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# Changing Our Minds: Reforming the FDA Medical Device Reclassification Process

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## ABSTRACT

The United States Food and Drug Administration's (FDA) initial classification decision regarding a medical device has an enormous impact on the cost and time required—both for the manufacturer and FDA—before the device may enter the market. And, of course, a medical device can do little good for patients prior to market entry. FDA's premarket device-review system has received substantial criticism and calls for reform from politicians, academics, manufacturers, and FDA itself. The system is widely perceived as slow, inefficient, and substantively unpredictable. At the same time, however, another important aspect of the regulatory framework for medical devices has received relatively little attention—the reclassification process. This paper explores FDA's procedures for reclassifying medical devices after market entry and argues that the same problems apparent in the premarket period recur in the postmarket period. Namely, FDA has used its reclassification authority in an infrequent, untimely, and unpredictable manner. This paper proposes various reforms designed to solve these problems and make reclassification a meaningful part of the federal regulatory framework for medical devices, rather than an administrative afterthought. By reviewing approved devices for reclassification on a regular timetable, adopting a clear standard for reclassification, increasing reliance on independent expert panels, and exhibiting greater flexibility in rescinding faulty decisions, FDA can make device reclassification more consistent, more accurate, and more efficient. These reforms will also allow FDA to shift time and money from premarket review to postmarket surveillance, thus permitting innovative new devices to reach consumers at a faster rate.

## INTRODUCTION

Since the middle of the last century, surgeons have used metal or polymeric surgical mesh to "reinforce and support weakened soft tissue or bone."[1] In the 1970s,

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gynecologists first used surgical mesh to treat pelvic organ prolapse, a painful condition in which the tissue separating a woman's pelvic organs collapses.[2] Later, physicians began using surgical mesh—called "transvaginal mesh" in this context—to treat stress urinary incontinence as well.[3] Surgical meshes are Class II medical devices under the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA)[4] and, therefore, receive lesser premarket scrutiny by the U.S. Food and Drug Administration (FDA) than more serious Class III devices.[5] The vast majority of Class II devices that make it to market do so after FDA has concluded, under its 510(k) process, that the device is "substantially equivalent to a predicate device" already available for sale.[6] The first transvaginal meshes designed specifically to treat pelvic organ prolapse and stress urinary incontinence entered the market in the late 1990s, after FDA deemed these products substantially equivalent to older surgical meshes.[7]

The problems appeared quickly. Boston Scientific's ProtoGen Sling device, the first transvaginal mesh cleared via the 510(k) process, was recalled three years after clearance when "it was associated with a high number of complications, including erosion of vaginal tissue."[8] But despite the fact that ProtoGen served as the predicate device for most subsequent meshes, over the next decade, "FDA cleared 168 510(k)s

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[1] William B. Curtis & Michael S. Wilson, *Transvaginal Mesh and the 510(k) Approval Process*, TRIAL, June 2012, at 27, 28. Surgical mesh was originally used "primarily to treat abdominal hernias." *Id.*

[2] *Id.*; *see also Pelvic Organ Prolapse*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGyn SurgicalMesh/ucm262299.htm (last updated Jan. 4, 2016) ("Pelvic organ prolapse (POP) occurs when the tissue and muscles of the pelvic floor no longer support the pelvic organs resulting in the drop (prolapse) of the pelvic organs from their normal position. The pelvic organs include the vagina, cervix, uterus, bladder, urethra, and rectum.").

[3] C. Gavin Shepherd, Comment, *Transvaginal Mesh Litigation: A New Opportunity to Resolve Mass Medical Device Failure Claims*, 80 TENN. L. REV. 477, 477–78 (2013); *see also* Curtis & Wilson, *supra* note 1, at 28 (defining stress urinary incontinence as "a condition resulting primarily from childbirth and pregnancy, in which weakened pelvic muscles allow the urethra to involuntarily leak urine").

[4] Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301–399f (2012)).

[5] U.S. FOOD & DRUG ADMIN., CTR. FOR DEVICES & RADIOLOGICAL HEALTH, UROGYNECOLOGIC SURGICAL MESH: UPDATE ON THE SAFETY AND EFFECTIVENESS OF TRANSVAGINAL PLACEMENT FOR PELVIC ORGAN PROLAPSE 4 (2011), http://www.fda.gov/downloads/MedicalDevices/Safety/Alertsand Notices/UCM262760; *see also infra* Part 0 (explaining the three classifications of medical devices).

[6] *See* INST. OF MED. OF THE NAT'L ACADS., MEDICAL DEVICES AND THE PUBLIC'S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS 85–86 (2011), https://www.nap.edu/read/13150/ chapter/6 (indicating that, from 2003 to 2007, 31% of all devices entered the market through the 510(k) process and that only 5% of Class II devices were approved by other means). Of the 11,690 Class II device submissions the agency reviewed from 2003 to 2007, FDA found 91% to be substantially equivalent. U.S. GOV'T ACCOUNTING OFFICE, MEDICAL DEVICES: FDA SHOULD TAKE STEPS TO ENSURE THAT HIGH-RISK DEVICE TYPES ARE APPROVED THROUGH THE MOST STRINGENT PREMARKET REVIEW PROCESS 17 (2009), http://www.gao.gov/assets/290/284882.pdf.

[7] U.S. FOOD & DRUG ADMIN., SURGICAL MESH FOR TREATMENT OF WOMEN WITH PELVIC ORGAN PROLAPSE AND STRESS URINARY INCONTINENCE 5 (2011) http://www.fda.gov/downloads/Advisory Commitrees/CommitteesMeetingMaterials/MedicalDevices/%20MedicalDevicesAdvisoryCommittee/Obs tetricsandGynecologyDevices/UCM270402.pdf [hereinafter SURGICAL MESH].

[8] Curtis & Wilson, *supra* note 1, at 28; *see also* SURGICAL MESH, *supra* note 7, at 5 (noting that use of transvaginal mesh did not become common until Ethicon, Inc., a Johnson & Johnson subsidiary, introduced the Tension-Free Vaginal Tape System to treat stress urinary incontinence in 1998 and the Gynemesh PS to treat pelvic organ prolapse in 2002).

for surgical mesh with urogynecologic indications."[9] ProtoGen's progeny soon developed complications of their own; from 2005 to 2011, FDA received over 4,000 reports of adverse events attributable to transvaginal mesh.[10] These malfunctions caused incredible suffering among a great many women: "Patients reported that bowel, bladder, and blood vessel perforation, in addition to transvaginal mesh erosion, had led to extreme pain and an overall decrease in patient quality of life."[11] Researchers have estimated that between 10% and 25% of all women who receive a transvaginal mesh implant will experience a mesh erosion event.[12]

FDA first responded to this crisis in 2008 by warning physicians to "[b]e vigilant for potential adverse events from the mesh, especially erosion and infection."[13] In 2011, FDA notified healthcare providers of a "previously unidentified risk," mesh contraction, and warned physicians that transvaginal mesh may actually "introduce[] risks not present in traditional non-mesh surgery."[14] In 2014, FDA proposed to reclassify transvaginal mesh from Class II to Class III,[15] thus "requir[ing] manufacturers to submit a premarket approval . . . application for the agency to evaluate safety and effectiveness."[16] Finally, in January 2016—17 years after the risks of transvaginal mesh first became apparent—FDA issued a final order reclassifying such products to Class III and requiring their manufacturers to undergo the rigorous premarket approval process.[17]

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9 SURGICAL MESH, *supra* note 7, at 6.

10 *See FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence*, U.S. FOOD & DRUG ADMIN. (Oct. 20, 2008), http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ PublicHealth Notifications/ ucm061976.htm [hereinafter *2008 FDA Health Notification*] ("Over the past three years, FDA has received over 1,000 reports from nine surgical mesh manufacturers of complications that were associated with surgical mesh devices used to repair POP and SUI."); *UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse: FDA Safety Communication*, U.S. FOOD & DRUG ADMIN. (July 13, 2011), http://www. fda.gov/ MedicalDevices/Safety/AlertsandNotices/ UCM262435.htm [hereinafter *2011 FDA Health Update*] ("[F]rom Jan. 01, 2008 through Dec. 31, 2010, the FDA received 2,874 additional reports of complications associated with surgical mesh devices . . . .").

11 Shepherd, *supra* note 3, at 480 (citing *2008 FDA Notification*, *supra* note 10).

12 Farnaz A. Ganj et al., *Complications of Transvaginal Monofilament Polypropylene Mesh in Pelvic Organ Prolapse Repair*, 20 INT'L UROGYNECOL J. 919, 919, 923 (2009) (finding a 10.2% erosion rate but noting alternative estimates of 7% and 25%); *see also* Peter S. Finamore, *Risk Factors for Mesh Erosion 3 Months Following Vaginal Reconstructive Surgery Using Commercial Kits vs. Fashioned Mesh-Augmented Vaginal Repairs*, 21 INT'L UROGYNECOL J. 285, 287 (finding an "overall erosion rate [of] 11.3%").

13 *2008 FDA Health Notification*, *supra* note 10 (admonishing physicians to "[o]btain specialized training for each mesh placement technique" and "[i]nform patients about the potential for serious complications . . . , including pain during sexual intercourse, scarring, and narrowing of the vaginal wall").

14 *2011 FDA Health Update*, *supra* note 10 ("FDA conducted a systematic review of the published scientific literature from 1996–2011 . . . . [that] showed that transvaginal POP repair with mesh does not improve symptomatic results or quality of life over traditional non-mesh repair.").

15 Effective Date of Requirement for Premarket Approval for Surgical Mesh for Transvaginal Pelvic Organ Prolapse Repair, 79 Fed. Reg. 24,642 (proposed Mar. 1, 2014) (codified at 21 C.F.R. § 884.5980).

16 *FDA Issues Proposals to Address Risks Associated with Surgical Mesh for Transvaginal Repair of Pelvic Organ Prolapse*, U.S. FOOD & DRUG ADMIN. (Apr. 29, 2014), http://www.fda.gov/NewsEvents/ Newsroom/ PressAnnouncements/ucm395192.htm.

17 *FDA Strengthens Requirements for Surgical Mesh for the Transvaginal Repair of Pelvic Organ Prolapse to Address Safety Risks*, U.S. FOOD & DRUG ADMIN. (Jan. 4, 2016), http://www.fda.gov/

This 17-year delay exemplifies the broader deficits in speed, accuracy, and consistency that plague the American medical-device regulatory system. FDA's initial classification decision regarding a medical device has an enormous impact on the cost and time required—both for the manufacturer and FDA—before the device may enter the market.[18] But FDA may also, "[b]ased on new information respecting a device, . . . change the classification of such device" after it has entered the market.[19] This reclassification procedure aims to inject flexibility into the otherwise-rigid statutory classification framework, thus permitting FDA to modify its original decision "[a]s experience and knowledge about a device increase."[20] Yet, as the transvaginal mesh episode reveals, FDA has often failed to exercise its reclassification authority in a timely manner. FDA has also used this power only sparingly—from 2013 to 2016, FDA reclassified a mere 16 devices,[21] in contrast to the "thousands of submissions for new devices" FDA receives and reviews each year.[22] And of those 16 reclassified decisions, only two increased the device's classification to a higher tier.[23] Moreover, while the Food and Drug Administration Safety and Innovation Act of 2012 changed device reclassification from a rulemaking to an administrative-order process to promote speed and efficiency,[24] reclassification remains slow and sporadic. Worse, FDA's reclassification decision-

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NewsEvents/Newsroom/ PressAnnouncements/ucm479732.htm; *see also* 21 C.F.R. § 884.5980(a), (b) (2016) (classifying "[s]urgical mesh for transvaginal pelvic organ prolapse repair" as "Class III (premarket approval)").

[18] *See* Medtronic, Inc. v. Lohr, 518 U.S. 470, 478–79 (1996) ("[I]n contrast to the 1,200 hours necessary to complete a [premarket approval] review, the § 510(k) review is completed in an average of only 20 hours."); JOSH MAKOWER, FDA IMPACT ON U.S. MEDICAL TECHNOLOGY INNOVATION: A SURVEY OF OVER 200 MEDICAL TECHNOLOGY COMPANIES 7 (2010), http://www.medtecheurope.org/sites/default/files/resource_items/files/01112010_FDA%20impact%20on%20US%20medical%20technology%20innovation_Backgrounder.pdf (finding that "the average total cost for participants to bring a low- to moderate-risk 510(k) product from concept to clearance was approximately $31 million," while "[f]or a higher-risk PMA [postmarket approval] product, the average total cost from concept to approval was approximately $94 million").

[19] 21 U.S.C. § 360c(e)(1)(A)(i) (2012); *see also infra* Part 0.

[20] *Reclassification*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm378724.htm (last updated July 26, 2016).

[21] *Id.*

[22] U.S. GOV'T ACCOUNTING OFFICE, MEDICAL DEVICES: FDA'S PREMARKET REVIEW AND POSTMARKET SAFETY EFFORTS 1 (2011), http://www.gao.gov/assets/130/126013.pdf.

