IN THE BUSINESS OF MEDICINE: WHY HOSPITALS SHOULD BE SUBJECT TO THE THEORY OF STRICT LIABILITY AS ANY OTHER SELLER

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INTRODUCTION

Drug pumps, pacemakers, and transvaginal mesh—each of these implantable medical devices[1] have saturated the courts with their own defect litigation in recent years.[2] Plaintiffs have alleged that the devices cause terrible pain, bowel problems, opioid overdose, and in the most severe cases, even death.[3] "[S]upersized federal court litigation" has attempted to hold ultra-profitable device manufacturers accountable for the devastation caused by these defective devices.[4]

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1. Yeun-Ho Joung, *Development of Implantable Medical Devices: From an En/gineering Perspective*, 17 INT'L NEUROLOGY J. 98, 98 (2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3797898/pdf/inj-17-98.pdf_ (explaining that a medical device is implantable when it is "either partly or totally introduced, surgically or medically, into the human body and is intended to remain there after the procedure").

2. *See* Matthew Goldstein, *As Pelvic Mesh Settlements Near $8 Billion, Women Question Lawyers' Fees*, N.Y. TIMES (Feb. 1, 2019), https://www.nytimes.com/2019/02/01/business/pelvic-mesh-settlements-lawyers.html; Joe Carlson, *Medtronic to Create $35M Settlement Fund for Implantable Drug Pump Lawsuits*, STAR TRIBUNE (Sept. 27, 2019, 6:17 PM), https://www.startribune.com/medtronic-to-create-35m-settlement-fund-for-implantable-drug-pump-lawsuits/561565622; Jackie Allen, *Humana Sues St. Jude and Abbott Laboratories for Faulty Pacemakers*, USA HERALD (Aug. 8, 2020), https://usaherald.com/humana-sues-st-jude-and-abbott-laboratory-faulty-pacemakers.

3. Carlson, *supra* note 2; Allen, *supra* note 2.

4. Goldstein, *supra* note 2; *see also* MEDPAC, REPORT TO THE CONGRESS: MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM 208 (2017), http://www.medpac.gov/docs/defaultsource/reports/jun17_ch7.pdf?sfvrsn=0 [https://web.archive.org/web/20210510033950/http://www.medpac.gov/docs/default-source/reports/jun17_ch7.pdf?sfvrsn=0]. Large medical device manufacturers typically see profit margins from 20 to 30%, *id.*

In 2020, the Food and Drug Administration ("FDA") recalled thirty-three additional medical devices.[5] The FDA categorized each of these as a Class I recall—denoting the most serious degree of risk.[6] The FDA defines a Class I recall as "[a] situation where there is a reasonable chance that a product will cause serious health problems or death."[7]

Considering the quantity and severity of recalls in 2020, it is unlikely that this "supersized federal court litigation" will slow down any time soon.[8] In fact, product liability cases swelled in 2019, and pharmaceutical and medical device manufacturers faced the brunt of these lawsuits.[9] Pharmaceutical and medical device companies topped the list of most active product liability defendants.[10] Recent jury verdicts have required medical device manufacturers to pay more than $1.9 billion to plaintiffs, in large part to compensate for injuries from defective hip implants.[11] Similarly, there are almost 15,000 hernia mesh device lawsuits structured as class actions currently pending against three other medical device manufacturers.[12] This is only a sample of the current litigation brought in attempt to compensate blameless plaintiffs for injuries that they sustained from so-called innovative, life-saving devices.

Although plaintiffs have slammed medical device manufacturers with litigation over defective products, courts have largely spared hospitals from liability for their roles in the cases.[13] Typically, manufacturers and those in the chain of product distribution can expect to be subject to strict liability when they sell a defective product.[14] However, "[a]n overwhelming majority of jurisdictions have refused to apply strict liability principles to claims against

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5. *2020 Medical Device Recalls*, U.S. FOOD & DRUG ADMIN. (Oct. 5, 2021), https://www.fda.gov/medical-devices/medical-device-recalls/2020-medical-device-recalls.

6. *Id.* (click each listed recall to view class type); *What Is a Medical Device Recall?*, U.S. FOOD & DRUG ADMIN. (Sept. 26, 2018), https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall [hereinafter FDA, *Medical Device Recall*].

7. FDA, *Medical Device Recall*, *supra* note 6.

8. Goldstein, *supra* note 2.

9. RONALD C. PORTER, LEX MACHINA, PRODUCT LIABILITY LITIGATION REPORT 4–5 (Rachel Bailey & Jason Maples eds., 2020).

10. *Id.* at 12–13.

11. Amanda Bronstad, *Report: Product Liability Cases Rose, Medical Devices and Pharma Hit Hardest*, LAW.COM (June 1, 2020, 10:30 PM), https://www.law.com/2020/06/01/report-product-liability-cases-rose-medical-devices-and-pharma-hit-hardest. In 2016 and 2017, juries awarded $913 million and $1 billion, respectively, against DePuy Orthopaedics—a unit of Johnson and Johnson., *id.*

12. Richard P. Console, Jr., *Are You in Pain After Hernia Surgery?*, NAT'L L. REV. (Jan. 5, 2021), https://www.natlawreview.com/article/are-you-pain-after-hernia-surgery.

13. 5 PROD. LIAB. PRAC. GUIDE § 64.07 (John Vargo ed., MB Rev. ed. 2020).

14. RESTATEMENT (SECOND) OF TORTS § 402A cmt. f (AM. L. INST. 1965).

hospitals . . . involving the distribution of allegedly dangerous . . . medical devices."[15] Courts have fashioned this exception to the theory of strict liability, reasoning that hospitals (even though they are instrumental in distributing medical devices to patients) are not sellers of medical devices and that public policy should guard against this type of liability.[16]

This Note will consider whether a hospital should be subject to strict liability when it plays a role in the implantation of a defective medical device. The purpose of this Note is to expose the profiteering nature of hospitals and urge the judiciary to reconsider its treatment of hospitals in strict liability actions. Part I of this Note will set forth the rule for strict liability per the Restatement (Second) of Torts and explain the purpose of the concept.

Part II of this Note will focus on the current state of the law as it relates to hospitals and delve into why most courts have refused to apply strict liability to hospitals. It will use contract theory as an aid to explain the essence of the transaction between hospital and patient, and also describe a hospital's heavy participation in device selection and procurement. These concepts, together, will justify the theory that a modern hospital acts as a seller and is in the business of selling, thus it could properly be subject to the theory of strict liability.

Finally, Part III of this Note will address the policy reasons courts are reluctant to apply the strict liability doctrine to hospitals and prove that this reluctance is not well-founded. To do so, Part III will illuminate the economic maturity of hospitals and their ability to bear the imposition of strict liability. It will also explain how recognizing hospitals as sellers in the chain of distribution will better serve the public, maximizing their protection, in part, by inducing investments in testing and safety.

I. THE THEORY OF STRICT LIABILITY

Strict liability is meant to protect the public.[17] The purpose of strict liability is, in part, to "insure that the costs of injuries resulting from defective products are borne by the manufacturers that put such products on the market

15. Von Downum v. Synthes, 908 F. Supp. 2d 1179, 1183 (N.D. Okla. 2012).

16. *See* PROD. LIAB. PRAC. GUIDE, *supra* note 13. *But see* Silverhart v. Mount Zion Hosp., 98 Cal. Rptr. 187, 191 n.4 (Ct. App. 1971) ("We apprehend that [diversion from the principle of strict liability] does not apply where the hospital is engaged in activities not integrally related to its primary function of providing medical services, such as the situation where the hospital operates a gift shop which sells a defective product.").

