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Cover Page Footnote

J.D. and Certificate in Law and Public Policy Candidate, May 2016, The Catholic University of America, Columbus School of Law; B.B.A., 2013, University of Portland. The author would like to thank her parents, Steve and Gigi Fekete, for their continuous love and support throughout her legal education. The author would also like to thank Linwood Rayford of the U.S. Small Business Administration's Office of Advocacy for his expert guidance and feedback during the writing of this Comment. Finally, the author would like to thank the Catholic University Law Review staff members and editors for their hard work during the editing of this Comment.

LITIGATING MEDICAL DEVICE PREMARKET CLASSIFICATION DECISIONS FOR SMALL BUSINESSES: HAVE THE COURTS GIVEN THE FDA TOO MUCH DEFERENCE? THE CASE FOR TAKING THE FOCUS OFF OF EFFICACY

Stephanie P. Fekete⁺

The manufacturing of innovative medical devices is important for the continued success and growth of the health care system and is a contributing factor to the growth of the U.S. economy. In 2007, the total market value of the medical device industry was \$98 billion,¹ and the market is estimated to experience an annual growth rate of over six percent through 2017.² The U.S. Small Business Administration's size standards classify a medical device manufacturer as a small business if it employs five hundred people or fewer.³ According to the U.S. Department of Commerce, only two percent of medical technology firms have more than five hundred employees, which strongly

⁺ J.D. and Certificate in Law and Public Policy Candidate, May 2016, The Catholic University of America, Columbus School of Law; B.B.A., 2013, University of Portland. The author would like to thank her parents, Steve and Gigi Fekete, for their continuous love and support throughout her legal education. The author would also like to thank Linwood Rayford of the U.S. Small Business Administration's Office of Advocacy for his expert guidance and feedback during the writing of this Comment. Finally, the author would like to thank the *Catholic University Law Review* staff members and editors for their hard work during the editing of this Comment.

1. U.S. INT'L TRADE ADMIN., MEDICAL DEVICES INDUSTRY ASSESSMENT 2 (2010), <http://www.ita.doc.gov/td/health/Medical%20Device%20Industry%20Assessment%20FINAL%20II%203-24-10.pdf>.

2. See David J. Dykeman et al., *Medical Devices in the Digital Age*, in HEALTH CARE IT: THE ESSENTIAL LAWYER'S GUIDE TO HEALTH CARE INFORMATION TECHNOLOGY AND THE LAW 83, 85 (Arthur Peabody, Jr., ed., 2013) (stating that "industry analysts estimate that medical device industry revenues will grow by 6.6 percent annually through 2017").

3. See generally U.S. SMALL BUS. ADMIN., TABLE OF SMALL BUSINESS SIZE STANDARDS MATCHED TO NORTH AMERICAN INDUSTRY CLASSIFICATION SYSTEM CODES 1-20 (2014), http://www.sba.gov/sites/default/files/Size_Standards_Table.pdf. For example, the following North American Industry Classification System (NAICS) Codes have a size standard of 500 employees: 325413 (In-Vitro Diagnostic Substance Manufacturing), *id.* at 10; 334510 (Electromedical and Electrotherapeutic Apparatus Manufacturing), *id.* at 16; 339112 (Surgical and Medical Instrument Manufacturing), *id.* at 19; 334517 (Irradiation Apparatus Manufacturing), *id.* at 16; 339113 (Surgical Appliance and Supplies Manufacturing), *id.* at 19; 339114 (Dental Equipment and Supplies Manufacturing), *id.*, 339115 (Ophthalmic Goods Manufacturing), *id.*

suggests that the medical device industry is almost exclusively comprised of small businesses.⁴

The U.S. Food and Drug Administration (FDA) regulates the medical device industry and employs a rigorous approval process to determine when products may enter the market.⁵ The process typically requires manufacturers to undergo either a 510(k) approval—an approval that a medical device is “substantially equivalent” to a device already on the market⁶—or a premarket approval (PMA)—an application subject to scientific review.⁷ When making premarket determinations, the FDA requires that all medical devices meet standards for both safety and efficacy in the treatment of medical conditions for which the device is intended.⁸

While the FDA’s goal is to authorize the sale of innovative medical devices that are safe for patient use,⁹ device manufacturers argue that the process to obtain FDA approval is unnecessarily expensive and burdensome.¹⁰ Device manufacturers assert that the approval process has systemic problems, including a lack of transparency, frequent turnover in FDA staff, and a strong insistence by the agency that manufacturers provide large amounts of data for each product submitted for approval.¹¹

4. U.S. FOOD & DRUG ADMIN., SECTION 1128 OF THE FOOD AND DRUG ADMINISTRATION SAFETY AND INNOVATION ACT (FDASIA): SMALL BUSINESS REPORT TO CONGRESS 3 (2013), <http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAAct/SignificantAmendments/totheFDCAAct/FDASIA/UCM360058.pdf>. Approximately 90% of all medical device manufacturers in the United States have fewer than 100 employees, and 80% of manufacturers have less than \$30 million in sales. CARL T. DEMARCO, MEDICAL DEVICE DESIGN AND REGULATION 6 (2011).

5. See Richard A. Merrill, *Symposium on Regulating Medical Innovation: The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1753 (1996) (“It is, therefore, virtually impossible to market a new medical product without the FDA’s review and concurrence.”).

6. See *510(k) Clearances*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/> (last updated Jan. 26, 2016).

7. See *Premarket Approval (PMA)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmission/PremarketApprovalPMA/default.htm> (last updated Aug. 19, 2014).

8. See 21 C.F.R. § 860.7(a)–(b) (2016).

9. DEMARCO, *supra* note 4, at 10 (“In addition to fostering medical device innovation, one of FDA’s missions is to get safe and effective devices to market expeditiously while ensuring that the devices on the market remain safe and effective.”).

10. See Bonnie Scott, *Oversight Overhaul: Eliminating the Premarket Review of Medical Devices and Implementing a Provider-Centered Postmarket Surveillance Strategy*, 66 FOOD & DRUG L.J. 377, 384 (2011). See also Merrill, *supra* note 5, at 1753–54.

11. See JOSH MAKOWER ET AL., FDA IMPACT ON U.S. MEDICAL TECHNOLOGY INNOVATION: A SURVEY OF OVER 200 MEDICAL TECHNOLOGY COMPANIES 6–7 (2010), <http://advamed.org/res.download/30> (noting that FDA regulatory processes compared unfavorably to those of the EU among respondents in a survey of over 200 medical technology companies). See

Such problems result in lengthy device approval procedures, which forces manufacturers to absorb significant product development costs and delays patients' access to state-of-the-art medical technology.¹² A 2010 survey indicated that "the average total cost . . . to bring a 510(k) product from concept to clearance was approximately \$31 million, with \$24 million spent on FDA dependent and/or related activities."¹³ For PMA products, the average total cost was \$94 million dollars, with \$75 million dollars attributed to FDA-related activities.¹⁴ In a struggling economy, potential investors may be reluctant to invest in a manufacturer that does not have a reasonably prompt timetable for releasing new products.¹⁵

As a result of the FDA's establishment of high premarket review standards to prevent unsafe devices from entering the market,¹⁶ several manufacturers have focused on international opportunities that allow them to place their devices into the market faster and at lower cost, while still maintaining safety as a priority.¹⁷ The medical device industry is experiencing a trend of manufacturers introducing their products in Europe before entering the U.S. market.¹⁸ The U.S. Congress took heed of this trend and passed legislation intended to prevent device manufacturers from exporting medical device innovation, manufacturing, and revenue abroad while still protecting the American public's safety.¹⁹ The FDA has acknowledged that it needs to proactively seek ways to reduce the lengthy medical device approval process while maintaining a stringent standard of patient safety.²⁰ The FDA commenced a comprehensive review of its

also Scott, *supra* note 10, at 384–87 (discussing the burdens of medical device manufacturers during the FDA premarket review process).

12. Scott, *supra* note 10, at 384–85.

13. MAKOWER ET AL., *supra* note 11, at 28.

14. *Id.*

15. Scott, *supra* note 10, at 390 (emphasizing that "[b]ecause of the risks involved in developing innovative products, [medical device] companies often have difficulty securing funding from 'regular capital markets'" and "[p]otential investors are hesitant to back new device companies with unproven track records").

16. *Id.* at 391 (acknowledging the FDA's reasonable success at securing the safety and effectiveness of medical devices).

17. *See id.* at 390–91.

18. *Id.* at 378 (noting that medical device approval in Europe usually takes less time and costs less than in the United States). *See also* John Chai, *Premarket Review of Medical Devices in the United States*, 7 EUR. J. HEALTH L. 293, 303 (2000) (noting that "[m]ost companies had to relocate their resources and change their marketing strategy in order to survive" and that "[u]p to 43 percent of the companies had increased their manufacturing in Europe due to the concern that their products would not receive FDA approval for export").

19. *See infra* Section I.A.

20. Jeffrey Shuren, *Report: CDRH on Track to Improve Device Submission Review Process*, FDA VOICE (June 11, 2014), <http://blogs.fda.gov/fdavoices/index.php/2014/06/report-cdrh-on-track-to-improve-device-submission-review-process/>.

regulations and procedures in 2014, and the medical device industry is anxiously waiting to see how the FDA will improve the approval process.²¹

This Comment reviews how a medical device approval system, designed with good intentions to both promote medical innovation and protect patient safety, became so unwieldy. To begin, this Comment discusses the statutory history behind FDA premarket review authority arising under the Food, Drug, and Cosmetics Act (FDCA), the FDCA's progeny, and the FDA's development of regulations designed to ensure that devices are deemed safe through product safety and efficacy determinations. In examining FDA regulations, this Comment reviews pertinent court decisions regarding device manufacturers' challenges of FDA approval determinations based on safety and efficacy standards. This Comment then addresses how premarket regulations have impacted small businesses and outlines approaches the FDA could adopt to ameliorate systemic problems in the current approval process. Finally, this Comment argues that FDA premarket regulations should focus on product safety and shift product efficacy into the postmarket surveillance regulatory system, which could remove significant hurdles that slow the device approval process without compromising patient safety.

