Left to Their Own Devices:

How the Dangers of Power Morcellators Went Undetected by FDA for Two Decades

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ABSTRACT

The power morcellator, a device for cutting tissue, was once a mainstay of minimally-invasive gynecological surgery. The devices were cleared by FDA through the 510(k) process and remained on the U.S. market for over twenty years. In 2013, a deadly risk associated with power morcellators came to the attention of FDA: in women with hidden uterine cancers, the devices were disseminating cancerous tissues throughout their bodies, severely accelerating the disease and harming their chances of survival. Though FDA had been aware of this potential problem associated with the devices, the magnitude of the risk had been severely underappreciated, leaving hundreds of women exposed to a dangerous procedure without any disclosure by their physicians of the potential for spreading cancer. Subsequent investigations by the media and the Government Accountability Office uncovered weaknesses in FDA's regulatory approach, with significant deficiencies in postmarket reporting and data collection hampering the agency's ability to ensure the safety and efficacy of medical devices. However, these accounts did not consider two additional gaps that led to the morcellation crisis, both of which fall primarily on the physician side, rather than the regulatory side, of the medical device world: first, the failure by doctors to fulfill their obligation to report adverse events, and, second, potential deficiencies in the training of gynecologists that have led to overly siloed practices. In order to truly empower FDA to identify and address problems with medical devices while still permitting a robust flow of potentially life-saving medical devices to the U.S. market, a holistic approach bridging gaps on both the regulatory and clinical sides of the medical device world is necessary.

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I. INTRODUCTION

By the age of forty-four, Dr. Amy Reed had accomplished more than most people could dream of. She held M.D. and PhD degrees from the University of Pennsylvania's School of Medicine and taught at Harvard Medical School.[1] A mother of six, she had three children while studying as a medical student and two while in residency and fellowship training.[2] She specialized in critical-care medicine and anesthesia at Beth Israel Deaconess Hospital, where she led the emergency room response to the Boston Marathon bombing in 2013.[3]

Not long after, in October 2013, Dr. Reed underwent what was intended to be a routine procedure to remove what was believed to be a harmless uterine fibroid tumor.[4] The surgeon used a power morcellator, a then-common tool for performing minimally invasive gynecological surgeries.[5] This device, which permitted the use of laparoscopic surgical techniques, would enable a quick surgery and should have resulted in fewer risks, a shorter recovery time, and reduced scarring for Dr. Reed. However, presurgery procedures had failed to detect a hidden leiomyosarcoma cancer within Dr. Reed's uterus.[6] The morcellator shredded and spewed malignant cancer cells throughout her body.[7] Instead of an easily treatable Stage 1 cancer, Dr. Reed immediately faced a Stage 4 cancer with an unsurmountable prognosis.[8] On May 24, 2017, after a four-year battle with the disease, Dr. Reed died at the age of forty-four.[9]

In the final years of her life, she was a fierce advocate for women's health, fighting to raise awareness about the little-known risks of morcellation.[10] Dr. Reed and her husband, Dr. Hooman Noorchashm, dedicated themselves to campaigning for a ban on the use of power morcellators in gynecological operations, while urging the Food and Drug Administration ("FDA") to bolster its regulation of medical devices. The adverse event report filed by Dr. Reed in late 2013, coupled with the

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1 Karen Weintraub, *Dr. Amy Reed, Whose Own Medical Battle Changed Physicians' Practices, Dies at 44*, BOS. GLOBE (May 26, 2017), https://www.bostonglobe.com/metro/obituaries/2017/05/25/amy-reed-whose-own-medical-battle-changed-physicians-practices/lP6dmwYV0tLpnJ62TLoqwM/story.html.

2 Marie McCullough, *Philly Patient-Safety Advocate, Physician Amy Reed, Dies at 44*, PHILA. INQUIRER (May 25, 2017, 10:12 AM), http://www.philly.com/philly/health/Philly-patient-safety-advocate-physician-Amy-Reed-dies-leiomyosarcoma-morcellator-Penn-FDA.html.

3 Weintraub, *supra* note 1.

4 *Id*.

5 *See* Denise Grady, *Amy Reed, Doctor Who Fought a Risky Medical Procedure, Dies at 44*, N.Y. TIMES (May 24, 2017), https://www.nytimes.com/2017/05/24/us/amy-reed-died-cancer-patient-who-fought-morcellation-procedure.html.

6 *See id.*

7 *Id.*

8 *Id*.

9 *Id.*

10 *Id*.

family's public-health campaign, generated a wave of reform that ultimately changed the standard of care in gynecology.[11]

As it turned out, even before Dr. Reed's report, FDA had long been aware of the possibility that power morcellators could spread cancer.[12] However, due to a drastic underappreciation of the magnitude of the risk, the agency cleared power morcellators under the expedited 510(k) premarket notification channel and failed to require any warnings by manufacturers or physicians regarding those risks.[13] And in the twenty-two years that had elapsed between the time that the first power morcellators reached the U.S. market and Dr. Reed's surgery in 2013, the agency had not received a single adverse effect report indicating any cancer risk associated with morcellation.[14] Thanks to the efforts of Dr. Reed and Dr. Noorchashm in bringing the dangers of morcellation to light, FDA received hundreds of such reports by September 2016,[15] and FDA, manufacturers, insurers, and practitioners alike have all taken steps to limit the use of the controversial tool.[16]

As the robust media response and an in-depth study by the Government Accountability Office (GAO) have pointed out, the morcellation issue illuminates several key inadequacies in FDA's 510(k) clearance process and its subsequent postmarket reporting schemes.[17] However, insufficient oversight and reporting failures alone do not fully account for the full range of problems that let morcellators onto the market. What these narratives have failed to grapple with are the persistent deficiencies on the physician's side when it comes to ensuring the safety of medical devices, including a lack of adherence to ethical requirements for reporting adverse events and the siloed nature of the gynecological profession.[18] Thus, in charting a path forward for reforming its device clearance mechanisms and improving data-gathering systems, FDA must not be left to operate in a vacuum. To avoid incidents like the morcellation crisis, a holistic approach that bridges gaps between regulators and physicians is critical, particularly in the historically fraught area of women's healthcare.