17. *See* E. River S.S. Corp. v. Transamerica Delaval, 476 U.S. 858, 866 (1986).

rather than by the injured persons who are powerless to protect themselves."[18] The Restatement (Second) of Torts provides the rule for strict liability:

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if (a) the seller is engaged in the business of selling such a product, and (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
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> (2) The rule stated in Subsection (1) applies although (a) the seller has exercised all possible care in the preparation and sale of his product, and (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.[19]

Strict liability only applies "where the defective condition of the product makes it unreasonably dangerous to the user or consumer."[20] A product is "unreasonably dangerous" if it is "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."[21]

While manufacturers are subject to strict liability, those acting as a link between product manufacturers and injured persons are not necessarily insulated from strict liability.[22] Those in the business of selling are typically subject to the doctrine, and "[i]t is not necessary that the seller be engaged solely in the business of selling such products."[23] The idea is such that:

> the seller, by marketing his product for use and consumption, has undertaken and assumed a special responsibility toward any member of the consuming public who may be injured by it; that the public has the right to and does expect, in the case of products which it needs and for which it is forced to rely upon the seller, that reputable sellers will stand behind their goods; that public policy demands that the burden of accidental injuries caused by products intended for consumption be placed upon those who market them, and be treated as a cost of production against which liability insurance can be obtained; and that the consumer of such products is entitled to the

18. Greenman v. Yuba Power Prods., Inc., 377 P.2d 897, 901 (Cal. 1963).
19. RESTATEMENT (SECOND) OF TORTS § 402A (AM. L. INST. 1965).
20. *Id.* at cmt. i.
21. *Id.*
22. *See* RESTATEMENT (SECOND) OF TORTS § 402A (AM. L. INST. 1965).
23. *Id.* at cmt. f. The rule, however, does not apply to the occasional seller or distributor, *id.*

> maximum of protection at the hands of someone, and the proper persons to afford it are those who market the products.[24]

A claim for strict liability is different than a negligence claim due to the underlying policy reasons for the tort.[25] The rationale for strict liability is as follows:

> (1) the public interest in human life and safety demands broad protection against the sale of defective products; (2) the manufacturer solicits and invites the use of his products by representing that they are safe and suitable for use; and (3) the losses caused by defectively dangerous products should be borne by those who have created the risks and reaped the profits by placing the products into commerce.[26]

An action in strict liability is, thus, focused on the nature of the product, and not necessarily the actions of the defendant.[27] Additionally, the rule "does not require any reliance on the part of the consumer upon the reputation, skill, or judgment of the seller who is to be held liable, nor any representation or undertaking on the part of that seller."[28]

Historically, courts have been reluctant to impose liability on hospitals as providers of health care except under, *inter alia*, traditional negligence and malpractice grounds.[29] While there is usually no question that a medical device is a product,[30] imposing strict liability on hospitals typically turns on whether the hospital engaged in a sale of the device and the underlying policy considerations of hospital liability.[31]

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24. *Id.* at cmt. c.

25. 5 STUART M. SPEISER ET AL., AMERICAN LAW OF TORTS § 18.30 (Monique C.M. Leahy ed., 2021).

26. Trans States Airlines v. Pratt & Whitney Can., Inc., 682 N.E.2d 45, 53 (Ill. 1997).

27. *See* SPEISER ET AL., *supra* note 25, at n.1.

28. RESTATEMENT (SECOND) OF TORTS § 402A cmt. f (AM. L. INST. 1965).

29. *See* PROD. LIAB. PRAC. GUIDE, *supra* note 13.

30. *See* Medtronic, Inc. v. Lohr, 518 U.S. 470, 498–99 (1996).

31. *See* Gile v. Kennewick Pub. Hosp. Dist., 296 P.2d 662 (Wash. 1956); Fischer v. Wilmington Gen. Hosp., 149 A.3d 749 (Del. Super. Ct. 1959); Goelz v. J.K. & Susie L. Wadley Rsch. Inst. & Blood Bank, 350 S.W.2d 573 (Tex. Civ. App. 1961); Dibblee v. Dr. W.H. Groves Latter-Day Saints Hosp., 364 P.2d 1085 (Utah 1961); Sloneker v. St. Joseph's Hosp., 233 F. Supp. 105 (D. Colo. 1964); Lovett v. Emory Univ., 156 S.E.2d 923 (Ga. Ct. App. 1967); White v. Sarasota Cnty. Pub. Hosp. Bd., 206 So. 2d 19 (Fla. Dist. Ct. App. 1968).

II. HOSPITALS AS SELLERS

Integral to determining whether hospitals should be subject to strict liability when a patient's implanted medical device is defective is deciding whether hospitals are in the business of selling that device.[32] A strong majority of courts hold that hospitals are not sellers of products.[33]

The "leading case"[34] characterizing a hospital as a provider of services, and not a seller, is *Perlmutter v. Beth David Hospital*.[35] In *Perlmutter*, the plaintiff brought an action against the defendant hospital to recover damages for personal injuries sustained as a result of a transfusion of "bad blood."[36] The sharply divided court determined that the hospital did not sell the blood to the plaintiff.[37] Rather, the court reasoned that while the transfer of blood or title thereto may have occurred, the transfer was not synonymous with a sale.[38]

The court considered "[*t*]*he essence* of the contractual relationship between hospital and patient," and noted that "when service predominates, and transfer of personal property is but an incidental feature of the transaction, the transaction is not deemed a sale."[39] The essence of the relationship between the patient and the hospital was one such "to obtain a course of treatment in the hope of being cured of what ails [the patient]," and "not to *buy* medicines or pills . . . [or] bandages or iodine or serum or blood."[40] "The patient bargain[ed] for, and the hospital agree[d] to make available, the human skill and physical materiel [sic] of medical science to the end that the patient's health be restored," and thus the "contract [was] clearly one for services, and, just as clearly . . . not divisible."[41]

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32. *See* RESTATEMENT (SECOND) OF TORTS § 402A (AM. L. INST. 1965).

33. Von Downum v. Synthes, 908 F. Supp. 2d 1179, 1183–84 (N.D. Okla. 2012).

34. St. Luke's Hosp. v. Schmaltz, 534 P.2d 781, 783 (Colo. 1975).

35. Perlmutter v. Beth David Hosp., 123 N.E.2d 792, 795 (N.Y. 1954).

36. *Id.* at 793. Plaintiff sought recovery on a theory of implied warranty and alleged the blood she received was not merchantable, *id.* However, this case is often cited in product liability suits for its discussion of the nature of the relationship between hospitals and patients. *See, e.g.*, *St. Luke's Hosp.*, 534 P.2d at 784.

37. *Perlmutter*, 123 N.E.2d at 794.

38. *Id.*

39. *Id.* (emphasis added).

40. *Id.* at 796 (emphasis added).

