansen v. Baxter Healthcare Corp.*, 764 N.E.2d 35, 42 (Ill. 2002).

98. *Breen v. Synthes-Stratec, Inc.*, 947 A.2d 383, 387 (Conn. App. Ct. 2008); *McNichols v. Johnson & Johnson*, 461 F. Supp. 2d 736, 739 (S.D. Ill. 2006) (noting that

that the patient is entitled to a rebuttable presumption of proximate causation where the manufacturer failed to adequately warn the learned intermediary.⁹⁹ Also, if the salespeople working for the manufacturer are guilty of over-promotion, the warning may be deemed inadequate.¹⁰⁰ Norms within the medical profession may make surgeons susceptible to an overreliance on misleading information leading to a belief that they are engaging in sound medical practice where medical device manufacturers influence surgeons in ways similar to pharmaceutical firms.¹⁰¹ Device manufacturers generally do not disclose to surgeons that USIMDs reached the market using “unreliable screening,” and many surgeons assume otherwise.¹⁰²

Physicians who have limited experience using a new device are not in the best position to recognize the presence of a learning curve because the subtle differences between implants are not always readily apparent. A device manufacturer that properly introduces and monitors a new medical device is in a much better position to recognize the presence of a learning curve, while a single surgeon has only his or her own experience to draw from. Thus, it would be proper to hold the manufacturer liable for failure to warn the surgeon of any learning curve risks.

III. MEDICAL MALPRACTICE: INFORMED CONSENT

under Illinois law, the learned intermediary doctrine is a shield against liability only where the manufacturer of a prescription drug has given adequate warning of known dangerous propensities of the drug to physicians); RESTATEMENT (SECOND) OF TORTS § 402A cmt. h (AM. LAW INST. 1965).

99. *Mampe v. Ayerst Labs.*, 548 A.2d 798, 801 (D.C. Cir. 1988); *Miller v. Pfizer, Inc.*, 196 F. Supp. 2d 1095, 1126 (D. Kan. 2002); *Woulfe v. Eli Lilly & Co.*, 965 F. Supp. 1478, 1483 (E.D. Okla. 1997).

100. *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 662 (Cal. 1973); *Hamilton v. Hardy*, 549 P.2d 1099, 1109 (Colo. App. 1976); *Incollingo v. Ewing*, 282 A.2d 206, 219 (Pa. 1971).

101. Marc A. Rodwin, *Institutional Corruption and the Pharmaceutical Policy*, 41 J. L. MED. & ETHICS 544, 548-49 (2013).

102. From my 20 years working as an orthopaedic surgeon, I do not recall any device company representative ever disclosing that a device was cleared via a “substantial equivalence” pathway, and I generally assumed that available devices on the open market had undergone testing with scientific rigor similar to publication standards in our industry—minimum of 2 years clinical follow-up with rigorous clinical evaluation. Likewise, I have heard other surgeons make similar assumptions throughout my career.

A violation of the standard of reasonable conduct¹⁰³ under the Informed Consent Doctrine occurs when a surgeon fails to inform a preoperative patient of his or her learning curve with a particular USIMD.¹⁰⁴ The learning curve risks of some USIMDs are within the required scope of disclosure of material facts to the patient for informed consent as a matter of public policy. In addition, the Affordable Care Act's "preference sensitive care" provisions may provide an added layer of obligation to disclose the learning curve for elective procedures.¹⁰⁵

A. Public Policy

Physicians have a fundamental duty to warn patients of the risks and consequences of a medical procedure under the Informed Consent Doctrine.¹⁰⁶ Under the doctrine, the patient's right to participate in the decision-making process regarding his or her personal health is regarded as one of the patient's "most fundamental rights."¹⁰⁷ Informed consent is important for many reasons, including preservation of personal autonomy and the right of self-determination.¹⁰⁸ It fosters communication between doctor and patient, encouraging doctors to be careful in decision-making while simultaneously fostering rational decision-making by the patient and involving the public in medical decision-making.¹⁰⁹ Patient outcomes may improve if patients are assisted in making informed decisions about their

103. W. PAGE KEETON ET AL., PROSSER & KEETON ON THE LAW OF TORTS 356 (W. Page Keeton ed., 5th ed. 1984) ("In other words, 'duty' is a question of whether the defendant is under any obligation for the benefit of the particular plaintiff; and in negligence cases, the duty is always the same—to conform to the legal standard of reasonable conduct in the light of the apparent risk.").