[23] *Reclassification*, *supra* note 20. The first such device was sunlamps used in tanning beds, which FDA reclassified from Class I to Class II in 2014. General and Plastic Surgery Devices: Reclassification of Ultraviolet Lamps for Tanning, 79 Fed. Reg. 31,205, 31,212 (June 2, 2014) (codified at 21 C.F.R. § 878.4635). The second such device was transvaginal mesh, which FDA reclassified from Class II to Class III in 2016. *See supra* note 17 and accompanying text.

[24] Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, § 608, 126 Stat. 993, 1055–56 (2012) (codified at § 360c(e)(1)) ("Based on new information respecting a device, [FDA] may . . . change the classification of [a] 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 . . . ." (emphasis added)).

making is inconsistent and difficult to predict,[25] due in large part to the vagueness of the "valid scientific evidence" standard that governs classification changes.[26]

This paper proposes various reforms designed to solve these problems and make reclassification a meaningful part of the federal regulatory framework for medical devices, rather than an administrative afterthought. By reviewing approved devices for reclassification on a regular timetable, adopting a clear standard for reclassification, increasing reliance on independent-expert panels, and exhibiting greater flexibility in rescinding faulty decisions,[27] FDA can make device reclassification more consistent, more accurate, and more efficient.[28] These reforms will also allow FDA to shift time and money from premarket review to postmarket surveillance, thus permitting innovative new devices to reach consumers at a faster rate.[29]

This paper proceeds in six parts. Part II first discusses the historical development of FDA's regulatory powers and explains the three-tiered classification system under the Medical Device Amendments (the MDA) of 1976.[30] The paper then describes the premarket approval, notification, and exemption requirements that attach to each of the classifications and concludes with a discussion of FDA's postmarket reclassification process. Next, Part III provides an overview of federal litigation arising out of FDA's reclassification decisions, including an explanation of the arbitrary and capricious standard of review courts apply to FDA decisions. The paper also examines several notable cases that illustrate both the slow pace and substantive unpredictability of FDA's reclassification decisions. Part IV then reviews the major policy goals of the device classification system—namely, ensuring safety and efficacy in new devices, increasing the speed of market entry, responding promptly to public health crises, and producing consistent and predictable results. Part V applies these policy objectives to the current state of the FDA reclassification system, proposing several substantive and procedural reforms. Finally, Part VI concludes by considering the broader implications of the paper's argument for the state of American medical-device regulation.

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[25] *See infra* Part 0 (describing divergent outcomes in cases arising out of FDA reclassification decisions).

[26] § 360c(e)(1)(A)(i); *see also* 21 C.F.R. § 860.7(c) (2016) (providing more detail on the *types* of data that constitute "valid scientific evidence," but failing to specify the *quantum* or *quality* of such evidence necessary to warrant reclassification).

[27] *See infra* Part 0 (outlining proposals for reform).

[28] *See infra* Part 0 (explaining the policy goals of the device classification system).

[29] Many commentators have argued that, to reduce the significant backlog of device submissions and increase the speed of the agency's review, FDA should shift resources from the premarket to the postmarket period. *See, e.g.*, 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, 379 (2011) (arguing for "the elimination of both the 510(k) and PMA processes as part of a sweeping overhaul of FDA's current scheme" for premarket regulation). Indeed, FDA itself has recognized the need to "strike the right balance between premarket and postmarket data collection." *See* U.S. FOOD & DRUG ADMIN., CTR. FOR DEVICES & RADIOLOGICAL HEALTH, 2014–2015 STRATEGIC PRIORITIES 7–8 (2014), http://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhvisionandmission/ucm384576.pdf.

[30] Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C. ch. 9).

## II. FEDERAL REGULATION OF MEDICAL DEVICES

This Part provides a broad overview of the regulatory framework for medical devices under federal law, from the historical development of FDA's power to regulate devices, to the current classification and reclassification systems under the MDA.

### *A. History of Medical-Device Regulation in the United States*

FDA's authority to "require advance approval for new medical products" is "the product of incremental changes in the statutory regime" over the past century.[31] Prior to the twentieth century, drug and medical device manufacturers bore no obligation under federal law to provide any assurance of the safety, efficacy, or quality of their products.[32] Although the federal government first undertook the task of regulating drugs early in the 1900s, FDA would not gain full-fledged authority to review medical devices prior to market entry until 1976.[33]

#### *1. Pre-1976 Regulation of Medical Devices*

The first steps toward filling this regulatory void came at the turn of the century with the Biologics Control Act of 1902[34] and the Pure Food and Drug Act of 1906.[35] The latter Act made it a crime to manufacture any "adulterated or misbranded" drug, defined as one bearing false or misleading statements regarding its identity, strength, quality, purity, or ingredients.[36] In *United States v. Johnson*, however, the Supreme Court severely limited the utility of the Act by construing it as "aimed not at all possible false statements, but only at such as determine the identity of the article."[37] Thus, a drug was misbranded if it falsely claimed to possess ingredient *X* but not if it claimed to cure ailment *Y*, without any evidence to that effect.[38]

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[31] Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1757–58 (1996).

[32] Kyle Lennox, Note, *Substantially Unequivalent: Reforming FDA Regulation of Medical Devices*, 2014 U. ILL. L. REV. 1363, 1370 (2014) ("Many remedies . . . for various ailments were not actually tested for their safety or effectiveness and were generally sold without guarantee of their safety, quality, or proven benefit.").

[33] *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, 743 (2012) ("Early medical devices did not present complex or serious patient risks. Medical devices circa 1906 . . . were essentially acute use products that worked by obvious and simple mechanical processes. . . . [But b]eginning in the 1960s, there was increasing attention on the need to enhance the regulatory oversight of medical devices." (footnotes omitted)).

[34] Biologics Control Act, Pub. L. No. 57-244, 32 Stat. 728 (1902) (codified as amended at 42 U.S.C. § 262 (2012)). This statute provided for limited premarket regulation of "vaccines and other arcane biological products . . . that Congress did not emulate for drugs generally until 1962." Merrill, *supra* note 31, at 1758 n.10. The Biologics Control Act was largely overshadowed, however, by the passage of the Pure Food and Drug Act four years later. *See id.*

[35] Pure Food and Drug Act, Pub. L. No. 59-384, 34 Stat. 768 (1906) (repealed 1938).

[36] *Id.* §§ 7–8, 34. Stat. at 769–70.

[37] 221 U.S. 488, 497 (1911).

[38] Merrill, *supra* note 31, at 1759.

"By the 1930s it was widely recognized that the [Pure Food and Drug Act] of 1906 was obsolete . . . ."[39] In 1938, spurred by public outcry over the Elixir Sulfanilamide disaster,[40] Congress passed the FDCA,[41] the "first federal regulation to require testing and proof of a drug's safety before allowing its release into the market."[42] The FDCA prohibited drug manufacturers from introducing any "new drug" into interstate commerce without first filing with FDA an application containing, among other things, "full reports of investigations which have been made to show whether or not such drug [was] safe for use."[43] If FDA determined that the submitted evidence was insufficient to prove the drug's safety, it could deny the application.[44] Further, while the FDCA did not require proof of a drug's efficacy before market entry, the law nullified *Johnson* by defining misbranding to include "labeling [that was] false or misleading in any particular."[45] Because the relevant standard was now whether "the product in fact worked as its label claimed[,] . . . . [i]t became common for manufacturers to consult with the agency" regarding the drug's efficacy.[46] By contrast, while the FDCA technically granted FDA jurisdiction over medical devices in addition to drugs, "this regulation was limited to ensuring that devices were not adulterated or misbranded."[47]

The lack of express statutory authority to regulate medical devices before market entry led FDA to classify some devices as "drugs" under the FDCA.[48] Congress approved this workaround in the Drug Amendments of 1962,[49] which allowed FDA to regulate certain devices—e.g., contact lenses and sutures—"under a broad definition of 'drugs.'"[50] But this authority was limited in scope, and thus "[t]he

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[39] Carol Ballentine, *Taste of Raspberries, Taste of Death: The 1937 Elixir Sulfanilamide Incident*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/Sulfanilamide Disaster/default.htm (last updated Oct. 7, 2010).

[40] In 1937, more than one hundred people died after ingesting a new liquid form of sulfanilamide, a drug "widely used and shown to be effective in tablet and powder form" for treating streptococcal infections. Lennox, *supra* note 32, at 1371. No law required the manufacturer to perform safety tests before marketing its elixir, and sulfanilamide "turned out to be a deadly poison" as a liquid. *Id.*; *see generally* Ballentine, *supra* note 39 (recounting the history of the Elixir Sulfanilamide disaster and the federal government's response).

[41] Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301–399f (2012)).

[42] Karen Baswell, Note, *Time for a Change: Why the FDA Should Require Greater Disclosure of Differences of Opinion on the Safety and Efficacy of Approved Drugs*, 35 HOFSTRA L. REV. 1799, 1809 (2007).

[43] Federal Food, Drug, and Cosmetic Act of 1938 § 505(a)–(b), 52 Stat. at 1052.

[44] *Id.* § 505(d), 52 Stat. at 1052.

[45] *Id.* § 502(a), 52. Stat. at 1050.

[46] Merrill, *supra* note 31, at 1763.

[47] Burgunda V. Sweet, *Review of the Processes for FDA Oversight of Drugs, Medical Devices, and Combination Products*, 17 J. MANAGED CARE PHARMACY 40, 40 (2011).

[48] Lennox, *supra* note 32, at 1377 (citing PETER BARTON HUTT ET AL., FOOD AND DRUG LAW 969 (3d ed. 2007)) (noting that the appearance of "several 'quack' devices and a revolution in biomedical technology" in the postwar years forced FDA to classify certain devices as drugs).

[49] Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (codified as amended in scattered sections of 21 U.S.C. ch. 9).

[50] 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, 904 (2008); *see also*

majority of medical devices . . . remained unregulated by FDA" prior to market entry.[51] The Amendments also altered the FDCA to require drug (and certain device) manufacturers to prove not just the safety of new products, but also their effectiveness in accomplishing their intended uses.[52] This "effectiveness requirement dramatically expanded the scope of the new drug approval process" by making FDA "responsible for judging, on the basis of evidence that it prescribed and makers supplied, whether new drugs worked."[53]

### *2. Post-1976 Regulation of Medical Devices*

Congress finally brought devices fully within the regulatory fold with the passage of the Medical Device Amendments of 1976.[54] Discussed more fully in Parts II.B and II.C, *infra*, the MDA arose largely in response to the massive controversy surrounding the Dalkon Shield, "a defectively designed contraceptive that injured thousands of women."[55] First, the MDA abrogated FDA's devices-as-drugs workaround by defining "device" broadly as any:

> instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or . . . intended to affect the structure or any function of the body of man or other animals . . . .[56]

Further, the MDA created a three-tiered classification structure for medical devices, with increasing levels of FDA "controls" for each class.[57] The MDA also established differing grades of FDA scrutiny required before a device can enter the market—the rigorous premarket approval process, the less burdensome 510(k) premarket notification process, and total exemption.[58]

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*United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969) (affirming regulation of devices under the 1962 Amendments because Congress intended the term "drug" to have a meaning "broader than any strict medical definition").

[51] Flaherty, *supra* note 50, at 904.

[52] *See* Drug Amendments of 1962 § 102(a)(1), 76 Stat. at 781.

[53] Merrill, *supra* note 31, at 1765, 1767.

[54] Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C. ch. 9).

[55] Jenéa M. Reed, Note, *In the Shadows of* Lohr*: The Disconnect within the Supreme Court's Preemption Jurisprudence in Medical Device Liability Cases*, 64 U. MIAMI L. REV. 305, 308 (2009). Congressional debate over the MDA focused heavily on the harm caused by the Dalkon Shield. *See, e.g.*, S. REP. NO. 94-33, at 2 (1975) ("[M]any of the deaths and much of the illness attributed to this device could have been prevented if medical device legislation . . . had been in effect when the Dalkon shield was developed."). Over 300,000 women sued the device's manufacturer, A.H. Robbins, over the next decade; indeed, "[f]rom 1974–1986, half of all product liability lawsuits filed in federal courts in the United States against pharmaceutical manufacturers were filed against A.H. Robins with respect to . . . the Dalkon Shield." Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 MO. L REV. 895, 911 n.84 (1994).

[56] Medical Device Amendments of 1976 § 3(a)(1)(A), 90 Stat. at 575 (codified at 21 U.S.C. § 321(h)).

[57] Hall & Mercer, *supra* note 33, at 745–46.

[58] *See* 21 U.S.C. § 360c(a) (2012) (describing the three classifications and corresponding levels of review).

