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Safety and Efficacy of Orthopaedic Surgical Devices Under the FDA's Updated Premarket Notification Program

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

*"The enemy of good is better."*¹

ABSTRACT

Orthopaedic surgical devices are recalled 11.5 times more when they obtain U.S. Food and Drug Administration ("FDA") clearance by Premarket Notification ("510(k)") than when they are cleared via the more vigorous Premarket Approval ("PMA") review. Recall of implanted orthopaedic devices can be devastating for patients – especially if the device must be removed or revised. 510(k) approval is also associated with other negative outcome issues among orthopaedic devices – including outlier devices, new devices underperforming their predicate ancestors, and significant statistical risks – which are discussed in this paper. In November 2018, the FDA announced changes to 510(k) including: (1) increasing premarket expectations for device submissions, (2) implementing a "Refuse-to-Accept" policy for incomplete applications, (3) improving the consistency and thoroughness of device review, (4) eliminating the use of 510(k) for devices considered to be of higher risk (i.e., Class III devices), and (5) eliminating over 1000 devices as 510(k) legal predicates. This article (1) explores the recent changes to 510(k) outlined by the FDA in 2018, (2) evaluates their likely effects on the outcomes of orthopaedic devices, and (3) proposes solutions to improve those outcomes, including FDA regulatory changes, litigation changes with regard to informed consent and Daubert rulings, and Congressional actions to hold device manufacturers more accountable based upon models currently in place affecting hospitals, doctors, and nursing homes.

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1. English variant of Italian proverb popularized by Voltaire in the 1600s. See SUSAN RATCLIFFE, CONCISE OXFORD DICTIONARY OF QUOTATIONS 389 (6th ed. 2011).

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I. INTRODUCTION

Orthopaedic surgical devices are recalled 11.5 times more commonly when they obtain FDA clearance by Premarket Notification (“510(k)”) than when they are cleared via the more vigorous Premarket Approval (“PMA”) review.² Recall of implanted orthopaedic devices that have been affixed to or implanted within a large bone, like the femur, can be devastating for patients – especially if the device must be removed or revised. For example, Medicare patients undergoing revision total hip replacements are at risk for infection (17.3%), blood clots (i.e., venous thromboembolic disease; 11.1%), dislocation (5.43%), pulmonary embolism (3.24%), and death (2.11%).³ Due to the significant potential for life-altering consequences of revision of recalled medical devices affixed to or implanted within large bones, recall of orthopaedic devices is unacceptable and the FDA should optimize orthopaedic device clearance pathways to minimize the chances that approved devices will later be recalled.

The FDA clears implantable medical devices using two main pathways: PMA review and 510(k).⁴ The PMA pathway is longer, more expensive, and requires clinical trials confirming safety and efficacy.⁵ The law presumes that implantable medical devices will undergo PMA review;⁶ but 510(k) provides a shortcut for most devices if the manufacturer/marketer (“submitter”) can show that the new device is “at least as safe and effective” (i.e., “substantially equivalent”) as a device that is already being legally marketed (i.e., a “predicate” device).⁷ The 510(k) program is the most common pre-market regulatory

2. Charles S. Day et al., *Analysis of FDA-Approved Orthopaedic Devices and Their Recalls*, 98 J. BONE & JOINT SURGERY 517, 517 (2016) (concluding, “Given that 510(k)-cleared devices were 11.5 times more likely to be recalled than PMA-approved devices, it is concerning that most orthopaedic devices are cleared through the 510(k) process with limited clinical trials data.”).

3. Sameer Badarudeen et al., *Complications After Revision Total Hip Arthroplasty in the Medicare Population*, 32 J. ARTHROPLASTY 1954, 1954 (2017).

4. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477–79 (1996) (noting that the 510(k) notification process is not comparable to the PMA process because the 510(k) review is “completed in an average of only twenty hours” whereas 1200 hours is necessary to complete a PMA review); see also Day et al., *supra* note 2, at 518 (describing 510(k) and PMA pathways); Kyle M. Fargen et al., *The FDA Approval Process for Medical Devices: An Inherently Flawed System or a Valuable Pathway for Innovation?*, 5 J. NEUROINTERVENTIONAL SURGERY 269, 271–72 (2013) (describing the approval pathways for medical devices).

5. 21 U.S.C. § 360e (2012).

6. § 360c(c)(2)(C)(1); § 360c(a)(1)(C)

7. § 360c(2)(C)(ii)(II); § 360c(c)(2)(C) (noting the 510(k) pathway allows for rapid approval of medical devices that are “substantially equivalent” to existing legally-marketed devices); 21 CFR § 807.92(a)(3) (2019); *Premarket Notification 510(k)*, U.S.

review pathway for new medical devices.⁸ In 2017, the FDA cleared 82% of its approved or cleared devices via the 510(k) pathway.⁹

In November 2018, the FDA announced changes to 510(k).¹⁰ In response to vociferous criticism of 510(k), the FDA asked the Institute of Medicine (“IOM”) to review 510(k) in 2011 and to make recommendations to protect the public health while also protecting legitimate industry interests.¹¹ The IOM concluded that the 510(k) process was fatally “flawed,”¹² that it generally does not evaluate safety and efficacy, and cannot be transformed into such a process.¹³ In addition, the IOM noted that 510(k) “lacks the statutory basis to be a reliable premarket screen for safety and effectiveness” of moderate risk devices and recommended that Congress replace the system.¹⁴ However, Congress failed to act.

FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k> [perma.cc/EZ4W-U2S3]; see *Medtronic, Inc.*, 518 U.S. at 478; Day, *supra* note 2, at 518.

8. *FDA has taken steps to strengthen the 510(k) Program*, U.S. FOOD & DRUG ADMIN. 3 (November 2018), <https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM626541.pdf> [perma.cc/2KNP-L6KM] [hereinafter, *FDA Steps to Strengthen 510(k)*].

9. *Id.*

10. *Id.*

11. See generally INST. OF MED., MEDICAL DEVICES AND THE PUBLIC’S HEALTH, MEDICAL DEVICES AND PUBLIC’S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS (2011), <https://www.nap.edu/read/13150/> [hereinafter IOM REPORT]; see, Barry Meier, *The Implants Loophole*, N.Y. TIMES (Dec. 16, 2010), <https://www.nytimes.com/2010/12/17/business/17hip.html> [perma.cc/F9AF-SZMM] (reporting on potential problems with several devices that had been cleared through the 510(k) process, including an artificial hip); *Dangerous Medical Implants and Devices: Most Medical Implants Have Never Been Tested for Safety*, CONSUMER REPS. (May 2012), <http://consumerreports.org/cro/magazine/2012/04/cr-investigates-dangerous-medical-devices/index.htm> [perma.cc/Q8UR-KEHQ] (detailing deficiencies in products as a result of the 501(k) process); Gardiner Harris, *F.D.A. Vows to Revoke Approval of Device*, N.Y. TIMES (Oct. 14, 2010), <https://nyti.ms/2JS67WH> [perma.cc/Y595-Q9U4] (noting that politics trumped science in the approval of a knee patch); Gardiner Harris, *U.S. Inaction Lets Look-Alike Tubes Kill Patients*, N.Y. TIMES (Aug. 20, 2010), <https://nyti.ms/2mfjDI6> [perma.cc/F6NA-2CN9] (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); Alicia Mundy & Jared A. Favole, *FDA Rips Approval of Medical Device*, WALL ST. J. (Sept. 25, 2009), <https://www.wsj.com/articles/SB125382260933538517> [perma.cc/6RKP-9LRH] (noting that Congressional pressure damaged the integrity of the FDA’s approval process).

12. IOM REPORT, *supra* note 11, at 3.

13. *Id.* at 2–3.

14. *Id.* at 2.

The FDA's recent 510(k) changes¹⁵ appear to be an attempt to address some of the concerns and offset Congress' lack of action. The FDA's November 2018 report outlined changes to strengthen the program, including: (1) increasing premarket expectations for device submissions, (2) implementing a "Refuse-to-Accept" policy for incomplete applications, (3) improving the consistency and thoroughness of device review, (4) eliminating the use of 510(k) for devices considered to be of higher risk (i.e., Class III devices), and (5) eliminating over 1000 devices as 510(k) legal predicates.¹⁶

First, this Article explores the recent changes to 510(k) outlined by the FDA in 2018. Then, it evaluates their likely effects on the outcomes of orthopaedic devices. Finally, this Article proposes solutions to improve those outcomes.

II. FDA'S RECENT CHANGES TO THE 510(K) PATHWAY

Late in 2018, the FDA announced changes to the 510k pathway to "strengthen" the path and highlighted some of the changes that have been occurring over the past several years.¹⁷ These changes include that the FDA has (1) "increased its premarket expectations for 510(k) submissions," (2) "implemented a Refuse-To-Accept policy to improve the quality of 510(k) submissions," (3) "improved consistency and thoroughness of 510(k) review," (4) "taken steps to eliminate the use of 510(k) for Class III devices," and (5) "eliminated the use of more than 1000 510(k)s as legal predicates."¹⁸

A. Increased Premarket Expectations for 510(k) Submissions

According to the FDA's report, the increased premarket expectations are primarily (1) the completion of more pages of paperwork and (2) the incorporation of benefit/risk factors into the paperwork analysis.¹⁹

1. More pages of paperwork

In 2017, the FDA updated its 510(k) Modifications Guidance for companies making changes to existing devices,²⁰ including how to incorporate Benefit-Risk Factors.²¹ The FDA's Center for Devices and Radiological Health ("CDRH") published over 50 guidance documents since 2009 "to help improve

15. *FDA Steps to Strengthen 510(k)*, *supra* note 8.

16. *Id.* at 2.

17. *Id.*

18. *Id.* at 2.

19. *Id.* at 4.

20. *Id.*

21. *Id.*

predictability, consistency, and transparency of submission content while clarifying expectations, policies[,] and procedures surrounding review of the submission.”²² The “average number of pages for each 510(k) has increased 150% since 2009” such that the average number of pages was 1,185 for each 510(k) submission in 2017.²³

2. Incorporation of Benefit/Risk factors

The FDA encourages inclusion of benefit and risk factors in the 510(k) application and notes that benefit and risk factors are considered during assessment of devices; the FDA provides examples of benefits and risks that should be included.²⁴

Possible device benefits may include (among others): (1) “Reduction in treatment time to achieve same effect”; (2) “Improvement of mechanical properties to reduce probable likelihood of adverse events or to improve handling”; (3) “Reduction of variability in device output”; and (4) “Improvements in clinical management, probability of survival, other aspects of patient health status (e.g., effect on patient management and quality of life, improvement of patient function, prevention of loss of function, relief from symptoms), and patient satisfaction in the target population, which may be measured with the use of PROs.”²⁵ In considering benefits, the FDA assesses information provided in the 510(k) by comparing potential benefits to the predicate device.²⁶

Possible device risks are likewise considered. In assessing risks, the FDA considers “among others, the following factors individually and in the aggregate as compared to the predicate device: (1) Severity, Types, Number, and Rates of Harmful events; (2) Probability of a Harmful Event; (3) Probability of the Patient Experiencing One or More Harmful Events; and (4) Duration of Harmful Events.”²⁷ Risk assessment is discussed further below in relation to orthopaedic devices.

Additional factors considered in the benefit/risk assessment include (1) uncertainty, (2) characterization of the disease/condition, (3) innovative technology, (4) patient tolerance for risk and perspective on benefit, (5) benefit for

22. *Id.*

23. *Id.*

24. *Id.*

25. *Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics*, U.S. FOOD & DRUG ADMIN. 12–13 (2018), <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM404773.pdf> [perma.cc/M836-UJVH] [hereinafter FDA BENEFIT-RISK FACTORS].

26. *Id.* at 13–14 (considering the following in comparison to the predicate device: (1) magnitude of benefits, (2) probability of the patient experiencing benefits, and (3) duration of effects).

27. *Id.* at 14–15.

the health care professional or caregiver, (6) risk mitigation, and (7) postmarket data.²⁸

B. *Refuse-To-Accept Policy*

To determine whether an application is administratively complete, the FDA does a review within 15 days of receipt.²⁹ The FDA updated its “Refuse-to-Accept” policy in January 2018; procedures were implemented, including criteria to assess “whether a 510(k) submission meets a quality threshold of acceptability for review” by evaluating submissions for completeness related to 52 elements – including biocompatibility, shelf life, performance data, and others.³⁰ If any one of the 52 elements is missing, the submitter is notified that the submission is not accepted for review; roughly 30% fall into this category initially.³¹ This is not a substantive review, just an initial checklist review for completeness of the application.³²

C. *Improved Consistency and Thoroughness*

To improve consistency and thoroughness, the FDA created the 510(k) SMART memo template for use by FDA reviewers for guidance during the 510(k) premarket process.³³ The FDA instituted the SMART memo template for mandatory use beginning in October 2015, and it guides the FDA’s review staff “by providing helpful links to applicable regulations and guidances [sic] and facilitating consistent analysis and documentation of scientific, clinical, administrative and regulatory information.”³⁴ In addition, “the SMART memo template is frequently updated to incorporate new review practices and policies, such as those published in final guidance to ensure a contemporary approach to 510(k) review” and includes “foundational and device-specific guidance.”³⁵ In addition, the SMART memo template training has been incorporated into the FDA’s Reviewer Certification Program.³⁶

28. *Id.* at 16–18.

29. *Refuse to Accept Policy for 510(k)s*, U.S. FOOD & DRUG ADMIN. 3 (2019), <https://www.fda.gov/media/83888/download> [perma.cc/4G5P-4CDS] [hereinafter *FDA Refuse to Accept Policy*].

30. *FDA Steps to Strengthen 510(k)*, *supra* note 8, at 5.

31. *Id.* at 5.

32. *FDA Refuse to Accept Policy*, *supra* note 29, at 3 (noting the purpose of the policy is to “whether a 510(k) submission meets a minimum threshold of acceptability and should be accepted for substantive review”).

33. *FDA Steps to Strengthen 510(k)*, *supra* note 8, at 6.

34. *Id.* at 6.

35. *Id.*

36. *Id.*

As a result, the FDA's staff now spends more time reviewing each 510(k) submission "than ever before."³⁷ This is partially due to the 150% increase in the number of pages involved in each submission.³⁸ The FDA estimates that its reviewers now spend twice as much time reviewing each 510(k) as they did just fifteen years ago and 32% more time than they did in 2009.³⁹ Even with these increased time commitments, "the FDA has continued to meet its Congressionally established review performance timelines."⁴⁰

D. Elimination of 510(k) for Class III Devices

The FDA's "oversight of devices is tailored to three risk-based classification[s]": Classes I, II, and III.⁴¹ Class I devices make up around 50% of all medical devices, are considered least risky, and can generally be marketed in the United States without prior FDA review.⁴² Elastic bandages and color change thermometers are examples of Class I devices.⁴³ Orthopaedic examples include basic manual surgical instruments⁴⁴ (e.g., needle holders, scissors, rongeurs, etc.), cast removal instruments,⁴⁵ etc.⁴⁶ Class I device makers are subject to "reporting, labeling, and good manufacturing practice requirements."⁴⁷

Class II devices make up about 43% of all medical devices and generally require FDA review of 510(k) submissions.⁴⁸ Examples include glucose test strips and infusion pumps.⁴⁹ Orthopaedic examples include most primary total

37. *Id.*

38. *Id.* (noting "Since 2009, the time spent reviewing each 510(k) submission has increased 32%, and it has almost doubled in the past 15 years.").

39. *Id.*

40. *Id.*

41. *Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health*, U.S. FOOD & DRUG ADMIN. 3 (2018), <https://www.fda.gov/media/112497/download> [perma.cc/U5QP-EE3E] [hereinafter *FDA Safety Action Plan*].

42. *Id.* at 3.

43. *Id.*

44. 21 C.F.R. § 888.4540 (2019).

45. § 888.5960.

46. For a complete list of medical devices, *see generally* 20 C.F.R. § 888.

47. *FDA Safety Action Plan*, *supra* note 41, at 3.