I. THE LEGAL HISTORY OF SAFETY AND EFFECTIVENESS

A. *Historical Overview of the FDA's Authority to Regulate and Approve Medical Devices*

Congress has acknowledged the importance of the medical device industry to the U.S. economy and, as a result, it continues to legislate ways to improve the FDA's premarket review process while simultaneously protecting the public from harmful devices.²² The FDA has authority to regulate medical devices that companies wish to place into the stream of commerce under the FDCA,²³ which was amended by the Medical Device Amendments of 1976 to provide for medical device regulations.²⁴ The Medical Device Amendments of 1976 created

21. *Id.*

22. *See generally*, 21 U.S.C §§ 301–399f (2012); Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended in scattered sections of 21 U.S.C. (2012)); Safe Medical Device Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511 (1990) (codified in scattered sections of 21 U.S.C. (2012)); Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (1997) (codified in scattered sections of 21 U.S.C. (2012)); Medical Device User Fee and Modernization Act of 2002, Pub. L. No. 107-250, § 101, 116 Stat. 1588, 1589 (2002) (codified as amended at 21 U.S.C. § 379(i) (2012)). *See also infra* text accompanying endnotes 23–34.

23. Federal Food, Drug, and Cosmetic Act, 21 U.S.C §§ 301–399f (2012). *See, e.g.*, 21 U.S.C § 360f(a) (describing the authority of the FDA to ban dangerous medical devices).

24. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended in scattered sections of 21 U.S.C. (2012)). Before 1976, the FDA had very limited control over regulating medical devices. Scott, *supra* note 10, at 380. The Medical Device

an FDA classification system²⁵ to categorize the wide range of medical devices invented by the industry based on each device's level of risk.²⁶

As the FDA promulgated medical device premarket regulations following the Medical Device Amendments of 1976, concerns arose regarding unsafe medical devices entering the market.²⁷ In response to these concerns, Congress passed the Safe Medical Device Act of 1990,²⁸ which granted the FDA additional authority to promulgate safety and effectiveness requirements.²⁹ One of the most notable changes affected the meaning of "substantial equivalence."³⁰ The substantial equivalence standard now requires manufacturers to show that a proposed device has the same intended use and technological characteristics as a device already in the market.³¹

In an effort to ensure that the FDA could more effectively regulate medical devices and strike a proper balance between patient safety and device

Amendments of 1976 granted the FDA the authority to regulate medical devices and expanded the FDA's regulatory framework with the classification system. *Id.*

25. See *infra* Section I.B.1.

26. § 513(a)(1), 90 Stat. at 540–42. See also Jeffrey K. Shapiro, *Substantial Equivalence Premarket Review: the Right Approach for Most Medical Devices*, 69 FOOD & DRUG L.J. 365, 367 (2014) (stating that "the congressional vision was to provide FDA with ample authority to conduct risk-based regulation of devices from cradle to grave"). Regarding safety and effectiveness, risk is not determined solely based on the patients:

The safety and effectiveness of a device are to be determined – (A) with respect to the persons for whose use the device is represented or intended, (B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and (C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

21 U.S.C. § 360c(a)(2)(A)–(C) (2012).

27. See Ralph F. Hall & Michelle Mercer, *Rethinking Lohr: Does "SE" Mean Safe and Effective, Substantially Equivalent, or Both?*, 13 MINN. J.L. SCI. & TECH. 737, 745–47 (2012) (discussing the development of medical device regulation following the Medical Device Amendments of 1976). See also Shapiro, *supra* note 26, at 367 (discussing the initial problems with the Medical Device Amendments of 1976, including issues with review times and performance standards).

28. Safe Medical Device Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511 (1990) (codified in scattered sections of 21 U.S.C. (2012)).

29. See Hall & Mercer, *supra* note 27, at 747–48. Hall and Mercer state:

The first major post-1976 reformation of the FDCA was the Safe Medical Device Act of 1990 (SMDA), which was adopted in response to concerns that devices were not being adequately regulated and in response to a number of mishaps in the medical device realm. The SMDA substantially expanded FDA authority over medical device regulation and increased burdens on manufacturers of medical devices.

Id. (footnote omitted).

30. § 12, 104 Stat. at 4523–24.

31. *Id.* See Hall & Mercer, *supra* note 27, at 748. See also Shapiro, *supra* note 26, at 369 (outlining the significance of the SMDA for substantial equivalence).

availability, Congress passed the FDA Modernization Act in 1997.³² The Act made changes to medical device premarket regulations. One of the major changes introduced the concept of “good guidance practices,” which attempts to clarify the FDA’s interpretation of regulations.³³ Subsequently, Congress enacted the Medical Device User Fee and Modernization Act in 2002, which attempts to provide the FDA with resources to help medical device manufacturers bring their devices into the market more expeditiously, subject to safety and effectiveness requirements.³⁴

B. The Premarket Review Process and an Examination of the FDA’s Standards of Review for Medical Device Approval

1. Overview of the FDA Premarket Review Process

The medical device classification system consists of three categories: Class I, Class II, and Class III.³⁵ Unless exempted, devices in all three classes are subject to general controls.³⁶ Controls are standards used “to provide reasonable assurance of the safety and effectiveness of the device.”³⁷

Class I devices are considered low risk devices, such as elastic bandages and tongue depressors, and are subject to general controls.³⁸ General controls, which

32. Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (1997) (codified in scattered sections of 21 U.S.C. (2012)). See THOMAS J. DUESTERBERG ET AL., HEALTH CARE REFORM, REGULATION, AND INNOVATION IN THE MEDICAL DEVICE INDUSTRY 83 (1994) (acknowledging that “it is not surprising that it has been difficult to balance the competing demands of safety and availability of high quality care within the regulatory apparatus”).

33. § 405, 111 Stat. at 2369.

34. Medical Device User Fee and Modernization Act of 2002, Pub. L. No. 107-250, § 101, 116 Stat. 1588, 1589 (2002) (codified as amended at 21 U.S.C. § 379(i) (2012)). See Hall & Mercer, *supra* note 27, at 751.

35. Medical Device Classification Procedures, 21 C.F.R. § 860.1 (2016).

36. See 21 U.S.C. § 360c(a)(1)(A) (2012) (describing the requirements for general controls).

37. *Id.* § 360c(a)(1)(A)(ii). See also Michael E. Wiklund, *Is Your Human Factors Program Ready for FDA Scrutiny?*, in DESIGNING USABILITY INTO MEDICAL PRODUCTS 21, 25–26 (Michael E. Wiklund & Stephen B. Wilcox, eds., 2005) (explaining the premarket review process and the types of concerns that FDA reviewers may have when reviewing a medical device for premarket clearance).

38. *FDA Device Guidance: Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types*, POL’Y & MED. (Jan. 29, 2015), <http://www.policymed.com/2015/01/fda-device-guidance-medical-device-accessories-defining-accessories-and-classification-pathway-for-n.html>. A device can still be classified as Class I even in instances where safety and efficacy cannot be reasonably determined:

A device is in class I if (i) general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, or (ii) there is insufficient information from which to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but the device is not life-supporting or life-sustaining or for a use which

all medical devices are subject to under the FDCA, include adulterated³⁹ and misbranded device prevention,⁴⁰ registration of producers of devices,⁴¹ banned devices,⁴² notifications and other remedies,⁴³ records and reports on devices,⁴⁴ and general provisions respecting control of devices intended for human use.⁴⁵

Class II devices are considered moderate risk devices, such as pregnancy test kits and powered wheelchairs.⁴⁶ These devices are subject to special controls when general controls are not enough “to provide reasonable assurance of [the device’s] safety and effectiveness.”⁴⁷ Special controls include “performance standards, postmarket surveillance, patient registries, . . . guidelines, . . . recommendations, and other appropriate actions that the [FDA] deems necessary.”⁴⁸ In most instances, Class II devices obtain FDA clearance to enter the market through the 510(k) premarket submission process.⁴⁹ The 510(k) submission, also referred to as a Premarket Notification (PMN), requires the applicant to submit clinical trial data and accompanying certifications.⁵⁰ Following a 510(k) submission, the FDA then has ninety days to make a determination.⁵¹ A Class II device can be exempted, and thus reclassified as a Class I device, if the FDA determines that a report “is not necessary to assure the safety and effectiveness of the device”; the determination is then published in the Federal Register.⁵²

Class III devices are considered high-risk devices, such as pacemakers and breast implants, and are subject to general controls as well as premarket approval.⁵³ Out of the three classifications of devices, a PMA submission requires the device manufacturer to provide the FDA with the most substantial

is of substantial importance in preventing impairment of human health, and which does not present a potential unreasonable risk of illness or injury.

21 C.F.R. § 860.3(c)(1).

39. 21 U.S.C. § 351 (2012).

40. *Id.* § 352.

41. *Id.* § 360.

42. *Id.* § 360f.

43. *Id.* § 360h.

44. *Id.* § 360i.

45. *Id.* § 360j.

46. *Learn if a Medical Device Has Been Cleared by FDA for Marketing*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/ResourcesforYou/Consumers/ucm142523.htm> (last updated June 4, 2014).