Next, the Safe Medical Devices Act of 1990 required "device user facilities"—i.e., hospitals, ambulatory surgical centers, nursing homes, and outpatient facilities[59]—to report to FDA any "information that reasonably suggests that there is a probability that a device has caused or contributed" to a patient's death or serious injury.[60] A corresponding reporting duty exists for device manufacturers and importers.[61] The Act also clarified that the 510(k) path to market entry requires proof of "substantial equivalence" to a predicate device, i.e., "that a proposed device has the same intended use and technological characteristics as a device already in the market."[62]

Furthermore, the FDA Modernization Act of 1997[63] attempted to aid FDA in its goal of "streamlining the process and . . . reduc[ing] a vexing backlog of 510(k) submissions that had developed" over the past decade.[64] The Act exempts most Class I devices from 510(k) premarket notification, so long as the device is not "intended for a use which is of substantial importance in preventing impairment of human health" and does not "present[] a potential unreasonable risk of illness or injury."[65] The Act also permitted FDA to exempt Class II devices from premarket notification when such review is unnecessary to ensure safety and effectiveness.[66]

Finally, the FDA Safety and Innovation Act of 2012[67] aspired to "expedite the overall medical device approval process."[68] In addition to empowering FDA to collect fees from the device industry to fund premarket and postmarket review,[69] Congress also "gave FDA the authority to alter device classification by administrative order rather than regulation, which should speed the process."[70] Whether the Act has proven successful in that regard remains doubtful.[71]

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[59] Safe Medical Devices Act of 1990, Pub. L. No. 101-629, § 2(a), 104 Stat. 4511, 4512 (codified as amended in scattered sections of 21 U.S.C. ch. 9).

[60] 21 U.S.C. § 360i(b)(1)(A)–(B) (2012).

[61] § 360i(a)(1).

[62] Stephanie P. Fekete, 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 Efficacy*, 65 CATH. U. L. REV. 605, 609 (2016); *see also infra* Part 0 (discussing substantial equivalence review and premarket notification in greater detail).

[63] Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (codified as amended at 21 U.S.C. § 301 (2012)).

[64] Jeffrey K. Shapiro, *Substantial Equivalence Premarket Review: The Right Approach for Most Medical Devices*, 69 FOOD & DRUG L.J. 365, 369–70 (2014) (noting that FDA had implemented a number of administrative reforms itself in 1996, which Congress supplemented with the 1997 Modernization Act).

[65] FDA Modernization Act of 1997 § 206, 111 Stat. at 2339.

[66] Notice: Medical Devices; Exemptions from Premarket Notification; Class II Devices, 63 Fed. Reg. 3142, 3143 (Jan. 21, 1998).

[67] Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, 126 Stat. 993 (2012).

[68] Fekete, *supra* note 62, at 622; *see also* FDA Safety and Innovation Act § 201(b), 126 Stat. at 1002 (finding that "the fees authorized under [the Act] will be dedicated toward expediting the process for the review of device applications and for assuring the safety and effectiveness of devices").

[69] FDA Safety and Innovation Act § 203, 126 Stat. at 1002–04.

[70] Shapiro, *supra* note 64, at 367 n.21.

[71] *See Reclassification*, *supra* note 20 (indicating that FDA has only reclassified sixteen devices over the past four years—with only two up-classifications—and has done so at a slow pace).

### *B. Overview of the Medical Device Classification System*

The MDA separates medical devices into Classes I, II, and III and sets out general controls, special controls, and premarket approval requirements for each, respectively.[72] Generally, "Class III [is] the default category for new (that is, post-1976) medical devices, unless and until FDA finds that one of two conditions has been met."[73] First, FDA may find that the device is "substantially equivalent" to another device—a "predicate device"—that FDA has already designated as Class I or II.[74] A new device is substantially equivalent to a predicate device if the two have the same intended use and either (1) share "the same technological characteristics," or (2) differ in such characteristics but raise the same "questions of safety and effectiveness."[75] Alternatively, "FDA may make a de novo determination that a device meets the statutory definitions of Class I or II,"[76] whether on its own initiative or after receiving a reclassification petition from the device's manufacturer.[77]

#### *1. Class I: General Controls*

Class I devices are those for which the MDA's "general controls" are "sufficient to provide reasonable assurance of the safety and effectiveness of the device."[78] Such general controls include the statutory protections regarding adulteration, misbranding, device registration, banned devices, notification, recording and reporting requirements, and other remedies.[79] These controls apply broadly to all devices—regardless of classification—but Class I devices generally receive *only* these protections.[80] This tier also encompasses devices that, while lacking sufficient information that general controls will reasonably ensure safety and effectiveness, both: (1) are not purported to support or sustain human life or be of "substantial importance in preventing impairment of human health"; and (2) present no "potential unreasonable risk of illness or injury."[81] Class I devices include adhesive bandages, tongue depressors, surgical gloves, and similar products.[82]

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[72] 21 U.S.C. § 360c(a)(1) (2012); *see also* Jordan Bauman, *The "Déjà Vu Effect": Evaluation of United States Medical Device Legislation, Regulation, and the Food and Drug Administration's Contentious 510(k) Program*, 67 FOOD & DRUG L.J. 337, 342–44 (2012) (describing the three tiers of medical devices in detail).

[73] Ivy Sports Med., LLC v. Burwell, 767 F.3d 81, 83 (D.C. Cir. 2014) (citing § 360c(f)(1)).

[74] § 360c(f)(1)(A)(i)–(ii).

[75] § 360c(i)(1)(A)(i)–(ii).

[76] *Ivy Sports Med.*, 767 F.3d at 83.

[77] § 360c(f)(2)–(3).

[78] § 360c(a)(1)(A)(i).

[79] 21 C.F.R. § 860.3(c)(1) (2016) (defining Class I devices).

[80] *See* Flaherty, *supra* note 50, at 905 n.37 ("[T]he MDA provided that all devices be subject to 'general controls' including, but not limited to, misbranding and adulteration provisions and good manufacturing practices (GMPs)." (citing HUTT, *supra* note 48, at 980)).

[81] § 360c(a)(1)(A)(ii)(I)–(II). Congress conferred Class I status on this additional group of devices under the Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 206, 111 Stat. 2296, 2339 (codified as amended at 21 U.S.C. § 301 (2012)).

[82] *Overview of Medical Devices and Their Regulatory Pathways*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm203018.htm (last updated Nov. 27, 2015) [hereinafter *Overview of Medical Devices*].

Formerly, all Class I devices were subject to 510(k)[83] "premarket notification," a procedure under which the device manufacturer must file a notification with FDA at least ninety days before introducing a device intended for human use into interstate commerce.[84] But because Class I devices present relatively few risks to human health or safety, "FDA has exempted most Class I and select Class II devices from premarket notification review."[85]

### *2. Class II: Special Controls*

Class II devices are those for which "[1] general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which [2] there is sufficient information to establish special controls to provide such assurance."[86] Such special controls may include performance standards, postmarket surveillance, recommendations, guidelines, and patient registries.[87] Congress originally intended for performance standards—"generic rules prescribing the key features and essential characteristics of all products of the type"—to serve as the main safeguards for the safety and effectiveness of Class II devices.[88] Over time, however, Congress and FDA realized that such standards "were too confining, too hard to develop, and could not address changing technology."[89] Thus, FDA has come to rely more on 510(k) substantial-equivalence review to ensure safety and effectiveness for Class II devices.[90] Examples of such devices are contact lenses, infusion pumps, powered wheelchairs, and CT scanners.[91]

In contrast to Class I devices, "nearly all Class II devices are required to fulfill FDA's 510(k) premarket notification requirement."[92] The dispositive question for most 510(k) submissions is whether the new device is substantially equivalent to a device already cleared and available for sale.[93] FDA's 510(k) decision-making has

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[83] Although the requirements for premarket notification are now codified at 21 U.S.C. § 360(k) (2012), such review is commonly termed the "510(k) process," in reference to section 510(k) of the original MDA. *See, e.g.*, Medtronic, Inc. v. Lohr, 518 U.S. 470, 478 (1996).

[84] 21 C.F.R. § 807.81(a) (2016); *see also* 21 C.F.R. § 807.87 (2016) (specifying the required contents of a premarket notification submission, including the device name, the owner's establishment registration number, the device class and classification panel, actions taken to comply with any performance standards, proposed labeling, and information supporting any claim of substantial equivalence to a predicate device).

[85] Scott, *supra* note 29, at 377–78.

[86] § 360c(a)(1)(B).

[87] *Id.*

[88] Merrill, *supra* note 31, at 1809; *see also* 21 U.S.C. § 360d(a)(2)(A)–(C) (2012) (providing that a device's performance standard must: (A) include "provisions to provide reasonable assurance of its safe and effective performance"; (B) contain, where necessary to provide such assurance, provisions respecting the device's construction, components, properties, and power systems, as well as measurement and results standards for testing the device; and (C) "where appropriate, require the use and prescribe the form and content of labeling for the proper installation, maintenance, operation, and use of the device").

[89] Hall & Mercer, *supra* note 33, at 744.

[90] *See id.*

[91] *Overview of Medical Devices*, *supra* note 82.

[92] Scott, *supra* note 29, at 380–81.

[93] Lennox, *supra* note 32, at 1381 ("[T]he majority of medical devices are *cleared* by the FDA for human use, rather than *approved* by the FDA like drugs. To be cleared, a device must be 'substantially

attracted significant criticism. From 2003 to 2007, for example, FDA reviewed 13,199 Class I and II submissions and 342 Class III submissions through the 510(k) process, clearing 90% and 67%, respectively.[94] Indeed, "98[%] of the estimated 5,000 devices that enter the market every year do so on the basis of" substantial equivalence.[95] Commentators[96] and government agencies[97] have widely argued that the ubiquity and relative ease of premarket notification diminishes the likelihood that new devices are reasonably safe and efficient.

### *3. Class III: Premarket Approval*

The greatest FDA scrutiny is reserved for Class III devices. Class III devices are those that lack sufficient evidence that general or special controls alone would reasonably assure safety and effectiveness, and that either: (1) are "represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health"; or (2) present "a potential unreasonable risk of illness or injury."[98] Class III includes such devices as pacemakers, breast and cochlear implants, and (as of 2016) certain surgical meshes.[99] Such devices must undergo the onerous premarket approval (PMA) process, unless deemed substantially equivalent under the alternative 510(k) process.[100] The former "generally requires extensive clinical research on a new device to ensure the device's safety, and it often takes significant time."[101]

The differences in administrative burden between premarket approval and premarket notification, both for FDA and the manufacturer, are stark. FDA's average review times for 510(k) and PMA submissions are 20 hours and 1200 hours, respectively.[102] Moreover, these numbers "understate the length of the total review process" because "FDA does not consider the statutory clock to start ticking until a

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equivalent' to a predicate device; to be approved, the applicant must provide a 'reasonable assurance' of the device's safety and effectiveness." (emphasis added) (footnote omitted)).

94 U.S. GOV'T ACCOUNTING OFFICE, *supra* note 6, at 6.

95 H.R. REP. NO. 101-808, at 14 (1990).

96 *See, e.g.*, Jonas Zajac Hines et al., *Left to Their Own Devices: Breakdowns in United States Medical Device Premarket Review*, 7 PLOS MED. 1, 6 (2010) (arguing that FDA should strengthen premarket device review by, *inter alia*, "insisting on higher scientific standards" and "tightening the interpretation of 'same intended use'"); Lennox, *supra* note 32, at 1394; Scott, *supra* note 29, at 379.

97 *See, e.g.*, INST. OF MED. OF THE NAT'L ACADS., *supra* note 6, at 196 (finding that the 510(k) process fails to accomplish its goals and recommending that the process 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"); U.S. GOV'T ACCOUNTING OFFICE, *supra* note 6, at 28 (finding that "a significant number of class III devices—including device types that FDA has identified as implantable; life sustaining; or posing a significant risk to the health, safety, or welfare of a patient—still enter the market through the less stringent 510(k) process").

98 21 U.S.C. § 360c(a)(1)(C)(i)–(ii) (2012).

99 *Overview of Medical Devices*, *supra* note 82; *see also* 21 C.F.R. § 884.5980(a), (b) (2016) (classifying surgical meshes intended for pelvic organ repair under Class III).

100 21 C.F.R. § 860.3 (2016) (defining Class III as "the class of devices for which premarket approval is or will be required").

101 Cytori Therapeutics, Inc. v. FDA, 715 F.3d 922, 923 (D.C. Cir. 2013).

102 Medtronic, Inc. v. Lohr, 518 U.S. 470, 478–79 (1996) (citing *Hearings Before the Subcomm. on Health and the Env't of the H. Comm. on Energy & Commerce*, 100th Cong. 384 (1987)).

complete [application] has been filed."[103] And the PMA process is three times more expensive for manufacturers than the 510(k) process, with average PMA expenditures approaching $100 million in 2010.[104] As such, manufacturers have a strong incentive to claim 510(k) substantial equivalence and avoid the rigors of the PMA process. Indeed, given FDA's high rate of affirmative substantial-equivalence determinations, manufacturers are statistically more likely than not to prevail in that effort.[105]

### *C. Reclassifying Devices after Market Entry*

The MDA also empowers FDA to reclassify a device after its initial clearance for sale:

> Based on new information respecting a device, [FDA] may, upon the initiative of [FDA] 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 under [21 U.S.C. §§ 360d, 360e (2012)] with respect to such device, by administrative order . . . .[106]

FDA must satisfy three procedural conditions to reclassify a device: The agency must (1) publish a proposed reclassification order in the *Federal Register*; (2) convene a "device classification panel" to study the proposal; and (3) receive and consider public comments.[107] FDA *may* voluntarily initiate this process either of its own accord or "in response to a request for change in classification based upon new information."[108] Alternatively, if an "interested person" files a reclassification petition, FDA *must* respond to the petition affirmatively or negatively within 180 days.[109]

If FDA elects to pursue reclassification, its proposed order must contain "a substantive summary of the valid scientific evidence" supporting its decision.[110] This summary must address both (1) the device's public health benefits and incidence of risk, and (2) why the types of controls that apply to new classification tier will more appropriately ensure the safety and effectiveness of the device.[111] FDA regulations specify the types of studies that can produce "valid scientific evidence," i.e., "well-

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[103] Jonathan S. Kahan, *Premarket Approval versus Premarket Notification: Different Routes to the Same Market*, 39 FOOD DRUG COSM. L.J. 510, 518 (1984). Kahan provides a helpful example: "FDA has, on average, taken less than four months to accept 510(k) notifications for pacemakers. However, for the more sophisticated models, which have not successfully claimed substantial equivalence, it has taken from [ten] to [eighteen] months to gain PMA approval." *Id.*

[104] MAKOWER, *supra* note 18, at 7.