48. *Id.*

49. *Id.*

knee replacement devices,⁵⁰ most primary total hip replacement devices,⁵¹ intramedullary fixation rods,⁵² PMMA bone cement,⁵³ thoracolumbosacral pedicle screw system,⁵⁴ plate/screw fixation devices,⁵⁵ and others.⁵⁶ In 2017, the FDA approved over 3000 class II devices.⁵⁷

Class III devices are those “with [the] greatest risk to patients.”⁵⁸ Class III devices generally require Premarket Applications (“PMAs”) “containing clinical and nonclinical data to determine whether there is a reasonable assurance of safety and effectiveness.”⁵⁹ Prior to 2018, some Class III devices could be cleared via 510(k).⁶⁰ But as a result of these recent changes, “not a single Class III device was cleared via the 510(k) process in 2018.”⁶¹ In 2017, the FDA approved 64 PMA devices.⁶² Orthopaedic examples of Class III devices include some metal on metal hips (as of 2016 after lawsuits), constrained total knees, knee hemiarthroplasty, and others.⁶³

50. 21 C.F.R. §§ 888.3490, 3500, 3520 (2019).

51. §§ 888.3340, 3350, 3353, 3358, 3360, 3390.

52. §§ 888.3020, 3023.

53. § 888.3027.

54. § 888.3070.

55. § 888.3030.

56. For a complete list of medical devices, *see generally* 20 C.F.R. § 888 (2019).

57. *FDA Steps to Strengthen 510(k)*, *supra* note 8, at 3 (noting 3173 devices were cleared in 2017); *see also*, *510(k) DEVICES CLEARED IN 2017*, FOOD & DRUG ADMIN. (2018), <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/Device-ApprovalsandClearances/510kClearances/ucm540522.htm> [perma.cc/9KU9-QWPT] (last visited February 5, 2019).

58. *FDA Steps to Strengthen 510(k)*, *supra* note 8, at 7.

59. *Id.*; *FDA Safety Action Plan*, *supra* note 41, at 3.

60. *FDA Steps to Strengthen 501(k)*, *supra* note 8, at 7.

Class III devices must generally obtain an approved Premarket Approval (PMA) application, but some device types on the market prior to the 1976 Medical Device Amendments were placed into Class III and may be cleared via the 510(k) process until the FDA issues regulations either requiring submission of a Premarket Approval application or down-classifying the device types into Class I or Class II. Between 2003 and 2009, the FDA annually cleared approximately 80 submissions for Class III devices through the 510(k) process. As of August 2009, 25 Class III device types were still eligible for the 510(k) process. Between 2011 and 2016, the FDA published 24 final rules and orders, either down-classifying the device types to Class I or Class II or requiring the submission of a Premarket Approval application and eliminating the use of the 510(k) process for evaluation of these high-risk medical devices. *Id.*

61. *Id.*

62. *FDA Safety Action Plan*, *supra* note 41, at 3.

63. 21 CFR §§ 888.3320, 888.3330 (2019) (metal on metal hips); § 888.3550 (constrained total knee); § 888.3570 (knee hemiarthroplasty). For a complete list of medical devices, *see generally* 20 C.F.R. § 888 (2019).

E. Elimination of More Than 1000 Devices as Legal Predicates

The FDA takes action to eliminate the use of devices previously cleared by 510(k) as predicates “when it raises safety concerns.”⁶⁴ For example, the FDA may reclassify a device from Class II to Class III and call for Premarket Approval applications “when [it] determine[s] that a device type should be regulated as high risk because general and special controls are not sufficient to assure its safety and effectiveness.”⁶⁵ This process eliminates some previously cleared 510(k)s as legal predicates.⁶⁶ Elimination of predicates has become more common in recent years, with 84% of predicates being eliminated in the past 6 years and a thirty-fold increase in the annual rate of elimination of 510(k) predicates since 2012.⁶⁷ A total of 1,477 predicates have been eliminated since 2012.⁶⁸

III. ORTHOPAEDIC IMPLANTS, 510(K), AND LIKELY EFFECTS OF FDA CHANGES

In addition to the fact that 510(k) leads to an 11.5 times higher risk of device recall than PMA for orthopaedic devices, there have been other negative side effects of 510(k) on orthopaedic devices. This section first reviews the history of 510(k) orthopaedic device concerns using a few specific examples. Then, with that orthopaedic device history in mind, this section analyzes the FDA’s 2018 changes to strengthen 510(k).

A. 510(k) and Orthopaedic Implants

The 510(k) program has affected orthopaedic implants in three distinct ways. First, 510(k) has facilitated orthopaedic device races with new devices often promoted before the patient outcomes of earlier predicate versions can be scientifically evaluated. Second, 510(k) has resulted in some examples of devices with higher and unexpected severe complications for patients than their predicate devices. Third, 510(k) has helped lead to the finding that sometimes older predicate orthopaedic devices have better long-term outcomes than their 510(k) descendants.

1. The 510(k) facilitated orthopaedic device “races”

From the 1980s through the 2000s, total joint replacement components were modified so quickly that there was almost no time for outcome assessment

64. *FDA Steps to Strengthen 510(k)*, *supra* note 8, at 8.

65. *Id.*

66. *Id.*

67. *Id.*

68. *Id.*

before the next modification hit the market. Augusto Sarmiento, a well-known orthopaedic surgeon, innovator, and leader, observed that one device manufacturer's company president considered the successful outcomes of an earlier version of one total hip to be "totally irrelevant data" to consider in the next version.⁶⁹ Sarmiento is a former president of the American Academy of Orthopaedic Surgeons⁷⁰ and former chairman of the Department of Orthopaedic Surgery at the University of Southern California.⁷¹ The company president explained to Dr. Sarmiento that "by the time his company released a new prosthesis to the public, they had already begun work on the next version."⁷² Because of this, there was no time for scientific analysis and feedback from patients and surgeons on the earlier version – often possibly a "predicate" device – to be considered in the next device. In a recent Mayo Clinic study, researchers similarly observed "newer and more expensive implants are rapidly adopted in clinical practice with limited evidence of their effectiveness in comparison with existing ones."⁷³

As an example, the evolution of one part of the total knee replacement – the tibial component – demonstrates the phenomenon. The modern total knee arthroplasty ("TKA" or "total knee replacement") consists of three parts: (1) the tibial component, (2) the femoral component, and (3) the patellar component.⁷⁴ The tibial component attaches to the lower leg bone (tibia) and is the focus of this example. Numerous companies developed TKAs, but for simplicity, this section will focus mostly on one company's line with which I am most familiar⁷⁵ and note that other companies' TKAs developed along somewhat parallel timelines.

69. AUGUSTO SARMIENTO, M.D., *BARE BONES: A SURGEON'S TALE: THE PRICE OF SUCCESS IN AMERICAN MEDICINE* 286 (2003).

70. *Id.* at 9.

71. *Id.*

72. *Id.*

73. H.M. Kremers et al., *Comparative Survivorship of Different Tibial Designs in Primary Total Knee Arthroplasty*, 96 *J. BONE & JOINT SURG* e121, 1 (2014).

74. The exact number of modifications to total knee design is likely impossible to determine because companies use different terminology in the FDA's database for total knee components. For example: two hundred, eighty-five entries are found when "total knee" is placed in the "device name" field in the FDA's 510(k) Premarket Notification search database. 510(K) PREMARKET NOTIFICATIONS, U.S. FOOD. AND DRUG. ADMIN., <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> [perma.cc/VBH7-GKNJ]. However, additional total knee components are found when searching under "tibial," "femoral," "patellar," "polyethylene," and potentially countless other search terms. Similar findings are likely with regard to the patellar and femoral components.

75. Disclosure: The author implanted Zimmer® NexGen® Legacy™ PS total knees throughout his career as an orthopaedic surgeon. The author completed a fellowship in knee reconstruction and sports medicine under the tutelage of Dr. Insall and his colleagues at the Insall-Scott-Kelly (ISK) Institute in New York City in 1996–97 and has co-authored several papers with Dr. Insall. See e.g., Frank M. Griffin et al., *Accuracy of Soft Tissue Balancing in Total Knee Arthroplasty*, 15(8) *J ARTHROPLASTY* 970

The tibial component is particularly important to TKA outcomes and has been modified via the 510(k) process many times with over 100 different models being on the market over the past twenty-five years.⁷⁶ Generally, the tibial component began as an all-polyethylene (“all-poly”) device, evolved into a fixed polyethylene and metal device (“nonmodular, metal-backed”), and emerged into the modular polyethylene and metal device (“modular, metal-backed”) used most commonly today.⁷⁷ An early example of a TKA with an all-poly tibial component was the Total Condylar Prosthesis (“TCP”; noted as the “first total knee of modern design”).⁷⁸ The TCP was in use prior to the Medical Device Amendments of 1976 – known as a pre-amendments device – and can serve as a predicate device in the 510(k) process.⁷⁹ The TCP was modified at least once after 510(k) approvals began.⁸⁰ In 1978, the TCP was modified to become the Insall-Burnstein (“IB1”) knee, still with the all-poly tibial

(2000); Frank M. Griffin et al., *The Posterior Condylar Angle in Osteoarthritic Knees*, 13(7) J ARTHROPLASTY 821 (1998); Frank M. Griffin et al., *Total Knee Arthroplasty in Patients Who Were Obese with 10 Years Follow-up*, 356 CLIN ORTHOP REL RES 28 (1998); Frank M. Griffin et al., *Anatomy of the Epicondyles of the Distal Femur*, 15(3) J ARTHROPLASTY 354 (2000); For a profile of Dr. Insall, see Giles R. Scuderi et al., *The Insall Legacy in Total Knee Arthroplasty*, 392 CLIN ORTHOP REL RES 3–14 (2001).

76. Kremers et al., *supra* note 73, at 6 (noting that “>100 tibial implants are available in the U.S. market”).

77. INSALL ET AL., *SURGERY OF THE KNEE* 690 (2d ed. 1993); Saverio Comitini et al., *Evolution in Knee Replacement Implant*, 4 SINGLE CELL BIOL. 109, 109 (2014); Chitranjan S. Ranawat and Thomas P. Sculco, *History of the Development of Total Knee Prosthesis at the Hospital for Special Surgery*, TOTAL-CONDYLAR KNEE ARTHROPLASTY 3–6 (1985); R.D. Scott, *Duopatellar Total Knee Replacement: The Brigham Experience*, 13 ORTHOP CLIN NORTH AM 89–102 (1982); Luca Amendola et al., *History of Condylar Total Knee Arthroplasty*, RECENT ADVANCES IN HIP AND KNEE ARTHROPLASTY 203, 204 (2012). Also note a discussion of the posterior-stabilized, cruciate-sacrificing total knee development versus the cruciate sacrificing knees is beyond the scope of this article.

78. A.L. Malkani et al., *Total Knee Arthroplasty with the Kinematic Condylar Prosthesis: A Ten Year Follow-up Study*, 77 J. BONE & JOINT SURG. 423 (1995) (noting “the total condylar prosthesis is the prototype from which most current total knee prostheses were derived” and was introduced in New York City in 1974).

79. 21 C.F.R. § 807.92(a)(3) (2019) (noting, “A legally marketed device to which a new device may be compared for a determination regarding substantial equivalence is a device that was legally marketed prior to May 28, 1976 . . .”); see also, *How to Market Your Device* U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/> [perma.cc/QDH5-RXD2] (last visited June 22, 2019) (noting submitters “must compare their device to one or more similar legally marketed devices and make and support their substantial equivalency claims.”).

80. See U.S. FOOD AND DRUG ADMIN., *510(k) Premarket Notification*, <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K790349> [perma.cc/L8XV-3SRF] (last updated June 17, 2019).

component.⁸¹ At least one version of IB1 reached the market via the FDA's 510(k) process.⁸²

In the late 1970s and early 1980s, a fixed metal backing was added to the all-poly tibial component.⁸³ Researchers believed that the metal backing "improv[ed] the transmission of load across the bone-implant interface" by improving force distribution.⁸⁴ Surgeons noted that even though the all-poly IB1 appeared to be performing well, when revisions were performed, "the primary mode of failure [was the] loosening of the tibial component due to poor [bone] support of the tibial tray."⁸⁵ The metal-backed IB1 appears to have been approved via the 510(k) process in 1981.⁸⁶

In the late 1980s, the next big step in tibial component design occurred when the metal baseplate became removable or "modular."⁸⁷ The old nonmodular tibial component was seen as a primitive design with minimal sizes available and no side-specific implants.⁸⁸ "Modularity" meant that the polyethylene could be removed and switched to thicker or thinner inserts on top of the metal tibial tray at the surgeon's choosing – giving the surgeon added intraoperative flexibility anticipated to improve outcomes due to a "multitude of sizes" along with "advanced alignment and cutting tools."⁸⁹ In addition, surgeons could add metal augments to the metal tray to fill in for bone defects and could attach a long stem to the metal tibial post.⁹⁰ The FDA approved the modular Insall-Burnstein II ("IB2") through the 510(k) pathway.⁹¹ In the mid-1990s, IB2

81. Insall et al., *The Posterior Stabilized Condylar Prosthesis: A Modification of the Total Condylar Design*, 64 J. BONE & JOINT SURG. 1317 (1982).

82. 510(k) Premarket Notification, *supra* note 80.

83. S. Stern & J. Insall, *Posterior Stabilized Prosthesis: Results after Follow-Up of 9 to 12 Years*, 74 J. BONE & JOINT SURG. 980 (1992).

84. *Id.*; D.L. Bartel et al., *Performance of the Tibial Component in Total Knee Replacement: Conventional and Revision Designs*, 64 J. BONE & JOINT SURG. 1026 (1982); J.L. Lewis et al., *A Comparative of Tibial Component Designs of Total Knee Prostheses*, 64(1) J. BONE & JOINT SURG. 129 (1982) (noting the single post, metal-backed design had the lowest stresses); Abdeen et al., *Fifteen-Year to 19-Year Follow-Up of the Insall-Burstein-1 Total Knee Arthroplasty*, 25(2) J. ARTHROPLASTY 173 (2010); G.S. Gill et al., *Long-Term Results of Kinematic Condylar Knee Replacement: An Analysis of 404 Knees*, 83(3) J. BONE & JOINT SURG. 355 (2001).

85. Thomas J. Allardyce et al., *The Insall-Burstein Posterior Stabilized Condylar Knee Prosthesis*, SURGICAL TECHNIQUES IN TOTAL KNEE ARTHROPLASTY 67 (2002).

86. 510(k) Premarket Notification, *supra* note 80.

87. Giles R. Scuderi et al., *The Insall Legacy in Total Knee Arthroplasty*, 392 CLINICAL ORTHOPAEDICS & RELATED RES. 3 (2001).

88. W.J. Long et al., *Total Knee Replacement in Young, Active Patients: Long-term Follow-up and Functional Outcome: A Concise Follow-up of a Previous Report*, 96(18) J. BONE & JOINT SURG. AM. e159(1–7) (2014).

89. *Id.* at e159(5).

90. Scuderi et al., *supra* note 87, at 6.

91. 510(k) Premarket Notification, *supra* note 80.

evolved into the NexGen Legacy Posterior Stabilized knee.⁹² The tibial component remained a modular metal-backed design but with some changes in the shape of the polyethylene part when compared to IB2.⁹³

While this particular line of TKAs was developing, numerous other companies were likewise developing, modifying, and marketing competing devices along a somewhat parallel path to the IB line.⁹⁴ By the 1990s, modular metal-backed designs were proliferating. Almost all knees of the modern era beginning in the 1990s incorporated metal-backed modular tibial components – not the all-poly design.⁹⁵ By the late 1990s, over thirty-seven different models of TKAs were being made by fourteen different companies; one researcher noted models were changing so fast that published data was difficult to interpret “owing to the frequent modification of the prostheses.”⁹⁶ Over 100 tibial component designs were marketed from 1985 to 2005 with most no longer on the market by 2014.⁹⁷

The growth in numbers was massive. The first “modern” TKAs were implanted in the mid-1970s.⁹⁸ By 1980, around 40,000 TKAs were implanted in the U.S. annually.⁹⁹ The number of TKAs grew rapidly in this lucrative, rapidly changing market and more than tripled to 140,000 per year by 1990.¹⁰⁰ In the 2000s, TKA use surged and was expected to continue to grow. In 2017, around 966,000 total knee replacements were implanted,¹⁰¹ and over 3.48 million are expected to be implanted annually by 2030.¹⁰² As the number of patients increases, the potential for significant harm related to a poorly analyzed

92. Scuderi, *supra* note 87, at 6 (describing the implant that the author (FMG) used throughout his orthopaedic career).