47. 21 C.F.R. § 860.3(c)(2) (2016).

48. 21 U.S.C. § 360c(a)(1)(B).

49. 21 C.F.R. § 860.3(c)(2).

50. 21 U.S.C. § 360(k) (2012).

51. *Id.* § 360(n)(1).

52. *Id.* § 360(m)(2).

53. *Id.* § 360c(a)(1)(C); *see also Learn if a Medical Device Has Been Cleared by FDA for Marketing*, *supra* note 46.

amount of information, including underlying clinical studies and information as to the device's efficacy and safety, which can take many years to complete.⁵⁴ Following a PMA submission, the FDA is given 180 days to approve or deny the submission.⁵⁵

Most medical devices begin in Class III by default.⁵⁶ However, if the device was introduced into the marketplace before 1976 or is "substantially equivalent to another device" that was previously classified as a Class I or Class II device (commonly referred to as substantial equivalence), then the proposed new device does not begin in Class III.⁵⁷ The Medical Device Amendments of 1976 created the substantial equivalence determination as a core component in the 510(k) premarket notification process.⁵⁸ Additionally, 21 U.S.C. § 360c(e) allows the FDA to change a device's classification and requires the FDA to publish a reclassification order in the Federal Register, conduct a device classification panel meeting, and consider public comments.⁵⁹

54. A PMA submission requires the following: (1) "full reports of all information . . . concerning investigations"; (2) "a full statement of the components, ingredients, and properties . . . of such device"; (3) "a full description of the methods used in . . . the manufacture, processing, . . . packing and installation of such device"; (4) "an identifying reference to any performance standard"; (5) "samples of such device"; (6) "specimens of the labeling proposed"; (7) "the certification required under [the Public Health Act]"; and (8) other relevant information that the FDA or panel may require. 21 U.S.C. § 360c(c)(1)(A)–(H).

55. *Id.* § 360c(d)(1)(A). The FDA may only deny the submission if there is: (1) "a lack of showing of reasonable assurance" in the safety or effectiveness of the device; (2) the "manufactur[ing], processing, packing, or installation" methods do not conform to the appropriate requirements; (3) there is "false or misleading" labeling; or (4) the device does not conform to the required standards. *Id.* § 360c(d)(2)(A)–(E).

56. *Id.* § 360c(f)(1) ("Any device intended for human use which was not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, is classified in class III . . .").

57. *Id.* § 360c(f)(1)(A)(i)–(ii).

58. *Id.* § 360c(f) (describing the 510(k) premarket notification process and the substantial equivalence determination).

59. *Id.* § 360c(e)(1)(A)(i). The provision states:

Based on new information respecting a device, the Secretary may, upon [his own] initiative . . . or upon petition of an interested person, change the classification of such device, and revoke, on account of the change in classification, any regulation or requirement in effect . . . with respect to such device, by administrative order published in the Federal Register following publication of a proposed reclassification order in the Federal Register, a meeting of a device classification panel . . . and consideration of comments to a public docket . . .

Id.

2. A Comparison of the FDA and the European Union's Safety and Performance Requirements for Medical Devices: "Clinically Significant Results" Versus Manufacturer's Intent

The FDA issued regulations designed to implement Congress's legislative initiatives, which require the FDA to use safety and effectiveness as the standards for approving medical devices.⁶⁰ Title 21 of the Code of Federal Regulations outlines factors that the FDA considers when making safety and efficacy determinations.⁶¹ For safety, the FDA uses a balancing test to weigh benefits against risks:

There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use.⁶²

For efficacy, the FDA focuses on results rather than conducting a balancing test:

There is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions

60. *See generally*, 21 C.F.R. § 860.7 (2016).

61. When classifying Class II and Class III devices, the FDA considers the following factors when determining safety and effectiveness:

(1) The persons for whose use the device is represented or intended; (2) the conditions of use for the device, including conditions of use prescribed, recommended, or suggested in the labeling or advertising of the device, and other intended conditions of use; (3) the probable benefit to health from the use of the device weighed against any probable injury or illness from such use; and (4) the reliability of the device.

Id. § 860.7(b).

62. *Id.* § 860.7(d)(1). *See also* Classification Procedures, 43 Fed. Reg. 32,988, 32,991 (July 28, 1978) (codified at 21 C.F.R. pts. 16, 20 & 860). In response to comments requesting a definition that is more objective and specific regarding "reasonable assurance of device safety" the FDA stated that

[t]he wording of the proposed section closely follows the wording of section 513 of the act. The legislative history . . . explains that determination of device safety involves balancing the probable benefits of a device against its probable risks. Consequently, proof of device safety is intended to establish that the risks are not unreasonably disproportionate to the benefits. The proposed section merely expands this concept, emphasizing that only valid scientific evidence may be used to establish device safety.

Id.

for use and warnings against unsafe use, will provide clinically significant results.⁶³

The European Union (EU) has a classification system for premarket regulations based on risk, not unlike the United States.⁶⁴ However, where the FDA evaluates safety and effectiveness, the EU evaluates medical devices based on a standard of safety and performance.⁶⁵ For safety, the EU employs a balancing test similar to the one used by the FDA:

The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise, directly or indirectly, the clinical condition or the safety of the patients, the safety or health of users or, where applicable, other persons, or the safety of property. Any risks which may be associated with their use must be acceptable when weighed against the benefits to the patient and be compatible with a high level of protection of health and safety.⁶⁶

The EU also conducts an assessment which, like the FDA's assessment, focuses on results, but instead uses a device's performance relative to the manufacturer's intent rather than effectiveness as the standard: "[The device] must achieve the performances, in particular, where appropriate, in terms of analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility, including control of known relevant interference, and limits of detection, stated by the manufacturer."⁶⁷

Based on standards for safety and performance, the EU strongly emphasizes safety and health when evaluating medical devices.⁶⁸ Unlike the United States, where the goal is for the manufacturer to "provide clinically significant

63. 21 C.F.R. § 860.7(e)(1). *See also* Classification Procedures, 43 Fed. Reg. at 32,990 (responding to comments regarding using scientific evidence for safety and efficacy). The Classification Procedures state:

The purpose of the act is to assure the safety and effectiveness of medical devices intended for human use. Because such assurance necessarily demands a high standard of proof, section 513(a)(3) of the act requires that device effectiveness be established only by valid scientific evidence. The Commissioner has extended this requirement to the establishment of device safety as well. The requirement that only valid scientific evidence be used to establish device safety and effectiveness, however, does not preclude consideration of other forms of evidence when determining whether a device is safe or effective.

Id.

64. *See* Christa Altenstetter, *US Perspectives on the EU Medical Devices Approval System, and Lessons Learned from the United States*, 4 EUR. J. OF RISK REG. 443, 447 (2013).

65. *See id.* at 455–56.

66. Council Directive, 98/79, 1998 O.J. (L 331) 16 (EC).

67. *Id.*

68. *See supra* notes 64–67 and accompanying text.

results,”⁶⁹ the EU’s performance standard stresses the device’s ability to perform in the way that the manufacturer intended.⁷⁰

3. *The Contact Lens Decision and the Beginning of Deference to the FDA for Medical Device Classifications*

One of the earliest legal challenges to the FDA’s safety and efficacy requirements occurred in 1985 when the Contact Lens Manufacturers Association (CLMA) challenged the FDA’s classification of rigid gas permeable contact lenses as a Class III device.⁷¹ During the premarket process, the FDA originally proposed to reclassify the contact lenses from Class III to Class I, even though CLMA requested that the contact lens be reclassified as a Class II device.⁷² The FDA asserted that there was sufficient information to establish a performance standard as a Class II device and that safety and efficacy could be established without the Class II performance standard, which is why the FDA proposed Class I for the contact lenses.⁷³ However, after receiving public comment on the proposed reclassification, the FDA withdrew the proposal and stated that the device should be classified as a Class III device because neither the Class I nor Class II designations could provide reasonable assurances of safety and effectiveness for the contact lenses.⁷⁴

CLMA argued that by withdrawing the reclassification proposal, the FDA disregarded the overall consensus in the medical industry that favored the reclassification and belittled the “valid scientific evidence” requirement for safety and effectiveness.⁷⁵ The court agreed that perhaps the lenses should not be subject to such strict regulatory requirements, but determined that it would not change the FDA’s decision because the FDA “acted within an area of its expertise, it ruled in a manner at least arguably consistent with the statutory

69. 21 C.F.R. § 860.7(e)(1) (2016).

70. *See supra* note 67 and accompanying text.

71. *Contact Lens Mfrs. Ass’n v. Food & Drug Admin.*, 766 F.2d 592, 594 (D.C. Cir. 1985) (deciding the first case where a device was considered for reclassification under the “transitional provisions” of the Medical Device Amendments of 1976).

72. *Id.* at 596.

73. *Id.*

74. *Id.* at 596–97. The FDA reasoned that the lenses should not be Class I devices because it “could not determine whether a new lens was ‘substantially equivalent’ to an already-marketed lens without securing a wealth of detailed information about both lenses’ composition and manufacture.” *Id.* at 597. The FDA then reasoned that the lenses could not be Class II devices because “even if such information could be gathered for the purpose of establishing a ‘performance standard’ and measuring new lenses against it, conformity with the standard would not guarantee that a lens would function safely and effectively in the human eye.” *Id.* at 597 (citing *Reclassification of Daily Wear Spherical Contact Lenses Consisting of Rigid Gas Permeable Plastic Materials; Withdrawal of Proposed Rule*, 48 Fed. Reg. 56,778, 56,780–81 (Dec. 23, 1983)).