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[11] Matthew Bin Han Ong, *Amy Reed, Physician and Patient who "Moved Mountains" to End Widespread Use of Power Morcellation, Dies at 44*, CANCER LETTER (May 26, 2017), https://cancerletter.com/articles/20170526_1/.

[12] U.S. GOV'T ACCOUNTABILITY OFF., GAO-17-231, CANCER RISK LED FDA TO WARN AGAINST CERTAIN USES OF POWER MORCELLATORS AND RECOMMEND NEW LABELING 16 (2017) [hereinafter GAO Report].

[13] *Id.* at 17–18.

[14] *Id.* at 19.

[15] *See id.* at 25.

[16] *See, e.g.*, *id.* at 19–24; Jon Kamp, *Aetna to Stop Covering Routine Use of Power Morcellator*, WALL ST. J. (May 5, 2015), https://www.wsj.com/articles/aetna-to-stop-covering-routine-use-of-power-morcellator-1430838666.

[17] GAO Report, *supra* note 12, at 8–9, 26.

[18] *See, e.g.*, Hooman Noorchashm, *An Open Letter to the American College of Surgeons: Residency Training in Gynecology is Dangerously Deficient*, MEDIUM (Oct. 1, 2017), https://medium.com/@noorchashm/an-open-letter-to-the-american-college-of-surgeons-residency-training-in-gynecology-is-dangerously-e1c4524ad638.

II. BACKGROUND: HOW POWER MORCELLATOR TOOLS REACHED THE U.S. MARKET

A. Design and Function of Power Morcellator Tools

Power morcellators were introduced into gynecological practice to aid in treatment of uterine fibroids—noncancerous growths in the uterus which may be removed surgically or treated with alternative methods such as drug therapy or focused ultrasound treatment.[19] The surgical option for treating fibroids consists of either a hysterectomy (removal of the uterus) or a myomectomy (removal of individual fibroids).[20] With minimally invasive surgery on the rise in other fields of medicine in the 1990s, gynecologists were eager to introduce those techniques into their own practice, and morcellators provided a solution.[21] The surgical devices, consisting of a spinning cylindrical blade within a tube, are used to cut tissue into small pieces for easier removal through a small incision site. Using the tools, surgeons can perform hysterectomies and myomectomies laparoscopically, resulting in a quicker recovery time and decreased risk of infection relative to open surgery.

The risk of morcellation, however, is that the tools may inadvertently disperse cancerous cells throughout the body. In a fraction of patients, what may appear to be a uterine fibroid may in fact be a difficult-to-detect cancer, which with current technology remains invisible on pre-operative diagnostic tests. For those women, the use of a power morcellator effectively detonates a cancer bomb within their abdomen, dramatically exacerbating what could have been a manageable cancer into a late-stage, highly progressed disease.[22]

Nevertheless, as of 2013, the tools were widely in use and functioned as the "centerpiece of an expanding practice of minimally invasive hysterectomy and myomectomy."[23] Furthermore, because doctors generally viewed the use of the tool as a minor technical aspect of the procedure, most women were not warned about any potential risks associated with the use of the device in their surgeries.[24]

B. Overview of the 510(k) Clearance Channel

Because power morcellators were categorized by FDA as Class II devices, they were cleared for the market through the abbreviated process under section 510(k) of the Food, Drug and Cosmetic Act ("FDCA"), known as premarket notification, rather than the more demanding premarket approval ("PMA") approach required for Class III devices.

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[19] GAO Report, *supra* note 12, at 5.

[20] *Id.*

[21] Tracilyn Hall et al., *Medical Device Safety and Surgical Dissemination of Unrecognized Uterine Malignancy: Morcellation in Minimally Invasive Gynecologic Surgery*, 20 THE ONCOLOGIST 1274, 1274 (2015).

[22] *Id.* at 1275–78.

[23] Hooman Noorchashm, *When the "Greater Good" Puts Lives at Avoidable Risk: The Lessons of Gynecologic Morcellation*, OP-(M)ED (July 15, 2017), https://opmed.doximity.com/when-medical-utilitarianism-conflicts-with-ethics-the-lessons-of-gynecological-morcellation-d7f6e168ab00.

[24] Jennifer Levitz & Jon Kamp, *'Hopes, Dreams, Plans': Medical Device Sidelined Too Late to Save Some*, WALL ST. J. (Nov. 22, 2014), at A1.

Part of the 1976 Amendments to the FDCA,[25] the 510(k) channel permits a device to be marketed if it is "substantially equivalent" to a predicate device. Under current law, predicate devices can fall into one of three categories: (1) those devices that were already on the market prior to May 28, 1976; (2) devices that have been previously cleared through the 510(k) process; and (3) devices that have been reclassified by FDA from Class III to Class II or Class I.[26] FDA finds a device to be "substantially equivalent" to a predicate device if, first, it "has the same intended use as the predicate" and, second, if it either has "the same technological characteristics as the predicate" or "has different technological characteristics and does not raise different questions of safety and effectiveness," or "information submitted to FDA demonstrates that the device is at least as safe and effective as the legally marketed device."[27] Manufacturers must submit their 510(k) materials ninety days before they hope to market a product. If FDA then determines that the device meets the "substantial equivalence" standard, it is cleared to be marketed in the United States.

Though 510(k) was originally developed in 1976 as a means of "grandfathering in" pre-classification devices and easing the transition to the new regulatory scheme, the exception has since become the rule.[28] The 510(k) process has become a key channel for new products, with 142,000 devices cleared via the process since 1976.[29] The pathway has generally proven to be attractive to manufacturers, given that 510(k) submissions are not information-intensive, are processed quickly, and are usually approved.[30] As of 2011, approximately one-third of all devices entering the market were cleared through 510(k), with approximately sixty-seven percent of devices exempt from any premarket review and only one percent entering the market through the PMA pathway.[31]

In light of the dominance of 510(k), the process has engendered controversy regarding whether it successfully balances the demands of facilitating access to technology and protecting public health. Because no clinical trials are required, 510(k) clearance is considerably more efficient and less costly than PMA or the more

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[25] Medical Device Amendments of 1976 ("MDA"), Pub. L. No. 94-295, 90 Stat. 539 (1976).