93. *Id.*

94. R.Y.L. Liow & D. W. Murray, *Which Primary Total Knee Replacement: A Review of Currently Available TKR in the United Kingdom*, 79 ANN. ROYAL C. SURG. ENG. 335, 338, 340 (1997).

95. Since beginning my orthopaedic residency in 1992, I have never personally witnessed a single non-modular tibial component being implanted by any of my professors or colleagues, nor did I ever personally implant a non-modular tibial component in my career from 1992 through 2013.

96. Liow & Murray, *supra* note 94, at 338, 340.

97. Kremers et al., *supra* note 73, at 6 (noting that “at least half of the implants included in our study are no longer available”).

98. Scuderi et al., *supra* note 87, at 3.

99. Richard Iorio et al., *Chapter 26: Economics of Revision Total Knee Arthroplasty: Increasing Prevalence, Decreasing Reimbursement* in J.V. BONO, REVISION TOTAL KNEE ARTHROPLASTY 269 (2005).

100. *Id.*

101. IDATA RESEARCH, *Total Knee Replacement Statistics 2017: Younger Patients Driving Growth* (Jul. 18, 2018), <https://idataresearch.com/total-knee-replacement-statistics-2017-younger-patients-driving-growth/> [perma.cc/283J-AA4D].

102. S. Kurtz et al., *Projections of Primary and Revision Hip and Knee Arthroplasty in the United States from 2005 to 2030*, 89 J. BONE & JOINT SURG. AM. 780, 780 (2007).

device likewise increases – especially in an area where there are already devices with proven track records.

510(k) played an important role in facilitating the rapid evolution of TKA designs at a rate that limited researchers' ability to analyze outcomes because devices changed so fast that by the time significant outcome research was available, the design was already "outdated" and had been replaced by a newer version. Long term patient results of the "TKA races" are now becoming available and are discussed below.

2. 510(k)'s Facilitation of Outlier Device Approval

The speed with which the FDA approves 510(k) devices and the limited information required regarding clinical results has led to approval of at least a few outlier devices; some of these outlier devices have had early, allegedly poor results – significantly worse than their predicates – and as a result have garnered legal attention. The FDA declares these outlier devices "substantially equivalent" to their predicates, but they still can have alarming alleged rates of complications leading to significant pain and suffering for affected patients.¹⁰³ This Part provides a few examples.

An example of a nonmodular metal-backed tibial component that allegedly had worse outcomes in the 1980s and received some attention of products liability attorneys was the Porous Coated Anatomic ("PCA") knee.¹⁰⁴ The cemented version of PCA was approved via 510(k).¹⁰⁵ The design used a thinner polyethylene surface that was heat pressed in fixing it to a special metal base.¹⁰⁶

The PCA knee was initially very successful with promising early and intermediate term results.¹⁰⁷ Eventually, however, excessive wear of the polyethylene part of the tibial component became evident and was often associated with implant loosening.¹⁰⁸ In one study of 487 consecutive PCA knees, there was a 7% failure rate at an average of 4.5 years¹⁰⁹ with a projected 20% failure

103. *Medical Devices: Are Current Regulations Doing Enough for Patients?: Hearing Before the H. Subcomm. on Health of the H. Comm. on Energy and Com.*, 111th Cong. (2009) (opening statement of Hon. John D. Dingell, Representative from Mich.).

104. D.S. Hungerford et al., *The Porous-Coated Anatomic Total Knee*, 13(1) ORTHOP. CLIN. NORTH AM. 103–122 (1982); Amendola et al., *supra* note 77, at 205; Comitini et al., *supra* note 77, at 109; Soren Toksvig-Larsen et al., *Porous Coated Anatomic Total Knee Arthroplasties*, 11 J. ARTHROPLASTY 11, 15 (1996).

105. *510(k) Premarket Notification*, *supra* note 80.

106. A. Tsao et al., *Failure of the Porous Coated Anatomic Prosthesis in Total Knee Arthroplasty Due to Severe Polyethylene Wear*, 75(1) J. BONE & JOINT SURG. AM. 19 (1993); Hungerford, *supra* note 104; Amendola, *supra* note 77, at 205; Comitini et al., *supra* note 77, at 109; Toksvig-Larsen et al., *supra* note 104.

107. Toksvig-Larsen, *supra* note 104.

108. *Id.*

109. Tsao et al., *supra* note 106, at 19.

rate expected at six years.¹¹⁰ Experts considered the thinness of the polyethylene tray and the heat-pressure technique of preparation of the polyethylene the likely culprits causing early PCA failures.¹¹¹

The PCA knee received some products liability attention by courts in the 1990s. In 1996, in *Haudrich v. Howmedica, Inc.*,¹¹² the Supreme Court of Illinois affirmed the lower court's finding that the cemented PCA knee in the case was "unreasonably dangerous."¹¹³ The opinion noted the manufacturer had determined that the seven millimeter plastic tray was "too thin" and "eventually advised doctors to stop using it."¹¹⁴ At trial, the plaintiff's expert witness described the manufacturing process such that "the polyethylene was processed using heat, which made it susceptible to certain defects like pitting, scratching, and 'delamination,' whereby the polyethylene breaks apart in layers."¹¹⁵ The manufacturer's director of sales acknowledged that if the premature failure was caused by "contact stresses, the use of heat to process the piece, and inadequate polyethylene thickness," the PCA knee "would be considered unsafe."¹¹⁶ Additionally, in *Bendocchi v. Howmedica, Inc.*,¹¹⁷ the jury found the manufacturer liable for failure to warn about the dangers of the PCA knee.¹¹⁸ Interestingly, in the 2014 Mayo Clinic survivorship study,¹¹⁹ the PCA knee was not the worst performer; in fact, nine of twenty-two TKAs had worse hazard ratios than the PCA knee.¹²⁰

Another example of a tibial component with questionable results approved via the 510(k) pathway is the Miller-Galante knee ("MG1") knee.¹²¹ In 1986, the MG1 knee was first implanted, and it included a modular tibial component with cemented and uncemented porous-coated versions coated with a titanium, aluminum, and vanadium alloy with improved biocompatibility predicted.¹²² The early results of the MG1 knee caused some researchers to "abandon this implant" due to "an unacceptably high rate of complications" within two years of follow-up in one study.¹²³

More recently, metal-on-metal total hip replacements ("MoM") facilitated by 510(k) have received substantial legal attention. Even though early

110. *Id.* at 25.

111. *Id.*

112. 662 N.E.2d 1248 (Ill. 1996)

113. *Id.* at 1258.

114. *Id.* at 1253.

115. *Id.* at 1252.

116. *Id.* at 1253.

117. 2 F. App'x 711 (9th Cir. 2001).

118. *Id.* at 715.

119. See discussion *infra* Section II.A.3.

120. Kremers, *supra* note 77, at 3 (Table 1).

121. 510(k) Premarket Notification, *supra* note 80.

122. Comitini et al., *supra* note 77, at 109; Amendola et al., *supra* note 77, at 205.

123. C.H. Rorabeck et al., *The Miller-Gallante Knee Prosthesis for the Treatment of Osteoarthritis*, 75A(3) J. BONE & JOINT SURG. AM. 407 (1993).

versions of MoM hips had high revision rates in the 1970–80s,¹²⁴ MoM hips reemerged in the late 1990s, and eventually over one million MoM hip replacements were performed worldwide after 1996.¹²⁵ In March 2013, scientific studies revealed more trouble with MoM hips when researchers noted that “metal-on-metal” total hips had “poor implant survival compared to other options and *should not be implanted.*”¹²⁶ In February 2016, the FDA reclassified two specific types of MoM hips as Class III and demanded that PMA applications must be filed with the FDA if the “manufacturer wants to continue marketing their MoM total hip replacement devices and/or market new MoM total hip replacement devices.”¹²⁷ MoM hips have gotten substantial legal attention with thousands of lawsuits filed and billions of dollars in settlements already underway.¹²⁸

Because outlier devices seem to slip through, 510(k) has proven to be a poor process to recognize risks associated with apparent minor changes to predicate devices in some significant orthopaedic devices, which has led to allegations of significant injury to many patients.

3. Back to the Future: Orthopaedic Device Predicates Are Often Better Than Their 510(k) Descendants

At least two recent long-term studies suggest that the original all-poly tibial TKA designs from the 1980s were likely to last longer than today’s TKA designs. First, in 2014, Mayo Clinic researchers concluded, “the theoretical advantages of the metal-backing of the tibial component may not necessarily

124. Brent M. Ardaugh et al., *The 510(k) Ancestry of a Metal-on-Metal Hip Implant*, 368 NEW ENG. J. MED. 97 (Jan. 10, 2013).

125. K.J. Bozic et al., *The Epidemiology of Bearing Surface Usage in Total Hip Arthroplasty in the United States*, 91(7) J BONE JOINT SURG AM 1614–1620 (2009); Michael Bolognesi & Cameron Ledford, *Metal-on-Metal Total Hip Arthroplasty: Patient Evaluation and Treatment*, 23(12) J AMER ACAD ORTHOP SURG 724–731 (Dec. 2015).

126. Alison J. Smith et al., *Failure Rates of Stemmed Metal-on-Metal Hip Replacements: Analysis of Data from the National Joint Registry of England and Wales*, LANCET 1199, 1199 (Mar. 31, 2012) (emphasis added).

127. *Metal-on-Metal Hip Implants: The FDA’s Activities*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/ucm241769.htm> [perma.cc/A6U5-PAM6] (specifically stating, “all manufacturers of MoM total hip implants are required to stop marketing their devices and submit premarket approval applications that must be approved before the devices can be marketed.”).

128. See, e.g., Jef Feeley, *J&J Is Willing to Pay \$400 Million-Plus in Hip-Device Cases*, BLOOMBERG, <https://www.bloomberg.com/news/articles/2018-12-12/j-j-is-said-willing-to-pay-400-million-plus-in-hip-device-cases> [perma.cc/QB5Y-4D7E] (last visited June 22, 2019) (noting one device company is in the process of settling “about 3300 of 10,000” lawsuits targeting just one line of its hip replacements).

translate into clinical outcomes, and all-polyethylene designs can be successfully used in many patients with substantial cost savings.”¹²⁹ The researchers noted, “Our findings strongly suggest that *all-polyethylene tibial components performed significantly better than the metal-backed modular designs.*”¹³⁰ Specifically, during the twenty year period from 1985 through 2005, surgeons at the Mayo Clinic used forty different types of tibial implants in performing 17,192 TKAs.¹³¹ When they studied the tibial implants, they found that “(n)one of the components was associated with a lower risk of revision compared with . . . a component used in the mid-1980s.”¹³² The researchers reported that the older “all-polyethylene” designs performed “better” than the more modern “metal-backed modular tibial designs.”¹³³

Additionally, other researchers have similarly found better survivorship of early designs. The early non-modular IB1 knees outperformed the more modern descendent IB2 in a 2014 study where researchers found that “[a]t thirty years, a significant difference existed in the survivorship . . . between the non-modular Insall-Burstein I component (92.3%) and the modular Insall-Burstein II component (68.3%).”¹³⁴ In other words, only 7.7% of the non-modular IB1s had to be revised within thirty years, whereas 31.7% of modular IB2s were revised within a similar thirty-year period.¹³⁵ Thus, IB2s were 4.1 times more likely to require revision over thirty years. Multiple other studies have likewise revealed that the older and cheaper all-poly design is likely superior to the currently prevalent modular designs.¹³⁶

The finding that older total knee designs were superior to new knee designs is not unique. Similar examples include the metal-on-metal total hip replacement and changes to the treatment of hip fractures. A British study of 400,000 total hip implant patients found a 6.2% failure rate for MoM hips compared to only 1.7% for older traditional total hip devices.¹³⁷ Another recent study suggests that the results of MoM hips appear to be inferior to traditional total hips.¹³⁸

129. Kremers et al., *supra* note 73, at 5 (emphasis added).

130. *Id.* (emphasis added).

131. *Id.* at 2.

132. *Id.* at 2–3 (emphasis added).

133. *Id.* at 5.

134. Long et al., *supra* note 88, at e159(1–7).

135. *Id.*

136. See e.g., T.J. Gioe et al., *Current Concepts Review: The All-Polyethylene Tibial Component in Primary Total Knee Arthroplasty*, 92A(2) J. BONE & JOINT SURG. AM. 478 (2010); T. Cheng et al., *Metal-backed versus all-polyethylene tibial components in primary total knee arthroplasty*, 82(5) ACTA ORTHOP. 589 (2011).

137. Smith et al., *supra* note 126.

138. William M. Mihalko et al., *How Have Alternative Bearings and Modularity Affected Revision Rates in Total Hip Arthroplasty?*, 472(12) CLIN. ORTHOP. RELAT. RES. 3747–58 (2014).

Similarly, a 2008 article authored by the Research Committee (“Committee”) of the American Board of Orthopaedic Surgeons (“ABOS”) reported a “striking shift” unsupported by scientific findings to a new device (“Nail”) from an older proven device (“Plate”) by newly trained orthopaedic surgeons fixing hip fractures.¹³⁹ The Committee found that over a seven year time frame, young surgeons went from using the Nail only 3% of the time to fix hip fractures to using the Nail 67% of the time – a “striking” 2,133% increase in market share for the Nail in just seven years.¹⁴⁰ According to the Committee, the shift to the Nail was not based on scientific evidence of improved outcomes for patients.¹⁴¹ The Committee noted “the *only consistent differences* found between the two fixation techniques seem to be an *increased rate of complications* (particularly intraoperative and postoperative fractures) and a *higher rate of re-operation* in association with [the Nail].”¹⁴² The Committee noted that the “consensus from the orthopaedic literature is that [Nail] fixation is associated with a higher complication rate and no better outcomes,”¹⁴³ in addition to “higher implant costs and surgeon fees.”¹⁴⁴ At least some of the Nail devices were approved using 510(k).¹⁴⁵

139. 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, 700, 705 (2008) (noting the newer nail fixation for hip fractures was associated with “increased rate of complications” and “no better outcomes.” Also noting, “Our data, which were collected from young orthopaedic surgeons in the beginning of their careers, confirm a higher rate of fracture and procedure-related complications and, at best, equivalent pain and deformity scores at the time of follow-up for patients managed with intramedullary nail fixation.”).

140. *Id.*

141. *Id.* at 706 (noting “higher implant costs and surgeon fees, with no improvement in patient outcomes”).

142. *Id.* at 705 (emphasis added).

143. *Id.* (emphasis added).

144. *Id.*

145. See, e.g., U.S. FOOD AND DRUG ADMIN., *510(k) Premarket Notification*, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K993670> [perma.cc/H23E-KQ5S] (last updated June 17, 2019); U.S. FOOD AND DRUG ADMIN., *510(k) Premarket Notification*, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K012158> [perma.cc/9YE3-PGZ4]; U.S. FOOD AND DRUG ADMIN., *510(k) Premarket Notification*, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K020773> [perma.cc/UG6K-VHMW] (last updated June 17, 2019).

B. Analysis of FDA's Recent 510(k) Changes on Orthopaedic Device Outcomes

In 2011, the IOM stated that 510(k) was “flawed” and should be replaced with an “integrated premarket and postmarket regulatory framework that effectively provides a reasonable assurance of safety and effectiveness throughout the device life cycle.”¹⁴⁶ However, Congress did not replace 510(k). This Section includes an analysis of whether the IOM’s goals were met by reviewing the things that have not changed as well as the things that have changed with the FDA’s recent 510(k) modifications.