75. *Contact Lens*, 766 F.2d at 597.

scheme, and it considered the matter in a detailed, adequately reasoned fashion.”⁷⁶

4. The Arbitrary and Capricious Standard of Review and the Chevron Doctrine Under the Administrative Procedure Act

When a device manufacturer disagrees with an FDA decision regarding premarket classification or approval, the manufacturer may seek redress through the courts. Because the FDA is a federal government agency, the Administrative Procedure Act (APA) governs FDA decisions regarding premarket review for medical devices, including safety and effectiveness determinations.⁷⁷ In particular, section 706 of the APA provides that any reviewing court must use the “arbitrary and capricious” standard of review, which provides that “[t]o the extent necessary to decision and when presented, the reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.”⁷⁸

Courts must presume that an agency’s action is valid under this standard.⁷⁹ This is a demanding threshold for any medical device manufacturer to overcome, and the validity presumption is difficult to overturn because it only requires that the FDA have a rational basis for its decision.⁸⁰ Indeed, courts have acknowledged the FDA’s considerable discretion when making decisions relating to safety and effectiveness of medical devices.⁸¹

76. *Id.*

77. *See* 5 U.S.C. § 704 (2012).

Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review. A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action.

Id. *See also* DEMARCO, *supra* note 4, at 24–25 (explaining how a regulated entity may seek judicial review in the courts).

78. 5 U.S.C. § 706(2)(A).

79. *See* *Ethicon, Inc. v. Food & Drug Admin.*, 762 F. Supp. 382, 386 (D.D.C. 1991) (explaining that “[u]nder this standard, there is a presumption in favor of the validity of administrative action. A court cannot substitute its judgment for that of the agency.”).

80. *See* *United States v. Snoring Relief Labs, Inc.*, 210 F.3d 1081, 1085 (9th Cir. 2000). The Ninth Circuit defined the arbitrary and capricious standard as being met when:

[T]he agency “has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or product of agency expertise.”

Id. (quoting *O’Keeffe’s, Inc. v. U.S. Consumer Prod. Safety Comm’n*, 92 F.3d 940, 942 (9th Cir. 1996)).

81. *See* *Ethicon*, 762 F. Supp. at 386 (examining congressional intent regarding safety and effectiveness decisions and stating that “Congress gave FDA sweeping discretion in determining the classification of devices and therefore in judging the safety and effectiveness of medical

Additionally, when a court reviews agency actions that interpret statutes, the *Chevron* doctrine applies, requiring courts to employ a two-step analysis.⁸² The first step requires the court to ask whether Congress expressly addressed the matter at issue.⁸³ If it has, then the inquiry ends there, and the agency must follow the express intent of Congress.⁸⁴ If Congress did not expressly address the matter at issue, then the second step requires the court to determine whether the agency adopted “a permissible construction of the statute.”⁸⁵ Under the *Chevron* doctrine, the court does not substitute its judgment for the agency’s action, even in cases where congressional intent may be implicit.⁸⁶ The second step is commonly viewed as a reasonableness inquiry,⁸⁷ which many scholars believe is similar to the arbitrariness inquiry under the APA.⁸⁸

C. A Chronology of Pertinent Court Holdings Regarding Safety and Effectiveness Determinations by the FDA Under the APA

While premarket medical device decisions regarding safety and efficacy do not typically occur in the courts outside of preemption determinations,⁸⁹ the

devices”). See also SHARON FRANK, A NEW MODEL FOR EUROPEAN MEDICAL DEVICE REGULATION: A COMPARATIVE LEGAL ANALYSIS IN THE EU AND THE USA 168 (2003) (acknowledging that “Congress did not find itself in the position to determine the appropriate classification of every medical device in existence or yet to be invented”).

82. *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984).

83. *Id.* at 842.

84. *Id.* at 842–43.

85. *Id.* at 843.

86. *Id.* at 844 (explaining that “[s]ometimes the legislative delegation to an agency on a particular question is implicit rather than explicit. In such a case, a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency.”).

87. See Emily Hammond Meazell, *Deference and Dialogue in Administrative Law*, 111 COLUM. L. REV. 1722, 1734 (2011); Ronald M. Levin, *The Anatomy of Chevron: Step Two Reconsidered*, 72 CHI.-KENT L. REV. 1253, 1260 (1997); Matthew C. Stephenson & Adrian Vermeule, *Chevron Has Only One Step*, 95 VA. L. REV. 597, 599 (2009).

88. Levin, *supra* note 87, at 1285 (arguing that “step two [of the *Chevron* doctrine] should be regarded as equivalent to arbitrariness review, because that mode of review, taken together with *Chevron* step one, can accommodate all the lines of analysis that courts have been pursuing under *Chevron* step two”).

89. While preemption is not the focus of this Comment, it is an important component of safety and efficacy determinations from a product liability perspective in a tort claim. Two Supreme Court cases provide the framework for preemption in product liability claims against medical devices. See DEMARCO, *supra* note 4, at 25–26 (explaining preemption of state laws and regulations for medical devices); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323–28 (2008) (deciding that 21 U.S.C. § 360k preempted state law product liability claims against PMA devices); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 500–08 (1996) (deciding that under certain circumstances 21 U.S.C. § 360k preempted state law product liability claims against 510(k) devices). See also Hall & Mercer, *supra* note 27, at 771–72 (analyzing medical device regulation and product liability preemption following the Supreme Court’s decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) from the perspective of the 510(k) system).

courts have articulated important factors in making safety and efficacy determinations and applying the arbitrary and capricious standard from the APA.

1. *Bowen: Placing Products in Class III By Operation of Law*

In *United States v. Bowen*,⁹⁰ Sterilization Systems, a dental handpiece sterilizer manufacturer, sought exemption from FDA premarket requirements because its device was “the substantial equivalent of a preexisting, legally marketed device” and was therefore subject to a 510(k) submission.⁹¹ The FDA denied the exemption, but Sterilization Systems continued to sell the product.⁹² Sterilization Systems argued that the FDA had “acted arbitrarily and capriciously” when it classified the product as a Class III device, making it subject to premarket approval.⁹³

The court noted that “the only question under the [FDCA] is whether the *intended use* of the product is to prevent disease, not whether the product *actually* prevents disease.”⁹⁴ Regarding Sterilization Systems’s argument that the FDA improperly classified the product as Class III, the court held that the classification was not arbitrary or capricious because the product was in Class III “by operation of law.”⁹⁵ Because all devices begin in Class III and the manufacturer “did not request reclassification before he introduced [the device] into interstate commerce,” the classification was not arbitrary or capricious, regardless of whether the FDA “had sufficient knowledge of [the product] to determine if it was ‘safe.’”⁹⁶

2. *Ethicon, Inc.: Applying Contact Lens and Interpreting Performance Standards*

In *Ethicon, Inc. v. Food & Drug Administration*,⁹⁷ Ethicon, a manufacturer of poly absorbable surgical sutures, brought suit against the FDA, alleging that the FDA improperly reclassified a class of surgical sutures from Class III to Class II.⁹⁸ Ethicon argued that the FDA reclassification decision was arbitrary and capricious, and therefore in violation of the APA, because the decision did not satisfy “both the substantive and procedural statutory requirements for reclassification.”⁹⁹ The court determined that the *Contact Lens* decision did not apply because the device at issue in *Ethicon* was similar to a device already on

90. 172 F.3d 682 (9th Cir. 1999).

91. *Id.* at 684.

92. *Id.*

93. *Id.*

94. *Id.* at 686.

95. *Id.* at 688.

96. *Id.* at 687–88.

97. 762 F. Supp. 382 (D.D.C. 1991).

98. *Id.* at 383–84.

99. *Id.* at 385–86.

the market, whereas *Contact Lens* involved a different device altogether.¹⁰⁰ The court then turned to the parties' differing interpretations of "what constitutes 'sufficient information to establish a performance standard' that will 'provide reasonable assurance of the safety and effectiveness of the device.'"¹⁰¹ According to the FDA, sufficient information means that "valid scientific evidence" supports the performance standards for safety and effectiveness.¹⁰² Under the arbitrary and capricious standard, the court upheld the FDA's determination because the safety and effectiveness requirement was satisfied.¹⁰³

Ethicon also questioned whether the FDA properly established a performance standard during Ethicon's premarket review process.¹⁰⁴ Ethicon argued that in order to establish a performance standard, the FDA must "determine what tests must be performed, and explain how the values obtained on those tests would assure the safety and effectiveness of the new device."¹⁰⁵ The court looked to congressional intent and explained that

Congress knew that FDA could not establish performance standards for the universe of Class II devices, and encouraged FDA to use its discretion to pursue such standards in order of priority. . . [T]he evidence showed that a performance standard was not immediately necessary to protect the public health.¹⁰⁶

The FDA is only responsible for determining "whether the generic class is sufficiently identified to permit comparisons of the safety and effectiveness of a newer device within that generic class" which, according to the court, the FDA accomplished.¹⁰⁷

100. *Id.* at 387–88 (distinguishing the *Contact Lens* holding from a poly suture with similar devices in interstate commerce).

101. *Id.* at 388 (quoting 21 U.S.C. § 360c(a)(1)(B) (2012)) (discussing the correct interpretation of the statutory definition for Class II devices).

102. *Id.* (noting that the issue was "whether the administrative record contains sufficient information for the agency to understand the device and sufficient evidence to demonstrate that factors determining the device's safety and effectiveness are controllable").

103. *Id.* at 388–89.

104. *Id.* at 389–91 (discussing the performance standard as required under 21 U.S.C. § 360c(a)(1)(B)).