41. *Id.* at 794. *But see* Easterly v. HSP of Tex., Inc., 772 S.W.2d 211, 213 (Tex. Civ. App. 1989). In *Easterly*, the court did not use the essence of the transaction test, but rather asked whether the product "was integrally related to the medical procedure." *Id.* That court held that the product was "so intimately connected to the service provided" that it "los[t] its separate character as a good" and was "not an ordinary good offered to the general public in regular commercial transactions." *Id.* Thus, the trial court granted summary judgment in favor of the defendant, precluding a claim of strict liability. *Id.*

Similarly, in *Hector v. Cedars-Sinai Medical Center*, the court exempted the defendant hospital from the theory of strict liability because the court found that the hospital "[was] not 'engaged in the business of selling' pacemakers, but [was] a provider of medical services which included the provision of the pacemaker implanted in plaintiff."[42] The court emphasized:

> [I]n the normal commercial transaction contemplated in the strict liability cases the essence of the transaction relates *solely* to the article sold, the seller is in the business of supplying the product to the consumer, and it is that, and that alone for which he is paid. The foregoing marked distinctions compel the conclusion that a *hospital* is not engaged in the business of distributing [devices] to the public and *does not put the* [*devices*] *as a product on the market in order to profit therefrom.*[43]

To reach its conclusion, the court examined the hospital's role in obtaining the pacemaker for the patient.[44] Namely, the surgeon, not the hospital, selected "the specific model and type of pacemaker to be implanted in [the] patient."[45] The surgeon ordered the pacemaker directly from the manufacturer, and the hospital only "facilitat[ed] the processing of the implantation by performing the management practice of completing a purchase requisition."[46] The hospital did not "routinely stock pacemakers, nor [was] it in the business of recommending, selling, distributing or testing pacemakers."[47] And, even though the "nonprofit California corporation . . . hospital added a routine surcharge of 85 percent to the patient's bill for the implanted pacemaker,"[48] it was only to "cover[] the hospital's projected expenditures."[49] The markup was "not designed to provide the hospital with a profit from the sale of the pacemaker."[50] The hospital did, however, provide the "pre- and post-operative care, nursing care, a surgical operating room and technicians."[51] Conclusively, the court held that the hospital was not a seller because it "*merely* provide[d]

42. Hector v. Cedars-Sinai Med. Ctr., 225 Cal. Rptr. 595, 602 (Ct. App. 1986).
43. *Id.* at 598 (citing Shepard v. Alexian Bros. Hosp. 109 Cal. Rptr. 132, 135 (Ct. App. 1973)).
44. *Id.*
45. *Id.*
46. *Id.* at 599.
47. *Id.*
48. *Id.*
49. *Id.* at 600.
50. *Id.*
51. *Id.* at 599.

administrative services in connection with the order and support services in connection with the implantation."[52]

Conversely, a minority of courts differ in opinion and hold that hospitals can be sellers.[53] In *Cunningham v. MacNeal Memorial Hospital*, the Illinois Supreme Court allowed a patient to bring suit against a hospital under the doctrine of strict liability when she contracted hepatitis from a blood transfusion during her stay in the hospital.[54] Relying on the definitions set forth in the Restatement (Second) of Torts, the court held that the supply of blood for a transfusion put the hospital in the business of selling.[55] Notably, the ancillary provision of blood as a hospital's minor function did not destroy the seller characterization.[56] The court analogized the blood transfusion to a movie theater selling popcorn for consumption.[57] Even though the theater provides an entertainment service, the popcorn, like the blood, is a product "either for consumption on the premises or in packages to be taken home."[58] According to the court, the hospital was "clearly within the distribution chain of the product involved," and thus plausibly a seller.[59]

The minority of courts that recognize hospitals as sellers of implantable medical devices are more in tune with the true role of hospitals in the transfer of a medical device from manufacturer to patient. Specifically, the minority properly recognize that (1) the essence of the contract between patient and hospital may still include a product sale even if the medical device is incidental to the services rendered; and (2) the modern hospital plays a vital function in

52. *Id.* (emphasis added).

53. *See* Ioli v. Zimmer Holdings, Inc., No. CV-14-00245-PHX-PGR, 2014 U.S. Dist. LEXIS 55744, at *8 (D. Ariz. Apr. 22, 2014) ("Arizona courts define [seller] in accordance with the justification for imposing strict liability, which is 'risk/cost spreading to those parties in the distribution chain that are best able to both bear the cost and protect the consumer from defective products.'" (quoting Antone v. Greater Ariz. Auto Auction, Inc., 155 P.3d 1074, 1076 (Ariz. Ct. App. 2007))); s*ee also* Sanders v. Medtronic, Inc., No. 4:06-cv-57, 2006 U.S. Dist. LEXIS 45516, at *21 (E.D. Va. June 26, 2006) (granting a motion to remand and recognizing the possibility that the hospital may be a seller of medical devices); Phillips v. Medtronic, Inc., 754 F. Supp. 2d 211, 217 (D. Mass. 2010) (finding it plausible that Massachusetts may categorize a hospital as a seller for the purpose of a products liability claim); Snyder v. Davol, Inc., No. CV 07-1081-ST, 2008 U.S. Dist. LEXIS 1675, at *4 (D. Or. Jan. 7, 2008).

54. Cunningham v. MacNeal Mem'l Hosp., 266 N.E.2d 897, 898 (Ill. 1970), *superseded by statute*, 745 ILL. COMP. STAT. ANN. 40/0.01-40/3 (LexisNexis 2021) (invalidating the decision in *Cunningham* as to blood products and human tissue, but not necessarily medical devices).

55. *Id.* at 899.

56. *Id.* at 901.

57. *Id.*

58. *Id.*

59. *Id.*

device selection to maximize its own profits. Thus, the modern hospital is properly considered to be in the business of selling.

A. *Sale Versus Service*

The majority describe the essence of the transaction between hospital and patient as one for services and not for a sale of goods, because the healing service of the hospital predominates, and the transfer of the product is incidental thereto.[60] Yet, this misses the mark because the Restatement (Second) of Torts only requires that the seller be in the business of selling, not that the seller is "*solely* in the business of selling."[61]

To determine the essence of the transaction between hospital and patient, courts turn to the predominant purpose test.[62] In interpreting contracts, courts use the predominant purpose test to determine whether the contract at issue should be analyzed under the Uniform Commercial Code or common law—i.e., whether the contract is for a sale of a good or services rendered.[63]

Consider *Brandt v. Boston Scientific Corporation*, in which the court contemplated whether a hospital could be liable for a defectively implanted device under an implied warranty of merchantability.[64] In *Brandt*, the court applied the predominant purpose test to categorize a medical transaction as one for primarily services rather than goods when a health center implanted a ProteGen sling to treat urinary incontinence.[65] In *Brandt*, the court stated that, "[t]he purchase of the sling was not an isolated transaction; it [was] not reasonable to infer that [the plaintiff] simply went to the hospital, bought the sling, and left."[66]

Yet, the court noted that this determination had limited relevance to the theory of strict liability, because the issues presented are different.[67] Specifically, the court stated that:

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60. *See, e.g.*, Perlmutter v. Beth David Hosp., 123 N.E.2d 792, 795 (N.Y. 1954).

61. RESTATEMENT (SECOND) OF TORTS § 402A cmt. f (AM. L. INST. 1965) (emphasis added).

62. *See, e.g.*, Porter v. Rosenberg, 650 So. 2d 79, 83 (Fla. Dist. Ct. App. 1995) (equating the predominant purpose test used in a contracts analysis to the essence of the transaction test).