1. Things that did not change

Considering the fact “that <5% of device-related complications were reported to the FDA,”¹⁴⁷ the FDA remains bafflingly deferential toward device manufacturers. 510(k) remains too deferential for devices implanted within or affixed to large bones because (1) it is designed to be the “least burdensome approach” for manufacturers instead of the best approach to protect patients, (2) a benefit-risk assessment is not required for the majority of devices and risks can be “mitigated” with labeling alone, and (3) it has too many exceptions.¹⁴⁸

First, an overly deferential framework in favor of manufacturers impedes 510(k)’s effectiveness because the FDA designs 510(k) “to provide the least burdensome approach for manufacturers”; the least burdensome provision says that the FDA “shall only request information that is necessary” and “shall consider the least burdensome means of demonstrating substantial equivalence.”¹⁴⁹ This means that for some types of device changes the “Quality System (QS)

146. IOM REPORT, *supra* note 11, at 196, 210.

147. Day et al., *supra* note 2, at 522.

148. *Id.*

149. *Deciding When to Submit a 510(k) for a Change to an Existing Device*, U.S. FOOD AND DRUG ADMIN., <https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm514771.pdf> [perma.cc/DLC7-LEMC].

regulation” can be relied on as the least burdensome approach without requiring manufacturers to submit a new 510(k).¹⁵⁰ The QS regulation basically requires some recordkeeping of the changed device.¹⁵¹ When the QS regulation “can reasonably assure the safety and effectiveness of the changed device,” submission of a new 510(k) may not be required.¹⁵²

In addition, FDA guidance¹⁵³ explains that reliance on postmarket controls like QS regulations, postmarket surveillance, and medical device reporting requirements will be considered as a mechanism “to reduce the extent of premarket data for 510(k)s.”¹⁵⁴ “In some cases, the FDA may accept greater premarket uncertainty regarding a device’s benefit-risk profile through greater reliance on postmarket controls, such as postmarket surveillance where applicable, in order to reduce the premarket burden for a 510(k).”¹⁵⁵ So, the process is tilted heavily in favor of device manufacturer convenience and facilitation of change over consumer safety and efficacy requirements. While postmarket surveillance may help identify devices that need to be recalled earlier, it does little to protect the consumer from the unsafe device in the first place when it has been affixed to or implanted within a large bone.

Second, according to the FDA, “a benefit-risk assessment is *not* recommended” or necessary for the *majority* of 510(k)s to support a determination of substantial equivalence.¹⁵⁶ Further, “despite differences in the benefit-risk profile, in some circumstances the new device may be determined to be substantially equivalent to the predicate device.”¹⁵⁷ In addition, the FDA will consider whether “mitigation strategies,” *like labeling changes*, are adequate to address benefit-risk profile differences between the new device and the predicate device.¹⁵⁸

150. See generally 21 CFR § 820 (2019); U.S. FOOD AND DRUG ADMIN., STATEMENT OF POLICY FOR REGULATING BIOTECHNOLOGY PRODUCTS, GUIDE TO MED. DEVICE REG. APP. III (Cum. Supp. Nov. 2018) (hereinafter STATEMENT OF POLICY) (noting, “Regardless of whether a change requires premarket review, the QS regulation requires manufacturers of finished medical devices to review and approve changes to device design and production (21 CFR § 820.30 and § 820.70) and document changes and approvals in the device master record (21 CFR § 820.181). Any process whose results cannot be fully verified by subsequent inspection and testing must be validated (21 CFR § 820.75), and changes to the process require review, evaluation, and revalidation of the process where appropriate (21 CFR § 820.75(c)).”).

151. STATEMENT OF POLICY, *supra* note 150.

152. *Id.*

153. *The Least Burdensome Provisions: Concepts and Principles*, U.S. FOOD AND DRUG ADMIN. (Feb. 2019), <https://www.fda.gov/media/73188/download> [perma.cc/446D-SN7Y].

154. FDA BENEFIT-RISK FACTORS, *supra* note 25, at 18.

155. *Id.*

156. *Id.* at 10.

157. *Id.* at 11.

158. *Id.*

Finally, a 510(k) is not required to “develop, evaluate, or test a device” – including clinical evaluation.¹⁵⁹

For orthopaedic devices, the problem with this deferential approach and failure to require a benefit-risk assessment is that seemingly innocuous changes (as noted above in some outlier case examples) can lead to unexpected complications for patients with severe consequences clinically. Additionally, many of these problems require mid- to long-term follow-up of clinical results to predict. Further, labeling strategies are of questionable benefit, at best, as discussed below.

2. Things that have changed: Numerous Holes in the November 2018 Changes

Unfortunately, the latest updates to 510(k) are unlikely to significantly alter the long-term results of orthopaedic devices, unless some additional changes are made, as noted below.

a. Increased Premarket Expectations for 510(k) Submissions

As described above, the increased premarket expectations are mostly paperwork requirements that can allow for “paper compliance” without real evidence of clinical safety and efficacy. The incorporation of risk/benefit factors would be helpful if the standards for their use were not so deferential. As noted above, the FDA states that “a benefit-risk assessment is *not* recommended” or necessary for the *majority* of 510(k)s to support a determination of substantial equivalence.¹⁶⁰

One of the risks considered in benefit-risk assessment is the “rate of harmful events.”¹⁶¹ This “refers to the number of harmful events per patient or the number of harmful events per unit of time associated with the use of the device.”¹⁶² The FDA considers harmful events, such as (1) “device-related serious adverse events” like death, life-threatening illness, permanent impairment or damage, etc., (2) “device-related non-serious adverse events,” and (3) “procedure-related complications” like indirect anesthetic complications, etc.¹⁶³ The probability of a harmful event reflects “the proportion of the intended population that could be expected to experience a harmful event,” and the “FDA

159. *Premarket Notifications 510(k)*, U.S. FOOD AND DRUG ADMIN., <https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k> [perma.cc/YU8J-2YWA] (noting “Please note that if you perform clinical trials with your device, you are subject to the Investigational Device Exemption (IDE) regulation (21 CFR § 812).”).

160. FDA BENEFIT-RISK FACTORS, *supra* note 25, at 10.

161. *Id.* at 14.

162. *Id.*

163. *Id.*

could factor whether an event occurs once or repeatedly into the measurement of probability.”¹⁶⁴

The FDA needs to reconsider its benefit-risk assessment rules for devices affixed to or implanted within large bones when there is already a predicate device with good to excellent outcomes. The FDA should also emphasize statistical risk of unnecessary morbidity and mortality when similar devices are already on the market to treat the specific orthopaedic malady. A closer look at the clinical outcomes with regard to morbidity and mortality likely reflected by the studies of all-poly versus modular metal-backed tibial TKA components helps explain why the FDA should be less deferential with devices like TKAs when it comes to benefit-risk assessment. Evolution of the TKA tibial component to today’s less durable and more expensive modular design facilitated by 510(k) has likely resulted in significant morbidity, mortality, and financial costs with questionable resultant benefit at best.¹⁶⁵ As calculated in the following paragraphs, *almost 8,700 people likely have died or will die as a result of revision surgeries related to the change from all-poly to modular metal-backed TKAs*, and many more have suffered unnecessary morbidity.¹⁶⁶

Quantitatively, Mayo Clinic researchers in 2014 discovered that the all-poly knees had a hazard ratio of 0.3 compared to modular knees – meaning that the all-poly knees were 0.3 times as likely to undergo a revision compared to the newer modular designs.¹⁶⁷ In a separate study, Kaiser-Permanente researchers likewise found a hazard ratio of 0.3 for all-poly tibial implants compared to modular metal-backed designs.¹⁶⁸ Using the hazard ratio of 0.3 for all-poly knees versus modular knees from the Mayo and Kaiser studies and using established TKA volume data, it is easy to roughly estimate the past and future costs of the changes to tibial design since 1990 – including morbidity, mortality, and financial costs.

In the twenty-seven years between 1990 and 2017, around 13,438,238 TKAs were performed in the U.S.¹⁶⁹ Using current techniques, the lifetime risk of revision surgery for someone with a TKA is 16.5%.¹⁷⁰ In the Mayo

164. *Id.* at 15.

165. *Id.*

166. *Id.*

167. Kremers et al., *supra* note 73, at 1 (stating, “In comparison with metal-backed modular implants, all-polyethylene tibial components had a significantly lower risk of revision (*hazard ratio, 0.3*; 95% confidence intervals: 0.2, 0.5 [$p < 0.0001$]).”).

168. Vivek Mohan et al., *Monoblock All-Polyethylene Tibial Components Have a Lower Risk of Early Revision than Metal-Backed Modular Components*, 84(6) ACTA ORTHOPAEDICA 530, 530 (2013) (reporting results of a “[r]egistry study of 27,657 primary total knee arthroplasties”).

169. *See infra* App. A.

170. Alexander M. Weinstein et al., *Estimating the Burden of Total Knee Replacement in the United States*, 95 J. BONE & JOINT SURG. AM. 385, 390 (2013) (quoting a rate of 14.9% for males and 17.4% for females; since 2/3 of primary TKAs involve

Clinic study, about 80% of the knees used were modular designs; so, if 80% of knees implanted during that time period were modular, then around 10,750,590 modular tibias were implanted from 1990 through 2016.¹⁷¹ So, if 16.5% of those 10.75 million modular tibias needed revision surgery, then 1,773,847 people underwent (or will undergo during the life of the implant) revision surgery. If those 1,773,847 people had all-poly tibias, only 532,154 of them would have to undergo revision surgery since the hazard ratio is 0.3 for the all poly tibia compared to the modular tibia. Therefore, there will be a total of around 1,241,693¹⁷² people who must undergo a revision total knee surgery that theoretically would not have been necessary if the original design had not been changed; hereinafter, I will refer to these as “avoidable revisions.”

The risk of perioperative death for revision TKA is around 0.7%.¹⁷³ If 0.7% of those 1,241,693 people undergoing avoidable revision TKA surgery die, then 8,692 people¹⁷⁴ have died or will die unnecessarily as a result of modular total knees performed from 1990 through 2017. In addition, some people have experienced or will experience avoidable, nonfatal, and costly life-altering complications related to those 1,241,693 avoidable revisions – estimated at approximately 12,417 deep infections (1%),¹⁷⁵ 7,823 symptomatic deep venous thromboses (DVT; i.e., blood clots; 0.63% rate),¹⁷⁶ and 3,353 pulmonary emboli (0.27%).¹⁷⁷

In addition, these 1,241,693 avoidable revision surgeries carry considerable financial costs. In 2016 dollars, each revision surgery costs around \$70,000 on average.¹⁷⁸ Therefore, 1.242 million avoidable revisions from 1990

females, the gender adjusted risk is 16.5% for the entire population—mathematically, $(2/3 \times 17.4) + (1/3 \times 14.9) = 16.5$).

171. Kremers et al., *supra* note 73, at 3 (stating, “Metal-backed modular tibial components constituted almost 80% of the tibial designs used in this cohort.”).

172. 1,773,847 minus 532,154 people.

173. Thomas Fehring et al., *Mortality Following Revision Joint Arthroplasty: Is age a factor?*, 24 J. ARTHROPLASTY e85 (2010) (0.2% in patients <70 years old; 0.8% in 70 to 79; and 2.63% in >80 years old).

174. $0.007 \times 1,241,693$ million = 8,692.

175. *Joint Replacement Infection*, AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS, <http://orthoinfo.aaos.org/topic.cfm?topic=A00629> [perma.cc/QG6D-JYPA] (last visited June 22, 2019) (quoting 1% infection rate for TKA).

176. Gregory M. Martin et al., *Complications of Total Knee Arthroplasty*, UPToDate, <http://www.uptodate.com/contents/complications-of-total-knee-arthroplasty> [perma.cc/QYV5-AUM5] (reporting symptomatic DVT rate of 0.63% and PE rate of 0.27%); Jean-Marie Januel et al., *Symptomatic In-Hospital Deep Vein Thrombosis and Pulmonary Embolism Following Hip and Knee Arthroplasty Among Patients Receiving Recommended Prophylaxis*, 307(3) J. AMER. MED. ASSN. 294–303 (2012).

177. Martin et al., *supra* note 176.

178. TKA prices are difficult to project because of wide variations between hospitals and suppliers. \$70,000 is based upon the average of two studies and conversion to 2016 dollars. M. Bhandari et al., *Clinical and Economic Burden of Revision Knee Arthroplasty*, 5 CLIN. MED. INSIGHTS ARTHRITIS MUSCULOSKEL. DISORD. 89–94 (2013)

through 2017 added or will add \$86.9 billion in avoidable expense to the healthcare system.¹⁷⁹ Additionally, modular knees cost an average of \$957 more per implant;¹⁸⁰ if the 10.75 million people had received all-poly knees instead of modular knees, then an additional \$10.3 billion would have been saved.¹⁸¹ Thus, from higher implant costs and unnecessary revisions alone, \$97.2 billion has been or will be unnecessarily spent on the modular knees performed from 1990 through 2017. This cost estimate is likely very conservative because it does not include the morbidity costs associated with complications, such as infection, DVT, PE, and other complications. Likewise, outlier implants with higher complication rates are not included.

Convincing evidence is lacking that 510(k) makes up for the losses sustained in TKAs with advances in other orthopaedic devices. Similar profiles to the TKA tibial component outlined above could potentially be exposed with regard to the other components of total knee replacement, to total hip replacements, to hip fracture treatment, and to other orthopaedic devices once more specific data similar to the Mayo study is produced – as there is little evidence that some of these components are better today than they were in the mid

(reporting \$49,000 in 2012 dollars and adjusted to \$51,510 in 2016 dollars using <http://www.usinflationcalculator.com>); Carlos Lavernia et al., *The Increasing Financial Burden of Knee Revision Surgery in the United States*, 446 CLIN. ORTHOP. 221–26 (2006) (reporting \$73,696 in 2006 dollars and adjusted to \$88,228 in 2016 dollars using <http://www.usinflationcalculator.com>).

179. \$70,000 per revision x 1.242 million avoidable revisions.

180. Gioe et al., *supra* note 136, at 478.

181. \$957 x 10.75 million.

1980s.¹⁸² Several devices seem likely to have worse cost profiles than the modular, metal backed tibial component,¹⁸³ and significant, proven device innovations to offset those costs are not readily and convincingly apparent. The consistent change with new devices is higher prices,¹⁸⁴ not better outcomes for patients.

Because well-established, safe, and effective devices are already on the market for many orthopaedic devices, benefit-risk analysis should take into account these types of calculations in order to avoid unnecessary morbidity, mortality, and financial costs associated with 510(k).

“When reviewing a new device and assessing different technological characteristics in accordance with this guidance, [the] FDA may consider post-market data (e.g., literature, recalls, registry data, medical device reports) collected on marketed devices of the same type.”¹⁸⁵ The FDA should consider the types of calculations above before clearing 510(k) orthopaedic devices that are meant to treat orthopaedic maladies that already have treatments with excellent long-term outcomes.

182. The tibial component of total knees simply now has a few studies that have produced specific hazard ratios to allow some simple computations; hopefully, similar studies will be done for other orthopaedic implants in the future. *Information Statement: Current Concerns with Metal-on-Metal Hip Arthroplasty*, AM. ACAD. OF ORTHOPAEDIC SURGEONS 1 (2012), https://www.aaos.org/uploadedFiles/PreProduction/About/Opinion_Statements/advistmt/1035%20Current%20Concerns%20with%20Metal-on-Metal%20Hip%20Arthroplasty.pdf [perma.cc/M8K2-R757] [hereinafter AAOS INFORMATION STATEMENT]; Michael P. Bolognesi et al., *Metal-on-Metal Total Hip Arthroplasty: Patient Evaluation and Treatment*, 23 J. AM. ACAD. ORTHOPAEDIC SURGERY 724, 724–25, 730 (2015) (noting issues with new metal-on-metal total hip replacements compared to older designs); Kevin J. Bozic et al., *The Epidemiology of Bearing Surface Usage in Total Hip Arthroplasty in the United States*, 91 J. BONE & JOINT SURG. AM. 1614 (2009); *Effectiveness of Metal-on-Metal Hip Implants*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/metal-metal-hip-implants/effectiveness-metal-metal-hip-implants> [perma.cc/RG4W-5WCM] (last updated Mar. 14, 2016) (noting issues with new metal-on-metal hip replacements compared to older designs); Anglen & Weinstein, *supra* note 139, at 705 (noting that the newer nail fixation for hip fractures was associated with “increased rate of complications” and “no better outcomes”); Wade R. Smith et al., *Locking Plates: Tips and Tricks*, 89 J. BONE & JOINT SURG. AM. 2298, 2303, 2306 (2007) (noting claims of increased healing rates with newer locking plates compared to older non-locking plates had “not been validated in any type of controlled trial” and that “few series had validated the long-term advantages of fixation with locking plates”); James C. Bailey et al., *Failure of the metal backed patellar component after total knee replacement*, 70 J. BONE & JOINT SURG. AM. 668 (1988) (noting problems with newer metal-backed patellar components compared to older all-poly patellar components).