105. *Id.* at 389. Ethicon argued that "publicly available scientific literature" is not enough to constitute a sufficient performance standard and should instead be used as a benchmark for end-product testing, which would then be used to develop the performance standard. *Id.* at 389–90. The FDA, however, argued that "it had a rational basis" for establishing a performance standard, with which the court agreed. *Id.* at 390.

106. *Id.* at 390.

107. *Id.* at 391. The court did note, however, that "[i]n a perfect world, performance standards would be set for each and all medical devices prior to their exposure to the public," and that "[i]n the imperfect, but not defective, world of medical device regulation created by Congress, performance standards are but a desired goal not required to be promptly reached." *Id.*

3. Cytori Therapeutics, Inc.: Applying a Rational Basis Standard of Review

As in *Ethicon*, courts have generally upheld FDA classification determinations. In *Cytori Therapeutics, Inc. v. Food & Drug Administration*,¹⁰⁸ a case from 2013, the court determined that an FDA decision to classify a device that harvested and concentrated stem and regenerative cells from fat as a Class III device was “reasonable and reasonably explained for purposes of the Administrative Procedure Act.”¹⁰⁹

The manufacturer, Cytori Therapeutics, Inc., claimed in its premarket notification that its device was “substantially equivalent” to other devices on the market that “harvest cells from blood and bone marrow.”¹¹⁰ The FDA, however, rejected Cytori’s claim both because “[f]at is not blood” and “the devices had different technological characteristics or posed different safety concerns.”¹¹¹ The court held that the FDA “reasonably determined – and reasonably explained its determination – that the [device] met neither the ‘intended use’ criterion nor the ‘technological characteristics’ criterion” that the FDA considers when classifying a device as a Class II device.¹¹²

4. Ivy Sports Med, LLC.: Reclassification and Reasonable Time for FDA Reclassification Decisions

Despite congressional enactments to improve the premarket process for medical devices, manufacturers argue that they still experience difficulties.¹¹³ For example, *Ivy Sports Med., LLC v. Sebelius*¹¹⁴ involved a medical device company, ReGen Biologics (ReGen), which had been undergoing the premarket review process in connection with one of its devices for over sixteen years.¹¹⁵ The FDA rejected multiple applications before initially approving the device in 2008.¹¹⁶ In 2011, however, the FDA reclassified the device at issue from Class II to Class III because “the differences between the technological characteristics” of the device and the devices on the market with which ReGen claimed substantial equivalency “raise different questions of safety and

108. 715 F.3d 922 (D.C. Cir. 2013).

109. *Id.* at 924.

110. *Id.* at 925.

111. *Id.* (discussing the FDA’s distinction between devices that harvest cells from blood and bone marrow from Cytori’s device that harvests cells from fat).

112. *Id.* at 927.

113. See Merrill, *supra* note 5, at 1753–54.

114. 938 F. Supp. 2d 47 (D.D.C. 2013), *rev’d sub nom.* *Ivy Sports Med., LLC v. Burwell*, 767 F.3d 81 (D.C. Cir. 2014).

115. *Id.* at 48.

116. The Class II classification came after the FDA consulted with an expert advisory panel, which concluded that the device was as safe and effective as devices already on the market. See *id.* at 52.

effectiveness.”¹¹⁷ A few months after the FDA reclassified the device, ReGen Biologics went bankrupt, and Ivy Sports Medicine, LLC (Ivy) became the successor in interest.¹¹⁸

Ivy sued, claiming that the FDA violated the APA because the FDA failed to follow correct reclassification procedures.¹¹⁹ The court acknowledged that “the Administrative Record contain[ed] several examples of misconduct affecting the integrity of the . . . device’s 2008 substantial equivalence determination.”¹²⁰ Even though the FDA departed from normal agency practices, the court ruled that the FDA could still exercise its inherent authority to reevaluate the premarket decision.¹²¹ When evaluating the standard for a reasonable amount of time, the court considered eight factors¹²² and ruled that those factors tended to favor the FDA, despite the fact that “Ivy invested time and money in reliance upon the FDA’s substantial equivalence determination.”¹²³

On appeal, Ivy argued that the FDA did not have inherent authority to reclassify the device and was required to exercise its statutory authority to reclassify the device under 21 U.S.C. § 360c(e).¹²⁴ In particular, Ivy argued that inherent authority does not apply in instances where Congress has spoken on the matter.¹²⁵ Because Congress devised a specific statutory scheme that governs how the FDA makes reclassification decisions, the FDA must follow the proper administrative procedures, including notice and comment.¹²⁶

117. *Id.* at 54. There was also evidence of political pressure from members of Congress and social pressure from an article published by the *Wall Street Journal*, which questioned the integrity of the review process. *See id.* at 52–53.; *see also* Alicia Mundy, *Political Lobbying Drove FDA Process*, WALL ST. J. (Mar. 6, 2009), at A1, <http://online.wsj.com/articles/SB123629954783946701>.

118. *Ivy Sports Med., Inc.*, 938 F. Supp. 2d at 54.

119. *Id.* at 55.

120. *Id.* at 57.

121. *Id.* at 59.

122. The eight factors included the following:

the complexity of the decision; whether the decision was based on fact or law; whether the agency acted according to its general procedures for review; the express time limit for appeals set forth in agency regulations; whether legally cognizable property interests had arisen through the initial decision; whether parties had relied upon the initial decision; whether the agency acted in bad faith by advancing a pretextual explanation to justify reconsideration; whether the agency provided notice of its intent to reconsider the initial decision; and the probable impact of an erroneous agency decision absent reconsideration.

Id. at 62.

123. *Id.*

124. *Ivy Sports Med., LLC v. Burwell*, 767 F.3d 81, 86–87 (D.C. Cir. 2014).

125. *Id.* (citing *Am. Methyl Corp. v. EPA*, 749 F.2d 826, 835 (D.C. Cir. 1984)).

126. *Id.* Ivy argued that “Congress precluded FDA from exercising inherent authority to rescind substantial equivalence determinations by creating in 21 U.S.C. §360c(e) a specific statutory mechanism to correct alleged device classification errors.” *Id.*

The appellate court agreed with Ivy and held that “because FDA concededly could have used Section 360c(e) to reclassify [the device] into Class III, it could not rely on a claimed inherent reconsideration authority to short-circuit that statutory process and revoke its prior substantial equivalence determination to achieve that same result.”¹²⁷ The court noted: “[N]otice and comment helps to prevent mistakes, because agencies receive more input and information before they make a final decision. [It] also helps ensure that regulated parties receive fair treatment. . . . So notice and comment, while somewhat burdensome, serves important purposes both generally and in this statute.”¹²⁸ The court did not specifically rule on whether the FDA properly reclassified the device on the merits, but noted that the FDA may have been correct in its decision to reclassify the device.¹²⁹

II. BECAUSE LEGAL PRECEDENT IS UNLIKELY TO FOSTER IMPROVEMENTS IN THE FDA’S PREMARKET APPROVAL PROCESS, CONGRESS, THE FDA, AND MEDICAL DEVICE MANUFACTURERS SHOULD CONSIDER AN ALTERNATIVE WAY TO IMPROVE THE APPROVAL PROCESS

Congress passed the Food and Drug Administration Safety and Innovation Act (FDASIA) in 2012 to simplify the process of developing and reviewing medical devices while continuing to maintain a focus on patient safety.¹³⁰ Congress intended the Act to, among other things, expedite the overall medical device approval process.¹³¹ Following the FDASIA, the FDA issued a proposed rule in March 2014 to amend its regulations regarding classification and reclassification of medical devices to conform to the FDASIA.¹³² One of the

127. *Id.* at 87. The court also discussed how revoking a substantial equivalence decision acts as a de facto reclassification decision:

It may well be correct, as FDA contends, that the statutory procedures [for determining substantial equivalence and for reclassification] are not mirror images of one another. But the fundamental question both provisions address – what is the appropriate classification of a new device? – is the same. And as a practical matter, the decision to revoke a substantial equivalence determination in circumstances like those present here is a de facto reclassification of the device into Class III, at least absent other FDA action. If FDA finds that a device is no longer substantially equivalent to any existing Class I or Class II devices, that device is automatically reclassified as a Class III device. In other words, to revoke a substantial equivalence determination is to “change the classification,” 21 U.S.C. § 360c(e)(2), of that device.

Id.

128. *Id.* at 87–88.

129. *See id.* at 87.

130. Food & Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, 126 Stat. 993 (2012) (codified in scattered sections of 21 U.S.C. (2012)).

131. *Id.* § 201(b), 126 Stat. at 1002.

132. Medical Device Classification Procedures, 79 Fed. Reg. 16,252, 16,253 (proposed Mar. 25, 2014) (to be codified at 21 C.F.R. pt. 860). The FDA extended the comment period to September 22, 2014, but no final rule has been issued as of the publication of this Comment. *See*

proposed changes would establish five subcategories of devices for Class III devices “based on the risks, benefits, and available controls” for the devices.¹³³

As part of the FDASIA, Congress also adopted the Medical Device User Fee Amendments of 2012.¹³⁴ In the same year, the FDA agreed to the medical device industry’s request to assess independently the medical device review process.¹³⁵ An independent assessment was undertaken to identify factors that were likely having a significant impact on overall premarket review times, and the FDA provided a set of priority recommendations addressing these factors.¹³⁶ The final report, which included an extensive list of recommendations spanning multiple areas, was released on June 11, 2014.¹³⁷ In response to the recommendations and criticisms, the FDA has developed plans to modernize the premarket review process, such as consulting with industry experts,¹³⁸ developing a more expedited 510(k) approval process,¹³⁹ and user fee programs.¹⁴⁰ None of the new initiatives, however, address the safety and effectiveness standard.