63. *See, e.g.*, Brandt v. Bos. Sci. Corp., 792 N.E.2d 296, 303 (Ill. 2003) ("When evaluating the predominant nature of contracts, . . . courts have considered contract language in addition to assessing the proportion of goods and services in the contract. . . . We must [also] consider the predominate nature of the transaction as a whole.").

64. *Id.* at 297.

65. *Id.* at 297, 303.

66. *Id.* at 301.

67. *Id.* at 302.

> Courts in strict liability cases must find that the defendant sold a product rather than services before imposing liability. In contrast, under article 2 of the UCC, the transaction between the plaintiff and the defendant must have been *predominantly* for goods rather than services.[68]

While the court ultimately characterized the transaction as one for services for the purposes of the warranty claim, it did define the transfer of the ProteGen sling to the patient as a sale of movable goods within the hybrid contract.[69] It thus follows that the predominant purpose test is inappropriate in a strict liability cause of action because it can improperly ignore the sale of a good in determining the essence of the transaction between hospital and patient, as it goes a step further in classifying the transaction than is required by the Restatement (Second) of Torts.

The predominant purpose test is not suitable to determine the essence of the transaction between hospital and patient for a second reason. A hospital could attempt to avoid strict liability, in part, by artificially charging more for its services than the implantable medical device.[70] A hospital's charges are subject to artificial inflation,[71] and "[f]ew states set any limits on what hospitals can charge."[72]

Moreover, there is large asymmetry in pricing information between hospitals making it difficult for patients to compare costs,[73] in part because hospitals can bundle the cost of implantable medical devices with the cost of other inputs used to provide a service.[74] This leaves hospitals able to mark up

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68. *Id.* (citations omitted).

69. *Id.* at 303.

70. One consideration of the predominant purpose test is the amount paid for services versus the amount paid for products. *Id.* at 303 (explaining, in part, that the plaintiff's "contract" with the Health Center was likely one for services in part because "51.4% [of her charges] were for services rather than goods [and] . . . the bill listed itemized charges under the heading 'service description.'"). The court considered the factors related to the price of the plaintiff's medical device in conjunction with what they considered the "primary purpose of the transaction" and ultimately held that "the purchase of the [medical device] was incidental to the treatment." *Id.*

71. Guy David et al., *Do Hospitals Cross Subsidize?* 2 (Nat'l Bureau of Econ. Rsch., Working Paper No. 17300, 2011), https://www.nber.org/papers/w17300.pdf; *see also* Austin B. Frakt, *How Much Do Hospitals Cost Shift? A Review of the Evidence*, 89 MILBANK Q. 90, 90 (2011).

72. Wendell Potter, Commentary, *Health Facility Charges Run Amok*, CTR. FOR PUB. INTEGRITY (June 15, 2015), https://publicintegrity.org/health/for-profit-hospitals-mark-up-prices-by-more-than-1000-percent-because-theres-nothing-to-stop-them.

73. Ge Bai & Gerard F. Anderson, *Extreme Markup: The Fifty US Hospitals with the Highest Charge-To-Cost Ratios*, 34 HEALTH AFFAIRS 922, 925 (2015).

74. MEDPAC, *supra* note 4, at 231.

prices for services as they see fit,[75] with some hospitals charging a markup of more than ten times their cost.[76]

To avoid strict liability, a hospital could, in theory, focus this markup on services related to the medical device rather than on the device itself or bundle the medical device into service pricing to further cement the hospital's position as providers of services rather than sellers of goods. The structure of the predominant purpose test lends itself to an already nebulous arena of hospital pricing and does not best protect the patient in bringing claims for defective devices.

The more suitable test to characterize the "essence of the transaction" between the hospital and patient is the gravamen test because it better illustrates the reason for the patient's strict product liability claim. Just as they use the predominant purpose test, courts employ the gravamen test to classify "hybrid contract[s] as either a contract for the sale of goods or a contract for the rendition of services."[77] Under the gravamen test, the contract is classified as one for a sale of goods "if that aspect of the transaction [for the good] formed the gravamen of the action for relief."[78] The gravamen is "the substantial point or *essence* of a claim, grievance, or complaint."[79]

In a strict liability action for defective medical devices, the thrust of the patient's *claim* is that the hospital sold a defective device (or product) and the device caused injury.[80] In these scenarios, there may be no concern about the hospital's service (i.e., the device implantation procedure or the treatment itself).[81] The *Perlmutter* dissent articulated the distinction between the services the hospital rendered and the goods (the blood) at issue.[82] Specifically, the dissent acknowledged that the plaintiff took issue with the blood product, and not the service of the transfusion—the "injecting [of] the blood into her bloodstream."[83] Consequently, evaluating the transaction under the gravamen test allows capture of the real issue and affords the patient maximum protection.

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75. *See* Potter, *supra* note 72. *See* Bai & Anderson, *supra* note 73, at 925–26.

76. Bai & Anderson, *supra* note 73, at 924.

77. Gary D. Spivey, Annotation, *Applicability of UCC Article 2 to Mixed Contracts for Sale of Business Goods and Services Other Than Distributorship, Computer, Manufacturing, Construction, and Similar Contacts*, 25 A.L.R.7th Art. 4 (2017).

78. *Id.*

79. *Gravamen*, BLACK'S LAW DICTIONARY (8th ed. 2004) (emphasis added).

80. *See* Cunningham v. MacNeal Mem'l Hosp., 266 N.E.2d 897, 898 (Ill. 1970).

81. *Id.*

82. Perlmutter v. Beth David Hosp., 123 N.E.2d 792, 796 (N.Y. 1954) (Froessel, J., dissenting) (4–3 decision).

83. *Id.*

In brief, the Restatement (Second) of Torts would allow for a strict liability claim against the movie theater for defective popcorn it sold even though the popcorn purchaser went to the theater primarily to see a movie.[84] Accordingly, using the predominant purpose test to characterize the essence of the transaction between hospital and patient is an erroneous application of the contract theory in a strict product liability claim because it ignores what the Restatement (Second) of Torts would allow—the recognition that a hybrid transaction can be divisible for the purpose of the tort. Yet, if the courts insist on borrowing a test from contract theory to define the relationship between hospital and patient, the gravamen test is better suited as it recognizes that a product may be ancillary to a service, but still supports a claim focused on the defective product.

B. *The Reality of Hospital Operations*

Furthermore, modern hospitals exercise significant control over their supply chains to reduce their expenditures and, in turn, increase profits, putting themselves in the business of selling implantable medical devices as the Restatement (Second) of Torts requires for a strict liability claim. The modern hospital is starkly different from the traditional hospital described in *Hector*. In *Hector*, the defendant hospital played an insignificant role in getting the implantable device from the manufacturer to the patient, essentially serving only as a bystander.[85] In fact, the court characterized the hospital's role as "*merely* provid[ing] administrative services in connection with the order and support services in connection with the implantation."[86]

Today, however, the reality is that hospitals go to great lengths to control the medical devices that are available for use in their operations, moving far beyond the simple provision of administrative services.[87] Hospitals are no longer bystanders when a patient needs an implantable medical device, but are now active participants—ringleaders, even—in selecting the device and collecting the profits.

Consider the process of receiving a pacemaker. A patient may present to his doctor with shortness of breath, fatigue, and fainting.[88] The general practitioner may refer the patient to a cardiologist who then diagnoses the

84. RESTATEMENT (SECOND) OF TORTS § 402A cmt. f (AM. L. INST. 1965).

85. *See* Hector v. Cedars-Sinai Med. Ctr., 225 Cal. Rptr. 595, 599–602 (Ct. App. 1986).