183. Bailey et al., *supra* note 182, at 668.

184. Kayode O. Oduwole et al., *Increasing financial burden of revision total knee arthroplasty*, 18 KNEE SURG SPORTS TRAUMATOL ARTHROSC. 945, 945–48 (2010).

185. FDA BENEFIT-RISK FACTORS, *supra* note 25, at 18.

b. Refuse-To-Accept Policy

The “Refuse-to-Accept” policy is basically a checklist that is used to make sure applications are complete before the FDA deploys additional resources to analyze the proposed 510(k) device.¹⁸⁶ In the sense that this makes the FDA more efficient and preserves time and resources for complete applications, the policy could help with orthopaedic device approval because resources may be better spent and used more efficiently.¹⁸⁷ However, since this is again a regulatory policy focused on paper compliance and not a substantive review, the effect on outcomes of the devices themselves is likely to be minimal.¹⁸⁸ This bureaucratic requirement merely ensures that the FDA only reviews complete applications, improving the efficiency of the FDA, but otherwise does not affect quality or long term performance evaluation.

c. Improved Consistency and Thoroughness

The 510(k) SMART memo template now used by FDA reviewers provides guidance that should meet the goal of improving consistency and thoroughness in evaluating the paper compliance of 510(k) applications.¹⁸⁹ The links provided by the template should facilitate more consistent analysis and help with documentation of pertinent information.¹⁹⁰ Likewise, the frequent updates will help facilitate consistency and help to make important information available to FDA reviewers.¹⁹¹ FDA reviewers spend more time on each 510(k) application in part because of this program.¹⁹² However, this tool mainly ensures that applicants follow checklists and that information is available, but it does not place any specific additional substantive requirements on device manufacturers to ensure clinical safety and efficacy.¹⁹³ It is hard to see how this will improve the ultimate outcome of orthopaedic devices like those mentioned earlier in this paper.

186. *FDA Steps to Strengthen 510(k)*, *supra* note 8, at 5.

187. *Id.*

188. *FDA Refuse to Accept Policy*, *supra* note 29, at 4 (explaining that this policy only assesses completeness of the application, not quality or substance).

189. *FDA Steps to Strengthen 510(k)*, *supra* note 8, at 6.

190. *Id.*

191. *Id.*

192. *Id.* (noting that the FDA’s staff now spend more time reviewing each 510(k) submission “than ever before.” The FDA estimates that its reviewers now spend twice as much time reviewing each 510(k) as they did just 15 years ago and 32% more time than they did in 2009).

193. *Id.*

d. Elimination of 510(k) for Class III Devices

Elimination of 510(k) for Class III devices is a major step in the right direction and would make a tremendous difference if more orthopaedic devices were classified as Class III. However, a surprising number of orthopaedic devices that require very invasive surgery to be affixed or implanted within large human bones deep within the body are still considered Class II, even though they are associated with major potential complications up to and including death.¹⁹⁴ In fact, from 1992 to 2012, “94% of orthopaedic devices were categorized as class II” even though many were affixed permanently to large, deep bones, and “during that same time period, orthopaedic devices were approximately thirteen times more likely to be cleared through the 510(k) process rather than the PMA process.”¹⁹⁵

Examples of orthopaedic devices affixed to or implanted within large bones still classified as Class II include: (1) bone fixation cerclage,¹⁹⁶ (2) intramedullary fixation rods,¹⁹⁷ (3) single/multiple component metallic bone fixation appliances and accessories,¹⁹⁸ (4) smooth or threaded metallic bone fixation fastener,¹⁹⁹ (5) most primary total hip replacement configurations,²⁰⁰ and (6) most primary total knee replacement configurations.²⁰¹

All of these devices can require deep dissection (to the bone) in the human body and can be associated with major complications ranging from pulmonary embolism to permanent disability to death. When modifications go bad, the results can devastate patients’ lives. For example, until May 2016, these metal on metal total hips with alleged major complications and multiple lawsuits were Class II.²⁰²

For the majority of orthopaedic devices, which are still Class II, this change will have minimal effect.

194. Day et al., *supra* note 2, at 522 (noting that “many high-risk implantable orthopaedic devices are miscategorized under class II and thus do not undergo PMA review”) (internal citations omitted).

195. *Id.*

196. 21 C.F.R. § 888.3010 (2019).

197. § 888.3020.

198. § 888.3030.

199. § 888.3040.

200. §§ 888.3310, 888.3340, 888.3350, 888.3353, 888.3358, 888.3360.

201. §§ 888.3500, 888.3510, 888.3520, 888.3530, 888.3535, 888.3540, 888.3560, 888.3565, 888.3590.

202. *Metal-on-Metal Hip Implants: The FDA’s Activities*, *supra* note 127 (specifically stating, “there is insufficient evidence and information to conclude that general controls in combination with special controls would provide reasonable assurance of the safety and effectiveness of these devices.”).

e. Elimination of More Than 1000 Devices as Legal Predicates

If elimination of predicates is based upon outcome studies that demonstrate the eliminated devices have questionable patient outcomes, then predicate elimination could be an important step. Clearly, “the unknown risks that . . . devices pose when they are cleared with inadequate predicates is a burden that patients should not have to bear.”²⁰³

Elimination of questionable predicates helps address “predicate creep.”²⁰⁴ Predicate creep is a 510(k) progression in which each generation of a new device evolves farther from any device that has been proven safe and effective with clinical data because once the FDA clears a device by 510(k) or PMA it can be used as a legal predicate.²⁰⁵ The cumulative design changes associated with predicate creep can lead to devices with little resemblance to the original predicate in a long “predicate chain,” which means the approved device is likely only as safe and effective as the weakest link in the chain.²⁰⁶

However, the FDA should base elimination of predicates on clinical results regarding safety and efficacy (including those available in postmarket surveillance and in registry studies) and *not on the age of the predicate*. In some cases, eliminating older devices as predicates could lead to worse devices where some older devices have proven safer and more effective than their descendants, as noted above in the Mayo Clinic and Kaiser-Permanente studies of total knees.²⁰⁷ Therefore, the predicate’s age should not be the main factor (or necessarily even a factor) in determining whether the predicate can still be used.

Unfortunately, the FDA focuses on eliminating predicates that are over ten years old based upon a recent call for public comment.²⁰⁸ The FDA believes “[t]he most impactful way that we can promote innovation and improved

203. Arianne Freeman, *Predicate Creep: The Danger of Multiple Predicate Devices*, 23 ANNALS HEALTH L. ADVANCE DIRECTIVE 127, 139 (2014). (“The unknown risks that Class III devices pose when they are cleared with inadequate predicates is an unethical burden that patients should not have to bear.”).

204. *Id.* at 127–28.

205. *Id.* at 128; Fargen et al., *supra* note 4, at 272, 275 n.27. (explaining that once the FDA clears a device via 510(k) or PMA, it can be used as a predicate for future devices without new safety or efficacy proof).

206. Frank M. Griffin, *Prejudicial Interpretation of Expert Reliability on the Cutting Edge Enables the Orthopaedic Implant Industry’s Bodily Eminent Domain Claim*, 18 MINN. J. L. SCI. TECH. 207, 220 (2017).

207. Mohan et al., *supra* note 168, at 535.

208. *Statement from FDA Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D., Director of the Center for Devices and Radiological Health, on Transformative New Steps to Modernize FDA’s 510(k) Program to Advance the Review of the Safety and Effectiveness of Medical Devices*, U.S. FOOD AND DRUG ADMIN. (November 26, 2018),

safety in the 510(k) program is to *drive innovators toward reliance on more modern predicate devices* or objective performance criteria when they seek to bring new devices to patients.²⁰⁹ The FDA is “looking at ways to promote the use of more recent predicates.”²¹⁰ To meet this goal, “in the next few months CDRH is considering making public on its website those cleared devices that demonstrated substantial equivalence to . . . predicates that are more than 10 years old.”²¹¹

In orthopaedics, this could foreseeably lead to a worsening of the design pool of predicates and weaken the safety and efficacy of new orthopaedic devices. While this change would be beneficial if newer devices performed better, recent studies noted above suggest the exact opposite is true in many cases.²¹² Focusing on new predicates may even worsen the problem of “predicate creep” noted above as devices get farther and farther away from any device with long term follow-up studies or registry data.

IV. ADDITIONAL PROPOSED SOLUTIONS

Additional potential solutions to improve outcomes of orthopaedic devices approved by the FDA include (A) regulatory changes by the FDA, (B) ensuring fairness in medical device products liability litigation, and (C) congressional action.

A. *Regulatory Changes by the FDA*

In addition to the changes noted above related to the FDA’s recent guidance, the FDA could potentially improve the results of orthopaedic device modifications by reclassifying all implants affixed to or implanted within long bones (e.g., the femur) as Class III devices.

Class III devices are those that “either ‘presen[t] a potential unreasonable risk of illness or injury,’ or which are ‘purported or represented to be for a use . . . which is of substantial importance in preventing impairment of human health.’”²¹³ The FDA subjects Class III devices to § 360e – the PMA process – to “provide reasonable assurance of [their] safety and effectiveness.”²¹⁴

For orthopaedic devices, the 11.5 times higher recall rate for 510(k) devices compared to PMA devices alone presents an “unreasonable risk of illness

<https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-jeff-shuren-md-director-center-devices-and> [perma.cc/XJ25-H2R7].

209. *Id.*

210. *Id.*

211. *Id.*

212. Freeman, *supra* note 203, at 132.

213. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996) (citing 21 U.S.C. § 360c(a)(1)(C) (1992)); 21 U.S.C. § 360c (2012).

214. 21 U.S.C. § 360c (2012).

or injury” because many of those recalled devices will require revision surgery bearing a significant and unnecessary risk of injury.²¹⁵ If those orthopaedic devices were simply reclassified to Class III, then the recall rate would drop by a factor of 11.5. In addition, when devices are available with proven long histories of safety and efficacy, modifications to those designs present “potential unreasonable risk of illness of injury” by outlier implants as described above.²¹⁶ Reclassification as Class III may have prevented some outlier devices from reaching a larger market where clinical data is required on the front end, and complications are avoided by restricting dispersion of the outlier device without more safety and efficacy data. Further, when new devices underperform their predicates, the avoidable revisions and resultant morbidity and mortality also represent an “unreasonable risk of injury or illness” – demonstrated by the likely almost 8700 deaths discussed above related to changes in the tibial component of TKAs alone.²¹⁷ If total knee replacements²¹⁸ were simply reclassified as Class III, many of those deaths could likely have been avoided because clinical data would have been required that may have beneficially throttled the speed of the “TKA races.”

Total hips²¹⁹ should also be moved to Class III for similar reasons. In addition, the FDA should move orthopaedic plates and screws²²⁰ to Class III because there are similar long-term proven devices and because risks of these devices include complications like (1) plate or screw breakage or bending leading to revision surgery and its attendant risks of morbidity and mortality, and (2) protruding screw tips injuring nerves (causing nerve damage), arteries (causing bleeding), and other soft tissues.²²¹ Similarly, intramedullary nails²²² carry a risk of fat or air embolism, mechanical failure or breakage, penetration of bones and joints, becoming stuck inside the bone, and other issues that can result in serious morbidity and mortality.²²³ 510(k) alone fails to adequately assess the safety and efficacy of modifications of current proven designs of

215. Day et al., *supra* note 2, at 522.

216. *See* discussion *supra* Section II.A.2.

217. *See* discussion *supra* Section II.B.2.

218. 21 C.F.R. §§ 888.3500, 888.3510, 888.3520, 888.3530, 888.3535, 888.3540, 888.3560, 888.3565, 888.3590 (2019).

219. §§ 888.3310, 888.3340, 888.3350, 888.3353, 888.3358, 888.3360; Day, *supra* note 2, at 522 (noting “only 15% of 510(k)-cleared total hip replacement devices had published data on clinical effectiveness”).

220. § 888.3030.

221. Jason A. Lowe, *Internal Fixation for Fractures*, ORTHOINFO (April 2019), <https://orthoinfo.aaos.org/en/treatment/internal-fixation-for-fractures/> [perma.cc/7BNU-DPEJ];

(noting plates may break); John E. Lonstein et al., *Complications Associated with Pedicle Screws*, 81 J. BONE JOINT SURG. 1519, 1519 (1999).

222. § 888.3020.

223. Duke Orthopaedics, *Complications of Femoral IM Nailing*, WHEELLESS TEXTBOOK OF ORTHOPAEDICS, http://www.wheellesonline.com/ortho/complications_of_femoral_im_nailing [perma.cc/7WH9-N2BJ].

devices affixed to or implanted within large bones without significant clinical data like that required by PMA.

B. Ensuring Fairness in Medical Device-Related Trials

Courts can improve orthopaedic recall and complication rates (1) by giving plaintiffs a voice and listening to arguments for liability against manufacturers (and possibly surgeons) under informed consent law and (2) by ensuring the plaintiffs have a fair chance to prove design defect by fairly analyzing expert witnesses under *Daubert*.

1. State Tort Law: Informed Consent

The FDA often cites labeling as a method of “risk mitigation” in benefit risk assessment of new devices with the FDA noting that “[e]ven if a new device has an increased risk and if the risk is appropriately mitigated, FDA may determine that the new device has a comparable benefit-risk profile to the predicate device and therefore determine that the new device is ‘as safe and effective’ as the predicate device.”²²⁴ The FDA added, “The most common form of risk mitigation is to include appropriate information within *labeling* (e.g., warnings, precautions, contraindications).”²²⁵ Further, the FDA stated, “Some risks can be mitigated through other forms of risk communication, including training and professional and patient *labeling*.”²²⁶

The FDA’s reliance on warning labels to mitigate risk is ineffective if surgeons and patients are not aware of the warnings. In my experience, FDA clearance information, device labels, and recall rates are rarely included in informed consent discussions regarding orthopaedic device implantations; often the surgeon has not even seen the label. In addition, surgeons and patients likely rarely understand the significance of 510(k) versus PMA clearance when it comes to orthopaedic devices and rarely are aware which pathway a particular device took to clearance.²²⁷ Therefore, courts should hold manufacturers and surgeons responsible for educating patients regarding the risks involved with 510(k) clearance of orthopaedic devices during the informed consent process; allowing patients and surgeons to become more aware of these issues and take them into account when choosing treatments would be a more “patient-centered” and “patient-driven” approach.

224. FDA BENEFIT-RISK FACTORS, *supra* note 25, at 17–18.

225. *Id.* at 18 (emphasis added).