104. See Alexander M. Capron, *Informed Consent in Catastrophic Disease Research and Treatment*, 123 U. PA. L. REV. 340, 370 (1975).

105. Patient Protection and Affordable Care Act § 936, 42 U.S.C. § 299b-36(b)(2), (d)(1)(A) (2012).

106. *Lucas v. Awaad*, 830 N.W.2d 141, 150 (Mich. Ct. App. 2013).

107. Yves Longtin et al., *Patient Participation: Current Knowledge and Applicability to Patient Safety*, 85 MAYO CLINICAL PROC. 53, 54 (2010).

108. Capron, *supra* note 104, at 365.

109. *Id.* at 365-76.

own treatments and illnesses.¹¹⁰ By participating in and understanding the process, patients can also improve quality of care by giving feedback to the healthcare system.¹¹¹ Some doctors feel that physician inexperience is not part of the informed consent equation.¹¹² The idea that a physician may not disclose his or her inexperience to the patient in order to gain experience to help future patients has been described as the “physician’s dodge” with one author saying, “[l]earning must be stolen, taken as a kind of bodily eminent domain.”¹¹³

Failure to inform the patient of a USIMD’s learning curve deprives the patient and the system of all of the benefits of informed consent doctrine. First, the patient’s fundamental rights of self-determination and personal autonomy are violated where the surgeon is allowed to choose a riskier USIMD over an established device without disclosing the risks involved with the learning curve, and allowing the patient to participate in the choice. Second, failure to reveal the learning curve to the patient deprives the patient of the opportunity to make a rational choice between competing devices. Third, an opportunity is missed to personalize the learning curve by encouraging the surgeon to reflect upon the consequences of the learning curve upon the individual patient. Finally, from a public policy standpoint, failure to inform the patient leaves the patient uneducated and unable to provide necessary feedback during the learning curve period for USIMDs. Informing the patient of the learning curve allows the patient to participate more vociferously during this phase of device implementation. Thus, an opportunity to gain a patient’s assistance in the assessment of quality of care is missed if the patient is uninformed.

110. BARRY R. FURROW ET AL., *LAW AND HEALTH CARE QUALITY, PATIENT SAFETY, AND MEDICAL LIABILITY* 185 (7th ed. 2013).

111. Longtin et al., *supra* note 107, at 53.

112. Ashley H. Wiltbank, Note, *Informed Consent and Physician Inexperience: A Prescription for Liability?*, 42 WILLAMETTE L. REV. 563, 573 (2006).

113. ATUL GAWANDE, *COMPLICATIONS: A SURGEON’S NOTES ON AN IMPERFECT SCIENCE* 32 (2002).

B. Scope of Disclosure

The scope of information that should be disclosed under the Informed Consent Doctrine clearly includes the risks associated with a learning curve where the courts have required that surgeons inform patients of material risks, alternative treatment options, and risks of death or serious injury.¹¹⁴ Whether the physician had a duty to warn of dangers associated with particular circumstances is generally a question to be submitted to the jury.¹¹⁵

Many courts adopt a rule that any material risk must be disclosed.¹¹⁶ “A material risk is a risk which a reasonable person would consider significant in deciding whether to undergo a particular medical treatment.”¹¹⁷ The risks of a learning curve for a USIMD are often material risks.¹¹⁸ A reasonable person would likely consider a learning curve significant in his or her decision to undergo surgery with a USIMD if that learning curve increases significantly the risk of the procedure over an established device. For example, at least one court has considered failure of a surgeon to disclose his inexperience with a particular procedure as admissible evidence for the jury to consider in an informed consent evaluation.¹¹⁹ Where the risk involves serious injury like a bone fracture for the Nail used in

114. *Canterbury v. Spence*, 464 F.2d 772, 786-88 (D.C. Cir. 1972).