[105] *See* U.S. GOV'T ACCOUNTING OFFICE, *supra* note 6, at 6.

[106] 21 U.S.C. § 360e(1)(A)(i) (2012).

[107] *Id.*

[108] 21 C.F.R. § 860.130(b)(1)–(2) (2016).

[109] § 860.130(b)(3), (e). The ambit of the term "interested person" is quite broad: Beyond the device manufacturer or its competitors, private citizens and unaffiliated organizations may also file "Citizen Petitions," asking FDA to reconsider its decisions. *See* Int'l Acad. of Oral Med. & Toxicology v. FDA, —F. Supp. 3d—, No. 14-356 (JEB), 2016 WL 3659887, at *3 (D.D.C. July 1, 2016).

[110] 21 U.S.C. § 360c(e)(1)(A)(i) (2012).

[111] § 360c(e)(1)(A)(i)(I)–(III).

controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device."[112] As for the safety requirement, this evidence must demonstrate that "the probable benefits to health from use of the device for its intended uses . . . outweigh any probable risks."[113] And as for the efficacy requirement, this evidence must prove that, "in a significant portion of the target population, the use of the device for its intended uses . . . will provide clinically significant results."[114] FDA regulations also list various other principles of reliable investigation.[115]

Notably, these regulations make no attempt to specify the types of studies or the quantum of evidence necessary for any particular reclassification decision. For example, while well-established clinical investigations may produce valid scientific evidence, clinical trials are generally unnecessary for FDA clearance of Class I and Class II devices.[116] Yet § 860.7 provides scant detail on the relevant scientific standards for other types of investigations.[117] More importantly, these regulations never attempt to establish an independent evidentiary standard for reclassification decisions, i.e., a standard distinct from FDA's general guidelines for classifying devices in the first instance.[118]

To reclassify a medical device, FDA is also required to consult with an advisory panel of experts regarding the reclassification petition.[119] The panel members must be "qualified by training and experience to evaluate the safety and effectiveness of the device[] . . . and [must], to the extent feasible, possess skill in the use of, or experience in the development, manufacture, or utilization of, such device[]."[120] FDA must distribute the reclassification petition to the panel members and consult with them in one of three ways: (1) telephone conversation with at least a majority of voting panel members; (2) conversation by mail with at least a majority of voting panel members; or (3) in-person discussion at a panel meeting, "[w]hen time and

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[112]21 C.F.R. § 860.7(c)(2) (2016).

[113]§ 860.7(d)(1).

[114]§ 860.7(e)(1).

[115]For example, § 860.7(f) lists "the essentials of a well-controlled clinical investigation," e.g., a clear statement of objectives, reliable methods of subject selection, an explanation of observation methods, comparison with a control group, and use of a standardized test device. But "well-established clinical investigations" are but one of many possible sources of valid scientific evidence, *see* § 860.7(c)(2), and the regulations provide no similar standards for other types of studies.

[116]*See, e.g.*, Phillips v. Stryker Corp., No. 3:09–CV–488, 2010 WL 2270683, at *4 (E.D. Tenn. June 3, 2010) ("Class III devices must undergo clinical trials and be approved by the FDA before they can be sold on the market."); Curtis & Wilson, *supra* note 1, at 28 ("If the FDA finds that a potential Class II device is substantially equivalent to a device it has already approved, the agency permits the marketing and sale of the new device without requiring clinical tests."); Fekete, *supra* note 62, at 611–12 (noting that a "PMA submission requires the device manufacturer to provide the FDA with the most substantial amount of information, including underlying clinical studies").

[117]*See* Kahan, *supra* note 103, at 512 (contrasting the "fair amount of research [that] must be done to generate the necessary data for a PMA" with the much simpler 510(k) process).

[118]*See* 21 C.F.R. §§ 860.1–860.7 (2016); *see also infra* Part 0 for a discussion of the problems inherent in this oversight.

[119]21 U.S.C. § 360c(e)(1)(A)(i) (2012).

[120]§ 360c(b)(2). Furthermore, "[n]o individual who is in the regular full-time employ of the United States and engaged in the administration of [the MDA] may be a member of any panel." *Id.*

circumstances permit."[121] Although FDA must publish the panel's recommendation in the *Federal Register*,[122] the agency is free to disregard the recommendation, so long as it explains its reasons for doing so.[123]

## III. LITIGATING FDA'S DEVICE CLASSIFICATION AND RECLASSIFICATION DECISIONS

Because much of FDA's decision-making under the regulatory framework just discussed "is a matter of judgment rather than law,"[124] substantial litigation over FDA's device classification and reclassification decisions is inevitable. This Part first explains the deferential standard of review that courts apply to FDA's classification decisions. The paper then briefly discusses several notable cases analyzing such decisions in an effort to illustrate both the slow pace and substantive inconsistency of FDA's classification decision-making.

### *A. The Arbitrary and Capricious Standard of Review*

Device manufacturers and other interested parties may challenge FDA's classification and reclassification decisions in court.[125] Under the Administrative Procedure Act, federal courts must set aside FDA decisions that are, among other things, "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[126] The Ninth Circuit, for example, has defined the arbitrary and capricious standard of review as follows:

A decision is arbitrary and capricious if the 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."[127]

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[121] 21 C.F.R. § 860.125(a)–(b) (2016). Of these three options, "[t]he method of consultation chosen by [FDA] will depend upon the importance and complexity of the subject matter involved." *Id.*

[122] § 360c(d)(1).

[123] § 360c(b)(7).

[124] *See* Hines et al., *supra* note 96, at 6 (arguing that FDA should insist on "more-rigorous review procedures where the optimal review pathway" is left to the agency's discretion).

[125] *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. . . . Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section whether or not there has been presented or determined an application for a declaratory order, for any form of reconsideration, or, unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative, for an appeal to superior agency authority."); *see also* CART T. DEMARCO, MEDICAL DEVICE DESIGN AND REGULATION 24 (2011) ("Under their constitutional authority, the courts have the final say on whether FDA, in any particular case, has correctly interpreted and applied the law and regulations or whether the regulated party is in compliance with the law and regulations.").

[126] Administrative Procedure Act of 1946, 5 U.S.C. § 706(2)(A) (2012). The reviewing court also holds a corresponding power to "compel agency action unlawfully withheld or unreasonably delayed." § 706(1).

[127] United States v. Snoring Relief Labs Inc., 210 F.3d 1081, 1085 (9th Cir. 2000) (quoting O'Keeffe's, Inc. v. U.S. Consumer Prod. Safety Comm'n, 92 F.3d 940, 942 (9th Cir. 1996)).

As such, "there is a presumption in favor of the validity of administrative action," and courts do not "substitute [their] judgment for that of the agency."[128] FDA thus wields "considerable discretion" when deciding whether and how to reclassify a medical device.[129] Further, FDA interpretations of its own enabling legislation will receive the significant protections of *Chevron* deference.[130]

## *B. Exemplary Case Law*

### *1.* Contact Lens Manufacturer's Ass'n v. FDA

In *Contact Lens Manufacturer's Ass'n v. FDA*, a group of contact lens manufacturers (CLMA) challenged FDA's withdrawal of its decision to reclassify rigid gas permeable contact lenses.[131] CLMA originally petitioned FDA to reclassify the lenses to Class II, but after consultation with an expert panel and a year's worth of review, FDA decided *sua sponte* that a Class I designation was preferable.[132] FDA then held multiple periods of public comment, and one year after its initial decision, FDA "repudiated its 'tentative conclusions' and withdrew its reclassification proposal altogether."[133] Public comment had convinced FDA that the clinical studies that originally persuaded the agency to reclassify the lenses were not "valid scientific evidence" at all, and even if they were, such evidence would still "fail to establish the safety and effectiveness of [the] lenses as a generic type of device."[134] CLMA objected that, in reversing course, FDA had "disregarded a medical consensus favoring reclassification and ha[d] rendered insensible the requirement of 'valid scientific evidence.'"[135]

While "recogniz[ing] substantial merit" in CLMA's argument, the United States Court of Appeals for the District of Columbia Circuit ultimately held that FDA's

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[128]Ethicon, Inc. v. FDA, 762 F. Supp. 382, 386 (D.D.C. 1991) (citing Citizens to Pres. Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971), *abrogated in part by* Califano v. Sanders, 430 U.S. 99 (1977)).

[129]Fekete, *supra* note 62, at 616 (citing *Ethicon, Inc.*, 762 F. Supp. at 386).

[130]Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837 (1984). *Chevron* requires courts to conduct a two-step inquiry when reviewing "an agency's construction of the statute which it administers." *Id.* at 842. First, has Congress directly spoken on the matter? If so, both the agency and the court must "give effect to th[at] unambiguously expressed intent." *Id.* at 842–43. Second, if the answer to the first question is negative, is the agency's construction of the statute reasonable? If so, it must stand. *Id.* at 843–44.

[131]766 F.2d 592, 594 (D.C. Cir. 1985). Unlike postmarket reclassification based on new evidence, the primary focus of this paper, the device at issue in *Contact Lens* was a "transitional" Class III device. *Id.* at 595; *see* 21 U.S.C. § 360j(1) (2012) (providing that devices regulated as "new drugs" prior to the MDA's enactment are automatically designated as Class III transitional products, unless and until FDA decides to grant a reclassification petition under § 360j(2)). The court's discussion of FDA's shifting decision-making on the reclassification question is, however, equally relevant to this paper's central argument.

[132]*Contact Lens*, 766 F.2d at 596.

[133]*Id.* (quoting Reclassification of Daily Wear Spherical Contact Lenses Consisting of Rigid Gas Permeable Plastic Materials, 48 Fed. Reg. 56,778, 56,781 (Dec. 23, 1983)).

[134]Reclassification of Daily Wear Spherical Contact Lenses, 48 Fed. Reg. at 56,780.

[135]*Contact Lens*, 766 F.2d at 597. Notably, a group of manufacturers that had already received approval under the PMA process for their own rigid gas permeable lenses were the "principal doomsayers" in the notice-and-comment period. *Id.* at 602. CLMA "barely disguised its suggestion"—which the court seemed to accept—that the political influence of these competitors had played a substantial role in FDA's decision to withdraw its reclassification proposal. *Id.* at 596.

tumultuous decision-making was "at least arguably consistent with the statutory scheme."[136] In justifying its ultimate decision, FDA was forced to deride the very studies it had once praised and to belittle dozens of medical professionals who favored reclassification.[137] While finding this reasoning "somewhat numbing," the court nevertheless held that FDA's concerns over the adequacy of rigid gas permeable lenses as a generic class were sufficient to uphold its decision.[138] The court did note that FDA's contemporaneous proposal to regulate hard contact lenses as Class II devices—while leaving rigid gas permeables in Class III—made little sense, as the same concerns over generic-class inadequacy applied to both.[139] But the court ultimately dismissed this worry because the hard-lens classification "remain[ed] only a proposal," which FDA might well amend in light of these emerging concerns.[140] After all, "FDA acts on classification initiatives at a pace fairly described as glacial."[141]

### *2.* Ethicon, Inc. v. FDA

*Ethicon, Inc. v. FDA*[142] presented the converse of the situation in *Contact Lens*. After receiving a private reclassification petition, FDA elected to transfer a generic class of absorbable surgical sutures from Class III to Class II.[143] Plaintiff Ethicon, the leading brand-name manufacturer of such sutures, challenged FDA's decision as arbitrary and capricious.[144] Ethicon principally argued that FDA's decision was inconsistent with the approach it adopted in *Contact Lens*.[145] After all, what FDA proposed to do here—i.e., to assume that Class II controls would sufficiently ensure safety and effectiveness for future generics based on evidence pertaining to current brand-name devices—was exactly the reasoning FDA rejected in *Contact Lens*.[146] But the court held that *Contact Lens* was "not applicable here because, simply put, it concerned a different device"; the reclassification inquiry is "fact-specific" and hinges on "the nature of the device and 'whether the available evidence, when taken as a whole, is adequate.'"[147] In essence, according to the court, the parties were

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[136] *Id.* at 597.

[137] *Id.* at 600.

[138] *Id.* at 600–02.

[139] *Id.* at 602–03.

[140] *Id.* at 603.

[141] *Id.*

[142] 762 F. Supp. 382 (D.D.C. 1991).

[143] *Id.* at 384–85.