[26] 21 C.F.R. § 807.92 (a)(3) (2016).

[27] *Premarket Notification 510(K)*, U.S. FOOD & DRUG ADMIN. (Oct. 27, 2017), https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm.

[28] *See* PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW: CASES AND MATERIALS 753 (2d ed. 1991) (describing the development of the 510(k) process as a means of ensuring equal treatment of pre- and post-amendment devices); *see also* Jim O'Reilly, *The Case for Leaving the 510(k) Argument Out of a Pleading*, 24 PROD. LIAB. LITIG., Summer 2013, at 16–17.

[29] EMERGO GRP., HOW LONG IT TAKES THE U.S. FDA TO CLEAR MEDICAL DEVICES VIA THE 510(K) PROCESS 10 (2017).

[30] *See* Robert Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 FOOD, DRUG, COSM. L.J. 511, 516 (1988); *but see* Benjamin A. Goldberger, *The Evolution of Substantial Equivalence in FDA's Premarket Review of Medical Devices*, 56 FOOD & DRUG J. 317, 318 n.14 (2001) (citing Jonathan S. Kahan, *Premarket Approval Versus Premarket Notification: Different Routes to the Same Market*, 39 FOOD, DRUG, COSM. L.J. 510, 519 (1984), for the proposition that "in certain situations, the PMA process may be preferable because it can establish a regulatory barrier to market entry by competitors who will also have to go through the time-consuming PMA process to sell a competing product.").

[31] COMM. ON THE PUB. HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS, INST. OF MED., MEDICAL DEVICES AND THE PUBLIC'S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS 4 (2011) [hereinafter IOM Report].

stringent approval process used for drugs, and is thus considered a critical mechanism for quickly getting medical devices to consumers who will benefit from them.[32] But because substantial equivalence focuses on similarity to predicate devices and not on a product's safety or effectiveness, the 510(k) channel has been criticized as being insufficiently protective of public safety.[33] Critics of 510(k) have pointed to disastrous product recalls,[34] as well as perceived loopholes such as the fact that a recalled product can continue to serve as a 510(k) predicate,[35] to argue for reform of FDA's regulatory approach for Class II devices.

Significantly, 510(k) does not stand alone in ensuring that products on the U.S. market are safe: rather, it is coupled with postmarket reporting, another significant component of FDA's regulatory scheme. Devices cleared through 510(k), after they reach the market, are subsequently subject to oversight in the form of Medical Device Reporting ("MDR").[36] FDA mandates that device manufacturers, importers, and user facilities (such as hospitals) report "adverse events," wherein a medical device may have contributed to or caused a serious injury or death. Precise reporting requirements vary depending on the identity of the party; for user facilities, for example, reports are mandatory to FDA and to the device manufacturer within ten work days after the user facility becomes aware of information that "reasonably suggests that a device has or may have caused or contributed to" the death or serious injury of a patient at that facility.[37]

However, other parties with access to information about potential adverse outcomes from the use of devices, including physicians and other caregivers as well as consumers and device distributors, are subject only to "voluntary" reporting.[38] FDA encourages adverse event reporting from those parties, but they are not subject to the mandatory reporting requirements outlined in 21 C.F.R. § 803. Health professionals and consumers can submit such reports through FDA's online MedWatch portal or through a mobile app.[39]

FDA may also undertake several other postmarket surveillance activities, such as ordering manufacturers to undergo postmarket surveillance studies if the failure of a

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[32] *See, e.g.*, James M. Flaherty, Jr., *Defending Substantial Equivalence: An Argument for the Continuing Validity of the 510(k) Premarket Notification Process*, 63 FOOD & DRUG J. 901 (2008) (arguing that the 510(k) scheme has successfully balanced the goals of "protecting public health through premarket review and promoting public health by providing access to medium-level risk devices more quickly," *id.* at 926–27).

[33] *See, e.g.*, IOM Report, *supra* note 31, at 193–96 (critiquing the 510(k) process as being insufficiently linked to safety and effectiveness and recommending that the "substantial equivalence" approach be abandoned in favor of a new regulatory framework for Class II devices).

[34] *See, e.g.*, Kyle Lennox, Note, *Substantially* Un*equivalent: Reforming FDA Regulation of Medical Devices*, 2014 U. ILL. L. REV. 1363, 1365–68, 1394–1400 (2014) (pointing to recalls of medical devices including artificial joints, heart defibrillators, and surgical mesh in arguing for reforms to 510(k)).

[35] *See* KEITH D. LIND, AARP PUB. POLICY INST., INSIGHT ON THE ISSUES: IMPLANTABLE DEVICES: REGULATORY FRAMEWORK AND REFORM OPTIONS 5 (2017).

[36] 21 C.F.R. § 803 (2017).

[37] *Id.* § 803.30.

[38] *See Medical Device Reporting (MDR)*, U.S. FOOD & DRUG ADMIN. (Feb. 1, 2018), https://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm

[39] *Medwatch Online Voluntary Reporting Form*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home (last visited Feb. 7, 2018).

device would likely have serious consequences.[40] FDA could also call for a postmarket surveillance study if a device is "expected to have significant use in pediatric populations," if it is intended to be "implanted in the human body for more than one year," or if it is a "life-sustaining or life-supporting device used outside a device user facility."[41]

C. Morcellators Hit the Market

FDA classified most power morcellators as Class II devices, therefore subjecting them to 510(k) premarket notification process.[42] Though one type of power morcellator was classified as a Class I device, that product was never marketed in the United States.[43] Power morcellators are thus subject to Class II general controls, including good manufacturing practices; however, no "special controls," such as specific FDA guidelines or postmarket surveillance, were established.