86. *Id.* at 599 (emphasis added).

87. *See* MEDPAC, *supra* note 4, at 222–23.

88. *Why You May Not Realize You Need a Pacemaker*, CLEVELAND CLINIC (Feb. 20, 2018), https://health.clevelandclinic.org/do-you-need-a-pacemaker-to-speed-up-your-heart.

patient with bradycardia—a condition in which the heart beats too slowly.[89] Then, after a series of tests, the doctor decides whether the patient is a suitable candidate for a pacemaker.[90] If he is, the doctor then "selects" the pacemaker model,[91] often without meaningful input from the patient,[92] and eventually performs the implantation.

The modern hospital's heavy involvement initially occurs behind the scenes—dictating from which devices a doctor may "choose"—and happens again when it is time to collect payment for the device. As the medical device industry has expanded, organizational behaviors in hospitals have changed.[93] While physicians have preferences in which medical devices they utilize in surgery,[94] the hospitals are now the ultimate purchasers.[95]

As medical device purchasers, hospitals have seen an increase in the cost of implantable devices—an average of 8% each year.[96] The cost of those devices can "consume between 40% and 80% of the total payment a hospital receives for the operation."[97] Therefore, hospitals have a clear financial incentive to bargain for medical device prices and ultimately select cost-effective devices despite physician preferences. Said differently, hospitals have reason to depart from their role as facilitators, as described in *Hector* in which the surgeon orders the medical device directly from the manufacturer,[98] and more actively control the medical devices used in their facilities.

Hospitals have attempted to "gain control" over their supply chains through purchasing coalitions,[99] and other centralized processes for

89. *Is Your Heart a Good Candidate for a Leadless Pacemaker?*, CLEVELAND CLINIC (Jan. 5, 2018), https://health.clevelandclinic.org/is-your-heart-a-good-candidate-for-a-leadless-pacemaker.

90. *How Do You Know When You Need a Pacemaker?*, MCLEOD HEALTH, https://www.mcleodhealth.org/blog/how-do-you-know-when-you-need-a-pacemaker (last visited Mar. 10, 2021).

91. CLEVELAND CLINIC, *supra* note 89.

92. Anna R. Gagliardi et al., *Factors Constraining Patient Engagement in Implantable Medical Device Discussions and Decisions: Interviews with Physicians*, 29 INT'L J. FOR QUAL. HEALTH CARE 276, 276 (2017).

93. *See* Kenneth McNeil & Edmond Minihan, *Regulation of Medical Devices and Organizational Behavior in Hospitals*, 22 ADMIN. SCI. Q. 475, 475–490 (1977).

94. Kathleen Montgomery & Eugene S. Schneller, *Hospitals' Strategies for Orchestrating Selection of Physician Preference Items*, 85 MILBANK Q. 307, 308 (2007) (explaining that the preferences of doctors often reflect "personal experience with a particular product, their assessments of a particular patient's interests, [and] their relationships with manufacturers' representatives").

95. *Id.*

96. *Id.* at 309.

97. *Id.*

98. Hector v. Cedars-Sinai Med. Ctr., 225 Cal. Rptr. 595, 598 (Ct. App. 1986).

99. Montgomery & Schneller, *supra* note 94, at 313.

purchasing devices to standardize processes and costs.[100] For example, one way that hospitals attempt to gain control over their supply chains is through participation in Group Purchasing Organizations (GPOs)—purchasing coalitions hospitals may use to reduce their cost of implantable medical devices.[101] GPOs are intermediary groups that negotiate with medical device companies on behalf of their members.[102] These coalitions rely on increased bargaining power—a strength in numbers approach—to negotiate lower-priced contracts on behalf of the hospitals that are members.[103] Hospital members reap the benefits of using GPOs directly through lower priced medical devices.[104] Moreover, though, the GPOs collect administrative fees from the medical device manufacturers during the negotiation process.[105] GPOs, in turn, distribute a portion of the fees back to the hospital customers.[106] So, not only do the hospitals reduce their overhead directly through lower cost products, they also indirectly increase by recouping fees paid by manufacturers. MedPAC reported that in 2012, "the five largest GPOs distributed about 70% of the $2.3 billion that they received in fees."[107] This model is drastically different from the hospital that only "facilitate[ed] the processing of the implantation by performing . . . a purchas[ing] requisition."[108] Now, the modern hospital does much more than complete a purchase requisition. It limits the surgeon's role in ordering the device, and actively negotiates the price with the manufacturer via its GPO intermediary.

Furthermore, the physician's preference no longer controls as it did in *Hector*. For example, in *Hector*, "the specific model and type of pacemaker to be implanted in a patient [was] *specified by the surgeon*."[109] However, the increase in physician employment in hospitals has lessened physician preference as a variable that hospitals consider when purchasing implantable medical devices.[110] Now, the modern hospital has more of a say in which devices are ultimately implanted.

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100. *Id.* at 317–18. Centralized processes may include limiting the number of manufacturers from which physicians may select products or placing a cap on the price that hospitals will pay for certain items—both limiting the physician's choice to contain cost, *id.*

101. MEDPAC, *supra* note 4, at 220.

102. *Id.*

103. *Id.*

104. *Id.* at 221.

105. *Id.* at 220.

106. *Id.*

107. *Id.*

108. Hector v. Cedars-Sinai Med. Ctr., 225 Cal. Rptr. 595, 599 (Ct. App. 1986).

109. *Id.* at 598 (emphasis added).

110. MEDPAC, *supra* note 4, at 223.

Similarly, in *Hector*, the manufacturer's representative delivered the pacemaker to the doctor in the operating room.[111] But, some modern hospitals have even instituted "gatekeeping models," limiting medical device representatives' access to doctors inside the hospital.[112] Again, this is the hospital's attempt to weaken the traditional physician-manufacturer relationship and take more of an active role to control device purchasing. For example, a hospital in Loma Linda, California reported more than a 50% reduction in cost for total knee and hip replacements by banning medical device representatives in the operating room.[113]

Further, the plaintiff in *Hector* argued, and the court rejected, that the hospital was in the business of selling because it applied an 85% markup to the charge for the medical device.[114] The court did not find this argument availing because "[the] surcharge [was] not designed to provide the hospital with a profit from the sale of the pacemaker but [was] part of an overall scheme to provide that the cost to patients of services and supplies covers the hospital's projected expenditures."[115]

Yet, modern hospitals have managed to turn medical devices into a lucrative profit center—inapposite to the "non-profit [] corporation" only covering its projected expenditures described in *Hector*.[116] Modern hospitals "apply whatever markup they please" to medical equipment and products.[117] Some of the worst offenders are marking up products more than 1,000%.[118] In a 2017 report to Congress, MedPAC explained how hospitals are able to increase the profit margin on implantable medical devices.[119] Typically, when a hospital negotiates the price of implantable medical device payment rates with private insurance companies, hospitals are able to "add a significant markup to their purchase price."[120] And, because the "markups are usually

111. *Hector*, 225 Cal. Rptr. at 598.