[144] *Id.* at 385 & nn.6–7 (noting that Ethicon controlled 80% of the suture market and had "participated extensively" in FDA's reclassification proceedings). Like the plaintiff's competitors in *Contact Lens*, *supra* note 135, Ethicon had already received premarket approval for its brand-name product, Vicryl, and thus had an incentive to prevent its competitors from securing an easier route to market via reclassification, *see Coated Vicryl Absorbable Surgical Suture (DYED/BRA)*, U.S. Food & Drug Admin., https://www.accessdata.fda.gov/ scripts/cdrh/cfdocs/cfpma/pma.cfm?id=N18175S012 (last updated Oct. 24, 2016) (indicating that, at least as of 1984, Ethicon had received premarket approval for Vicryl).

[145] *Ethicon, Inc.*, 762 F. Supp. at 387.

[146] *Id.*

[147] *Id.* at 387–88 (quoting 21 C.F.R. § 860.7(c)(1) (2016)).

"disputing the quantity and quality of the evidence FDA considered."[148] In reviewing agency actions, however, courts do not "weigh the evidence" available; they merely determine whether the record contains "*some* evidence" to support the agency's decision.[149] Because FDA could point to such evidence in this case, its decision was neither arbitrary nor capricious.[150]

### *3. Ivy Sports Medicine, LLC v. Burwell*

*Ivy Sports Medicine, LLC v. Burwell*[151] offers an even starker example of the inconsistencies and inefficiencies that infect FDA's reclassification procedures. The device manufacturer, ReGen Biologics, Inc., submitted a premarket notification in 2004, seeking Class I or II status for its knee-repair surgical mesh.[152] FDA determined that the device was not substantially equivalent to predicate devices, and "[f]ollowing more back-and-forth between ReGen and FDA, the agency issued another finding that the [device] was not substantially equivalent."[153] After certain Members of Congress complained to the FDA Commissioner, however, FDA permitted ReGen to submit a revised premarket notification.[154] FDA then disregarded the recommendations of its staff reviewers and, after convening an expert panel that deemed the device substantially equivalent, designated the mesh as Class II.[155] But when a *Wall Street Journal* article accused FDA of succumbing to "political and industry pressure" to clear the device,[156] FDA commenced an internal investigation that found "multiple departures from processes, procedures, and practices" and "a clear deviation from the principles of integrity."[157] Finally, when a new review team issued (yet another) finding of no substantial equivalence in 2010, FDA rescinded its earlier Class II designation and ordered the device to undergo the PMA process.[158]

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[148]*Id.* at 388.

[149]*Id.* at 389–90 (emphasis added) (citing Nat'l Soft Drink Ass'n v. Block, 721 F.2d 1348, 1354 (D.C. Cir. 1983)).

[150]*Id.* at 393. Ethicon also argued that FDA failed to prove that a performance standard, as required for Class II devices, could be established for the surgical sutures. *Id.* at 389. The court dismissed this argument because 21 U.S.C. § 360c(a)(1)(B) (2012) only requires FDA to consider *whether* there is sufficient evidence to establish a performance standard for the device, not to actually implement such a standard at the time of classification. *See id.* at 390. Indeed, "Congress recognized that performance standards might not be in place, that Class II devices 'eventually will be required to conform to performance standards,' and that 'a considerable period of time may elapse between classification of a device into class II and development of a standard for it.'" *Id.* (emphasis omitted) (citation omitted) (quoting H.R. REP. NO. 94-853, at 26 (1976)).

[151]767 F.3d 81 (D.C. Cir. 2014).

[152]*Id.* at 84. ReGen had originally submitted a PMA application for the device, but the company quickly withdrew this submission and replaced it with a premarket notification.

[153]*Id.*

[154]*Id.*

[155]*Id.*

[156]Alicia Mundy, *Political Lobbying Drove FDA Process*, WALL ST. J., Mar. 6, 2009, at A1.

[157]U.S. FOOD & DRUG ADMIN., REVIEW OF THE REGEN MENAFLEX®: DEPARTURES FROM PROCESSES, PROCEDURES, AND PRACTICES LEAVE THE BASIS FOR A REVIEW DECISION IN QUESTION 1 (2009), http://www.fda.gov/downloads/NewsEvents/PublicHealthFocus/UCM183642.pdf.

[158]*Ivy Sports Med.*, 767 F.3d at 85.

ReGen challenged this decision in court, but—its funding depleted after years of battling FDA before ever marketing its product—went bankrupt while the case was pending.[159] Its successor in interest, Ivy Sports, continued the litigation.[160] Ivy Sports argued that FDA's actions were unlawful because it changed the device's settled classification without the procedures required under 21 U.S.C. § 360c(e) (2012) for reclassification.[161] FDA, by contrast, pointed out that "administrative agencies are assumed to possess at least some inherent authority to revisit their prior decisions, at least if done in a timely fashion."[162] The court, however, ultimately agreed with Ivy Sports that "Congress precluded FDA from exercising inherent authority to rescind substantial equivalence determinations by creating . . . a specific statutory mechanism" for reclassification.[163] In other words, FDA may not rely on the inherent-authority doctrine to "short-circuit" the procedural safeguards of the reclassification process.[164]

## IV. POLICY GOALS OF THE MEDICAL DEVICE CLASSIFICATION SYSTEM

This Part describes the general policy goals of the MDA classification system—both those expressed in the statutory scheme itself and those identified by commentators over the past decades.

### *A. Ensuring Safety and Effectiveness in New Devices*

The MDA itself repeatedly identifies the primary objective of the device classification system: "provid[ing] reasonable assurance of the safety and effectiveness" of devices that FDA permits to enter the market.[165] A device is safe when its "probable benefits to health" outweigh its "probable risks"; a device is effective when it produces "clinically significant results" in a "significant portion of the target population."[166] Indeed, the Center for Devices and Radiological Health (CDRH)—the FDA center principally responsible for device regulation—conceives of its mission as "to protect and promote the public health" by ensuring that "patients and providers have timely and continued access to safe, effective, and high-quality

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[159] *Id.*

[160] *Id.*

[161] *Id.* at 86.

[162] *Id.*; *see* Daniel Bress, Note, *Administrative Reconsideration*, 91 VA. L. REV. 1737, 1739 (2005) ("While there has been no systematic study of the frequency with which petitions for reconsideration are filed or granted in federal agencies, the large number of reconsideration provisions in federal statutes and agency rules suggests that reconsideration is by no means a rare occurrence.").

[163] *Ivy Sports Med.*, 767 F.3d at 86 (citing 21 U.S.C. § 360c(e) (2012)).

[164] *Id.* at 89.

[165] *See, e.g.*, § 360c(a)(1)(A)(i)–(ii), (a)(1)(B), (a)(1)(C)(i), (e)(2)(A)–(B); *see also* 4 ROSEANN B. TERMINI, FOOD AND DRUG LAW 79 (8th ed. 2015) (indicating that, among various FDA responsibilities and objectives regarding medical devices, "[e]nsuring the safety and effectiveness of [new] devices" is the agency's overriding mission).

[166] 21 C.F.R. § 860.7(d)(1), (e)(1) (2016).

medical devices."[167] Thus, to adequately guarantee the safety and effectiveness of a device, FDA's review process must accurately predict the device's future effects on human health across a wide variety of circumstances.[168]

Although device safety must surely remain the lodestar of the classification process, certain commentators now argue that FDA should reduce (or eliminate) its premarket efficacy review.[169] According to these critics, FDA should instead analyze a device's effectiveness in achieving its intended results among its target population after market entry.[170] FDA's current postmarket surveillance for cleared or approved devices features "a variety of programs, including medical device report[s (MDRs)] by manufacturers and user facilities as well as third-party safety monitoring."[171] FDA collects two types of MDRs, the vast majority of which are submitted by manufacturers: (1) adverse-event reports, which pertain to "incidents resulting in a death or serious injury"; and (2) malfunction reports, which pertain to "incidents in which a device fails without an adverse event resulting."[172] In addition, FDA can order manufacturers to track certain Class II and III devices throughout the distribution chain "to facilitate notifications and recalls ordered by FDA in the case

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[167] *CDRH Mission, Vision and Shared Values*, U.S. FOOD & DRUG ADMIN., CTR. FOR DEVICES & RADIOLOGICAL HEALTH, http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/ucm300639.htm (last updated May 5, 2015).

[168] *See* 21 C.F.R. § 860.7(c)–(e).

[169] *See, e.g.*, Fekete, *supra* note 62, at 633 ("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."); Scott, *supra* note 29, at 402–04 (arguing that Congress should eliminate nearly all FDA premarket review—in regard to *both* safety and efficacy—and instead permit "devices to be regulated through tort liability and an enhanced postmarket surveillance system"); *see also* Ralph F. Hall, *The Risk of Risk Reduction: Can Postmarket Surveillance Pose More Risk than Benefit?*, 62 FOOD & DRUG L.J. 473, 473–74 (2007) ("Questioning the value of an enhanced postmarket surveillance system is akin to questioning motherhood, apple pie and the flag. Politically and publicly there is an overwhelming force driving us towards expending significant public and private resources on creating more robust postmarket surveillance systems . . . ."); Lennox, *supra* note 32, at 1394–99 (proposing a "middle-ground approach" that streamlines premarket review while increasing the effectiveness of postmarket surveillance tools, i.e., by creating a national registry of medical devices).

[170] Fekete, *supra* note 62, at 629–30. FDA itself has recognized that, for certain devices, "a greater reliance on postmarket collection, including real-world data collection, can reduce the extent of premarket data collection and directly impact when patients will have access to high-quality, safe and effective medical devices." U.S. FOOD & DRUG ADMIN., BALANCING PREMARKET AND POSTMARKET DATA COLLECTION FOR DEVICES SUBJECT TO PREMARKET APPROVAL: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 5 (2015), http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm393994.pdf. At the same time, the agency warns that overreliance on postmarket controls "could undermine patient safety if the necessary and timely data collection does not occur." *Id.*

[171] Amanda Swanson, *510(k) Clearance: Opportunities to Incentivize Medical Device Safety Through Comparative Effectiveness Research*, 10 IND. HEALTH L. REV. 117, 135 (2013).

[172] INST. OF MED. OF THE NAT'L ACADS., *supra* note 6, at 123. FDA requires both manufacturers and user facilities to report adverse events or malfunctions to the agency within specified time frames, ranging from thirty to five days, depending on the circumstances. DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., ADVERSE EVENT REPORTING FOR MEDICAL DEVICES 3 (2009), https://oig.hhs.gov/oei/reports/oei-01-08-00110.pdf. By contrast, as a general rule, "patients, healthcare professionals, and caregivers have no legal obligation to report adverse medical events; however, they can provide voluntary reports through the FDA's MedWatch program." Swanson, *supra* note 171, at 135 (citing INST. OF MED. OF THE NAT'L ACADS., *supra* note 6, at 124).

of serious risks to health."[173] Devices eligible for supplemental tracking include, *inter alia*, those "intended to be implanted in the human body for more than one year" and those "the failure of which would be reasonably likely to have serious adverse health consequences."[174]

Those who favor eliminating premarket efficacy review argue that these postmarket protocols are both sufficient and better suited to ensure the utility of devices in the lives of actual patients.[175] Opponents respond that some measure of premarket efficacy review is essential to prevent unscrupulous manufacturers from selling sham products to providers and consumers.[176] This paper takes no position in this debate because the reforms proposed in Part V, *infra*, are necessary under both scenarios—i.e., the status quo and the premarket-safety/postmarket-efficiency model. That said, if Congress were to shift some or all of FDA's efficacy review to the postmarket period, reclassification considerations would presumably increase in frequency.[177] Under such a regime, an efficient and consistent reclassification procedure would be all the more critical.

### *B. Hastening Market Entry for Innovative Devices*

In direct tension with the goal of ensuring safe and effective medical devices is the critical need to bring innovative new products to market in a timely manner.[178] In the

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[173] *Medical Device Tracking*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/medicaldevices/deviceregulationandguidance/postmarketrequirements/medicaldevicetracking/default.htm (last updated Aug. 7, 2014).

[174] 21 U.S.C. § 360i(e)(1)(A)–(B)(i) (2012).

[175] Scott, *supra* note 29, at 398 (asserting that "[s]trong postmarket regulation would encourage device safety while allowing device innovation to thrive"). Others have gone further still in arguing for the total privatization of the safety and efficacy review process, both before and after market entry. *See, e.g.*, Elizabeth C. Price, *Teaching the Elephant to Dance: Privatizing the FDA Review Process*, 51 FOOD & DRUG L.J. 651, 666 (1996). But given the significant strides that the federal government has made in improving the safety and effectiveness of medical devices since taking their regulation out of the hands of private industry in 1938, *see supra* Part 0, such an extreme measure strikes the author of this paper as foolhardy.

[176] *See* Flaherty, *supra* note 50, at 926 (arguing that the current predominance of the 510(k) clearance process "strikes the proper balance between 'the appropriate level of regulatory scrutiny [and] the potential dangers of a particular medical device,' which is critical to the proper functioning of FDA in view of its limited resources" (quoting Benjamin A. Goldberger, *The Evolution of Substantial Equivalence in FDA's Premarket Review of Medical Devices*, 56 FOOD & DRUG L.J. 317, 317 (2001)); Hall, *supra* note 169, at 474 (disputing the common assumption that "enhanced postmarket surveillance will lead to the more complete and faster identification of risks or problems associated with a drug, biologic or device"); *Shapiro*, *supra* note 64, at 382–83 (arguing that the current system is "relatively efficient," "relatively predictable," and effective in "keep[ing] pace with technological innovation in a self-executing manner").