Between 1991 and 2014, FDA cleared twenty-five power morcellators to be marketed in the United States.[44] The first power morcellator was cleared through 510(k) in 1991, with FDA finding the device to be substantially equivalent to a previously marketed electromechanical device used to cut tissue for minimally invasive joint surgery — a device that had never been used inside the abdomen.[45] All twenty-four of the other power morcellators cleared by FDA were cleared based on a finding of substantial equivalence to a previously cleared morcellator as a predicate device.[46] The KSEA Steiner Electromechanic Morcellator, the first power morcellator indicated for use in gynecological procedures—with uterine fibroid surgery specifically included among the indications—was cleared in May 1995.[47] FDA's finding of substantial equivalence to a predicate device did not consider whether uterine fibroid surgery was a critically different context, particularly from the perspective of encountering obscured cancers, relative to orthopedic surgery.

FDA found that six power morcellator devices had different technological characteristics relative to the predicates listed in their 510(k) submissions.[48] The differences identified by FDA included the use of forceps to grip tissue in lieu of a vacuum to suction tissue and the shift from single-use to reusable blades, among others.[49] For three of these devices, FDA determined that the technological changes could not affect safety or effectiveness.[50] For the remaining three devices, FDA assessed performance data and concluded that the data demonstrated substantial

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40 21 U.S.C. § 360l(a)(1)(A).

41 *Id.*

42 GAO Report, *supra* note 12, at 5.

43 *Id.*

44 *Id.* at 9.

45 *See id.*; *see also* Denise Grady, *Weak Reporting System Let Risky Surgical Device Stay in Use*, N.Y. TIMES (Feb. 8, 2017), https://www.nytimes.com/2017/02/08/health/morcellator-gao-report-fda.html. This predicate device, the PacesetterTM 3500 Arthroscopic Surgical System, was cleared for the U.S. market in 1988. GAO Report, *supra* note 12, at 41.

46 GAO Report, *supra* note 12, at 9.

47 *Id.* at 41.

48 *Id.* at 14.

49 *Id.*

50 *See id.* at 13.

equivalence.[51] Thus, all twenty-five power morcellators were cleared to reach the U.S. market. In the years before concerns about morcellation broke into the mainstream, an estimated 80,000 hysterectomies were being performed in the United States annually using power morcellators.[52]

III. The Risks Revealed

In December 2013, Dr. Reed and Dr. Noorchashm—no doubt in part because of their own expertise as physicians—made the connection that so many had missed: that the use of a power morcellator in Dr. Reed's surgery accelerated the spread of her cancer. Dr. Reed filed the first adverse event report received by FDA linking the use of power morcellators to the upstaging of previously undetected gynecological cancer.[53] Soon afterwards, the *Wall Street Journal* picked up the story, thrusting the morcellation issue into the public eye with a bombshell exposé[54] and subsequently conducting an in-depth investigative series that was a finalist for the Pulitzer Prize.[55] After Dr. Reed's initial report of morcellation spreading uterine cancer, the floodgates opened; FDA received 285 such reports by September 2016.[56] This press coverage, combined with the ongoing public health campaign waged by Dr. Reed and Dr. Noorchashm, which included petitions calling for an immediate ban of the tool,[57] generated enough public pressure to prompt a swift response from FDA, despite ongoing debate within the gynecological profession regarding the true magnitude of the risk and whether banning the procedure would leave women better off.

FDA convened a signal review team to investigate and determine how to respond to the emerging morcellation issue.[58] FDA's investigation included a review of existing scientific literature that suggested a link between morcellation and the spread of undetected gynecological cancer.[59] Studies dating back to 1990 pointed to this risk,[60] but because they lacked consensus, were not comprehensive, and had

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[51] *Id.*

[52] Jennifer Levitz, *Doctors Eye Cancer Risk in Uterine Procedure*, WALL ST. J. (Dec. 18, 2013), https://www.wsj.com/articles/doctors-eye-cancer-risk-in-uterine-procedure-1387328455.

[53] *See* Vicki Brower, *FDA Considers Restricting or Banning Laparoscopic Morcellation*, J. NAT'L CANCER INST., Oct. 2014, at 3.

[54] Levitz, *supra* note 52.

[55] *See, e.g.*, Jon Kamp & Thomas M. Burton, *How FDA Approved Hysterectomy Tools It Now Disfavors*, WALL ST. J. (Dec. 16, 2014), https://www.wsj.com/articles/how-fda-approved-hysterectomy-tools-it-now-disfavors-1418700781; *see also The 2015 Pulitzer Prize in Public Service*, PULITZER PRIZES, http://www.pulitzer.org/finalists/wall-street-journal (last visited Feb. 4, 2018).

[56] GAO Report, *supra* note 12, at 25.

[57] *See, e.g.*, *Health Alert: Many Women Have Died Unnecessarily Because Dangerous Cancers of the Uterus and Ovaries Are Being Spread Using Morcellators*, CHANGE.ORG, https://www.change.org/p/women-s-health-alert-deadly-cancers-of-the-uterus-spread-by-gynecologists-stop-morcellating-the-uterus-in-minimally-invasive-and-robot-assisted-hysterectomy.

[58] *See* GAO Report, *supra* note 12, at 20.

[59] *See Quantitative Assessment of the Prevalence of Unsuspected Uterine Sarcoma in Women Undergoing Treatment of Uterine Fibroids: Summary and Key Findings*, U.S. FOOD & DRUG ADMIN. (Apr. 17, 2014), http://www.fda.gov/downloads/MedicalDevices/Safety/AlertsandNotices/UCM393589.pdf [hereinafter FDA Study].