112. Montgomery & Schneller, *supra* note 94, at 324*; see also* Blake Farmer, *Sales Reps May Be Wearing Out Their Welcome in the Operating Room*, NPR (Nov. 23, 2018, 4:03 PM), https://www.npr.org/sections/health-shots/2018/11/23/659816082/sales-reps-may-be-wearing-out-their-welcome-in-the-operating-room.

113. Farmer, *supra* note 112.

114. *Hector*, 225 Cal. Rptr. at 600.

115. *Id.*

116. *Id.* at 599.

117. David Lazarus, *When a Hospital Sling Costs 900% More Than Amazon's Price, Something Is Very Wrong*, L.A. TIMES (Sept. 13, 2019, 5:00 AM), https://www.latimes.com/business/story/2019-09-12/medical-equipment-pricing.

118. Bai & Anderson, *supra* note 73, at 924.

119. MEDPAC, *supra* note 4, at 231.

120. *Id.* However, "Medicare bundles the average cost of medical devices into its overall payment rate for many services, giving hospitals, for example, an incentive to use lower cost devices." *Id.* at 208.

calculated on a percentage basis," hospitals are incentivized to use more expensive devices, turning the scheme into a "significant source of profit."[121]

Similarly, there are strong financial relationships between modern hospitals and implantable medical device manufacturers that *Hector* did not consider. The Centers for Medicare & Medicaid Services ("CMS"), a department of the United States Department of Health and Human Services, requires that medical device companies, among others, report "payments or transfers of value they make to certain healthcare providers and teaching hospitals for research, meals, travel, gifts, speaking fees, and more."[122] CMS publishes this information on its publicly available database, Open Payments.[123] According to CMS, Open Payments is a program to "promote[] a more financially transparent and accountable healthcare system, . . . [but] CMS does not offer an opinion on what financial relationships may cause conflicts of interests."[124]

It is worth noting, though, that in 2019, Medtronic (the largest medical device manufacturer in the U.S.[125]) made more than $16 million in payments directly to teaching hospitals.[126] Admittedly, this information does not necessarily confirm a conflict of interest between hospitals and device manufacturers nor any kind of reciprocal relationship. However, it is something to consider in evaluating why hospitals procure certain medical devices over others. These payments could serve as a reason that modern hospitals are willing to take over the device selection role traditionally trusted to physicians. The modern hospital's move from passive facilitator to procurement czar is seemingly profitable in more ways than one.

Finally, by no stretch of the imagination are hospitals "occasional sellers" of implanted medical devices.[127] It is estimated that "7.2 million Americans are living with joint implants . . . and receive about 370,000 cardiac

121. *Id.* at 231.

122. *Newly Added Covered Recipients*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/OpenPayments/Program-Participants/Newly-Added-Covered-Recipients (last visited Mar. 13, 2020).

123. *Id.*

124. *Id.*

125. *The 2020 Top 30 Global Medical Device Companies*, MED. PROD. OUTSOURCING (July 21, 2020), https://www.mpo-mag.com/issues/2020-07-01/view_top30/the-top-30-679842.

126. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 122 (search for "Medtronic" and collate each Medtronic division's payments).

127. RESTATEMENT (SECOND) OF TORTS § 402A cmt. f (AM. L. INST. 1965) (explaining that those who make only an occasional sale are not in the business of selling, and thus strict product liability would not apply).

pacemakers and 1 million hip and knee replacements per year."[128] The implantation of medical devices is increasingly common in the United States.[129]

In sum, modern hospitals are plainly in the business of selling medical devices, as contemplated by the Restatement (Second) of Torts.[130] Organizations that actively participate in the medical device market and control their supply chains to increase profits have replaced the hospital described in *Hector*, one that merely facilitated the implantation of medical devices and marked up devices only to cover their costs.[131]

III. POLICY SUPPORT FOR HOLDING HOSPITALS ACCOUNTABLE

In addition to denying any sale between the hospital and patient, courts often cite to public policy considerations as equally important reasons in refusing the imposition of strict liability.[132] The majority argues that "hospital[s] [are] devoted to the care and healing of the sick,"[133] and allowing strict liability would "ultimately thwart the fulfillment of the hospitals' worthy mission by drainage of their funds for purposes other than those intended."[134] Yet, the cited policy concerns—making hospitals virtual insurers of medical devices,[135] diverting resources to product testing,[136] and increasing costs for patients[137]—are not justified, and imposing strict liability may, in fact, better protect the public for the same reasons the majority warns against.

A. *Virtual Insurers*

First, courts argue that imposing strict liability for defective medical devices would make the hospitals virtual insurers of the success of the implant.[138] According to the majority in *Perlmutter*, "[i]f [] the court were to stamp as a sale the supplying of [product] . . . it would mean that the hospital,

128. KEITH D. LIND, AARP PUB. POL'Y INST., UNDERSTANDING THE MARKET FOR IMPLANTABLE MEDICAL DEVICES 1 (2007).

129. *Id.*

130. *See generally* RESTATEMENT (SECOND) OF TORTS § 402A (AM. L. INST. 1965).

131. *See* Hector v. Cedars-Sinai Med. Ctr., 225 Cal. Rptr. 595, 599–601 (Ct. App. 1986).

132. *See, e.g.*, *id.* at 601.

133. Perlmutter v. Beth David Hosp., 123 N.E.2d 792, 793 (N.Y. 1954).

134. Cunningham v. MacNeal Mem'l Hosp., 266 N.E.2d 897, 904 (Ill. 1970).

135. *Perlmutter*, 123 N.E.2d at 795.

136. *See Hector*, 225 Cal. Rptr. at 602.

137. *Id.*

138. *Perlmutter*, 123 N.E.2d at 795.

no matter how careful . . . would be held responsible, virtually as an insurer, if anything were to happen to the patient as result of [the] 'bad' [product]."[139] Yet, this argument fails because courts have said that strict liability "has never meant absolute liability."[140]

Interestingly, there is evidence that some hospitals are piloting express warranties for implanted medical devices.[141] These express warranties, in themselves, insinuate that hospitals are, in fact, selling goods but also that hospitals may be willing to "stand behind their goods"[142]—at least for ninety days from the implantation,[143] thus providing insurance in some respect for any defects. Alternatively, when legislatures require hospitals to give an express warranty on devices to receive state payment (i.e., via Medicare),[144] it could evince that law-makers are also ready to see hospitals take responsibility as insurers for the medical devices that they implant.

Further, the Restatement (Second) of Torts states, in part, that one justification for the theory of strict liability is "that public policy demands that the burden of accidental injuries caused by products intended for consumption be placed upon those who market them, and [it can] be treated as a cost of production against which liability insurance can be obtained. . . ."[145]

Assuming, arguendo, hospitals would serve as insurers of medical devices, strict liability theory could encourage hospitals to select products based on whether the manufacturer could provide indemnification.[146] According to the majority in *Hector*, the hospital as a seller "[would] have to insure itself and distribute the risk of injury among the public as a cost of doing business."[147]

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139. *Id.*

140. 5 STUART M. SPEISER ET AL., AMERICAN LAW OF TORTS § 18:27 (Monique C.M. Leahy ed., 2021).