Medical Device Classification Procedures; Extension of Comment Period, 79 Fed. Reg. 33,711, 33,711 (proposed June 12, 2014) (to be codified at 21 C.F.R. pt. 860).

133. Medical Device Classification Procedures, 79 Fed. Reg. at 16,255. The five categories include the following: (1) “devices that present known risks that cannot be controlled”; (2) “devices for which the risk-benefit profile is unknown or unfavorable”; (3) “devices for which a full review of manufacturing information is necessary”; (4) “devices for which premarket review of any change affecting safety or effectiveness is necessary”; and (5) “combination products.” *Id.* at 16,255–56.

134. Food & Drug Administration Safety and Innovation Act §§ 201–208, 126 Stat. at 1002–08. Congress intended for the amendments to ensure that fees were put toward “expediting the process for the review of device applications.” § 201(b), 126 Stat. at 1002.

135. *See* 21 U.S.C. § 379j-1 (2012).

136. U.S. FOOD & DRUG ADMIN., MDUFA II/III EVALUATION—PRIORITY RECOMMENDATIONS 1–5 (2013), <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGDeviceR/Overview/MDUFAlII/UCM378202.pdf>.

137. *See* U.S. FOOD & DRUG ADMIN., DELIVERABLE 10: FINAL REPORT ON FINDINGS AND RECOMMENDATIONS 1–4 (2014), <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAlII/UCM400676.pdf>. *See also* Shuren, *supra* note 20. The author states:

Initially, the contractor identified 31 unique issues related to the device submission review process. They concluded that CDRH had taken steps to address 21 of those 31 issues—either through the development and implementation of new MDUFA III provisions, updated systems, and/or processes for review staff—and that we had at least begun to address another nine of the issues.

Id.

138. U.S. FOOD & DRUG ADMIN., IMPROVEMENTS IN DEVICE REVIEW: RESULTS OF CDRH’S PLAN OF ACTION FOR PREMARKET REVIEW OF DEVICES 11 (2012), <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM329702>.

139. *Id.* at 5–7.

140. *See* U.S. FOOD & DRUG ADMIN., SECTION 1128 OF THE FOOD AND DRUG ADMINISTRATION SAFETY AND INNOVATION ACT (FDASIA): SMALL BUSINESS REPORT TO CONGRESS, *supra* note 4, at 5–7; Altenstetter, *supra* note 64, at 462–63. *See also* Kurt H. Kruger & Max A. Kruger, *The Medical Device Sector*, in *THE BUSINESS OF HEALTHCARE INNOVATION* 376, 445 (Lawton Robert Burns ed., 2d ed. 2012) (“The potential clarifications regarding the 510(k)

III. THE IMPACT OF THE FDA SAFETY AND EFFECTIVENESS REGULATIONS ON SMALL BUSINESS MEDICAL DEVICE MANUFACTURERS

A. *The Problem with Premarket Safety and Efficacy Requirements Decisions*

Despite efforts by Congress and the FDA to make the premarket process faster and less burdensome, medical device manufacturers continue to experience undue delays during premarket review.¹⁴¹ *Ivy Sports* illustrates how burdensome the premarket process can be: the manufacturer underwent the premarket review process for over sixteen years, only to have its device reclassified by the FDA.¹⁴² At that point in time, the manufacturer was forced to file for bankruptcy.¹⁴³ Small medical device manufacturers can be justifiably concerned that the FDA still has the power to force a company to face approval delays that are so long that those manufacturers may lack sufficient finances to stay in business.

Similarly, the statutory history and case law regarding safety and effectiveness determinations suggest that the FDA has acquired a greater amount of control and discretion in making premarket decisions.¹⁴⁴ A common criticism of the FDA premarket review process is that the requirements to satisfy the safety and efficacy standards are ambiguous, allowing the FDA to apply multiple interpretations during review process procedures.¹⁴⁵ Additionally, the FDA's

clearances and the recent introduction of user fees – fees paid by the companies to the agency in order to hire more reviewers to speed the process – may help improve this costly and slow gateway to the market.”).

141. See MAKOWER ET. AL, *supra* note 11, at 28 (discussing the results of a survey of over 200 medical technology companies and comparing approval times and costs to the EU). *But see* 5-24 KATE H. MURASHIGE ET AL., TREATISE ON HEALTH CARE LAW § 24.12[1] (2015) (citing a report by the Government Accountability Office that suggested that the FDA “ha[d] been too lax in its classification and oversight of approving certain Class II and III medical devices, and that it failed ‘to subject some of the riskiest devices to a rigorous [pre-market approval] review mandated by Congress.’” (citing U.S. GOV’T. ACCOUNTABILITY OFFICE, GAO-09-190, MEDICAL DEVICES: FDA SHOULD TAKE STEPS TO ENSURE THAT HIGH-RISK DEVICE TYPES ARE APPROVED THROUGH THE MOST STRINGENT PREMARKET REVIEW PROCESS 16 (2009), <http://www.gao.gov/new.items/d09190.pdf>).

142. See *Ivy Sports Med., Inc. v. Sebelius*, 938 F. Supp. 2d 47, 48–49 (D.D.C. 2013), *rev’d sub nom.* *Ivy Sports Med., LLC v. Burwell*, 767 F.3d 81 (D.C. Cir. 2014).

143. *Id.* at 54.

144. See Hall & Mercer, *supra* note 27, at 771–72 (discussing the impact of the Safe Medical Device Act of 1990 on the medical device industry). Hall and Mercer note:

[T]he purpose of Congress in enacting the SMDA is clear – the Act was to further a policy promoting the safety and effectiveness of medical devices by providing a more stringent or robust regulatory frame to effectuate that purpose. After the SMDA, the FDA had substantially more robust authority to ensure the safety and effectiveness of medical devices in furtherance of congressional policy.

Id.

145. U.S. FOOD & DRUG ADMIN., REPORT ON FDA’S POLICY TO BE PROPOSED REGARDING PREMARKET NOTIFICATION REQUIREMENTS FOR MODIFICATIONS TO LEGALLY MARKETED DEVICES 8–9 (2014) (stating that AdvaMed, a medical industry trade association, had provided

authority has been supported and expanded by medical device reform, such as the Safe Medical Device Act (SMDA) of 1990.¹⁴⁶ The continued existence of this problem is evident from the case law regarding safety and efficacy determinations, as courts continue to grant the FDA a great deal of discretion under both the “arbitrary and capricious” standard of the APA and the *Chevron* doctrine.¹⁴⁷ Such deference makes it difficult for manufacturers to challenge an FDA premarket decision in court.¹⁴⁸ In cases such as *Bowen*, the courts have appropriately applied the arbitrary and capricious standard of review.¹⁴⁹ Even in situations such as *Ivy Sport*, where the court ruled that the FDA failed to follow the correct reclassification procedures, the court did not indicate whether the reclassification decision itself was incorrect.¹⁵⁰

The statutory and regulatory history of medical devices and relevant case law illustrate how Congress and the courts have granted the FDA added discretion and control.¹⁵¹ Indeed, while the court in *Ivy Sports* seemed to rule in favor of business, it also required the FDA to undergo additional steps to reclassify the device at issue; an outcome that can further delay premarket review decisions.¹⁵² In this sense, *Ivy Sports* is not really a win for small businesses. Because the FDA must undergo additional procedural steps before reclassifying a device, small medical device manufacturers must wait longer in the premarket review process, and the manufacturer is not guaranteed clearance.¹⁵³ All *Ivy Sports*

analysis to the FDA opinion that “existing guidance was vague, confusing, or not consistently implemented”).

146. See Hall & Mercer, *supra* note 27, at 747–48.

147. See *supra* Section I.C.

148. See *supra* Section I.C. See also Elizabeth C. Price, *Teaching the Elephant to Dance: Privatizing the FDA Review Process*, 51 FOOD & DRUG L.J. 651, 653–54 (1996). Price comments:

Assuming suit is filed and the affected company prevails, the company whose survival hinges on the agency’s continued good graces, likely will lose in the long run. Moreover, the chances of winning are slim because, in such cases, the available checks on agency abuse – Congress and the courts – face a debate between the regulated entity and the FDA over the facts and circumstances of the alleged abuse. Not surprisingly, neither Congress nor the courts are eager to second-guess an agency charged with consumer protection. Most likely, they will defer to agency expertise.

Id.

149. See *supra* Section I.C.1.

150. See *supra* Section I.C.4.

151. See *supra* Section I.A–C.

152. See *supra* Section I.C.4.

153. See, e.g., Walter Eisner, *FDA Abused Power, ReGen Biologics Exonerated*, ORTHOPEDICS THIS WEEK (Oct. 15, 2014), <http://ryortho.com/2014/10/fda-abused-power-regen-biologics-exonerated/> (noting that the FDA may still classify the device at issue in *Ivy Sports* as a Class III device even after spending over \$30 million to obtain clearance).

seemed to do was highlight the FDA's growing regulatory control over medical devices.¹⁵⁴

Critics of the premarket process also assert that patients are harmed because devices intended for medical treatment are withheld from the market and, by implication, their end users.¹⁵⁵ Patients must wait a long time to receive medical care with a specific device, arguably placing the United States at a disadvantage compared to other countries that facilitate faster regulatory approval and market entry.¹⁵⁶ While the FDA may argue that long wait times allow it to ensure that only safe and effective medical devices enter the market, some patients may go untreated or without more effective treatment because devices that could make a difference in their care are mired in the approval process.¹⁵⁷

B. Proposed Reforms to Medical Device Premarket Regulation

1. Start All Over By Rewriting the Premarket Process

Possible solutions to the problems inherent in the FDA's current premarket review process have surfaced both in the medical device industry and in the law. Some manufacturers suggest that premarket regulations should be rewritten completely, especially the 510(k) process.¹⁵⁸ This proposition is supported by the independent assessment of the FDA process that was conducted pursuant to the Medical Device User Fee Amendments¹⁵⁹ and an assessment conducted by the Institute of Medicine in 2009.¹⁶⁰ However, a complete rewrite of medical

154. See Thomas Sullivan, *Ivy Sports Medicine v. Burwell, et al.: FDA May Not "Short-Circuit" the Process for Reclassifying Medical Devices*, *Rules Federal Appeals Court*, POL'Y & MED. (Sept. 29, 2014, 5:40 AM), <http://www.policymed.com/2014/09/fda-may-not-short-circuit-the-process-for-reclassifying-medical-devices-rule-dc-circuit-court.html>.