[177] This point assumes that device efficacy is a motivating factor in spurring reclassification, i.e., that not all reclassifications decisions are (or should be) rooted solely in safety concerns. The fact that FDA explicitly such efficacy concerns in deciding to reclassify transvaginal mesh lends support to this assumption. *See 2011 FDA Health Update*, *supra* note 10.

[178] *See* JEFFREY SHUREN, CTR. FOR DEVICES & RADIOLOGICAL HEALTH, FOREWORD: A MESSAGE FROM THE CENTER DIRECTOR 1 (2010), http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM220782.pdf ("The [510(k)] medical device review program is intended to meet two important goals: making available to consumers devices that are safe and effective, and fostering innovation in the medical device industry. In recent years, however, concerns have been raised both within and outside of FDA about whether the current 510(k) program optimally achieves these goals."); *see also* Bauman, *supra* note 72, at 352 (noting the difficulty of striking the correct "balance between device safety and effectiveness and FDA inefficiency," a problem that was apparent even during legislative debates over enactment of the MDA).

FDA Modernization Act of 1997, for example, Congress adopted a new FDA mission statement that "made clear that [FDA's] mission is not limited to protection of public health by preventing distribution of unsafe products, but also requires timely review and approval of beneficial new products."[179] Because the medical device industry is "[a]t the forefront of technological innovation," FDA must perform its safety and efficacy evaluations at an efficient pace so that approved products make their way into the hands of patients and providers without undue delay.[180] All the regulatory oversight in the world counts for little if patients never actually benefit from a new device.[181]

Unfortunately, the American device regulatory system is commonly viewed as "too slow, risk adverse, and expensive," especially in comparison to the faster European Union model.[182] Indeed, as of 2010, "U.S. patients waited an average of two years longer than those in Europe to gain access to new medical technologies."[183] This gap is attributable to corresponding differences in premarket-review time between American and European authorities: In the United States, as of 2010, the lag-time between first communication with FDA concerning a prospective device and clearance or approval was, on average, 31 months for 510(k) submissions and 54 months for PMA submissions.[184] In Europe, those numbers were seven months and eleven months, respectively.[185] The fact that the European system features both a more relaxed efficacy standard than the MDA—devices need only "work[] as intended"—and a decentralized, flexible command structure may explain these timing differences.[186] And, while there is some evidence that this gap has diminished in the past few years, recent studies have continued to find a lag-time in device approval between American and European authorities.[187] The current

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[179]Goldberger, *supra* note 176, at 329 (alteration in original) (quoting Larry R. Pilot & Daniel R. Waldmann, *Food and Drug Administration Modernization Act of 1997: Medical Device Provisions*, 53 FOOD & DRUG L.J. 267, 267 (1998)).

[180]Hall & Mercer, *supra* note 33, at 739. *But see* PWC HEALTH RESEARCH INST., MEDTECH COMPANIES PREPARE FOR AN INNOVATION MAKEOVER 4 (2013), http://www.pwc.com.ar/es/publicaciones/assets/pwc-medical-technology-innovation-report-2013.pdf ("For decades, the medtech industry was on the forefront of innovation. But now as the health industry undergoes significant change, . . . . [g]rowth through purely product innovation has slowed substantially, and the benefits from incremental improvements to existing devices pale in comparison to the cost of making those devices.").

[181]*See, e.g.*, Scott, *supra* note 29, at 377–78 (describing the extensive delays in FDA review that forced the manufacturer of a Transcranial Magnetic Stimulation device used in treating migraines to take its product overseas and forgo the U.S. market, thus depriving American migraine sufferers of the opportunity to benefit from the breakthrough device).

[182]Corinna Sorenson & Michael Drummond, *Improving Medical Device Regulation: The United States and Europe in Perspective*, 92 MILBANK Q. 114, 115 (2014); *see also* Scott, *supra* note 29, at 378 ("U.S. patients must wait months, and sometimes even years, before the latest American-developed device technologies are available in the U.S.").

[183]MAKOWER, *supra* note 18, at 32.

[184]*Id.* at 22–23.

[185]*Id.*

[186]Daniel B. Kramer, Shuai Xu & Aaron S. Kesselheim, *Regulation of Medical Devices in the United States and European Union*, 366 NEW ENG. J. MED. 848, 849–51 (2012).

[187]*See* Gail A. Van Norman, *Drugs and Devices: Comparison of European and U.S. Approval Processes*, J. AM. C. CARDIOLOGY 399, 405–06 (2016) (reviewing multiple recent studies that indicate a three-year lag-time for PMA submissions and a much shorter—or nonexistent—lag-time for 510(k) submissions); *accord* Travis G. Maak & James D. Wylie, *Medical Device Regulation: A Comparison of*

disparity appears to be more pronounced with regard to PMA submissions than 510(k) submissions.[188]

Commentators have, accordingly, argued that FDA should shift some or all of its premarket review to the postmarket period to decrease the lag time in bringing new devices to market.[189] As with similar proposals discussed in Part IV.A, *supra*, this paper's central thesis would apply with even greater force under such a system, as enhanced reliance on postmarket review would require robust tools for reclassifying devices based on new information.

### *C. Responding to Public Health Crises in a Timely Manner*

Medical-device regulation in the United States has largely arisen in response to public health crises concerning dangerous or defective medical products. From Elixir Sulfanilamide in the 1930s,[190] to the Dalkon Shield in the 1970s,[191] to transvaginal mesh in the 2000s,[192] the history of American device regulation is one of individual suffering, public outcry, and government action. As such, FDA must possess the capacity to respond to public health crises involving medical devices with speed and tenacity.[193] Because such crises necessarily occur *after* a device enters the market, however, premarket review alone is insufficient, unless such review could accurately detect unsafe devices at a 100% success rate. Absent such a breakthrough, postmarket reclassification—and the increased scrutiny and surveillance it may produce—is the most promising tool for dealing with device-spawned crises as they surface.

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*the United States and the European Union*, 24 J. AM. ACAD. ORTHOPAEDIC SURGEONS 537, 540–41 (2016). Of course, "[a]pproval and adoption timelines do not tell the whole story," and the extent to which this disparity impacts the speed of patient access to new devices is unclear under current evidence. Van Norman, *supra*, at 406. A more complete comparison of the American and European medical device markets is beyond the scope of this paper.

[188] Van Norman, *supra* note 187, at 405. By contrast, the situation now seems to be reversed with regard to approval of new drugs. *See id.* at 402 ("Closer examination shows that, in fact, drug review times are significantly shorter at the FDA than the [European Medicines Agency].").

[189] *See, e.g.*, Fekete, *supra* note 62, at 631–33 (arguing that FDA should shift its efficacy review to the postmarket period to better match the efficiency of the European model); *see also* U.S. FOOD & DRUG ADMIN., CTR. FOR DEVICES & RADIOLOGICAL HEALTH, *supra* note 29, at 7–8 (acknowledging the need to shift some of the agency's premarket data collection to the postmarket period to increase the speed of market entry for new devices); *cf.* R. Alta Charo, *Speed Versus Safety in Drug Development*, *in* FDA IN THE TWENTY-FIRST CENTURY: THE CHALLENGES OF REGULATING DRUGS AND NEW TECHNOLOGIES 251, 262–63 (Holly Fernandez Lynch & I. Glenn Cohen eds., 2015) (arguing, in the related context of FDA regulation of drugs, that transitioning to greater reliance on postmarket review could, with appropriate reforms, produce a system that is "both faster and safer").

[190] *See supra* Part 0.

[191] *See supra* Part 0.

[192] *See supra* Part 0.

[193] *See* U.S. FOOD & DRUG. ADMIN., OFFICE OF CRISIS MGMT., FDA EMERGENCY OPERATIONS PLAN 1 (2014), http://www.fda.gov/downloads/EmergencyPreparedness/EmergencyPreparedness/UCM230973.pdf ("Emergencies and disasters . . . have the potential to cause adverse health and safety effects for large segments of the human and animal populations. FDA must possess the resources and capabilities necessary to prevent, prepare for, protect against, and rapidly and effectively respond to and recover from all hazards."); *see also id.* at 51 (outlining the responsibilities of the CDRH in crises situations).

### *D. Constructing a Predictable and Consistent Regulatory Framework*

In addition to producing accurate results in a majority of cases, the medical device classification system "should be clear, predictable, straightforward, and fair."[194] After all, "[i]f the regulatory process is too difficult, it will deter even the most talented and creative innovators from entering the system."[195] Such consistency and clarity is essential because "[m]any innovations in [medical-device] technology and procedure come from practicing physicians,"[196] and because the medical-technology industry largely consists of small businesses and start-up companies.[197]

As FDA's fractured and inconsistent decision-making in *Contact Lens*[198] and *Ethicon, Inc.*[199] demonstrate, however, FDA has often fallen short of this goal—particularly in its classification and reclassification decisions. Indeed, 53% device manufacturers surveyed in 2010 described FDA's classification decisions as either "mostly unpredictable" or "very unpredictable," while 85% percent of the same companies rated European authorities as either "highly predictable" or "mostly predictable."[200] In 2009, in response to concerns of this sort, FDA launched a comprehensive reevaluation of its device classification process and ultimately concluded that:

> The biggest problem . . . in the premarket review process was unpredictability, including uncertainty about the requirements for approval and the likely length of the review process, as well as inconsistencies and mid-stream changes in what information was required to obtain approval. When a premarket review process is unpredictable, it can increase costs for industry and the FDA and create delays in bringing safe and effective products to market. It can also make it difficult for small and startup companies to obtain investors.[201]

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[194] INST. OF MED. OF THE NAT'L ACADS., *supra* note 6, at 9.

[195] INST. OF MED. OF THE NAT'L ACADS., PUBLIC HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS 21 (Theresa Wizemann ed., 2010), https://www.nap.edu/read/12960/chapter/5. The Institute also found that venture capitalists and entrepreneurs are unlikely to invest in new medical devices that may be subject to more expensive or complex FDA oversight—i.e., those devices likely to have to undergo PMA review. *Id.*

[196] *Id.* at 17.

[197] *See* 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/SignificantAmendmentstotheFDCAct/FDASIA/UCM360058.pdf ("It is widely known that the medical device industry is largely made up of small companies—the U.S. Department of Commerce estimates that 62 percent of medical technology firms have fewer than 20 employees and only 2 percent have more than 500 employees.").

[198] Contact Lens Mfrs. Ass'n v. FDA, 766 F.2d 592 (D.C. Cir. 1985).

[199] Ethicon, Inc. v. FDA, 762 F. Supp. 382 (D.D.C. 1991).

[200] MAKOWER, *supra* note 18, at 24.

[201] U.S. FOOD & DRUG ADMIN., CTR. FOR DEVICES & RADIOLOGICAL HEALTH, IMPROVEMENTS IN DEVICE REVIEW 5 (2012), http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM329702.pdf.

Thus, boosting public confidence in the accuracy and consistency of FDA decision-making must be a central goal of any reform program for the American device regulatory regime. As explained further in the next Part, a heightened focus on the postmarket reclassification process can help achieve this goal while, at the same time, increasing the efficiency of FDA premarket review.

# V. PROPOSALS FOR REFORMING THE DEVICE RECLASSIFICATION PROCESS

Despite widespread disagreement over *how* best to remedy the MDA's shortcomings, courts, commentators, and FDA itself generally agree on *what* the problem is—namely, the medical device classification process is too slow,[202] too expensive,[203] and too unpredictable.[204] Those criticisms apply with equal force in the context of device *re*classification, where FDA's decision-making has proven particularly lethargic.[205] This Part proposes four simple measures that will increase the efficiency and consistency of the device reclassification process. While a more comprehensive reform of the MDA classification system is necessary to fully address the policy concerns raised in Part IV, *supra*, the postmarket reclassification process can also play a meaningful role in ensuring that safe, effective, and innovative medical devices reach consumers.

## *A. A Regular Schedule for FDA Reclassification Review*

In addition to responding to reclassification requests or petitions from interested persons,[206] FDA may also initiate reclassification proceedings on its own motion.[207]

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[202] *See Contact Lens*, 766 F.2d at 603 (noting that "FDA acts on classification initiatives at a pace fairly described as glacial"); *see also* Riegel v. Medtronic, Inc., 552 U.S. 312, 318 (2008) (noting that each individual PMA application requires over 1,200 hours of FDA review); *Continuing America's Leadership: Advancing Research and Development for Patients: Hearing Before the Sen. Comm. on Health, Educ., Labor & Pensions*, 114th Cong. 8 (2015) (testimony of Michael A. Mussallem, Chairman & CEO, Edwards Lifesciences) ("Whether created by large or small firms, medical technologies are characterized by a rapid innovation cycle. . . . Focus should be put on reducing the delay and expense that data collection adds at every step in the [FDA review] process."); Margaret A. Hamburg, *FDA Advances Medical Product Innovation*, U.S. FOOD & DRUG ADMIN.: FDA VOICE (Mar. 17, 2015), http://blogs.fda.gov/fdavoice/index.php/2015/ 03/fda-advances-medical-product-innovation (indicating that, while "FDA approves *drugs* faster on average than all other advanced nations," device review has lagged behind (emphasis added)). *But see* Marie Thibault, *FDA Approving Devices Faster*, MED. DEVICE & DIAGNOSTIC INDUS. (Mar. 26, 2015, 3:35 PM), http://www.mddionline.com/article/fda-approving-devices-faster-03-26-15 (observing that "FDA is getting faster at approving devices" and that "[i]t took an average 17.6 months for a first-time [PMA] in 2014, compared to almost twice as long in 2013").