[60] *See, e.g.*, S. Leibsohn et al., *Leiomyosarcoma in a Series of Hysterectomies Performed For Presumed Uterine Leiomyomas*, 162 AM. J. OBSTETRICS & GYNECOLOGY 968 (1990); I.S. Hagemann et

never been systematically analyzed, the magnitude of the risk had been severely underestimated, according to FDA's new calculation.[61] In April 2014, FDA published the results of its investigation, stating that the risk of spreading a uterine sarcoma via power morcellation was approximately 1 in 350 for women undergoing uterine fibroid surgery—a staggeringly high risk and a significant departure from the previously accepted figure of approximately 1 in 10,000 women.[62]

In conjunction with this study, FDA issued a safety communication expressing its "concern[] about women undergoing laparoscopic power morcellation for the treatment of uterine fibroids and the risk of inadvertent spread of unsuspected cancer to the abdominal and pelvic cavities."[63] The safety communication—directed at health care providers, medical professional associations, cancer advocacy organizations, health care facilities, patients, and manufacturers—reported the higher 1 in 350 rate of undetected cancer in women seeking uterine fibroid treatment and discouraged the use of power morcellator tools in those gynecological procedures.[64] The safety communication emphasized that the type of cancer at issue, uterine sarcoma, could not be reliably detected prior to surgery, and described the risk of upstaging the cancer and "significantly worsening the patient's likelihood of long-term survival."[65] FDA also provided a series of recommendations for health care providers and patients. In addition to expressing that the use of morcellators was now considered disfavored in surgery for uterine fibroid treatment, the communication advised health care providers to consider all available treatment options, thoroughly discuss benefits and risks with patients, and consider using containment bags during morcellation to minimize the risk of spreading cancerous tissues.[66] For patients, the communication recommended discussing risks and benefits of the procedure and seeking routine follow-up care.[67]

In the meantime, hospitals and manufacturers took steps on their own to respond to the growing controversy over morcellation. Temple University Hospital required containment bags to be used during morcellation procedures and banned the use of morcellation for fibroids exceeding seven inches in February 2014.[68] Brigham and Women's Hospital, where Dr. Reed had undergone her surgery, and Massachusetts General Hospital required the use of containment bags in March 2014.[69] On the manufacturer side, Johnson & Johnson, an industry heavyweight that was at the time

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al., *Risk of Occult Malignancy in Morcellated Hysterectomy: A Case Series*, 30 INT'L J. GYNECOLOGY & PATHOLOGY 476 (2011).

[61] *See* GAO Report, *supra* note 12, at 17.

[62] *See* FDA Study, *supra* note 59, at 1.

[63] *Laprascopic Uterine Power Morcellation in Hysterectomy and Myomectomy: FDA Safety Communication*, U.S. FOOD & DRUG ADMIN. (Apr. 17, 2014), https://wayback.archive-it.org/7993/20170722215731/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm393576.htm.

[64] *Id.*

[65] *Id.*

[66] *Id.*

[67] *Id.*

[68] Stephanie Cajigal, *The Morcellation Controversy: A Timeline*, MEDSCAPE (Apr. 24, 2014), https://www.medscape.com/viewarticle/824081#vp_2.

[69] *Id.*

the largest manufacturer of the device, halted sales following FDA's April 2014 safety communication and formally left the market that July.[70]

In July 2014, FDA convened a meeting of the Obstetrics and Gynecological Medical Device Advisory Committee. The purpose of the meeting was to discuss the role of power morcellators, whether techniques such as containment bags could address the risk of using the devices, and whether a "boxed warning" should be implemented.[71] The advisory panel heard testimony from scientists, doctors, and patients as it formulated its recommendations,[72] including powerful testimony by Dr. Reed and Dr. Noorchashm.

Also testifying were physicians and representatives from medical societies who were opposed to FDA's restrictions on morcellation. Some doctors and professional associations resisted FDA's assessment of the risks of morcellation and continued to defend the devices, emphasizing the benefits of minimally invasive surgery. After all, power morcellators had been in use for decades and had brought the benefits of minimally-invasive surgery to the gynecological profession—permitting efficient surgeries that usually produced optimal patient outcomes with reduced surgery risks and recovery time. The devices were thus good for business and good for patients in the majority of cases. Some doctors maintained that the risks of the procedure had been overstated, decrying what they saw as needless government intervention into patient treatment.[73] "It is none of their business," said Dr. Jeffrey Thurston, a gynecologist in Dallas who had practiced for thirty years and performed the majority of his hysterectomies using the device.[74] Dr. Thurston stated that while he now required his patients to sign an informed-consent form listing FDA's estimated risk of undetected sarcoma, he stated that "we tell [patients] verbally that we don't think those numbers are correct" and that no reliable data demonstrated that morcellation worsened sarcomas.[75] Several professional associations and medical societies took similar stances in opposition to FDA's critique of morcellation. At the July hearings, the Society of Gynecologic Oncology (SGO) spoke in defense of power morcellators, emphasizing the vital benefits of minimally invasive surgery, including "significant reduction in blood loss, transfusion, pulmonary compromise, surgical site infection, venous thrombosis, length of hospital stay, and postoperative pain," as well as improved "quality of life, body image and return to base line function."[76]

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[70] Jon Kamp & Jennifer Levitz, *Johnson & Johnson Pulls Hysterectomy Device from Hospitals*, WALL ST. J. (July 30, 2014), https://www.wsj.com/articles/johnson-johnson-to-call-for-voluntary-return-of-morcellators-1406754350.

[71] A "boxed warning," also termed a "black box warning," is FDA's most severe warning label, placed in a prominently displayed box on the device's packaging. This label is used in only the most serious cases, where a warning is considered necessary for the continued safe use of the device. *See* Raymond G. Mullady Jr., *Everything You Need and Wanted to Know About Black Boxed Warnings*, 68 DEF. COUNS. J. 50, 50–51 (2001).

[72] *See* Vicki Brower, *FDA Likely to Further Restrict or Ban Morcellation*, 15 LANCET ONCOLOGY e369, e369 (2014).

[73] *See, e.g.*, Jennifer Levitz & Jon Kamp, *Gynecologists Resist FDA Over Popular Surgical Tool*, WALL ST. J. (Sept. 22, 2014), at A1.