141. DR. ROBERT BREE COLLABORATIVE, TOTAL KNEE AND TOTAL HIP REPLACEMENT BUNDLE AND WARRANTY 13 (2017), http://www.breecollaborative.org/wp-content/uploads/TKRTHR-Bundle-Warranty-Final-Updated-072018.pdf. The Washington State Legislature commissioned the Collaborative to make recommendations for solutions aimed at improving the quality of the Washington health care market, *id.* at 3. The Collaborative recommended that hospitals provide a ninety-day warranty for mechanical complications of total knee and hip replacements, *id.* at 14. The Collaborative noted that the warranty is "intended to balance financial gain for providers and institutions performing [total knee replacement and total hip replacement] surgery with financial accountability for complications attributable to these procedures. In this warranty the intent is to distribute financial risk across professional and facility components in proportion to the revenue generated by the procedure." *Id.* at 13.

142. RESTATEMENT (SECOND) OF TORTS § 402A cmt. c (AM. L. INST. 1965).

143. *See* DR. ROBERT BREE COLLABORATIVE, *supra* note 141, at 14.

144. *See id*. at 13.

145. RESTATEMENT (SECOND) OF TORTS § 402A cmt. c (AM. L. INST. 1965).

146. *See* Brumbaugh v. Cejj, 547 N.Y.S.2d 699, 701 (App. Div. 1989).

147. Hector v. Cedars-Sinai Med. Ctr., 225 Cal. Rptr. 595, 602 (Ct. App. 1986).

Frankly, hospitals are in a good position to negotiate indemnification into the deals with manufacturers when they purchase medical devices. To explain, hospitals are changing the way they conduct business, as more and more hospitals integrate into systems.[148] Approximately 56% of U.S. community hospitals are now part of a system.[149] Some of the largest hospital systems operate with more than 100 hospitals in the group.[150] As hospitals converge into hospital systems, their overall bargaining power increases, which may make indemnification a possibility when selecting devices.[151] When hospitals have more bargaining ability, negotiating as part of a system with multiple hospitals at a time, they are able to contract for better deals,[152] factoring in price and indemnification, on medical devices.

Selecting a product that comes with indemnification may be prudent for a hospital:

> By aligning itself with other reputable and responsible partners, a client will be less likely to become entangled in product liability claims arising from such other parties' actions. While clients may be tempted to select the supplier that submits the lowest bid, such approach will not always be prudent or cost effective. While the client may initially save some money, the client could incur costs that exponentially exceed any savings if it utilizes shoddy or defective parts or materials that result in product liability claims.[153]

Additionally, although the courts may be concerned about the rising cost of healthcare for patients, lawmakers could take action and counter price increases for patients through policy. Notably, states have already turned to reference pricing and efforts in pricing transparency to lower healthcare

148. Emily Gee, *The High Price of Hospital Care*, CTR. FOR AM. PROGRESS (June 26, 2019), https://www.americanprogress.org/issues/healthcare/reports/2019/06/26/471464/high-price-hospital-care; *see also Fast Facts on U.S. Hospitals, 2019*, AM. HOSP. ASS'N, https://www.aha.org/statistics/2020-01-07-archived-fast-facts-us-hospitals-2019 (last visited Nov. 1, 2020) (defining a hospital system as: "two or more hospitals owned, leased, sponsored, or contract managed by a central organization").

149. *See* AM. HOSP. ASS'N, *supra* note 148.

150. Laura Dyrda, *100 of the Largest Hospitals and Health Systems in America*, BECKER'S HOSP. REV. (Jan. 15, 2020), https://www.beckershospitalreview.com/largest-hospitals-and-health-systems-in-america-2019.html.

151. *See* AM. HOSP. ASS'N, *supra* note 148; *see* Matthew Grennan, *Bargaining Ability and Competitive Advantage: Empirical Evidence from Medical Devices*, 60 MGMT. SCI. 3011, 3024 (2014).

152. Grennan, *supra* note 151, at 3011, 3017, 3019, 3024.

153. ROBERT J. GUITE, PRODUCT LIABILITY CLAIMS PREEMPTION AND MITIGATION, Lexis (database updated May 2021), https://plus.lexis.com/api/permalink/606818db-52c2-4619-985b-7978635baca/?context=1530671.

costs.[154] As an aside, the fear of price increase has not stopped the extension of strict liability to other industries.[155]

In conclusion, although the majority argues that if hospitals were subject to strict liability, they would be virtual insurers of implantable medical devices, the modern hospital is in a good position as a part of a system to negotiate for indemnification from the manufacturer—ultimately saving itself and the patient money in the long run.

B. *Diversion of Resources to Product Testing*

Another policy concern is that imposing strict liability could force hospitals to divert resources to product testing and otherwise duplicate FDA medical product testing. The court in *Hector* asserted that "the hospital is in a poor position to protect itself by inquiring about or testing the devices, pressuring the manufacturer to promote product safety or selling a different [product] which is not defective," because the surgeon selects the device.[156] However, as the reader now understands, the modern hospital is intimately involved in device selection, and the physician's preference is no longer as important. Now, the modern hospital is not only in an appropriate position to test the product, but also it *should* because the FDA's "approval" regimen frequently allows defective products to slip through to patients.

The FDA has the authority to regulate medical devices.[157] There are three pathways for a device to gain the FDA's approval or clearance.[158] Some devices can gain clearance through the 510(k) process.[159] In those cases where the FDA "clears" products through the 510(k) process, there may be no testing duplication at all.[160] The "510(k) is a premarket submission made to the FDA to demonstrate that the device to be marketed is as safe and effective, that is,

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154. Jay Zhu, Christopher Park, Leena Gupta & Debanshu Mukherjee, *New Payment Models in Medtech*, DELOITTE (Mar. 2, 2020), https://www.deloitte.com/us/en/insights/industry/life-sciences/medical-device-business-model-payments.html.

155. *See* Allan E. Korpela, Annotation, *Products Liability: Proof of Defect Under Doctrine of Strict Liability in Tort*, 51 A.LR.3d 8 (2020) (showcasing cases imposing strict liability on products such as machines and vehicles).

156. Hector v. Cedars-Sinai Med. Ctr., 225 Cal. Rptr. 595, 602 (Ct. App. 1986).

157. Federal Food, Drug, and Cosmetic Act, 21 U.S.C.S. § 301 (LEXIS through Pub. L. No. 117-65, with a gap of Pub. L. No. 117-58).

158. Gail A. Van Norman, *Drugs, Devices, and the FDA: Part 2: An Overview of Approval Processes: FDA Approval of Medical Devices*, 1 JACC: BASIC TO TRANSLATIONAL SCI. 277, 278–81 (2016).

159. *Id.*

160. *See Premarket Notification 510(k)*, U.S. FOOD & DRUG ADMIN. (MAR. 13, 2020), https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k.

substantially equivalent, to a legally marketed device. . . ."[161] In 1976, the FDA actually "grandfathered in all devices that were already on the market."[162] This 510(k) process "permits certain medical device approvals on the basis of observational studies and 'clinical experience' rather than randomized controlled trials. . . . [which] raise[] serious concerns about whether the safety and efficacy of medical devices will be compromised."[163] Once the FDA clears the device, the manufacturer is able to market the device.[164] Medical devices can also reach the consumer market without significant trials through the "supplement pathway . . . [which] allows manufacturers to inform the FDA that they want to market an updated version of a device with minor changes—once again, allowing them to circumvent clinical trials."[165]

Researchers have linked defective medical devices to approximately 83,000 deaths and more than 1.7 million injuries since 2008 in the U.S.[166] Clearly, FDA controls meant to ensure safety are failing the public. Thus, it is likely a net positive for patients if hospitals divert resources to do their own testing before selling the medical devices to patients.