115. *Mitchell v. Robinson*, 334 S.W.2d 11, 16 (Mo. 1960).

116. *See, e.g., Hill v. Medlantic Health Care Grp.*, 933 A.2d 314, 329-30 (D.C. Cir. 2007); *Chamberlain v. Giampapa*, 210 F.3d 154, 161 (3d Cir. 2000); *Hahn v. Mirda*, 54 Cal. Rptr. 3d 527, 532 (Ct. App. 2007); *DeGennaro v. Tandon*, 873 A.2d 191, 196 (Conn. App. Ct. 2005); *Heinrich ex rel. Heinrich v. Sweet*, 118 F. Supp. 2d 73, 81 (D. Mass. 2000).

117. *Hill*, 933 A.2d at 330.

118. P. Healey & J. Samanta, *When Does the ‘Learning Curve’ of Innovative Interventions Become Questionable Practice?*, 36 EUR. J. VASCULAR & ENDOVASCULAR SURGERY 253, 256 (2008).

119. *Willis v. Bender*, 596 F.3d 1244, 1255 (10th Cir. 2010) (finding “a number of courts have concluded physician-specific information such as experience is relevant to the informed consent issue and physicians have a duty to voluntarily disclose such information prior to obtaining a patient’s consent”); *Barriocanal v. Gibbs*, 697 A.2d 1169, 1170, 1172 (Del. 1997) (noting that failure to disclose that physician had not recently performed aneurism surgery and there were other nearby hospitals that specialized in aneurism surgery were important considerations for informed consent); *Johnson ex rel. Adler v. Kokemoor*, 545 N.W.2d 495, 506 (Wis. 1996) (“[T]he defendant was not unduly or unfairly prejudiced by the admission of evidence reflecting his failure to disclose his limited prior experience in operating on basilar bifurcation aneurysms.”).

the case illustration discussed earlier, a reasonable person would probably consider that information significant in making the decision.

Many courts require the surgeon disclose reasonable alternative treatment options.¹²⁰ A reasonable rule is that “where a physician or surgeon can ascertain in advance of an operation, alternative situations and no immediate emergency exists, a patient should be informed of the alternative possibilities and given a chance to decide before the doctor proceeds with the operation.”¹²¹ Where an established device has a proven track record and the new USIMD has merely hypothetical projections, the established device would be the reasonable, alternative treatment option. In any jurisdiction that requires disclosure of a reasonable, alternative treatment option under the Informed Consent Doctrine, the fact that the established device is available as a reasonable alternative and has not been shown to be inferior to the new USIMD is a material fact that must be disclosed. Failure to do so subjects the surgeon to potential liability for failure to provide informed consent.

Finally, informed consent almost always requires the surgeon disclose risks of death or serious injury.¹²² Where a USIMD has a known learning curve with a risk of death or serious injury, the physician has a duty to disclose those risks. If the information available to the physician is controversial, then the surgeon may simply disclose the facts of the information available and leave the decision to the patient.¹²³

120. See, e.g., *Canterbury v. Spence*, 464 F.2d 772, 781 (D.C. Cir. 1972); *Sweet v. Sisters of Providence in Wash.*, 895 P.2d 484, 493 (Alaska 1995); *Miller v. Van Newkirk*, 628 P.2d 143, 146 (Colo. App. 1980); *Ray ex rel. Ray v. Kapiolani Med. Specialists*, 259 P.3d 569, 581 (Haw. 2011); *Bang v. Charles T. Miller Hosp.*, 88 N.W.2d 186, 190 (Minn. 1958); *Stanley v. Chevathanarat*, 664 S.E.2d 146, 149 (W. Va. 2008).