[74] *Id.*

[75] *Id.*

[76] Society of Gynecologic Oncology, *Statement of the Society of Gynecologic Oncology to the Food and Drug Administration's Obstetrics and Gynecology Medical Devices Advisory Committee Concerning*

While acknowledging the risks of the use of morcellators in cases of potential malignancy, SGO challenged FDA's assessment of the prevalence of the risk, stating that their literature review methodology was flawed and based on unreliable studies with questionable data.[77] Arguing in favor of permitting unrestricted use of power morcellators in the United States with informed consent, SGO called for a utilitarian balancing between the benefits of minimally invasive surgery and the "very low risk of disseminating a sarcoma through morcellation."[78] The gynecological professional association AAGL[79] took a similar stance in response to FDA's safety communication, extolling the virtues of avoiding open abdominal hysterectomies and arguing that "[a] critical review of the literature supports that tissue morcellation can be performed safely and effectively by properly trained and experienced surgeons in appropriately screened and selected patients."[80]

Against this backdrop of awareness, action, and resistance, FDA made its next regulatory move. In November 2014, FDA issued an updated safety communication and an "immediately in effect" guidance recommending the use of a boxed warning as well as other contraindications.[81] FDA's decision to exercise its authority to issue an "immediately in effect" guidance, rather than following the ordinary procedure of issuing a draft guidance, permitting a comment period, and then issuing a final guidance, was an extraordinary move that underscored the urgency of the situation.[82] The new guidance stated that review of scientific literature and discussions with the patient and clinical communities had raised awareness of the high risks of used power morcellators in uterine fibroid surgery.[83] The guidance called for manufacturers to comply with the labeling recommendations[84] and stated that within

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Safety of Laparoscopic Power Morcellation (July 2014), https://www.sgo.org/wp-content/uploads/2014/04/SGO-Testimony-to-FDA-on-Power-Morcellation-FINAL.pdf.

[77] *Id.*

[78] *Id.* This utilitarian approach is modeled by studies such as Pietro Bortoletto et al., *Cost-Effectiveness Analysis of Morcellation Hysterectomy for Myomas*, 22 J. MINIMALLY INVASIVE GYNECOLOGY 820 (2015), which sought to "estimate the cost-effectiveness of eliminating morcellation in the surgical treatment of leiomyomas from a societal perspective" and concluded that "[e]liminating morcellation hysterectomy as a treatment for myomas is not cost-effective under a wide variety of probability and cost assumptions. Performing laparotomy for all patients who might otherwise be candidates for morcellation hysterectomy is a costly policy from a societal perspective." *Id.* at 820.

[79] The AAGL is a professional association that promotes minimally invasive gynecological surgery globally. Though it was initially known as the American Association of Gynecologic Laparoscopists, it later dropped this full name to reflect its expanding mission. *See About AAGL*, AAGL.org, https://www.aagl.org/service/about-aagl/ (last visited Feb. 15, 2018).

[80] AAGL, *AAGL Practice Report: Morcellation During Uterine Tissue Extraction*, 21 J. MINIMALLY INVASIVE GYNECOLOGY 517, 526 (2014).

[81] *Immediately In Effect Guidance Document: Product Labeling for Laparoscopic Power Morcellators: Guidance for Industry and Food and Drug Administration Staff,* U.S. FOOD & DRUG ADMIN. (Nov. 25, 2014), http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM424123.pdf.

[82] *See* Matthew Bin Han Ong, *Urgent FDA Action Turns Power Morcellation Into Rarely Used Gynecological Procedure*, CANCER LETTER (Nov. 26, 2014), https://cancerletter.com/articles/20141126_1/.

[83] *Id.* at 2.

[84] FDA recommended the following boxed warning to be prominently displayed on the product label: "***WARNING***: Uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer, and decrease the long-term survival of patients.

120 days, manufacturers with existing 510(k) clearances should update their labeling with the contraindications and boxed warning, submit their amended labeling to FDA, and provide the new labeling to prior purchasers to whom the product had already been distributed.[85] The black-box warning stopped short of a total ban, leaving open the possibility that power morcellators could still be used for some women, such as younger patients who are at a low risk for cancer and wish to preserve their fertility through minimally invasive surgery targeting fibroids specifically rather than removing the entire uterus.[86] Despite this narrow opportunity for the continued use of the devices, FDA's decision to invoke its strongest warning was a severe limitation upon the use of morcellators, expected to largely curtail their use.[87] William Maisel, deputy director for science and chief scientist at FDA's Center for Devices and Radiological Health, framed FDA's guidance in sweeping terms during a November 24 press call, stating: "We believe that in the vast majority of women, the procedure should not be performed."[88]

FDA's immediately-in-effect guidance was generally met with approval by those opposed to morcellation, though some felt that it did not go far enough. Like some other anti-morcellation activists, Dr. Noorchashm saw the victory as bittersweet: while acknowledging that FDA's strong language in the November guidance was a major step forward in the battle to end the use of morcellators, he expressed disappointment that the agency did not opt for an outright ban. "We saw it as a failure because they had everything they needed to ban the device, but they faced pressure from the industry," Dr. Noorchashm stated in a January 2018 interview with the author of this paper. "And to this day they are still under pressure; they are still tit-for-tatting over the exact magnitude of the risk."[89] Nevertheless, the agency's swift action was seen as a decisive restriction that would sharply curtail the use of the device.[90]

Others continued to defend morcellation in the face of FDA's harsher restrictions. Dr. Hal Lawrence, executive vice president and chief executive officer of the American College of Obstetricians and Gynecologists (ACOG), took a measured approach, emphasizing that morcellation could still be appropriate in some circumstances, such as "if a patient is thought to be at low risk for an occult leiomyosarcoma or endometrial malignancy and is trying to spare her fertility, or has

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This information should be shared with patients when considering surgery with the use of these devices." *Id.* at 4. The recommended labeling also included two contraindications. The first contraindication stated that "Laparoscopic power morcellators are contraindicated in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy." *Id.* The second stated: "Laparoscopic power morcellators are contraindicated for removal of uterine tissue containing suspected fibroids in patients who are: (1) peri- or post-menopausal, or (2) candidates for *en bloc* tissue removal, for example, through the vagina or via a mini-laparotomy incision." *Id.*

[85] *Id.*

[86] Jon Kamp & Jennifer Levitz, *Surgical Tool Gets Strongest Warning*, WALL ST. J. (Nov. 24, 2014), https://www.wsj.com/articles/fda-adds-new-warning-to-labels-for-laparoscopic-power-morcellator-1416842439.

[87] *Id.*

[88] *Id.*

[89] Telephone Interview with Hooman Noorchashm (Jan. 18, 2018) [hereinafter Noorchashm Interview] (on file with author).