155. See Scott, *supra* note 10, at 389 (explaining that premarket regulation places a burden on patients "because FDA's premarket pathways can be prohibitively expensive to navigate, manufacturers are discouraged from developing new devices in the first place; this limits patient treatment options and halts device technology progression . . . [and also] forc[es] suffering patients to wait for beneficial new devices"); see also Sullivan, *supra* note 154 (noting that allowing the FDA to reclassify devices without going through the proper procedures "would be detrimental not only to countless companies . . . but also to patients in need of new, innovative devices").

156. See Scott, *supra* note 10, at 389–91 (describing the "device lag" phenomenon, where the availability of devices in the United States lags significantly behind other countries because of long FDA approval times).

157. See *id.*

158. See Altenstetter, *supra* note 64, at 461.

159. The independent assessment identified thirty-one unique issues in the FDA's premarket review process for medical devices. U.S. FOOD & DRUG ADMIN., MDUFA II/III EVALUATION – PRIORITY RECOMMENDATIONS, *supra* note 136, at 31.

160. The Institute of Medicine's first recommendation stated that:

The Food and Drug Administration should obtain adequate information to inform the design of a new medical-device regulatory framework for Class II devices so that the current 510(k) process, in which the standard for clearance is substantial equivalence to

device regulations would be difficult, if not impossible, to implement from a practicality and timeliness standpoint. Congress is unlikely to completely rewrite existing legislation, and existing political gridlock could further stymie this task.

2. Remove Premarket Review and Place More Emphasis on Postmarket Surveillance

Premarket review could be removed altogether.¹⁶¹ This alternative approach involves the FDA completely eliminating premarket regulatory review processes and utilizing the postmarket evaluation system to make safety and efficacy decisions instead.¹⁶² Proponents of an all-postmarket method of medical device regulation argue that, while it may seem that such a system could result in a dangerous regulatory environment, a strong postmarket regulation system would more adequately allow medical device manufacturers to bring innovative products to market without getting caught up in burdensome premarket delays such as the 510(k) and the PMA.¹⁶³ Proponents argue that the market, competition, and the threat of tort liability are enough to incentivize and motivate manufacturers to take the steps necessary to ensure that their devices are safe.¹⁶⁴

However, completely removing the premarket review process and moving it to postmarket surveillance places too much reliance on the market to self-

previously cleared devices, can 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. Once adequate information is available to design an appropriate medical-device regulatory framework, Congress should enact legislation to do so.

INST. OF MED. OF THE NAT'L ACADS., *MEDICAL DEVICES AND THE PUBLIC'S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS 196* (2011). The Institute of Medicine concluded that the 510(k) process was outdated and should be replaced with a regulatory framework that is "more in line with the requirements of modern science, medicine, and technology." Altstetter, *supra* note 64, at 461.

161. See Scott, *supra* note 10, at 398–99, 402–04 (outlining the advantages of eliminating premarket FDA review and placing safety and efficacy decisions on postmarket surveillance).

162. *Id.* at 398 ("Rather than reforming its premarket review programs, FDA should eliminate them, utilizing postmarket activities as the primary means of promoting device safety.").

163. *Id.* Scott writes:

Under this proposed approach, very limited premarket controls would remain in place. FDA would keep its registration and device listing requirements, as well as its GMP and labeling regulations, but it would get rid of both the 510(k) and PMA programs. It can be argued that this approach would result in a "loose" and unsafe regulatory environment, however, the protections offered by premarket programs would be preserved through the creation of a sharp and efficient postmarket surveillance system. Strong postmarket regulation would encourage device safety while allowing device innovation to thrive.

Id.

164. *Id.* at 398–99 (discussing the checks that would exist under a provider-centered postmarket surveillance system).

regulate device safety. Some oversight from a common entity (in this case, the FDA) is prudent and justifiable to ensure that manufacturers do not introduce devices into the stream of commerce that could potentially harm patients. Additionally, removing the entire premarket review process would be contrary to congressional intent. Congress enacted, and continues to enact, legislation to address and review the requirements for a premarket review process for medical devices.¹⁶⁵ Removing the premarket review process conflicts with Congress's statutory scheme focusing on a premarket regulatory system that has been deemed important to ensure Americans' health and safety.¹⁶⁶

3. Privatize the Premarket Review Process

Premarket review could be privatized and conducted by third parties, rather than a government agency.¹⁶⁷ Proponents of privatization argue that there would be benefits to both manufacturers and the FDA, as privatizing premarket review would allow the FDA to move its resources to other parts of the agency while still ensuring that medical devices placed in the market are safe and effective.¹⁶⁸ Additionally, if premarket decisions are offered by a third party rather than a government agency, the courts would not have to apply an "arbitrary and capricious" standard, making manufacturers more likely to succeed in a lawsuit.¹⁶⁹ However, it is unlikely that Congress would allow private entities to control premarket review because government oversight of the medical device

165. See *supra* Section I.A.; see also *Ivy Sports Med., Inc. v. Sebelius*, 938 F. Supp. 2d 47, 62 (D.D.C. 2013), *rev'd sub nom. Ivy Sports Med., LLC v. Burwell*, 767 F.3d 81 (D.C. Cir. 2014); *Ivy Sports Med., LLC v. Burwell*, 767 F.3d 81, 86–87 (D.C. Cir. 2014).

166. See *supra* notes Section I.A.

167. See generally Price, *supra* note 148, at 665–66 (discussing the benefits of privatizing premarket medical device regulations).

168. *Id.* Price writes:

Perhaps the most immediate and noticeable effect of privatization, under either domestic or foreign review, would be a liberation of FDA resources, enabling the agency to focus on other areas such as providing unbiased information to consumers, setting safety and efficacy standards, enforcing those standards, and, perhaps most important, determining when to exercise its veto power over third-party recommendations. A post-privatization FDA thus would not be a mere administrative shell, but instead would continue to be the regnant protector of consumer safety. Products would be judged by the same stringent safety and efficacy standards used today, ensuring the consumer that, no matter what entity conducts the review (public or private), the American "gold standard" of safety and efficacy would remain uncompromised.

Id. (footnote omitted).

169. *Id.* at 666 (discussing how "potentially arbitrary or capricious action by the FDA is unchecked by courts reluctant to second-guess agency decisions cloaked in the mantra of safety or efficacy. This lack of judicial oversight, in turn, effectively establishes an irrebuttable presumption of validity to FDA decisions, creating the potential to abuse its monopolistic position.").

approval process promotes an efficient and structured oversight.¹⁷⁰ If a third party oversaw the premarket process, the FDA would have less control, which could lead to different interpretations of what is required for a device to be safe and effective.

IV. THE CASE FOR REMOVING EFFICACY FROM PREMARKET MEDICAL DEVICE REGULATIONS

While there are valid arguments for the three premarket reform propositions, one radical approach incorporates these three ideas. This approach would have FDA premarket regulations be primarily concerned with product safety. The premarket process would be reformed to focus on product safety during the premarket phase and shift product efficacy to postmarket surveillance. Congressional initiatives and court decisions to modify the administrative procedural process have not reduced the burden on small medical device manufacturers, as they continue to experience delays and find no relief in court.¹⁷¹ Legislative efforts to reform the medical device premarket process have been unsuccessful in making the process less burdensome and have resulted in the FDA receiving more authority and control over the process.

Additionally, the courts have strengthened the FDA's authority through their application of the arbitrary and capricious standard and the *Chevron* doctrine.¹⁷² The *Ivy Sports* decision may have required the FDA to undergo notice and comment procedures when it reclassifies a medical device,¹⁷³ but the notice and comment process as written in FDA regulations appears to only require that the FDA take public comments into "consideration" when drafting an order.¹⁷⁴ The FDA is not required to change a classification decision if the public disagrees with the decision, as demonstrated in the *Contact Lens* case where the

170. Critics of third-party review also express concern that private reviewers will pose a bias based on financial incentives. See Merrill, *supra* note 5, at 1859. Merrill writes:

Critics of third party-review have also focused on the temptation for private reviewers to find products safe and effective in order to attract patrons for their service. The concept presents another kind of potential conflict of interest as well. It seems likely that those who are best equipped to assess the reported results of clinical trials for drugs and devices will be individuals who already perform such tasks for manufacturers of drugs and devices. Some will have had experience at FDA. Few are likely to be free of financial relationships that ordinarily would render them unemployable by FDA, either as consultants or members of advisory committees. If such individuals were eligible to serve as reviewers, safeguards against conflict of interest would be extremely cumbersome or they would collapse entirely.

Id. (footnote omitted).