121. *Bang*, 88 N.W.2d at 190.

122. *Canterbury*, 464 F.2d at 787-88; *Ray*, 259 P.3d at 584; *Mitchell v. Robinson*, 334 S.W.2d 11, 19 (noting the physician must warn of “possible serious collateral hazards”).

123. *Canterbury*, 464 F.2d at 786-87.

C. Standard of Care

Whether the jurisdiction requires surgeons to follow the reasonable patient standard or the reasonable doctor standard, disclosure of the learning curve risks of the USIMD is required.¹²⁴ The states are evenly divided on which standard is applied.¹²⁵

In states that use the reasonable patient standard, the doctor breaches his or her duty of informed consent where a reasonably prudent patient with the plaintiff's characteristics would have declined the operation with the USIMD if he or she had been properly informed.¹²⁶ Because a reasonably prudent patient would want to be informed of the learning curve and its risks as well as reasonable alternative methods of treatment (e.g., the established device), a surgeon who has failed to disclose risks and alternatives can be found to have breached his or her duty. A few jurisdictions replace the reasonably prudent patient (objective standard) with the particular plaintiff (subjective standard)¹²⁷ so that the duty is to disclose information that the particular plaintiff would consider important. In those jurisdictions, the plaintiff can easily claim that he or she would have wanted to know about the learning curve and would have chosen the safer alternative if given the choice.

A reasonably prudent patient would want to know of an increased risk of death or serious injury associated with a learning curve. Likewise, if the doctor is on the learning curve because of limited experience with a new USIMD, a reasonable patient would probably want to know that information. In addition, if there are less risky alternatives, the reasonable patient would likely want to know of the alternative and participate in any decision to accept the added risk of a USIMD. All of those factors are material to the patient's ability to make a rational decision in giving informed consent.

124. See Healey & Samanta, *supra* note 118, at 256.

125. FURROW ET AL., *supra* note 110, at 195.

126. Giles v. Brookwood Health Servs., Inc., 5 So. 3d 533, 553-54 (Ala. 2008); *Ex parte Mendel*, 942 So. 2d 829, 837 (Ala. 2006); Harrold v. Artwohl, 132 P.3d 276, 280 (Alaska 2006).

127. Scott v. Bradford, 606 P.2d 554, 557-58 (Okla. 1979).

In jurisdictions where the reasonable physician standard is used, the doctor has a duty to disclose “any known risks of death or serious bodily injury”¹²⁸ and “such additional [risks] as a skilled practitioner of good standing would provide under similar circumstances.”¹²⁹ The applicable community standard is a question of fact for the jury¹³⁰ and expert testimony is required to establish the standard of care.¹³¹ In these jurisdictions, some doctors doubtless disclose learning curve risks, including the risks and benefits of the new USIMD versus the established device as well as the specific doctor’s personal experience and preferences.¹³² Therefore, it may be possible to show that the standard of care is to disclose that information via expert testimony.

However, even if the learning curve is not routinely disclosed by the surgeons in a reasonable doctor jurisdiction, the court can still adopt the rule that disclosure of the learning curve is the standard of care.¹³³ Judge Learned Hand pointed out that “[w]hat usually is done may be evidence of what ought to be done, but what ought to be done is fixed by a standard of reasonable prudence.”¹³⁴ Hand notes that “a whole calling may have unduly lagged” the adoption of “reasonable prudence,” and in those cases, “[c]ourts must . . . say what is required.”¹³⁵ Hand goes on to say that “there are precautions so imperative that even their universal disregard will not excuse their omission.”¹³⁶

128. *Jones v. United States*, 933 F. Supp. 894, 901 (N.D. Cal. 1996), *aff’d*, 127 F.3d 1154 (9th Cir. 1997) (holding that physician has a duty to disclose known risks of death or serious bodily injury to the patient and to explain the complications that might occur); *see also* *Cobbs v. Grant*, 502 P.2d 1, 10-11 (Cal. 1972).

129. *Jones*, 933 F. Supp. at 901-02.