[203] Mussallem, *supra* note 202, at 8 (noting that "[e]vidence development can be an extremely costly endeavor at each stage of the [FDA review] process" because "manufacturers are required to gather a great deal of clinical and economic evidence"). A 2010 survey of over two hundred medical technology companies in the United States found that the cost of obtaining PMA was nearly $100 million, with $75 million spent on FDA-related activities (and excluding any marketing costs). MAKOWER, *supra* note 18, at 7. The cost of obtaining 510(k) clearance was $31 million on average, with $24 million spent on FDA-related activities. *Id.*

[204] *See supra* Part 0.

[205] *See Reclassification*, *supra* note 20 (demonstrating that, over the past four years, FDA has down-classified fourteen devices and up-classified two devices); *see also supra* Part 0 (describing the slow pace and substantive unpredictability of FDA's reclassification decisions in several notable cases).

[206] 21 C.F.R. § 860.130(b)(2)–(3) (2016).

But neither the MDA nor its applicable regulations provide any systematic procedure for FDA to do so.[208] The regulations do not specify, for example, whether FDA should review approved or clear devices on any particular timetable to determine whether reclassification may be warranted.[209] Of course, device manufacturers—especially those seeking to bring a new device to market when its generic class has already received Class II or III designation[210]—have a strong incentive in many cases to petition FDA to reclassify a device or class of devices into a lower tier.[211] But manufacturers obviously have no reason to request that FDA reclassify their devices into a higher tier.[212] Thus, unless FDA systematically reviews cleared or approved devices to ascertain whether their assigned classifications are still proper, postmarket up-classification will occur rarely if ever. This perhaps explain why, of the sixteen reclassification decisions FDA has issued since the FDA Safety and Innovation Act went into effect in 2013, only two resulted in up-classifications.[213]

To correct this imbalance, FDA should promulgate new regulations that establish a framework for regular, in-house review of cleared or approved devices. FDA can accomplish this goal most efficiently by tasking a body of staff reviewers with monitoring such devices for a change in apparent safety or effectiveness.[214] Unlike the independent-expert panels FDA must convene once the reclassification process is underway,[215] this periodic-review body need not render a final decision on the merits of reclassification. Instead, when a device comes due for reevaluation, the body should review the available scientific literature to determine whether a device is performing as expected, given the level of controls and premarket scrutiny for its particular class.[216] If the periodic-review body finds reason to believe that the device is over-performing or under-performing in either the safety or effectiveness

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[207] § 860.130(b)(1).

[208] *See generally* 21 C.F.R. §§ 860.120–8.60.136 (2016) (covering device reclassification under five different statutory provisions but providing no guidance as to when or how FDA should review cleared or approved devices to determine reclassification eligibility).

[209] *See generally id.*

[210] *See* § 860.120(b) ("The reclassification of any device within a generic type of device causes the reclassification of all substantially equivalent devices within that generic type. Accordingly, a petition for the reclassification of a specific device will be considered a petition for reclassification of all substantially equivalent devices within the same generic type.").

[211] This was precisely what the plaintiffs in *Contact Lens* sought. 766 F.2d 592, 595 (D.C. Cir. 1985).

[212] Indeed, manufacturers that have already brought a device to market have a strong interest in *opposing* up-classification, which will generally force them to submit further evidence of safety and effectiveness to FDA—perhaps even a dreaded PMA application. *See* 21 U.S.C. § 360c(e)(1)(A)(i) (2012) (permitting FDA, upon reclassification, to revoke any performance standards, special controls, or approval status for an affected device); *see also FDA Strengthens Requirements for Surgical Mesh*, *supra* note 17 (requiring transvaginal mesh manufacturer to submit new PMA applications to prove the safety and effectiveness of their devices).

[213] *Reclassification*, *supra* note 20; *see also supra* note 23 for more information.

[214] FDA employs a host of in-house staff with various scientific and technical backgrounds to review premarket submissions and postmarket surveillance related to medical devices. *See FDA Announces New Staff Training for Medical Device Reviewers*, U.S. FOOD & DRUG ADMIN. (Sept. 6, 2011), http://www.fda.gov/ NewsEvents/Newsroom/PressAnnouncements/ucm270858.htm.

[215] § 360c(e)(1)(A)(i).

[216] *See infra* Part 0 for the relevant standard of review.

categories, it should recommend to the Commissioner that FDA initiate reclassification proceedings *sua sponte*.[217] Once more, this finding need only be tentative—upon further study, the Commissioner may come to the opposite conclusion. The critical point is that FDA will at least *consider* reclassification on a periodic basis.[218]

The obvious next question is how often the periodic-review body should consider a cleared or approved device for reclassification. The frequency of the body's reevaluations will depend to some degree on agency budgetary limitations beyond the scope of this paper. Given that FDA staff reviewers are notoriously overworked as it is,[219] Congress may need to authorize additional funds for this reclassification initiative. Congress could, alternatively, raise the scheduled registration and application fees under the Medical Device User Fee and Modernization Act to cover the body's expenses.[220] In any event, if feasible, FDA should review Class III devices for reclassification every two years after market entry. Because Class III devices are subject to the most stringent premarket scrutiny and postmarket controls,[221] they offer the greatest potential cost and time savings—both for FDA and the industry—upon down-classification. By contrast, FDA should review Class II

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[217]21 C.F.R. § 860.130(b)(1) (2016) ("A proceeding to reclassify a device under [§ 360c(e)] may be initiated . . . [o]n the initiative of the Commissioner alone . . . .").

[218]FDA's "Sentinel Initiative," launched in May 2008, could work in conjunction with this proposal. *FDA's Sentinel Initiative*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Safety/FDAsSentinelInitiative/ ucm2007250.htm (last updated Nov. 8, 2016). This program "aims to create a linked, sustainable system that will draw upon the electronic healthcare data of many sources to enable continuous active monitoring of product safety" after market entry. Swanson, *supra* note 171, at 139. In other words, the system will complement FDA's existing adverse-event reporting system with additional electronic data-collection tools. *See FDA's Sentinel Initiative*, *supra*. FDA has already launched a "mini-Sentinel" pilot program as the "first step" toward realizing the vision of a "nationwide rapid-response electronic safety surveillance system." *A Major Milestone Towards a Nationwide Electronic Medical Product Safety System*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/downloads/Safety/FDAsSentinelInitiative/UCM268035.pdf (last visited Dec. 10, 2016). While this program would (if it reaches maturity) certainly provide critical information for any reclassification decision, the Sentinel Initiative imposes no requirement on FDA to actively consider reclassification upon a periodic basis. Thus, a further step is needed.

[219]*See* FDA SCI. BD., SUBCOMM. ON SCI. & TECH., FDA SCIENCE AND MISSION AT RISK 4 (2007), http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20 Science%20and%20Technology.pdf ("Due to constrained resources and lack of adequate staff, FDA is engaged in reactive regulatory priority setting or a fire-fighting regulatory posture instead of pursuing a culture of proactive regulatory science."); *FDA Understaffed*, NBC NIGHTLY NEWS (Dec. 13, 2016), http://www. nbcnews.com/video/ nightly-news/22903658#22903658 (discussing new reports "that the FDA is overworked and understaffed"); Jordan Schwakopf, Opinion, *The Underfunded and Overworked FDA*, GUSTAVIAN WKLY. (Nov. 20, 2015), https://weekly.blog.gustavus.edu/2015/11/20/the-underfunded-and-overworked-fda (noting that FDA's lack of adequate funding curtails its facility inspections and that, "[i]n 2012, over one-fourth of [FDA]'s staff consisted of temporary employees with two to four year contracts").

[220]Medical Device User Fee and Modernization Act of 2002, 21 U.S.C. §§ 379f–379j-62. As amended by the Medical Device User Fee Amendments of 2007, Pub. L. No. 110-85, §§ 201–30, 121 Stat. 823, 842–59 (codified as amended at 21 U.S.C. §§ 379f–379j-62), this Act permits FDA to collect fees from device manufacturers when they submit applications for approval or clearance of new devices and later register those devices, *Medical Device User Fee Amendments (MDUFA)*, U.S. FOOD & DRUG. ADMIN., http://www.fda.gov/ ForIndustry/UserFees/Medical DeviceUserFee/ucm20081521.htm (last updated Sept. 23, 2016). FDA uses these fees to "increase the efficiency of regulatory processes with a goal of reducing the time it takes to bring safe and effective medical devices to the U.S. market." *Id.*

[221]*See supra* Part 0.

devices for either up- or down-classification every four years after market entry. These devices present reduced risks of harm relative to Class III devices,[222] so less frequent reevaluation is proper. There are also far more Class II devices than Class III devices; thus, FDA can afford to review the latter more frequently.[223] Finally, the periodic-review body need not systematically consider Class I devices at all—the risks of harm or inefficacy they pose are simply too minor.[224]

### *B. An Intelligible Evidentiary Standard for Reclassification Decisions*

Neither the MDA nor FDA regulations currently provide any evidentiary standard for reclassifying a device after market entry, other than the general guidelines that apply to all classification decisions.[225] Instead, the MDA merely states that FDA may reclassify a device "based on new evidence respecting" its safety or effectiveness.[226] And the regulations' general guidelines for device classification are ill-suited to reclassification decisions, as they pertain to the kinds of studies and trials a manufacturer must conduct *before* a device becomes generally available.[227] After market entry, however, FDA and manufacturers are much more likely to rely on adverse-incident reports, product tracking, and other postmarket-surveillance tools to determine whether reclassification is necessary.[228] As *Contact Lens* and *Ethicon, Inc.* amply demonstrate, this gulf in guidance often leads courts to uphold FDA reclassification decisions so long as "some evidence" is present to justify the decision[229]—even if it contravenes the current consensus of the medical community.[230]

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[222]*See supra* Part 0.

[223]U.S. GOV'T ACCOUNTING OFFICE, *supra note* 6, at 17 (noting that, from 2003 to 2007, FDA received 1,509 Class I submissions, 11,690 Class II submissions, and 342 Class III submissions).

[224]*See supra* Part 0. Of course, should FDA receive a significant number of adverse-event or malfunction reports or other postmarket red flags relating to a Class I device, the agency should consider reclassification. But periodic review of all such devices for reclassification is unnecessary.

[225]*See generally* 21 C.F.R. § 860.7(c)–(g) (2016) (listing the types of data that may constitute "valid scientific evidence" and defining the standards for reasonable assurances of safety and effectiveness).

[226]21 U.S.C. § 360c(e)(1)(A)(i) (2012). The MDA does require FDA to publish a summary of the evidentiary basis for its decision to reclassify a device—including the reasons why its former classification is no longer sufficient—but this requirement says nothing about the quantum or quality of evidence necessary in the first instance. § 360c(e)(1)(A)(i)(I)–(III).

[227]*See* Megan S. Wright, Comment, *A Case for Randomized, Double-Blinded, Sham-Controlled Class III Medical Device Trials*, 34 YALE L. & POL'Y REV. 199, 201–03, 207 n.58 (2015) (describing FDA's requirements for clinical trials prior to approval of Class III devices and noting that FDA lacks sufficient resources to fully surveil and demand additional studies for devices after market entry); *see also* Kramer, Xu & Kesselheim, *supra* note 186, at 848–51 (indicating that FDA's limited resources permit the agency to require supplemental trials after device approval or clearance only for certain high-risk devices).

[228]*See* U.S. FOOD & DRUG ADMIN., CTR. FOR DEVICES & RADIOLOGICAL HEALTH, STRENGTHENING OUR NATIONAL SYSTEM FOR MEDICAL DEVICE POSTMARKET SURVEILLANCE 2 (2013), http://www.fda.gov/downloads/MedicalDevices/Safety/CDRHPostmarketSurveillance/UCM348845.pdf (discussing FDA's current plans to reform its postmarket surveillance protocols, largely by modernizing adverse-event reports, developing a national device registry, and making other reporting-related improvements).

[229]Ethicon, Inc. v. FDA, 762 F. Supp. 382, 386 (D.D.C. 1991).

[230]Contact Lens Mfrs. Ass'n v. FDA, 766 F.2d 592, 597 (D.C. Cir. 1985).