171. See *supra* Part II.

172. See *supra* Section I.B.4.

173. See *Ivy Sports Med., LLC v. Burwell*, 767 F.3d 81, 86–87 (D.C. Cir. 2014).

174. See 5 U.S.C. § 553(c) (2012).

manufacturer disagreed with the FDA's reclassification decision.¹⁷⁵ As a result, judicial interpretations of FDA regulations, such as that in *Ivy Sports*,¹⁷⁶ have placed an additional burden on small medical device manufacturers because the process now involves more steps rather than fewer. The courts have not made it any easier for manufacturers to bring their innovative devices to market.

A. *Case Law's Tendency to Favor Product Safety Over Efficacy*

The case law interpreting premarket review reflects the importance the courts attach to product and patient safety.¹⁷⁷ However, the case law has been less focused on the importance of efficacy, which further suggests that product safety is the more important component in premarket review. For example, the *Bowen* court emphasized that "the only question under the [FDCA] is whether the *intended use* of the product is to prevent disease, not whether the product *actually* prevents disease."¹⁷⁸ This tends to indicate that whether a device is effective at treating a disease is not as important of an inquiry as whether the manufacturer intends to treat a disease.

B. *The FDA's Goal of Balancing Patient Safety with Device Innovation: Removing Efficacy Will Not Compromise Device Safety*

The premarket process suggests that product safety takes precedence over efficacy requirements. As a consequence, higher-risk devices are considered to have a stronger likelihood of being dangerous¹⁷⁹ because the FDA's premarket

175. See *Contact Lens Mfrs. Ass'n v. Food & Drug Admin.*, 766 F.2d 592, 596–97 (D.C. Cir. 1985).

176. See *Ivy Sports Med., LLC*, 767 F.3d at 87–88.

177. See *Ethicon, Inc. v. Food, & Drug Admin.*, 762 F. Supp. 382, 390 (D.D.C. 1991) ("[T]he evidence showed that a performance standard was not immediately necessary to protect the public health."). See also *Cytori Therapeutics, Inc. v. Food & Drug Admin.*, 715 F.3d 922, 925 (D.C. Cir. 2013) ("[T]he devices had different technological characteristics or posed different safety concerns.").

178. *United States v. Bowen*, 172 F.3d 682, 686 (9th Cir. 1999).

179. See James M. Flaherty, Jr., *Defending Substantial Equivalence: An Argument for the Continuing Validity of the 510(k) Premarket Notification Process*, 63 *FOOD & DRUG L.J.* 901, 923–24 (2008) (discussing the relationship between regulatory burdens in the premarket process and the risk-based nature of the FDA's classification system). See also FRANK, *supra* note 81, at 3. Frank writes:

Due to the risky nature of some of [the] potentially harmful devices, a certain degree of regulation must be attained in relation to the risks inherent in each device. Introducing new (advanced) medical devices to provide better health care improves medical treatment and overall care for patients, and, thus, innovation in the medical device field should be stimulated. However, inflexible and over-strict regulatory demands may hamper medical innovation or drive even medical device manufacturers out of business. Time has shown that unsafe medical devices have the ability to cause harm to the health of individuals.

Id.

classification system is risk-based.¹⁸⁰ The FDA classification system, notably, does not correlate risk and efficacy in the same manner as risk and safety.¹⁸¹ Statutes such as the FDA Modernization Act were enacted to assist manufacturers in getting safe devices to market more quickly.¹⁸²

Additionally, the FDA's classification system and practice of placing all devices into Class III by default illustrates that the system places a strong emphasis on safety. *Bowen* highlighted that safety was a priority for the FDA, given that the agency placed devices into Class III "by operation of law."¹⁸³ Removing efficacy would not affect the weight the FDA places on properly evaluating risk and safety. In fact, removing efficacy would allow the FDA to focus on confirming a device's safety instead of fixating on efficacy requirements, which can be evaluated after implementation into the marketplace. Premarket evaluation standards may not always reduce risk and safety, as medical devices may perform differently once they are on the market.¹⁸⁴ Therefore, postmarket surveillance is an important tool to monitor safety and efficacy.

C. A Less Stringent Premarket Review Process in the EU Indicates That Device Safety is Not Compromised

A strong argument against removing efficacy from premarket regulation is that safety would be compromised because systems that have used a similar approach, such as the process used by the EU, have experienced device recalls.¹⁸⁵

180. Shapiro, *supra* note 26, at 373 (noting that the FDA's "classification determination is based upon a generalized risk assessment of the device type").

181. See *supra* notes 179–80 and accompanying text.

182. See *supra* text accompanying notes 32–34.

183. *United States v. Bowen*, 172 F.3d 682, 687–88 (9th Cir. 1999). According to the Ninth Circuit:

Defendant did not request reclassification before he introduced [the device] into interstate commerce. Therefore, even if FDA had sufficient knowledge of [the device] to determine that it was "safe," [the device] nevertheless would remain a class III device by operation of law. That being so, the FDA's classification was not arbitrary or capricious.

Id. (footnote omitted).

184. James Williams & Jens Weber-Jahnke, *Regulation of Patient Management Software*, 18 HEALTH L.J. 73, 87 (2010) ("In general, even the best manufacturing, engineering, and communications discipline is not sufficient to prevent every form of failure or misuse. In particular, devices that perform well in the laboratory may have different characteristics when they are finally put to use outside of a controlled environment.").

185. See generally Jean-Pierre Boutrand, *EU Medical Device Regulatory Framework: Practical Impact of New Regulations*, N. AM. SCI. ASSOCS., INC. 2–4 (2013), <https://www.namsa.com/wp-content/uploads/2015/10/WP-EU-Medical-Device-Regulatory-Framework.pdf> (discussing how the EU's medical device premarket regulations have resulted in controversies and recalls, along with recent initiatives to improve the process).

The EU's safety and performance standards focus on the manufacturer's intent, revealing that the EU's regulations are more concerned with whether the device serves its intended purpose.¹⁸⁶ In comparison, the FDA's safety and effectiveness standards focus on "clinically significant results," and the FDA's performance standards are only one element that the agency considers when evaluating medical devices.¹⁸⁷ One might assume, then, that the EU's less stringent legal standard of safety and performance would lead to a higher number of unsafe devices on the market.

However, experts suggest that medical devices are statistically safe, regardless of whether they are approved in the United States or the EU.¹⁸⁸ The similar number of recalls indicates that unsafe devices are prevented from entering the market in the United States at a similar rate as in the EU because the EU imposes "a high level of protection of health and safety" in its premarket regulations.¹⁸⁹ However, using a performance standard instead of effectiveness during premarket review would not be a suitable alternative for the FDA. The *Ethicon* court even acknowledged that "Congress knew that FDA could not establish performance standards for the universe of Class II devices, and encouraged FDA to use its discretion to pursue such standards in order of priority" and "that a performance standard was not immediately necessary to protect the public health."¹⁹⁰

Moreover, unlike the EU, the FDA's experience with premarket regulations would allow the agency to anticipate problems that may arise if it shifted efficacy determinations to postmarket surveillance.¹⁹¹ The FDA has the authority to reclassify medical devices that have been cleared based on postmarket clinical data under the Federal Food, Drugs, and Cosmetics Act, which is a common practice for 510(k) devices.¹⁹² Given that the FDA already monitors efficacy

186. See *supra* Section I.B.2.

187. See *supra* notes 47–48 and accompanying text (discussing special controls in Class II devices); 21 C.F.R. § 860.7(e)(1) (2016).

188. Altenstetter, *supra* note 64, at 460–61 (noting that one U.S. lawmaker remarked that "according to recent studies, medical devices [...] are statistically as safe as FDA-cleared or approved devices and have comparable outcomes"). Altenstetter also says that "[an] extensive review of recent literature on the FDA hardly suggests that the FDA's record is superior to that of EU regulation." *Id.*

189. Council Directive 98/79, 1998 O.J. (L 331) 16 (EC).

190. *Ethicon, Inc. v. Food & Drug Admin.*, 762 F. Supp. 382, 390 (D.D.C. 1991).

191. The FDA's premarket regulations have existed since 1976, and the EU introduced premarket regulation starting in the 1990s. See John Y. Chai, *Medical Device Regulation in the United States and the European Union: A Comparative Study*, 55 FOOD & DRUG L.J. 57, 60–61 (2000) (comparing the FDA's premarket regulatory system to the EU's newer premarket regulatory system). See generally FRANK, *supra* note 81, at 239–53 (comparing and contrasting specific components of the FDA's medical device regulatory system to the EU's medical device regulatory system, from both a substantive and institutional view).

192. See Shapiro, *supra* note 26, at 385–86.

requirements in the postmarket surveillance process, shifting premarket efficacy determinations to the postmarket surveillance process would not be a dramatic change.

V. CONCLUSION

Establishing a proper evaluation method to determine when medical devices are safe to enter the market is necessary to ensure that patients have access to safe medical treatment. While Congress and the FDA have attempted to make it less burdensome for small manufacturers to bring innovative devices into the market,¹⁹³ these initiatives are not enough. Litigation surrounding FDA safety and efficacy determinations demonstrates that courts make favorable presumptions for the FDA, making it difficult for small business medical device manufacturers to be successful in a courtroom.¹⁹⁴ By shifting efficacy determinations into the postmarket regulatory system, the FDA can maintain its focus on ensuring that only safe devices make it to market, while removing difficult barriers that manufacturers face under the current premarket review system.¹⁹⁵

193. *See supra* Sections I.A–B.1.

194. *See supra* Section I.C.1–4.

195. *See supra* Part IV.