130. *Fuller v. Starnes*, 268 Ark. 476, 479, 597 S.W.2d 88, 90 (1980); *Stauffer v. Karabin*, 492 P.2d 862, 865 (Colo. App. 1971).

131. *Mather v. Griffin Hosp.*, 540 A.2d 666, 670 (Conn. 1988).

132. *See* Am. Acad. of Ophthalmology, Advisory Opinion on the Code of Ethics: Learning New Techniques Following Residency (Oct. 10, 2014), <http://www.aao.org/ethics-detail/advisory-opinion—learning-new-techniques-followin#related-comments>.

133. *See* Anna C. Mastroianni, *Liability, Regulation and Policy in Surgical Innovation: The Cutting Edge of Research and Therapy*, 16 HEALTH MATRIX J. L. MED. 351, 427-28 (2006).

134. *Tex. & Pac. Ry. Co. v. Behymer*, 189 U.S. 468, 470 (1903).

135. *The T.J. Hooper*, 60 F.2d 737, 740 (2d Cir. 1932).

136. *Id.*

William L. Prosser¹³⁷ explained that “in negligence cases, the duty is . . . to conform to the legal standard of reasonable conduct in the light of the apparent risk.”¹³⁸ The doctor must satisfy this duty by informing the patient of the risk of the learning curve especially where those risks are material to the patient’s decision, are unnecessary due to an alternative treatment option, or are risks of serious injury or death.¹³⁹ Disclosure of the material facts necessary to allow the patient to make rational decisions is such a basic right that it might be time for courts to overrule the profession in any jurisdiction where the disclosure of learning curves is not standard practice.

D. Affordable Care Act: “Preference Sensitive Care”

The Affordable Care Act (ACA) provides evidence of changing professional standards of care for informed consent with regard to “preference sensitive care”¹⁴⁰ that may be used as evidence in matters of state informed consent law. Preference sensitive care is defined the following way:

[M]edical care for which the *clinical evidence does not clearly support one treatment option* such that the appropriate course of treatment depends on the *values . . . and preferences of the patient . . .* regarding the benefits, harms and scientific evidence for *each treatment option*, the use of such care should depend on the informed patient choice among clinically appropriate treatment options.¹⁴¹

For USIMDs with learning curves, the device manufacturers have foregone safety and effectiveness testing, and thus, conceivably do not have “clinical evidence” to “clearly support” or favor the use of the USIMD over an established

137. William L. Prosser, a former dean of the University of California Law School at Berkeley, was widely considered “a great Master at Torts.” Lawrence H. Eldredge, *William Lloyd Prosser*, 60 CAL. L. REV. 1245, 1245, 1247 (1972).

138. KEETON ET AL., *supra* note 103.

139. *Canterbury v. Spence*, 464 F.2d 772, 786-88 (D.C. Cir. 1972).

140. Patient Protection and Affordable Care Act § 936, 42 U.S.C. § 299b-36(b)(2), (d)(1)(A) (2012).

141. Patient Protection and Affordable Care Act § 936, 42 U.S.C. § 299b-36(b)(2) (emphasis added).

device.¹⁴² In those instances, the ACA appears to advocate allowing the patient to hear about “each treatment option” and use his or her own “values and preferences” in the decision making process.¹⁴³ This cannot be done if the physician fails to inform the patient of the learning curve, the risks of the USIMD, and the presence of a safe alternative device.

IV. OVERARCHING PUBLIC POLICY CONSIDERATIONS

Innovation is an important part of the advancement of medical science;¹⁴⁴ however, newness is not the same as innovation. An advancement should move the field forward, not backwards or sideways.¹⁴⁵ Arguably, surgeons’ adoption of the Nail did not advance the field of orthopedic treatment of hip fractures and may have actually set it back. This shift from the Screw to the Nail resulted in many patients experiencing unnecessary disability and probably some deaths.¹⁴⁶ Today, there is still no evidence the Nail is better than the Screw it replaced. That is not advancement—that is marketing. Where the USIMD is more profitable than the established device, it may also be profiteering at the expense of the harmed patient. Therefore, the court system should reward the patients who suffered for these innovations by recognizing the failures of the device manufacturers and the surgeons involved.