226. *Id.*

227. Day et al., *supra* note 2, at 517.

If the manufacturer properly educates the surgeon²²⁸ about the risks associated with its device (e.g., through effective warnings included in sales discussions), then the duty will fall upon the surgeon under the learned intermediary doctrine to properly inform the patient.²²⁹ When surgeons are unaware, they cannot function as effective learned intermediaries.²³⁰ In those instances, liability should remain with the manufacturer with regard to educating surgeons and patients. In order to avoid liability, the manufacturer should have to transparently inform the surgeon of the data and FDA clearance pathway by which the device reached the market (especially in orthopaedics where FDA clearance pathway changes the recall risk by a factor of 11.5); in addition, manufacturers should be held liable where salesmanship dupes the surgeon into believing the device stands on more solid scientific grounds than reality.²³¹

Under informed consent doctrine, patient and physician notification of orthopaedic device clearance pathway should be required because the much higher recall rate of 510(k) orthopaedic devices makes the information material to the patient's decision to consent to the implantation of, and the surgeon's decision to use, the particular device.²³²

Informed consent “requires a physician to warn a patient of the risks and consequences of a medical procedure.”²³³ This should include a fundamental duty to warn patients of the risks and consequences of a procedure involving an evolving medical device like a 510(k) device.²³⁴ Many regard the patient's right to participate in decision-making as one of the patient's “most fundamental rights.”²³⁵ Informed consent fosters personal autonomy and doctor-patient

228. *Id.* (noting the clinical relevance of 510(k) information and saying, “When orthopaedic surgeons are considering using a new device clinically in their patients, it is important for them to consider how the new device was approved by the FDA. If the device was approved by the 510(k) pathway, then it may have been approved without additional clinical studies confirming efficacy or safety.”).

229. Frank M. Griffin, *The Trouble with the Curve: Manufacturer and Surgeon Liability for “Learning Curves” Associated with Unreliably-Screened Implantable Medical Devices*, 69 ARK. L. REV. 755, 773–74 (2016); Diane Schmauder Kane, Annotation, *Construction and Application of Learned-Intermediary Doctrine*, 57 A.L.R.5th 1, §2[a] (1998) (explaining that in many jurisdictions under the learned intermediary doctrine, the manufacturer cannot be held liable for failing to directly warn the consumer as long as the consumer's doctor, acting as a learned intermediary, was given adequate warnings of the device's inherent dangers).

230. See *Kowalski v. Rose Drugs of Dardanelle, Inc.*, 378 S.W.3d 109, 120 (Ark. 2011) (stating physicians are in the best position to inform patients of risks of treatment); *Schenebeck v. Sterling Drug, Inc.*, 423 F.2d 919, 922 (8th Cir. 1970).

231. Kane, *supra* note 229, at 34–35; *Schenebeck*, 423 F.2d at 922.

232. Day et al., *supra* note 2, at 522.

233. *Lucas v. Awaad*, 830 N.W.2d 141, 150 (Mich. Ct. App. 2013) (citing *Wlosinski v. Cohn*, 713 N.W.2d 16, 20 (Mich. Ct. App. 2005)) (emphasis added).

234. *Id.* at 150–51.

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

communication; informed consent also allows patients to improve quality of care where they understand the procedures that they undergo and can provide feedback to the healthcare system.²³⁶ Informed consent is also important because it involves the public in medical decision-making, adding a layer of transparency to surgical decision-making.²³⁷

The Affordable Care Act (“ACA”) emphasizes “preference sensitive care,”²³⁸ which is defined as

[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.²³⁹

Thus, the ACA advocates allowing the patient to hear about “each treatment option” and to use his or her own “values and preferences” in the decision-making process.²⁴⁰ In order for this to happen, surgeons or manufacturers must educate patients regarding the recall risks and other risks (noted above) associated with orthopaedic 510(k) devices. The ACA requirements may be used as evidence in matters of state informed consent law.

Ultimately, the surgeon’s duty to warn of particular dangers is typically a question to be submitted to the jury.²⁴¹ Generally, a jury decides exactly how much information should be disclosed to the patient.²⁴² Courts commonly adopt a rule that any “material risk” must be disclosed.²⁴³ “A material risk is a risk which a reasonable person would consider significant in deciding whether

236. Alexander M. Capron, *Informed Consent in Catastrophic Disease Research and Treatment*, 123 U. PA. L. REV. 340, 365–376 (1974); Longtin et al., *supra* note 235, at 53–54.

237. Capron, *supra* note 236, at 376.

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

239. §§ 299b-36(b)(2).

240. *Id.*

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

242. *Id.*

243. *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 (Cal. 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), *vacated sub nom Heinrich v. Sweet* 308 F.3d 48 (1st Cir. 2002); *Canterbury v. Spence*, 464 F.2d 772, 786–88 (D.C. Cir. 1972); *Mitchell*, 334 S.W.3d at 16–17.

to undergo a particular medical treatment.”²⁴⁴ Given the 11.5 times higher recall rate of 510(k) orthopaedic devices,²⁴⁵ many juries might decide that patients have a right to know when a device has been cleared by the riskier 510(k) pathway in orthopaedic implant cases. An 11.5 times higher recall rate is likely “material” to many patients in deciding to undergo a major orthopaedic procedure in which a device is affixed permanently to a large bone. Risks of 510(k) devices should become part of the standard of care for informed consent disclosure to patients, so that patients and the public can have a say in which devices become mainstream.²⁴⁶

Second, many courts require surgeons to disclose reasonable alternative treatment options.²⁴⁷ One court ruled 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.”²⁴⁸ Where established orthopaedic devices with proven track records are available or where PMA devices are available, the surgeon should be obliged to disclose these facts to obtain informed consent due to the huge difference in recall rates and potential consequences related to use of the comparatively unproven device or the 510(k) device. As noted above, new implants often carry a risk of death or disability statistically associated with avoidable revisions, and risks of death or serious injury should always be disclosed under informed consent doctrine.²⁴⁹

Requiring surgeons to disclose 510(k) status and corresponding orthopaedic statistics gives patients a much-needed voice in these important decisions. Patients may cast their 510(k) vote financially for safer and more proven devices if they are given the opportunity to actively participate in the process.

2. Ensuring a Fair Trial under *Daubert* in Medical Device Cases

Harmed patients deserve a voice on the issue of 510(k) devices that lead to avoidable complications, and courts are often in the best position to provide that voice. Courts should become less deferential to insider medical experts and more diligent in recognizing the conflicts of interest (e.g., being on the

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

245. Day et al., *supra* note 2, at 517.

246. Griffin, *supra* note 206, at 755.

247. See, e.g., *Canterbury*, 464 F.2d at 781; *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, 582 (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).

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

249. *Canterbury*, 464 F.2d at 787–78; *Kapiolani Med. Specialists*, 259 P.3d at 584; *Mitchell v. Robinson*, 334 S.W.2d 11, 19 (Mo. 1960) (noting the physician must warn of “possible serious collateral hazards”).

company's payroll, owning stock in the company, or receiving royalties on sales of the device) that taint their opinions.²⁵⁰ Courts should realize that they are often the last and best protection between patients and dangerous medical devices, and that “the unknown risks that . . . devices pose when they are cleared with inadequate predicates is a burden that patients should not have to bear.”²⁵¹ In addition, courts should stop shifting the blame for poor device performance onto doctors and hospitals; preferential laws toward implant companies encourage lawyers to go after doctors and hospitals, driving up the cost of medical malpractice in the healthcare market.²⁵² Finally, courts should demand that patients be informed of the dangers of unproven medical devices as part of informed consent doctrine to improve transparency for patients in the decision-making process.

a. A Balanced Approach to Expert Testimony: Stop Favoring Insider Defendants' Experts with Conflicts of Interest and Disfavoring Plaintiffs' Experts

First, courts should be more critical in pre-trial *Daubert* rulings of insider medical experts who will testify at trial.²⁵³ Courts have a tendency in their *Daubert* rulings to favor industry experts and disfavor plaintiffs' experts.²⁵⁴ One court stated, “Law lags science; it does not lead it.”²⁵⁵ However, courts can distinguish insider bias and self-interest marketing from valid independent scientific expert opinion testimony.²⁵⁶ Courts can look to author disclosure statements in the orthopaedic literature as one source for evidence of conflicts of interest, which orthopaedic publishers consider very important (with good reason).²⁵⁷ Some paid orthopaedic implant consultant surgeons make millions of dollars from their consulting agreements, royalties on devices, or other arrangements.²⁵⁸ One study found that insider surgeons report almost exclusively positive outcomes with the devices in which they are personally invested – in-

250. Griffin, *supra* note 206, at 271 (noting, “A close look at some recent orthopaedic design cases supports the idea that judges are being too deferential in admitting defense experts while being overzealous in excluding plaintiffs' experts.”).

251. Freeman, *supra* note 203, at 139 (“The unknown risks that Class III devices pose when they are cleared with inadequate predicates is an unethical burden that patients should not have to bear.”).

252. Griffin, *supra* note 206, at 268.

253. *Id.* at 271–72.

254. *Id.* at 271.

255. *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996).

256. See Kanu Okike et al., *Conflict of Interest in Orthopaedic Research: An Association Between Findings and Funding in Scientific Presentations*, 89 J. BONE JOINT & SURGERY AM. 608, 611 (2007) [<https://perma.cc/6PUM-LEMM>].

257. Griffin, *supra* note 206, at 248.

258. *Id.*

cluding 100% of the surgeons with stock options, 98.4% of those with royalties, and 97.8% of those who were employees of implant companies reporting positive outcomes in their scientific presentations.²⁵⁹ Another study found that published results were only usually reproducible if less than 25% of the published data was reported by device developers when compared to data from the joint replacement registries.²⁶⁰ Under Federal Rule of Evidence 702 and *Daubert*, the trial judge's role is to "exclude unreliable expert testimony,"²⁶¹ and *unreproducible studies are unreliable by definition*.

Orthopaedic journal editors consider it "*essential* that an author disclose *potential* conflicts of interest."²⁶² The American Academy of Orthopaedic Surgeons agrees and has a "Mandatory Disclosure Policy" for educational programs in which it requires presenters to disclose "relevant potentially conflicting interests or commercial relationships."²⁶³ Similarly, many orthopaedic journals – at least eighteen – have signed onto a consensus statement saying readers of medical journals are "entitled to a full disclosure of all financial conflicts of interest of the authors of those articles"²⁶⁴ and agreeing to use the universal disclosure form developed by the International Committee of Medical Journal Editors ("ICMJE").²⁶⁵

Similar to orthopaedic journal readers, judges and juries are entitled to full disclosure. Courts should develop disclosure forms like the ICMJE universal disclosure form and require all medical experts to fill out and sign this form under penalty of perjury.²⁶⁶ Research has shown that even with disclosure policies in place, compliance can be an issue. For example, one study showed "a 46% nondisclosure rate of conflicts of interest among thirty-two orthopaedic surgeons . . . who were known to have been paid over \$1 million" in the year

259. Okike, *supra* note 256, at 611.

260. Gerold Labek et al., *Impact of Implant Developers on Published Outcome and Reproducibility of Cohort-Based Clinical Studies in Arthroplasty*, 93 J. BONE JOINT SURG. 55, 55 (2011).

261. FED. R. EVID. 702, advisory committee's note to 2000 amendment [hereinafter FRE 702 Committee Notes]; *see also* *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 579–93 (1993).

262. Vernon T. Tolo, Editorial, *Orthopaedic Journals and Conflicts of Interest*, 93 J. BONE & JOINT SURGERY 2145, 2145 (2011).

263. *AAOS Mandatory Disclosure Policy*, AM. ACAD. OF ORTHOPAEDIC SURGEONS, <https://www.aaos.org/About/disclosure/?ssopc=1> [<https://perma.cc/K6VR-T82H>] (last visited June 22, 2019).

264. Jeffrey S. Fischgrund, *Conflict of Interest in Orthopaedic Journals*, 20 J. AM. ACAD. ORTHOPAEDIC SURGEONS 263, 263 (2012).

265. *See Conflicts of Interest*, INT'L COMM. MED. J. EDITORS., <http://www.icmje.org/about-icmje/faqs/conflict-of-interest-disclosure-forms/> (last visited June 22, 2019); Griffin, *supra* note 206, at 247.

266. Griffin, *supra* note 206, at 249.

before publication of their article.²⁶⁷ Therefore, the perjury penalty should have teeth.

In addition, courts should stop deferring to industry polycentricity arguments,²⁶⁸ where medical devices have a history of innovation leaps documented in their predicate chain that should be used to give plaintiffs' experts a similar degree of deference.²⁶⁹ With the roadmap of the implant companies' own leaps of "innovation" available in their 510(k) documentation, these conflicts are capable of rational resolution whether adjudication is easy or not.²⁷⁰

b. Stop Blame-Shifting Liability onto Hospitals and Doctors for Poorly Performing 510(k) Devices

Second, courts should stop allowing device-makers to shift blame to doctors and hospitals for failure of poorly researched medical devices. Unfortunately, doctors and hospitals likely often pay the price for early device failures because the legal system makes malpractice claims much easier than product liability claims in these complex cases. Device manufacturers often blame the operating surgeon – even their insider experts – for the failures of their medical devices.²⁷¹ From a public policy standpoint, implant companies are in a much better position than the public or doctors and hospitals to reduce the hazards associated with their devices because the manufacturer can choose better pre-market testing, can insure potential complications prospectively, and can perform better postmarket surveillance of its devices.

As noted in *Escola*, "[P]ublic policy demands that responsibility be fixed wherever it will most effectively reduce the hazards to life and health inherent

267. *Id.* at 248; see also Kanu Okike et al., *Accuracy of Conflict of Interest Disclosures Reported by Physicians*, 361 NEW ENG. J. MED. 1466, 1471 (2009).

268. *Grundberg v. Upjohn Co.*, 813 P.2d 89, 98 (Utah 1991).

269. Griffin, *supra* note 206, at 262.

270. James A. Henderson Jr., *Judicial Review of Manufacturers' Conscious Design Choices: The Limits of Adjudication*, 73 COLUM. L. REV. 1531, 1538 (1973).

271. See e.g., Barry Meier, *Surgeon vs. Knee Maker: Who's Rejecting Whom?*, N.Y. TIMES (June 19, 2010), http://www.nytimes.com/2010/06/20/business/20knee.html?pagewanted=all&_r=1 [perma.cc/RR23-S9HP] (noting the company suggested the surgeon's "technique was the problem" when he reported problems with an implant Dr. Berger noted, "Suddenly, I went from someone who was their master teacher to someone who didn't know what he was doing."); Barry Meier, *Doctors Who Don't Speak Out*, N.Y. TIMES (Feb. 15, 2013), <http://www.nytimes.com/2013/02/17/sunday-review/the-hip-replacement-case-shows-why-doctors-often-remain-silent.html> [https://perma.cc/778G-QCZ6] (Dr. Dorr noted, "'The first thing that a company does is to put out a campaign that a surgeon does not know how to operate" when problems are reported with a device, and Dr. Dorr was the victim of a "whisper campaign").

in defective products that reach the market.”²⁷² Since 88% of orthopaedic devices are cleared via the 501(k) shortcut compared to only 53% for other medical devices, the orthopaedic device manufacturers must be making a calculated business decision to absorb the costs of the 11.5 times higher recall rate of devices cleared via this pathway with resultant predictable patient injuries.²⁷³ Patients and society will benefit if the court system adjusts the calculus to make company executives consider more premarket testing to lower recall rates by placing risky devices through the PMA process prior to release on the general public. Otherwise, “[t]he cost of an injury and the loss of time or health may be an overwhelming misfortune to the person injured.”²⁷⁴ It is a cost that the implant companies should share and insure, since they are the ones who stand to profit from the new – not better – devices. Doctors and hospitals should not bear the cost by default.

C. Congressional Action

Congress should use programs already in place to encourage quality among hospitals, doctors, and nursing homes as models to similarly encourage quality among medical device makers. A “Medicare 510(k) Payment Reduction Program” should be instituted to help offset the costs to Medicare of the 11.5 times higher recall rate associated with orthopaedic 510(k) devices.²⁷⁵ In addition, the government should create a MedicalDeviceCompare.gov website to allow patients to participate in decision-making by comparing their medical devices to other devices in the same category. Finally, residency programs funded by the government should be required to train young doctors to use proven devices instead of the latest 510(k) devices.

1. Introduction of a “Medicare 510(k) Payment Reduction Program”

Congress could start a new program – possibly named the “Medicare 510(k) Payment Reduction Program” – to offset the added costs to Medicare posed by 510(k) device recalls and other 510(k) issues²⁷⁶ by ensuring that Medicare pays less for 510(k) approved devices than for PMA devices.