Further, hospitals are best suited to do this "extra" testing because they select the medical device to sell, and thus can "pressur[e] the manufacturer to promote product safety."[167] There is evidence that hospitals are already conducting research on these products. For example, in 2019 teaching hospitals received $1.48 billion in research payments.[168] According to CMS, a research payment is one for "enrolling patients into studies of new drugs or devices."[169] This supports the inference that hospitals are already involved in the testing of these products. At the very least, the payments may evince that

161. *Id.*

162. Jeanne Lenzer & Shannon Brownlee, *The FDA Is Still Letting Doctors Implant Untested Devices into Our Bodies*, WASH. POST (Jan. 4, 2019), https://www.washingtonpost.com/outlook/the-fda-is-still-letting-doctors-implant-untested-devices-into-our-bodies/2019/01/04/d85207ae-0edf-11e9-831f-3aa2c2be4cbd_story.html.

163. Van Norman, *supra* note 158, at 279.

164. *See id.*

165. Lenzer & Brownlee, *supra* note 162.

166. *Medical Devices Harm Patients Worldwide as Governments Fail on Safety*, INT'L CONSORTIUM OF INVESTIGATIVE JOURNALISTS (Nov. 25, 2018), https://www.icij.org/investigations/implant-files/medical-devices-harm-patients-worldwide-as-governments-fail-on-safety.

167. Hector v. Cedars-Sinai Med. Ctr., 225 Cal. Rptr. 595, 602 (Ct. App. 1986).

168. *The Facts About Open Payments Data*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://openpaymentsdata.cms.gov/summary (select the year "2019" from the drop down box) (last visited Mar. 13, 2021).

169. *Natures of Payments*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/OpenPayments/About/Natures-of-Payment (last visited Mar. 13, 2021).

there is already a sufficient avenue for hospitals to be involved in research, the quality of products, and ensuring safety.

C. *Hospital Profitability*

Finally, as one court explained, "the major purpose of strict liability is to place the loss caused by a defective product on those who create the risk and reap the profit by placing such a product in the stream of commerce."[170] Strict liability is foolishly exempted from a world where hospital executives can earn an upwards of $20 million in compensation,[171] and hospitals spend even more on lobbying activities and campaign contributions.[172] These are not the endeavors of modern corporations, but rather "non-profit" hospitals.[173] Hospital profitability in the U.S. has risen to its highest level in decades.[174] In 2019, health care spending in the United States reached $3.81 trillion.[175] As a part of that, hospitals boasted higher margins than the pharmacy or insurance industries at a whopping 8 to 11%.[176] More than ever, hospitals are focused on the bottom line,[177] and they earn these unparalleled profits, in part, through marking up the price of implantable medical devices.[178]

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170. Phillips v. Howmedica Osteonics Corp., No. 07-833-GPM, 2007 U.S. Dist. LEXIS 92235, at *11–12 (S.D. Ill. Dec. 17, 2007).

171. Adam Andrzejewski, *Top U.S. "Non-Profit" Hospitals & CEOs Are Racking Up Huge Profits*, FORBES (June 26, 2019, 8:48 AM), https://www.forbes.com/sites/adamandrzejewski/2019/06/26/top-u-s-non-profit-hospitals-ceos-are-racking-up-huge-profits/?sh=35cdee8419df.

172. Greg Rosalsky, *How Non-Profit Hospitals Are Driving Up The Cost of Health Care*, NPR (Oct. 15, 2019, 6:31 AM), https://www.npr.org/sections/money/2019/10/15/769792903/how-non-profit-hospitals-are-driving-up-the-cost-of-health-care.

173. *Id.*

174. Gee, *supra* note 148.

175. Sean P. Keehan et. al., *National Health Expenditure Projections, 2019-28: Expected Rebound in Prices Drives Rising Spending Growth*, 39 HEALTH AFFS. 704, 704–05 (2020) (explaining that national health expenditures in the United States, including those for medical goods and services, are expected to grow).

176. Gee, *supra* note 148.

177. Martha C. White, *Hospitals Made $21B on Wall Street Last Year, but Are Patients Seeing Those Profits?*, NBC NEWS (Feb. 7, 2018, 12:59 PM), https://www.nbcnews.com/business/business-news/hospitals-made-21b-wall-street-last-year-are-patients-seeing-n845176.

178. *See generally* Bai & Anderson, *supra* note 73, at 924-25.

As Justice Starcher stated:

> [I]n recent years, the economics of the medical industry have changed. . . . At the start of the 21st century, both the health care and hospital industry have evolved to become one of the most profitable industries in the United States and therefore could be economically mature to handle strict products liability.[179]

In short, the general policy reasons that courts often cite in refusing to impose strict liability on hospitals do not necessarily warrant their refusal. In fact, these policy arguments may not be concerns at all, but worthy motivators to improve the industry. The court in *Hector* opined:

> [T]he defendant profit[ing] from the sale of the products, [] is in a good strategic position to protect itself by inquiring about or testing the products, promoting safety through pressure on the manufacturer, selling another product which is not defective, or insuring itself and distributing the risk of injury among the public as a cost of doing business.[180]

Hospitals are no longer the non-profit entities trying only to cover their costs,[181] but rather economically mature organizations well-positioned to bear the costs of doing business.

CONCLUSION

Hospitals have routinely escaped strict liability for defective implanted medical devices, and it is no longer prudent for courts to allow hospitals to hide behind the "essence"[182] of the transaction between patient and hospital. Plainly, modern hospitals are sellers of implantable medical devices and not solely service providers.

The market for implanted medical devices has grown exponentially as more Americans are being fit with such devices.[183] As the demand for implantable medical devices increases, hospitals have reaped the benefits as

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179. Blankenship v. Ethicon, Inc., 656 S.E.2d 451, 462 (W. Va. 2007) (Starcher, J., concurring in part and dissenting in part) (quoting Robert R. Willis, *Strict Products Liability and Hospitals: Liability of the Modern Hospital and the Use of Surgically Implanted Medical Products, Tools, and Prosthetic Devices*, 34 W. ST. U. L. REV. 191, 203–04 (2007)).

180. Hector v. Cedars-Sinai Med. Ctr., 225 Cal. Rptr. 595, 601 (Ct. App. 1986).

181. *Id.* at 600.

182. Perlmutter v. Beth David Hosp., 123 N.E.2d 792, 794 (N.Y. 1954).

183. LIND, *supra* note 128, at 1.

sellers. Hospitals, profitable even as non-profits,[184] are tweaking their operating models to best leverage implantable medical devices as profit centers. Because hospitals are taking a more active role in selecting implantable medical devices and inflating the price of devices as they see fit, the law should see fit to hold them strictly liable for defective devices as any other entity in the business of selling who introduces the risk to the public. Ultimately, the policy concerns that courts cite to are refutable and, in fact, these "concerns" are not really concerns at all, but rather incentives for hospitals to get serious about devices that are safe for patients.

As the court said in *Cunningham*, one of the biggest businesses in the country should bear the costs of distributing a product for consumption.[185] The time has come to treat hospitals as the profit-turning businesses that they are and impose strict products liability appropriately.

184. Andrzejewski, *supra* note 171.

185. Cunningham v. MacNeal Mem'l Hosp., 266 N.E.2d 897, 904 (Ill. 1970).