Understanding why surgeons adopt ineffective, harmful technology may help provide a solution to the problem. A former president of the American Academy of Orthopaedic Surgeons (the “world’s largest medical association of musculoskeletal specialists” now with over 39,000 members

142. *See id.*

143. *See id.*

144. IOM REPORT, *supra* note 1, at 193 (“The committee believes that given the broad interpretation of the term it should define innovation not simply as a change but as a favorable change in the context of public health The committee defined innovation broadly as improving the quality of, efficiency of, or access to health care.”).

145. *Id.*

146. Anglen & Weinstein, *supra* note 12, at 704-05.

worldwide)¹⁴⁷ described medicine as a “marketing arm of industry.”¹⁴⁸ Similarly, a prominent medical ethicist noted that “there is no necessary correlation between the kind of innovation generated by the market and the kind of technology needed to improve overall health.”¹⁴⁹

The cost of USIMDs with learning curves is substantial. For example, hip fractures of the type treated with the Nail and the Screw are a “major source of morbidity and financial burden” in the United States accounting for seven percent of osteoporotic fractures and approximately \$6 billion annually.¹⁵⁰ According to a 2008 study, government insurers like Medicare spent an average of \$950 more per surgery on the Nail than the Screw during the first year after implantation.¹⁵¹ If the Nail were used in approximately 150,000 intertrochanteric hip fractures in the U.S. each year, the extra cost would have been around 142.5 million (i.e., 150,000 x \$950) per year for this single device.¹⁵² By 2008 when this study was published, the learning curve phenomenon with the Nail was largely complete.¹⁵³ These numbers could very well underestimate the actual cost of adopting the Nail considering that from 1999 through 2004 the complication rate for Nail-related bone fracture alone was between 300% and 800% that of the Screw.¹⁵⁴ If only a small percentage of the 48,000 USIMDs cleared from 1996 through 2009 had the same financial impact as the Nail adoption, then the costs to the U.S. healthcare system would be staggering.¹⁵⁵

Regulation of high-risk devices released through pathways intended for lower risk devices is a great challenge.¹⁵⁶

147. American Academy of Orthopaedic Surgeons, *Background*, AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS, <http://www.aaos.org/CustomTemplates/Content.aspx?id=1604>.

148. AUGUSTO SARMIENTO, BARE BONES: A SURGEON’S TALE: THE PRICE OF SUCCESS IN AMERICAN MEDICINE 284 (2003).

149. DANIEL CALLAHAN, FALSE HOPES: WHY AMERICA’S QUEST FOR PERFECT HEALTH IS A RECIPE FOR FAILURE 225 (1998).

150. Swart et al., *supra* note 24, at 1612.

151. Aros et al., *supra* note 3, at 2831.

152. *See id.*; *see also* Swart et al., *supra* note 24, at 1612.

153. *See* Anglen & Weinstein, *supra* note 12, at 704 (Figure 4-A).

154. *See id.* at 703-04.

155. IOM REPORT, *supra* note 1, at 136.

156. Daniel B. Kramer et al., *Regulation of Medical Devices in the United States and European Union*, 366 NEW ENG. J. MED. 848, 852 (2012).