272. *Escola v. Coca Cola Bottling Co.*, 150 P.2d 436, 440–41 (Cal. 1944); *see also*, Griffin, *supra* note 206, at 268.

273. Day et al., *supra* note 2, at 517.

274. *Escola*, 150 P.2d at 440; *see also*, *In re Wagner*, 530 B.R. 695, 697 (E.D. Wis. 2015).

275. Day et al., *supra* note 2, at 517.

276. *See, e.g.*, discussion *supra* Section II.A (discussing tibial component of TKA).

Models for such a program are already in place. The Affordable Care Act included the Hospital Readmission Reduction Program,²⁷⁷ the Hospital Acquired Conditions Reduction Program,²⁷⁸ and the Value-Based Purchasing Program,²⁷⁹ which all shifted extra costs associated with hospital issues away from government payers as described below. Congress should institute similar programs for 510(k) approved orthopaedic devices due to their higher recall rates and associated costs.

The Medicare Hospital Readmission Reduction Program (“HRRP”) created by the ACA applies to most acute care hospitals.²⁸⁰ HRRP penalizes hospitals by reducing their reimbursement rates from Medicare by up to 3% if they have “higher-than-expected readmission rates for a key set of conditions common in the Medicare population” and by making the penalty public.²⁸¹

Similarly, Medicare penalizes hospital acquired conditions under its Hospital-Acquired Conditions Reduction Program, which focuses on reducing the incidence of adverse safety events in hospitals.²⁸² Under the program, Medicare uses patient safety measures to assign hospitals a Total Hospital Acquired

277. Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (2010) (codified in part as 42 U.S.C. § 3025 (2012)).

278. *See* Social Security Act, 42 U.S.C. § 1395ww (2012).

279. § 1886(o).

280. U.S. DEP’T OF HEALTH AND HUMAN SERVICES, *Social Risk Factors and Performance Under Medicare’s Value-Based Purchasing Programs: A Report Required by the Improving Medicare-Post-Acute Care Transformation (IMPACT) Act of 2014*, HHS REPORT TO CONGRESS 70 [hereinafter HHS Report]; *see also*, Patient Protection & Affordable Care Act, 42 U.S.C. § 1186(d)(1)(B) (2012); 42 C.F.R. § 412.152 (2019).

281. HHS Report, *supra* note 280, at 70 (noting the maximum penalty was set at 3% in 2015, “where it will remain”); Cristina Boccuti and Giselle Casillas, *Aiming for Fewer Hospital U-turns: The Medicare Hospital Readmission Reduction Program* THE KAISER FAM. FOUND. MAR. 2017 ISSUE BRIEF 2 (2017), <http://files.kff.org/attachment/Issue-Brief-Fewer-Hospital-U-turns-The-Medicare-Hospital-Readmission-Reduction-Program> [perma.cc/4LVJ-F23Z] (noting, “The HRRP was established by a provision in the Affordable Care Act (ACA) requiring Medicare to reduce payments to hospitals with relatively high readmission rates for patients in traditional Medicare.”). The HRRP is especially punitive because “hospitals with readmission rates that exceed the national average are penalized by a reduction in payments across all of their Medicare admissions – not just those which resulted in readmissions.” *Id.* After some adjustments, each hospital is annually assigned a penalty for the upcoming year based on CMS’s calculation of that hospital’s rate of excess readmissions; “the greater each hospital’s rate of excess readmissions, the higher its penalty.” *Id.* The hospital’s penalty is posted in the Federal Register and listed on the Medicare website) *Id.*; *see also* *Hospital Readmissions Reduction Program (HRRP)*, CTR. FOR MEDICARE AND MEDICAID SERVS., <https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps/readmissions-reduction-program.html> [perma.cc/4DKF-UP82] (last visited Feb. 6, 2019) (explaining that the Center for Medicare and Medicaid Services uses “excess readmission ratios” to measure performance in treating conditions like chronic lung disease, heart attacks, pneumonia, and coronary artery bypass surgery).

282. HHS Report, *supra* note 280, at 100.

Conditions score and penalizes 25% of hospitals with the worst scores “a flat 1% of their total inpatient Medicare revenues” – including 1% of disproportionate share payments and medical education payments.²⁸³

Another example is Medicare’s Hospital Value-Based Purchasing Program, which redistributes a percentage – up to 2% – of hospitals’ Medicare payments annually based on the hospital’s performance on quality measures like (1) “clinical outcomes (e.g., mortality for patients admitted with pneumonia),” (2) “efficiency (costs of care per episode),” and (3) “safety measures (e.g., in-hospital infection rates).”²⁸⁴

Given the 510(k) cost estimates above for the tibial component of TKAs (almost \$100 billion as calculated above) and the fact that Medicare paid over \$20 billion²⁸⁵ in 2010 for TKAs, the cost savings for TKAs alone could be substantial; this is especially true considering that over 3.4 million people per year (mostly paid for by Medicare) are expected to undergo TKAs annually by 2030.²⁸⁶ Further, “Medicare is responsible for paying for over 70% of all TKA procedures in the United States.”²⁸⁷

Using those existing programs as models, Medicare’s Payment Advisory Commission should review its payment policies and recommend lower payment rates for new 510(k) devices that threaten older established devices in stable device markets with proven long term outcomes related to certain devices, like orthopaedic total knees and hips.²⁸⁸ Further, programs developed under the Medicare Shared Savings Program should reward surgeons and Accountable Care Organizations who implant well-established devices while penalizing those who implant new, unproven 510(k) devices.²⁸⁹

To determine which techniques are “proven” or well-established, payors should look to devices that have been approved by the PMA pathway over 510(k) devices, should discount studies published by the developers of the device in favor of independent studies, and should rely on emerging American and established overseas registry databases. First, payors should favor devices that the FDA approves by the PMA pathway over 510(k) devices by paying less for 510(k) approved devices in areas where PMA-approved devices are available.²⁹⁰ As noted earlier, the Institute of Medicine found that 510(k) is “flawed”²⁹¹ and is not a “reliable premarket screen for safety and effectiveness”

283. *Id.*

284. *Id.* at 143 (noting cap was set at 2% for 2017 and beyond).

285. Eric M. Padegimas et al., *Medicare Reimbursement for Total Joint Arthroplasty: The Driving Forces*, 98 J. BONE AND JOINT SURGERY 1007, 1007 (2016).

286. Kurtz et al., *supra* note 102, at 782.

287. Lavernia et al., *supra* note 178, at 221.

288. 42 U.S.C. § 1395b-6(a)–(b) (2012).

289. § 1395jjj.

290. Day et al., *supra* note 2, at 522; Fargen, *supra* note 4, at 271.

291. IOM REPORT BRIEF, *supra* note 11, at 3.

for many devices.²⁹² There is a much higher chance (11.5 times higher in orthopaedics)²⁹³ that a device will be recalled when it does not undergo more rigorous FDA approval through the PMA process; these recalls result in additional costs and morbidity associated with (1) repeat surgeries for revision, (2) complications from those surgeries (such as DVT or infection), and (3) other add-on expenses to the payment system that could have been avoided had the new 510(k) device not been used. Orthopaedic devices are much more likely to be cleared by shortcut FDA pathways than non-orthopaedic medical devices, with 88% of orthopaedic devices cleared by the 510(k) process in 2012 versus only 53% of nonorthopaedic devices.²⁹⁴ Payors should pay *less* for devices cleared via 510(k) than those cleared via PMA until those 510(k) devices have a proven track record.

Second, in analyzing devices, payors should discount studies published by the developers of the devices and emphasize independent and registry studies when they assess the cost-effectiveness of medical devices. The orthopaedic literature is unreliable and biased because an inherent “positive outcome bias” taints orthopaedic research when studies with positive outcomes have historically been preferentially published over negative or neutral studies.²⁹⁵ Indeed, one study showed that 74% of published original papers reported positive outcomes,²⁹⁶ and another study estimated that 85% of orthopaedic epidemiology studies “may assert biased conclusions.”²⁹⁷ This “publication bias” overestimates the clinical relevance of some orthopaedic implants by disregarding negative and neutral data that is not being published.²⁹⁸ Some authors consider this bias to be a “severe challenge to patient safety.”²⁹⁹ Further, research quality is an issue with only 11.3% of orthopaedic studies using Level 1 evidence (the most reliable) and only 3% being randomized, controlled trials (the gold standard for clinical research).³⁰⁰

292. *Id.* at 2; IOM REPORT, *supra* note 11, at 193.

293. Day et al., *supra* note 2, at 522.

294. *Id.* at 520.

295. Erik A. Hasenboehler et al., *Bias Towards Publishing Positive Results in Orthopaedic and General Surgery: A Patient Safety Issue?*, PATIENT SAFETY SURGERY (Nov. 2007).

296. *Id.* at 3–4.

297. Harman Chaudhry et al., *How Good Is the Orthopaedic Literature?*, 42 INDIAN J. ORTHOPAEDICS 144, 146 (2008).

298. Hasenboehler, *supra* note 295, at 4 (“[T]rials with ‘significant’ results were more likely to be published than studies with ‘non-significant’ data, by an adjusted odds-ratio of 12.30.”).

299. *Id.* at 2; *see also* Mohit Bhandari et al., *Meta-Analyses in Orthopaedic Surgery: A Systematic Review of Their Methodologies*, 83 J. BONE AND JOINT SURG. 15, 15 (2001); David Moher et al., *Epidemiology and Reporting Characteristics of Systematic Reviews*, 4 PLoS MED. 447, 455 (2007).

300. Chaudhry, *supra* note 298, at 146.

Payors must learn to recognize industry-paid showmen (often including doctors and lawyers) and look past their “razzle dazzle”³⁰¹ to obtain solid information upon which to make decisions. Surgeons on implant companies’ payrolls are biased in their public presentations – with one study showing that 100% of those with stock options reported positive results.³⁰² This is not surprising when the companies are less interested in finding scientists and instead are “concerned only with identifying those surgeons who [are] the most likely to be good salespeople for [their] products.”³⁰³

One way to overcome this bias is for payors to look to studies that involve less than 25% of the data reported by the developers of the implant because a recent study found “published results were usually reproducible in clinical practice if [less than] 25%” of the data was reported by the developers of the implant.³⁰⁴ In addition, payors should start looking more to registry data to analyze clinical effectiveness as a tool for postmarket surveillance of medical devices.³⁰⁵ The American Joint Replacement Registry is beginning to produce significant data with 612 hospitals enrolled by 2015 and over 427,000 cumulative procedures followed in the database between 2012 and 2015.³⁰⁶ Other countries have well-established and long-standing databases that can also be analyzed. For example, joint registries in the U.K. and Australia played a major role in detecting the problems associated with metal-on-metal hips.³⁰⁷ One author recently noted, “Registry data can contribute substantial added value to an informed discussion of arthroplasty outcomes.”³⁰⁸

Before paying higher prices for new technology, payors should recognize that device manufacturers need to “hit a home run” in order to improve the already excellent outcomes for some procedures like TKA. According to a study co-authored by researchers at Yale and Harvard, *in order to be cost effective*, an “innovative implant” must decrease actual TKA failure rates – not

301. BOB FOSSE AND FRED EBB, CHICAGO: THE MUSICAL.

302. Okike et al., *supra* note 256, at 610–11.

303. SARMIENTO, *supra* note 69, at 286.

304. Labek et al., *supra* note 260, at 55.

305. IOM REPORT, *supra* note 11, at 11.

306. *Annual Report 2016*, AM. JOINT REPLACEMENT REGISTRY 1, 6 (2016), http://www.ajrr.net/images/annual_reports/AJRR_2016_Annual_Report_final.pdf [perma.cc/4TQN-E4E8]; David Ayers & Patricia Franklin, *Joint Replacement Registries in the United States: A New Paradigm*, 96 J. BONE AND JOINT SURG. 1567, 1568 (2014); *All About the Data*, AM. JOINT REPLACEMENT REGISTRY, <https://www.ajrr.net/enroll-with-us/all-about-the-data> [perma.cc/26B2-F56S] (last visited June 22, 2019).

307. Brent M. Ardaugh et al., *The 510(k) Ancestry of a Metal-on-Metal Hip Implant*, 368 NEW ENG. J. MED. 97, 98 (2013).

308. Labek et al., *supra* note 260, at 55.

just radiographic wear – by at least 50%.³⁰⁹ If the patient has limited life expectancy due to comorbidities or advanced age, even higher success rates are required for broad cost effectiveness.³¹⁰

Therefore, reasonable clinical trials associated with PMA will likely be required to justify added expenses associated with devices now being approved using unproven 510(k) modifications. Theoretical changes and marketing rarely, if ever, advance science. Therefore, as outlined earlier in this paper, it is not surprising that changes to the tibial component of TKAs have led to billions of dollars of unnecessary costs. Real improvements will almost always require hard work and real science – like clinical trials – and payors should stop paying more money for less science.

2. Start “MedicalDeviceCompare.gov” to Give the Public Access to Clearance Pathway Information and Statistics

Transparency is important. Oliver Wendell Holmes once noted, “When you get the dragon out of his cave on to the plain and in the daylight, you can count his teeth and claws, and see just what is his strength.”³¹¹ Louis Brandeis also noted, “Sunlight is said to be the best of disinfectants; electric light the most efficient policeman.”³¹²

Congress seems to have adopted the transparency philosophy behind these famous mantras because it adopted public websites allowing the public to compare hospitals (i.e., HospitalCompare.gov),³¹³ nursing homes (i.e., NursingHomeCompare.gov),³¹⁴ and physicians (i.e., PhysicianCompare.gov).³¹⁵ Why not adopt similar websites allowing patients to compare the clearance pathway and reported results for orthopaedic (and other) medical devices and call it “MedicalDeviceCompare.gov”? Such a website would allow market forces to influence device makers decisions regarding clearance pathway and pursuit of valid clinical data.

309. Lisa G. Suter et al., *Placing a Price on Medical Device Innovation: The Example of Total Knee Arthroplasty*, 8(5) PLoS ONE e62709 7 (May 2013).

310. *Id.*

311. Oliver Wendell Holmes, *The Path of the Law*, 10 HARV. L. REV. 457, 469 (1897).

312. *Justice Louis D. Brandeis*, BRANDEIS U., <https://www.brandeis.edu/legacy-fund/bio.html> [perma.cc/9XYN-6FX8] (last visited June 22, 2019).

313. *See Hospital Compare*, CTR. FOR MEDICARE AND MEDICAID SERVS., <https://www.medicare.gov/hospitalcompare/search.html>? [perma.cc/N84Y-RWLR] (last visited June 22, 2019).

314. *See Nursing Home Compare*, CTR. FOR MEDICARE AND MEDICAID SERVS., <https://www.medicare.gov/nursinghomecompare/search.html>? [perma.cc/ML6Q-SJV6] (last visited June 22, 2019).

315. *See Physician Compare*, CTR. FOR MEDICARE AND MEDICAID SERVS., <https://www.medicare.gov/physiciancompare/> [perma.cc/5XPK-H3JY] (last visited June 22, 2019).

3. Medicare Should Make Sure Future Doctors Are Trained Preferentially Using Proven Medical Devices

Orthopaedic surgeons theoretically control which devices become popular and are implanted. Therefore, proper unbiased education – so that individual surgeons have a solid foundation upon which to make implant choices – is essential to providing quality patient-centered care. Unfortunately, today’s surgeons are often trained to use the newest devices – whether they are better for the patient or not.³¹⁶ Medicare and the Accreditation Council of Graduate Medical Education (“ACGME”) are in the best position to regulate surgeon training requirements because Medicare pays for training doctors (and later pays for the implant choices of those same doctors) and ACGME oversees surgeon training programs.³¹⁷

First, Medicare should get involved because Medicare pays both for doctor training³¹⁸ and for the end results when bad device choices are made,³¹⁹ therefore, the Department of Health and Human Services (“HHS”) and Centers for Medicare and Medicaid Services (“CMS”) should take a greater regulatory interest in this area. Better surgeon training on the front-end rewards Medicare’s investment in physician training when those doctors perform patient-centered procedures later in their careers on Medicare patients.