To improve the consistency and predictability of its reclassification decision-making, FDA should promulgate new regulations that provide an intelligible evidentiary standard for changing a device's classification after market entry. These regulations should require that a device's classification reflect the *current consensus of the American medical community* as to the device's safety and effectiveness in fulfilling its intended uses among its target population, thus avoiding the result in *Contact Lens*.[231] Therefore, if the medical consensus remains unchanged since FDA issued its initial classification decision, or if differing opinions on a device's safety or effectiveness have yet to congeal into a clear consensus, reclassification is not warranted. Furthermore, the party that initiates reclassification proceedings (whether FDA, the manufacturer, or another interested party[232]) should bear the burden of proving that the current medical consensus favors a different classification by a preponderance of the evidence. Such a standard should prove familiar for courts to apply in any subsequent litigation: Under both the *Frye*[233] and *Daubert*[234] standards for admission of scientific evidence, courts have long been in the business of determining whether a particular expert opinion adheres to the consensus of the relevant scientific community. This standard also reflects the dynamic, adaptive nature of scientific experimentation and debate, the ultimate objective of which is "a consensus of rational opinion over the widest possible field."[235]

### *C. A Rebuttable Presumption of Expert-Panel Correctness*

Before reclassifying a device, the MDA requires FDA to convene a panel of "persons who are qualified by training and experience to evaluate the safety and effectiveness of the devices to be referred to the panel."[236] After this panel of independent experts reaches a decision on whether to reclassify the device, FDA must publish the recommendation in the *Federal Register*.[237] But no provision of the MDA requires FDA to actually adopt the panel's recommendation.[238] Indeed, FDA

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[231] *See id.*

[232] 21 C.F.R. § 860.130(b)(1)–(3) (2016).

[233] *See* Frye v. United States, 293 F.3d 1013, 1014 (D.C. Cir. 1923) ("[W]hile courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained *general acceptance in the particular field* in which it belongs." (emphasis added)). *Frye* remained the guiding standard for assessing the reliability of expert testimony in federal court until its partial displacement in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Bert Black et al., *Science and the Law in the Wake of* Daubert*: A New Search for Scientific Knowledge*, 72 TEX. L. REV. 715, 722–24 (1994).

[234] *See Daubert*, 509 U.S. at 594 (retaining the *Frye* general-acceptance inquiry as part of a broader four-part test: "Widespread acceptance can be an important factor in ruling particular evidence admissible, and 'a known technique which has been able to attract only minimal support within the community' may properly be viewed with skepticism." (citation omitted) (quoting United States v. Downing, 735 F.2d 1224, 1238 (3d Cir. 1985))).

[235] JOHN ZIMAN, PUBLIC KNOWLEDGE: AN ESSAY CONCERNING THE SOCIAL DIMENSION OF SCIENCE 9 (1st ed. 1968).

[236] 21 U.S.C. § 360c(b)(2), (e)(1)(A)(i) (2012).

[237] § 360c(d)(1).

[238] *See* Stephanie Tai, *Comparing Approaches Towards Scientific Advisory Bodies on Food Safety in the United States and the European Union*, 2010 WISC. L. REV. 627, 647 (2010) ("Under its own regulations, the FDA still retains a significant degree of discretion regarding the extent to which it uses [the expert panel's] advice.").

need only "review [its] conclusions and recommendations" and "make a final decision on the matter."[239] Ignoring the panel's recommendation, however, contributes to both the substantive unpredictability of and lack of industry confidence in FDA's reclassification decisions. *Ivy Sports Medicine* offers a clear example: There, FDA rejected a substantial-equivalence finding by two separate expert panels in concluding that a device required PMA.[240] The agency did so in large part because of media backlash regarding the politicization of its review process[241] and concerns over the propriety of the manufacturer's communications with the first expert panel.[242] This troubling episode emphasizes the importance of having a truly independent body of medical experts review a reclassification proposal, free of outside influence,[243] as well as the need for FDA to take a panel's final recommendation seriously.

To boost the consistency and predictability of FDA decision-making, an independent expert panel's recommendation as to device reclassification should carry a rebuttable presumption of correctness.[244] Assuming that the panel deliberated in compliance with its statutory and regulatory authority, this presumption should apply against FDA in subsequent litigation arising out of the device's classification.[245] Thus, if FDA elects to ignore a panel's recommendation and either the manufacturer or another interested party challenges that decision in court, FDA will have to produce evidence demonstrating why the panel's recommendation was in error. Of course, FDA may well prevail on this count; for example, new material evidence may arise after the panel adjourns but before FDA issues a final order.[246] This presumption will, however, reduce the "rubber-stamp" effect that the arbitrary and capricious standard produces for FDA reclassification decisions, no matter how dubious.[247] Given that the relevant sections of the MDA plainly incorporate no such

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[239] § 360c(b)(7).

[240] Ivy Sports Med., LLC v. Burwell, 767 F.3d 81, 84–85 (D.C. Cir. 2014).

[241] *Id.* at 85.

[242] U.S. FOOD & DRUG ADMIN., *supra* note 157, at 19–21.

[243] *See* Tai, *supra* note 238, at 643–44 ("Several FDA requirements seem to govern potential bias of these voting academician/practitioner members. . . . This restriction, however, contains a number of exceptions, including the ability of an individual to remain on the committee if the appointing FDA official certifies in writing that the need for that member outweighs the conflict.").

[244] *Cf.* Tummino v. Von Eschenbach, 427 F. Supp. 2d 212, 232–33 (E.D.N.Y. 2006) (permitting discovery beyond the administrative record in part because FDA ignored the recommendation of an expert advisory panel); Tai, *supra* note 238, at 647 (citing *Tummino* for the proposition that "FDA must provide a *reasoned basis* for declining to follow an advisory committee's recommendation" (emphasis added)).

[245] If adopted, this proposal would abrogate (and reverse) the presumption of validity that courts typically apply to administrative action, albeit only in a limited context. *See* Citizens to Pres. Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971), *abrogated in part by* Califano v. Sanders, 430 U.S. 99 (1977)).

[246] In *Contact Lens*, for example, FDA rejected an expert panel's recommendation after subsequent public comment convinced the agency that the clinical trials on which the panel relied were invalid. 766 F.2d 592, 596 (D.C. Cir. 1985). Whether FDA's assessment of that particular situation was correct, however, was greatly disputed. *See id.* at 600.

[247] *See* Michael Herz, *The Rehnquist Court and Administrative Law*, 99 NW. U. L. REV. 297, 315–16 (2004) (deeming the use of arbitrary and capricious review under *Chevron* a "toothless," "rubber-stamp" test). *But see* Ryan G. Weldon & Michael E. Patterson, *Maintaining the Ninth Circuit's Clarified Arbitrary and Capricious Standard of Review for Agency Science after* Lands Council v. McNair, 31 PUB. LAND & RESOURCES L. REV. 55, 56–57 (2010) (arguing that the Ninth Circuit's clarified arbitrary and

presumption[248]—and given the unlikelihood of FDA adopting a regulation imposing one against itself—this reform will likely require congressional action.

### *D. Inherent FDA Authority to Rescind Classification Decisions*

In *Ivy Sports Medicine*, the District of Columbia Circuit held that FDA lacks inherent agency authority to reconsider its classification decisions after issuing a final order to that effect.[249] While as a general principle of administrative law "[t]he power to reconsider is inherent in the power to decide,"[250] under the MDA, Congress provided "a specific statutory mechanism to correct alleged device classification errors."[251] As such, § 360c(e) displaced FDA's inherent authority to correct its mistakes, even if limited to the statutory period for taking an appeal (as such authority generally is).[252] Whether this decision was correct is debatable: FDA plausibly argued in *Ivy Sports Medicine*, and Judge Pillard agreed in dissent, that subsection (e) simply does not apply to the reversal of a substantial-equivalence finding, rather than a full-throated reclassification.[253] But in any event, so long as *Ivy Sports Medicine* remains good law,[254] FDA lacks the power of administrative reconsideration and must turn to § 360c(e) for any classification changes based on new information. Yet, as explained throughout this paper, that process can be slow and inefficient.

Congress should amend the MDA to expressly provide that, within the statutory period for appeal, FDA may rescind a classification decision without performing the full administrative-order procedures of § 360c(e).[255] A legislative amendment, rather than further FDA rulemaking, is necessary because the District of Columbia Circuit has deemed FDA's interpretation of its enabling legislation to be contrary to

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capricious standard, *see supra* Part 0, "precludes courts from either acting as rubber stamps or substituting their judgments for that of the agency").

[248]*See generally* 21 U.S.C. §§ 351–360n-1 (2012).

[249]Ivy Sports Med., LLC v. Burwell, 767 F.3d 81, 87 (D.C. Cir. 2014).

[250]Albertson v. FCC, 182 F.2d 397, 399 (D.C. Cir. 1950); *accord* Prieto v. United States, 655 F. Supp. 1187, 1991 (D.D.C. 1987) ("There can be no dispute that administrative agencies have inherent power to reconsider their own decisions, since the power to decide in the first instance carries with it the power to reconsider. This power does not depend on statutory authority." (citation omitted)).

[251]*Ivy Sports Med.*, 767 F.3d at 86 (assuming that "Congress intends to displace an administrative agency's inherent reconsideration authority when it provides statutory authority to rectify the agency's mistakes").

[252]Am. Methyl Corp. v. EPA, 749 F.2d 826, 835 (D.C. Cir. 1984).

[253]*Ivy Sports Med.*, 767 F.3d at 100–02 (Pillard, J., dissenting).

[254]FDA declined to file a petition for writ of certiorari with the United States Supreme Court in this case.

[255]Under 21 U.S.C. § 360g(a)(1) (2012), within thirty days after FDA issues a classification or reclassification decision under § 360c, "any person adversely affected . . . may file a petition with the United States Court of Appeals for the District of Columbia or for the circuit wherein such person resides or has his principal place of business for judicial review." Thus, under the traditional model of administrative reconsideration, FDA would have only a limited window in which to rescind its prior decisions or entertain motions for reconsideration. *See* Am. Methyl Corp., 749 F.2d at 835. Alternatively, because congressional action will be necessary to implement this proposal, Congress could expressly provide for a time period in which FDA may reconsider its past decisions, e.g., thirty days, sixty days, one year, etc.

Congress's express intent.[256] Such a change will eliminate the inefficiency of multiple incarnations of the § 360c process when new evidence arises shortly after approval or clearance. And limiting this power to the appeals period will prevent FDA from "short-circuit[ing]" its statutory duties in cases where more thorough reevaluation is appropriate due to the passage of time.[257] Further, the power to rescind a decision will not, by itself, permit FDA to bypass the other procedural requirements for assigning a device to a particular class under the MDA. Thus, this reform, while minor in the grand scheme of things, would eliminate any needless waste of time and resources when the facts change shortly after the classification process concludes.

## VI. CONCLUSION

The American medical device market is a $140 billion industry that produces almost half of the world's medical devices.[258] The MDA classification system largely determines the level of premarket and postmarket federal oversight these devices receive. As such, to protect consumers from dangerous and defective devices, FDA's classification decisions must accurately identify the controls necessary to reasonably ensure the safety and effectiveness of new devices. At the same time, premarket review must not unduly hinder innovative new products from reaching patients and improving their lives. Thus, the device classification system must accomplish the difficult task of "balanc[ing] medical devices' risks and their potential public-health benefits."[259]

Postmarket reclassification is a long-neglected piece of this regulatory puzzle. The MDA's reclassification procedures permit FDA to alter a device's classification—and thus to fundamentally change the level of federal oversight it and similar devices receive—based on new evidence that comes to light after the device enters the market. This powerful tool can help ensure that the regulatory attention paid to medical devices always reflects the best understanding of the scientific community, rather than an isolated moment in time. Yet FDA has exercised this power sporadically over the past decades, and only after great delay. Moreover, FDA's reclassification decisions have proven inconsistent and unpredictable, depriving device manufacturers and investors of needed confidence in the system's reliability. But FDA and Congress can make reclassification a meaningful part of the device regulatory system by: (1) adopting a regular schedule for FDA review of approved or cleared devices to determine whether reclassification is warranted; (2) promulgating an intelligible evidentiary standard for reclassification decisions that tracks the current consensus of the medical community; (3) establishing a rebuttable presumption of correctness for advisory-panel recommendations regarding device reclassification; and (4) conferring upon FDA the authority to rescind its classification decisions within a limited time after issuance.

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[256] *See Ivy Sports Med.*, 767 F.3d at 87 (majority opinion); *see also* Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 842–43 (1984) (requiring courts and federal agencies to "give effect to [Congress's] unambiguously expressed intent," unless Congress subsequently chooses to act otherwise).

[257] *Ivy Sports Med.*, 767 F.3d at 87.

[258] U.S. DEP'T OF COMMERCE, INT'L TRADE ADMIN., 2016 TOP MARKETS REPORT: MEDICAL DEVICES 8 (2016), http://trade.gov/topmarkets/pdf/Medical_Devices_Top_Markets_Report.pdf.

[259] INST. OF MED. OF THE NAT'L ACADS., *supra* note 6, at 22.

These reforms will become all the more critical as postmarket surveillance assumes an increasingly important role in the American system of medical device regulation. As more and more commentators call for FDA to shift some or all of its safety and efficacy review to the postmarket period, a robust reclassification protocol can protect the health of consumers while accommodating a hastened rate of market entry. Ultimately, a greater role for reclassification means a medical-device regulatory system more adaptable to changing times.