In 2010, there was public outcry over several specific devices and the methods through which the FDA cleared them.¹⁵⁷ Calls for change to the FDA's approval process for implantable medical devices have been emphatic and have come from highly respected authorities, yet Congress has still failed to act.¹⁵⁸ In 2011, the FDA asked the Institute of Medicine (IOM) to review the 510(k) clearance process and make recommendations to protect the health of the public while protecting the legitimate interests of industry.¹⁵⁹ The IOM concluded that the 510(k) process was fatally "flawed"¹⁶⁰ because it generally does not evaluate safety and efficacy and cannot be transformed into such process.¹⁶¹ The IOM noted that the assessment utilized ("substantial equivalence") does not provide a "reasonable assurance of safety and efficacy" as required by statute for some of the devices at issue (Class III).¹⁶² The IOM Committee recommended that the FDA scrap the current system and replace it with an "integrated premarket and postmarket regulatory framework that effectively provides a reasonable assurance of safety and effectiveness throughout the device life cycle."¹⁶³ Obviously, the life-cycle would include the learning curve

157. Gardiner Harris, *U.S. Inaction Lets Look-Alike Tubes Kill Patients*, N.Y. TIMES (Aug. 20, 2010), http://www.nytimes.com/2010/08/21/health/policy/21tubes.html?pagewanted=all&_r=0 [<https://perma.cc/Q3ZX-XLCU>] (noting resistance from the medical device industry and an approval process that discourages safety-related changes as factors in deaths related to some tubing connections); Gardiner Harris, *F.D.A. Vows to Revoke Approval of Device*, N.Y. TIMES (Oct. 14, 2010), <http://www.nytimes.com/2010/10/15/health/policy/15fda.html> [<https://perma.cc/3CSU-FJAS>] (noting politics trumped science in approval of knee patch); Barry Meier, *The Implants Loophole*, N.Y. TIMES (Dec. 16, 2010), http://www.nytimes.com/2010/12/17/business/17hip.html?_r=0 [<https://perma.cc/5BHK-8QFZ>] (recognizing potential problems with several devices that had been cleared through the 510(k) process, including an artificial hip); Alicia Mundy & Jared A. Favole, *F.D.A. Rips Approval of Medical Device*, WALL ST. J. (Sept. 25, 2009, 12:01 AM), <http://www.wsj.com/articles/SB125382260933538517> [<https://perma.cc/FM6Z-BXVB>] (noting Congressional pressure damaged the integrity of the F.D.A.'s approval process).

158. IOM REPORT, *supra* note 1, at 16 n.5 (noting that concern is being raised about the 510(k) process not fostering innovation nor making safe and effective devices available to patients citing letters from House Representatives).

159. IOM REPORT, *supra* note 1, at xi.

160. *Id.* at 3.

161. *Id.* at 5.

162. *Id.*

163. *Id.* at 8.

period. However, there are no signs that such changes are forthcoming, and implant manufacturers continue to argue for more lenient standards.¹⁶⁴

This leaves the court system as the patient's best protector against unreasonable harm, or death, at the hands of medical device manufacturers and overly-eager, early-adapter surgeons who promote USIMDs. Where it can be proven a device has a learning curve by showing that the surgeon has not done many procedures with the device, and the literature or experts agree that a learning curve is expected, the patient injured during the learning curve has a valid argument for defective design. When the patient is uninformed, he or she may also have claims for failure to warn (if the manufacturer did not inform the surgeon) or for lack of informed consent against the doctor.

V. CONCLUSION

The presence of a learning curve with significant patient injuries for a USIMD is prima facie evidence of defective design, and unless the device manufacturer can demonstrate a benefit to offset the risk, the patient should prevail in a design defect case where the patient was harmed by the device implanted by a surgeon on the learning curve. Risk-utility balancing in close cases should be left to the trier of fact. When the patient is not warned about the presence of the learning curve with a USIMD, the patient may have a claim against the manufacturer for failure to warn if the learned intermediary was not properly informed of the risk, or against the physician for lack of informed consent if the surgeon fails to notify the patient of the risks of the learning curve. As it is, there are overarching public policy concerns that support the courts taking up this issue to protect the interests of patients and of society as a whole.

164. *Dangerous Medical Implants and Devices: Most Medical Implants Have Never Been Tested for Safety*, CONSUMER REPORTS (May 2012), <http://consumerreports.org/cro/magazine/2012/04/cr-investigates-dangerous-medical-devices/index.htm> [<https://perma.cc/P7PH-MBFJ>].