Medicare is the “largest single program providing explicit support for graduate medical education” paying an estimated \$112,642 per resident trained in 2010 with Medicare residency subsidies totaling over \$10.1 billion annually.³²⁰ Further, two of the most expensive conditions billed to Medicare in 2013 included “complication of device, implant or graft” (costing Medicare around \$7.1 billion) and “complications of surgical procedures or medical

316. SARMIENTO, *supra* note 69, at 284 (asserting that medicine functions primarily as a “marketing arm of industry”); Anglen & Weinstein, *supra* note 139, at 705–06 (noting residents being preferentially trained in the device with poorer results). Likewise, as an example in my personal experience, I was trained to use modular tibial components and have never personally witnessed any surgeon implant an all-poly tibia.

317. *What We Do*, AM. COUNCIL FOR GRADUATE MED. EDUC., <https://www.acgme.org/What-We-Do/Overview> (last visited June 22, 2019) [hereinafter ACGME].

318. Catherine Rampell, *How Medicare Subsidizes Doctor Training*, N.Y. TIMES (Dec. 17, 2013), http://economix.blogs.nytimes.com/2013/12/17/how-medicare-subsidizes-doctor-training/?_r=0 [perma.cc/Y8TW-MQ5L].

319. Lavernia et al., *supra* note 178, at 221 (noting that Medicare pays for over 70% of TKAs in the U.S.).

320. *Medicare Payments for Graduate Medical Education: What Every Medical Student, Resident, and Advisor Needs to Know*, ASS’N OF AM. MED. CS., <https://members.aamc.org/eweb/upload/Medicare%20Payments%20For%20Graduate%20Med%20Ed.pdf> [perma.cc/G27J-V5RY] (last visited June 22, 2019); Rampell, *supra* note 318.

care” (costing an additional \$2.9 billion)³²¹ – both of which likely involved a significant number of TKAs and other implants.³²²

Medicare is facing financial hardship.³²³ Concern over the increasing Medicare expenditures related to TKA led CMS to implement reductions in payment for physician services and hospitals for TKA.³²⁴ Specifically, surgeon per-case reimbursement for TKA fell from “approximately \$3000 in 1995 to \$1560 in 2009.”³²⁵ Growth projections for coming years indicate Medicare’s TKA burden is going to get heavier.³²⁶ Therefore, funding for orthopaedic residency training programs tied to Medicare should be prefaced upon training programs teaching residents techniques that are cost-effective and beneficial to Medicare beneficiaries – not techniques that lead to higher costs, more revision surgeries, and poorer health for its Medicare patients.

Medicare funding for graduate medical education flows to teaching hospitals through two separate streams: (1) Direct Graduate Medical Education (“DGME”) funding covers resident and faculty salaries and benefits along with some other overhead costs, and (2) Indirect Medical Education (“IME”) funding bolsters payments to teaching hospitals by adjusting individual hospitals’ inpatient rates to help defray additional costs associated with sponsoring residency programs.³²⁷ In 2010, IME payments accounted for 71% of the Medicare payments to teaching hospitals.³²⁸ IME payments are already adjusted based on differences in local wages, disproportionate share of low-income patients, and other factors.

321. Celeste M. Torio & Brian J. Moore, *National Inpatient Hospital Costs: The Most Expensive Conditions by Payor, 2013*, HEALTHCARE COST AND UTILIZATION PROJECT STATISTICAL BRIEF 204 (May 2016), <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb204-Most-Expensive-Hospital-Conditions.pdf> [perma.cc/FP32-9PGW].

322. *Id.*

323. Nick Timiraos, *Social Security, Medicare Face Insolvency Over 20 Years*, *Trustees Report*, WALL ST. J. (June 22, 2016), <http://www.wsj.com/articles/social-security-medicare-trust-funds-face-insolvency-over-20-years-trustees-report-1466605893> [perma.cc/35BG-LXK3].

324. Iorio et al., *supra* note 99, at 269.

325. P.B. Derman et al., *The Role of Overweight and Obesity in Relation to the More Rapid Growth of Total Knee Arthroplasty Volume Compared with Total Hip Arthroplasty Volume*, 96 J. BONE & JOINT SURG. 926, 924 (2014).

326. Kurtz et al., *supra* note 102, at 782.

327. *Graduate Medical Education that Meets the Nation’s Health Needs: GME Financing*, NAT’L CTR. FOR BIOTECH. INFO., U.S. NAT’L LIBR. OF MED., <https://www.ncbi.nlm.nih.gov/books/NBK248024/> [perma.cc/8MTA-EXCE] (last visited June 2, 2019).

328. *Id.* (“Of the \$9.6 billion Medicare paid to acute care teaching hospitals for GME in 2010, about \$6.8 billion (70.8 percent) were via the IME adjustment and \$2.8 billion via DGME payments (29.2 percent).”).

To improve surgeon training, HHS should add adjustments to the IME payments based upon whether surgeons are being trained in proven, effective medical device use. Residency training programs that demonstrate residents are not being preferentially trained in newer, unproven 510(k) pathway devices over older, proven, cheaper devices should get higher IME payments than those that are exclusively training their residents to use more expensive and unproven 510(k) devices. In addition, Medicare could link IME payments to training in procedures and devices that the Medicare Payment Advisory Committee evaluates and chooses.³²⁹ A board similar to the former Independent Payment Advisory Board³³⁰ or some other board or committee that could be charged with device review. Medicare should stop indiscriminately paying for resident education in the newest and most expensive unproven techniques in order to help solve long-term funding issues and ensure Medicare's long-term viability.

Second, accreditation of residency training programs should be based on training young surgeons to use proven techniques and devices. The ACGME is a private, 501(c)(3), nonprofit organization that sets standards for U.S. graduate medical education in surgical (and other) residency programs.³³¹ The ACGME bases accreditation decisions on compliance with those standards.³³² Standards should be added requiring training in best proven techniques and devices, not just the newest 510(k) devices. Specific lists of proven device classifications and techniques should be added to ACGME's "Institutional and Program Requirements"³³³ as quality standards and chosen by independent organizations (like perhaps the ABOS³³⁴ and the AAMC³³⁵) acting as patient advocates. In the 2015-16 academic year, 830 ACGME-accredited institutions sponsored around 10,000 residency and fellowship programs covering 150 specialties and subspecialties³³⁶ – making ACGME a potential powerful force for change in this area.

ACGME accreditation should also be prefaced upon efforts by residency training programs to eliminate industry influence upon professors and teaching hospitals. In 2003, Professor Augusto Sarmiento wrote, "I feel comfortable in stating that the *education of today's orthopedists is structured, to a great extent, to satisfy the marketing needs of industry,*" adding that orthopaedic residents simply "learn to use industry's tools."³³⁷

329. 42 U.S.C. § 1395b-6(a)–(b) (2012).

330. 42 U.S.C. § 1395kkk (repealed Feb. 9, 2018).

331. ACGME, *supra* note 317.

332. *Id.*

333. *Id.*

334. *About ABOS*, AM. BOARD OF ORTHOPAEDIC SURGERY, <https://www.abos.org/about-abos.aspx> [perma.cc/WGU2-TXLE] (last visited June 2, 2019).

335. *About the AAMC*, ASS'N OF AM. MED. CS., <https://www.aamc.org/about> [perma.cc/55QR-Z7YN] (last visited June 2, 2019).

336. ACGME, *supra* note 317.

337. SARMIENTO, *supra* note 69, at 284 (emphasis added).

Sarmiento's observations appear to be validated by the findings of the Research Committee ("Committee") of the American Board of Orthopaedic Surgeons ("ABOS") in a 2008 article finding a "striking shift" to a new device ("Nail"); this "shift" resulted in a 2133% increase in market share by newly trained orthopaedic surgeons fixing hip fractures from an older proven device (the "Plate") although scientific findings did not support the shift – as described above in section II.A.3.³³⁸ The Committee noted that the "consensus from the orthopaedic literature" was that the "shift" to the Nail was "associated with a higher complication rate and no better outcomes,"³³⁹ in addition to "higher implant costs and surgeon fees."³⁴⁰ The Committee acknowledged the role of resident education in the "striking shift." To explain the shift, the Committee noted that, "[i]t may be that younger surgeons are responding to a change in training and that for some reason *residents are currently being trained preferentially in [the Nail]*."³⁴¹ Young orthopaedic surgeons likely perform the procedures that they learned in residency training, and Sarmiento observed that device manufacturers probably control that education process.³⁴² In 2015, companies gave \$6.5 billion to doctors and teaching hospitals influencing research and patient care at academic medical centers.³⁴³

Orthopaedic residents likely "accept the reality . . . presented" during their residency training programs by their attending professors – like Truman in *The Truman Show*.³⁴⁴ Accrediting organizations, like ACGME, must do a better job ensuring that at least some of the "reality" taught to residents is based upon sound scientific evidence regarding safety and effectiveness and therefore, likely to lead to reliable and good patient outcomes.³⁴⁵

Together, Medicare and ACGME are in the best position to help fix the problem of newer, more expensive, and worse performing devices becoming standard of care in the orthopaedic community.

338. Anglen & Weinstein, *supra* note 139, at 704–06 (noting "our data, which were collected from young orthopaedic surgeons in the beginning of their careers, confirm a higher rate of fracture and procedure-related complications and, at best, equivalent pain and deformity scores at the time of follow-up for patients managed with intramedullary nail fixation." and "higher implant costs and surgeon fees, with no improvement in patient outcomes").

339. *Id.* at 705 (emphasis added).

340. *Id.* at 706.

341. *Id.* (emphasis added).

342. Griffin, *supra* note 206, at 209; SARMIENTO, *supra* note 69, at 200-01.

343. Chad Terhune, *University of California OKs \$8.5 Million Payout in Spine Surgery Cases*, KAISER HEALTH NEWS (Aug. 1, 2016), <http://khn.org/news/university-of-california-oks-8-5-million-payout-in-spine-surgery-cases> [perma.cc/BUY5-RY37] (last visited June 22, 2019) (commenting on federal data).

344. THE TRUMAN SHOW (Paramount Pictures 1998).

345. Griffin, *supra* note 206, at 209.

V. CONCLUSION

Even though it is not sexy, policymakers would be wise to remember the maxim, “The enemy of good is better,” and reign in the physical and financial devastation left in the path of medical device “races” facilitated by easy 510(k) pathways to device approval. There is little if any evidence that 510(k) facilitates real innovation. In fact, for orthopaedic devices, 510(k)’s past is checkered at best. Instead of facilitating innovation, there is evidence that orthopaedic 510(k) devices are 11.5 times more likely to be recalled than PMA devices.³⁴⁶ Similarly, there is evidence that 510(k) TKA devices have historically not outperformed their predicate ancestors.³⁴⁷ In addition, some 510(k) outlier devices unexpectedly underperform almost immediately and lead to relatively quick legal attention, but not before many lives are negatively altered unnecessarily.³⁴⁸

The FDA changes to 510(k) could positively impact its shortcomings if (1) a less deferential approach is taken toward device manufacturers, (2) more information is required specific to safety and efficacy of the new device before approval, (3) more emphasis is placed on risk benefit analysis and including statistical analysis using simple math with comparison of existing proven devices, and (4) more orthopaedic devices are reclassified into Class III.

However, even these changes alone are unlikely to meet the goals of the IOM’s recommendations regarding replacement of 510(k). Therefore, courts should get involved by ensuring fairness in medical device products liability and malpractice litigation by including medical device information in the informed consent process and by fairly analyzing witnesses on both sides in *Daubert* rulings. Finally, Congress does not seem to have the appetite to replace 510(k) as recommended by the IOM, so it should take the following actions: (1) introduce a “Medicare 510(k) Payment Reduction Program” to hold device manufacturers more accountable for the patient outcome costs of 510(k) similar to other programs holding hospitals, doctors, and nursing homes responsible for added costs associated with the care delivered; (2) start “MedicalDeviceCompare.gov” to improve transparency by giving patients access to device information similar to that provided for hospitals, doctors, and nursing homes on HospitalCompare.gov, PhysicianCompare.gov, and NursingHomeCompare.gov; and (3) shore up medical education funding to ensure that Medicare pays for residency training programs that train surgeons to use proven medical devices instead of the latest sexy 510(k) device.

With the changes outlined in this paper, orthopaedic medical devices should be safer, more effective, and should produce better outcomes in the future.

346. Day et al., *supra* note 2, at 517.

347. Kremers et al., *supra* note 73; Mohan et al., *supra* note 168.

348. See discussion *supra* Section II.A.

APPENDIX A: ESTIMATED NUMBERS OF TKAS PERFORMED IN THE
U.S.

FROM 1990 THROUGH 2017.

Year	# of TKAs	Source
2017	966,000	349
2016	700000	350
2015	726000	351
2014	752941	352
2013	732570	353
2012	700064	354
2011	689381	355
2010	701213	356
2009	659745	357
2008	656872	358
2007	588266	359
2006	533448	360
2005	524223	361
2004	481400	362
2003	421700	363

349. I DATA RESEARCH, *supra* note 101.

350. Martin et al., *supra* note 176.

351. Estimation: midpoint between 2014 and 2016 numbers.

352. HEALTHCARE COST AND UTILIZATION PROJECT, FAST STATS: MOST COMMON OPERATIONS DURING INPATIENT STAYS, <https://www.hcup-us.ahrq.gov/faststats/NationalProceduresServlet> [perma.cc/6XHY-F6NK] (last visited June 2, 2019).

353. *Id.* (Year 2013).

354. *Id.* (Year 2012).

355. *Id.* (Year 2011).

356. *Id.* (Year 2010).

357. *Id.* (Year 2009).

358. *Id.* (Year 2008).

359. *Id.* (Year 2007).

360. *Id.* (Year 2006).

361. *Id.* (Year 2005).

362. C. Allison Russo et al., HEALTHCARE COST AND UTILIZATION PROJECT STATISTICAL BRIEF #28, PROCEDURES WITH THE MOST RAPIDLY INCREASING HOSPITAL COSTS, 2000–2004 6 (2007), <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb28.pdf> [perma.cc/85HJ-K4SW].

363. Kathryn R. Fingar et al., HEALTHCARE COST AND UTILIZATION PROJECT, STATISTICAL BRIEF #186 MOST FREQUENT OPERATING ROOM PROCEDURES PERFORMED

2002	407100	364
2001	371600	365
2000	328152	366
1999	318152	367
1998	309200	368
1997	329000	369
1996	301794	370
1995	274587	371
1994	247380	372
1993	220173	373
1992	192966	374
1991	165759	375
1990	138552	376
Total	13,438,238	

IN U.S. HOSPITALS, 2003–2012 4 (2014), <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb186-Operating-Room-Procedures-United-States-2012.pdf> [perma.cc/P3CM-CXJP].

364. Chaya Merrill et al., Healthcare Cost and Utilization Project, Statistical Brief #34, Hospital Stays Involving Musculoskeletal Procedures, 1997–2005 8 (2007) <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb34.pdf> [perma.cc/DY8U-EKW8].

365. Audrey J. Weiss et al., Healthcare Cost and Utilization Project, Statistical Brief #171, Trends in Operating Room Procedures in U.S. Hospitals, 2001–2013 3 (2014), <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb171-Operating-Room-Procedure-Trends.pdf> [perma.cc/U2C7-5G4M].

366. Russo et al., *supra* note 365, at 6.

367. Merrill et al., *supra* note 367, at 8.

368. *Id.*

369. Anne Pfuntner et al., HEALTHCARE COST AND UTILIZATION PROJECT, STATISTICAL BRIEF #149, MOST FREQUENT PROCEDURES PERFORMED IN U.S. HOSPITALS, 2010 2 (2013) <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb149.pdf> [perma.cc/H9DV-TZSC].

370. 1991 through 1996 were estimated by assuming a linear progression from the 138,552 cases in 1990 to the 329,000 in 1997.

371. *Id.*

372. *Id.*

373. *Id.*

374. *Id.*

375. *Id.*

376. Iorio et al., *supra* note 99, at 269.