[90] *See, e.g.*, Kamp & Levitz, *supra* note 86.

multiple comorbidities."[91] A group of prominent gynecologists critiqued FDA's November guidance in an open letter in 2016, stating that while "problems with [FDA's November 2014] ruling were immediately apparent, the passage of time has allowed for more clarity on the related medical issues."[92] Emphasizing that "[w]omen have a right to self-determination," the open letter argued that "[m]odification of the FDA's current restrictive guidance regarding power morcellation would empower each woman to consider the pertinent issues and have the freedom to undertake shared decision making with her surgeon to select the procedure most appropriate for her."[93] A 2016 article by Dr. Lisa Rosenbaum in the *New England Journal of Medicine* took a more aggressive approach, critiquing FDA's approach to morcellation as misguided "n-of-one policymaking" driven by anecdotal tragedy like the story of Dr. Reed.[94] Dr. Rosenbaum critiqued FDA's approach as lacking a measured consideration of the utilitarian benefits of morcellation for society as a whole.[95] While opponents of morcellation have maintained that such utilitarian-based reasoning is unethical,[96] Dr. Rosenbaum insisted that "evaluating such trade-offs is our job."[97] Dr. Noorchashm characterized Dr. Rosenbaum's position as "ignor[ing] both the epidemiological data and the fact that literally hundreds, if not thousands, of women worldwide had been subjected to cancer upstaging by morcellation for well over two decades."[98]

FDA followed up on its guidances in December 2015 by conducting a series of inspections at selected hospitals to monitor their compliance with FDA reporting requirements.[99] The inspections uncovered persistent deviations from reporting requirements, including failure to report adverse events and maintain correct documentation.[100] FDA worked with the facilities to implement corrective action plans.[101]

The morcellation controversy is now being litigated in the courts. More than 100 women have filed lawsuits, some of which have ended in settlements with Johnson & Johnson, once the dominant manufacturer of morcellators for the U.S. market.[102]

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[91] Stephanie Cajigal, *ACOG Leader Defends Morcellation*, MEDSCAPE (Jan. 15, 2015), https://www.medscape.com/viewarticle/837932#vp_2.

[92] William Parker et al., *An Open Letter to the Food and Drug Administration Regarding the Use of Morcellation Procedures in Women Having Surgery for Presumed Uterine Myomas*, 23 J. MINIMALLY INVASIVE GYNECOLOGY 303 (2016).

[93] *Id.* at 305.

[94] Lisa Rosenbaum, *N-of-1 Policymaking — Tragedy, Trade-offs, and the Demise of Morcellation*, 374 NEW ENG. J. MED. 986 (2016). Dr. Noorchashm struck back at this argument in a letter to the editor. *See* Hooman Noorchashm, *To the Editor*, 374 NEW ENG. J. MED. 2605 (2016).

[95] Rosenbaum, *supra* note 94, at 989–90.

[96] *See, e.g.*, *id.* at 989.

[97] *Id*.

[98] Noorchashm, *supra* note 23.

[99] GAO report, *supra* note 12, at 23.

[100] *Id.*

[101] *Id.*

[102] Jennifer Levitz, *Johnson & Johnson Settling Cases Tied to Device That Can Spread Uterine Cancer*, WALL ST. J. (Mar. 18, 2016), https://www.wsj.com/articles/johnson-johnson-settling-cases-tied-to-device-that-spread-uterine-cancer-1458324981/

Dr. Noorchashm is pursuing a civil lawsuit in Suffolk County Superior Court against Brigham & Women's Hospital; Michael Muto, the director of the Gynecological Oncology Fellowship at Brigham & Women's; Karen Wang, the surgeon who treated Dr. Reed; and Karl Storz, the German manufacturer of the morcellator used in Dr. Reed's procedure.[103]

Today, the use of power morcellators has dramatically decreased, but the devices continue to be used in some cases.[104] Major insurers like Aetna no longer cover procedures using morcellators.[105] Many doctors have turned to alternative procedures, such as a "mini-laparotomy" surgery, which involves removing the uterus via a small incision.[106] The conversation has largely shifted focus to the efficacy of various safeguards such as containment bags, and whether the use of such alternate techniques and devices could justify bringing morcellation back into the mainstream.[107] FDA cleared the marketing of one such containment device in April 2016.[108] Meanwhile, while supporters of morcellation had feared that reducing the use of minimally invasive surgery in gynecology would lead to increases in complications from hysterectomies, these fears have not materialized, according to a 2016 study published in the *Journal of the American Medical Association*.[109] In December 2017, FDA reaffirmed its position on morcellation in an updated assessment.[110] The agency confirmed that "FDA continues to caution against the use of [morcellators] in the majority of women undergoing myomectomy or hysterectomy for treatment of fibroids. The Agency also continues to recommend that the advantages and risks of using [morcellators] during fibroid surgery be thoroughly discussed between the patient and physician before surgery."[111]

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[103]Reed v. Muto, No. 1584-CV-03245 (Mass. Super. Ct. Oct. 31, 2017).

[104]*See, e.g.*, Sharon Worcester, *Survey: Litigation Fears Drive Response to FDA Power Morcellator Warnings*, MDEDGE: OB.GYN. NEWS (Mar. 20, 2018), https://www.mdedge.com/obgynnews/article/161335/business-medicine/survey-litigation-fears-drive-response-fda-power (reporting that in a survey of 126 OB-GYNs in the Charlotte, North Carolina area, seventy-five percent reported that "they always or sometimes used power morcellation prior to receiving the FDA communication, [and] more than eighty percent reported rarely or never using it after receiving the communication.").

[105]*See* Kamp, *supra* note 16.

[106]*See* Jennifer Levitz, *Five Things to Know About Morcellation*, WALL ST. J. (Mar. 18, 2016), https://blogs.wsj.com/briefly/2016/03/18/5-things-to-know-about-morcellation/.

[107]*See, e.g.*, Enes Taylan, *Contained Morcellation: Review of Current Methods and Future Directions*, FRONTIERS IN SURGERY (Mar. 14, 2017) (Concluding that "morcellation of the specimen in an enclosed fashion should be the preferred method as many developed techniques and several specimen retrieval bags for this method have been widely available," *id.* at 3, while acknowledging that "there is currently no available method for tissue extraction that completely eliminates the risk of cellular dissemination," *id.* at 4).

[108]*See* Food & Drug Admin. Press Release, FDA Allows Marketing Of First-Of-Kind Tissue Containment System For Use With Certain Laparoscopic Power Morcellators In Select Patients (Apr. 7, 2016), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm494650.htm.

[109]*See* Jason D. Wright et al., *Trends in Use and Outcomes of Women Undergoing Hysterectomy With Power Morcellation*, 316 J. AM. MED. ASSOC. 877 (2016). The study compared outcomes for hysterectomies before and after FDA's April 2014 safety communication and found that "[t]he overall complication rate was unchanged over time." *Id.* at 877.

[110]FOOD & DRUG. ADMIN, FDA UPDATED ASSESSMENT OF THE USE OF LAPAROSCOPIC POWER MORCELLATORS TO TREAT UTERINE FIBROIDS (2017).

[111]*Id.* at 12.

IV. LESSONS LEARNED: DEFICIENCIES IN 510(K) AND REPORTING SYSTEMS

Even many of those who continue to defend the use of morcellation in some cases have now recognized that the indiscriminate use of the devices for more than two decades in the United States caused devastating damage to hundreds of women, as well as their families and loved ones. How were these devices permitted to reach the market for use in gynecological surgeries, and how did it take until 2013 for FDA to receive an adverse event report linking morcellation to dissemination of cancerous tissues? After the controversy came to light and FDA stepped in to discourage the use of the devices, the media, politicians, and, ultimately, the Government Accountability Office (GAO) turned to exploring these questions.

The GAO issued a comprehensive report in response to a congressional request that the Office examine "FDA's clearance of the devices for the U.S. market, the agency's response to adverse event reports, and relevant information and training on the use of power morcellators."[112] The GAO's account of how morcellators were cleared through the 510(k) process—with the first morcellator cleared based on an orthopedic surgery tool as a predicate device, and all subsequent morcellators cleared based on a previously-cleared morcellator as the predicate[113]—suggests certain weaknesses in the capacity of the 510(k) process to ensure public safety. In clearing these devices through 510(k), FDA did not depart from its usual procedures or inadvertently approve faulty devices.[114] Yet, the 510(k) evaluation of "substantial equivalence" was fundamentally ill-suited for prompting the kind of analysis that could have flagged concerns about the safety of using power morcellators for gynecological surgeries prior to these devices reaching the market. The expedited 510(k) process, developed in 1976 as part of a transition to the new device classification scheme and not intended as a form of "approval" or guarantor of safety, was simply not designed to include the kind of rigorous, data-driven study that could have unveiled the risks of morcellators at the clearance stage or suggested that the gynecological context differed critically from the orthopedic context that provided the initial predicate device. Subsequently, because newer morcellators could use previously-cleared morcellators as their predicate devices for 510(k) purposes, the clearance process was subject to the phenomenon of "equivalence creep," whereby new devices become increasingly attenuated in their features and functions relative to the original device that was considered safe for the market.[115]

However, none of these inherent features of the 510(k) process made the damage caused by power morcellators inevitable. The 510(k) process is not designed to stand alone in ensuring that medical devices are safe for the public; rather, it is paired with postmarket reporting and surveillance. Ultimately, the GAO report homed in on

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[112]GAO Report, *supra* note 12, at 2. Like many aspects of the reform efforts surrounding morcellation, the report arose in part due to advocacy by Dr. Reed and Dr. Noorchashm, who appealed to former U.S. Representative Mike Fitzpatrick to call for an investigation by the GAO. *See* Noorchashm Interview, *supra* note 89.

[113]*See* GAO Report, *supra* note 12, at 9–16.

[114]*See id.* at 10; Kamp & Burton, *supra* note 55.

[115]*See* Robert B. Leflar, *Public Accountability and Medical Device Regulation*, 2 HARV. J.L. & TECH. 1, 51 (1989).

failures of reporting and the overall weakness of FDA's data collection methods as the root cause of the morcellation crisis.

According to the GAO, the passive nature of FDA's post-clearance reporting requirements allowed power morcellators to be deployed for decades without accountability. Shockingly, officials from health care providers told the GAO that prior to FDA's 2014 safety communication and subsequent guidance, physicians would not have considered the spread of uterine cancers resulting from the use of a power morcellator to be the type of "adverse event" that should be reported to FDA.[116] Rather, because in such circumstances "the device would have performed as intended (e.g., cutting and extracting tissue)," they would have viewed such as incidents as non-reportable, despite the fact that the device's operation may have upstaged cancer and led to a patient's death.[117] This remarkably limited interpretation of what constitutes an "adverse event" among the very parties who are best positioned to observe and report the negative consequences of morcellation is a clear failure of reporting that permitted the use of morcellators to continue for decades despite the damage they wrought upon women with undetected uterine cancers. As Dr. Noorchashm put it: "If you have a 510(k) mechanism based on predicate, at the very least you have to have very robust reporting requirements. You can't have your cake and eat it too. You can't speed innovation and get life-saving products to market and at the same time have lax surveillance."[118] While "it's understood that technology moves faster than science," meaning that a predicate-based clearance process may be favorable because of its capacity for quickly bringing potentially beneficial innovations to the market, "a recipe for disaster" results when such a process is conducted without robust surveillance and reporting requirements.[119]

In response to the GAO report, FDA has acknowledged the deficiencies in its passive reporting system for medical devices and has implemented a plan to improve its data collection methods. In a written statement to the *New York Times*, the agency said that it agreed with the GAO's findings and wrote: "the FDA has noted the shortcomings of the current passive postmarket surveillance system and has been taking steps to establish a better system to evaluate device performance in clinical practice."[120] FDA is working to build a new, more active surveillance system called the National Evaluation System for Health Technology, known as NEST. According to the agency, the purpose of NEST is to "more efficiently generate better evidence for medical device evaluation and regulatory decision-making. NEST will generate evidence across the total product lifecycle of medical devices by strategically and systematically leveraging real-world evidence and applying advanced analytics to data tailored to the unique data needs and innovation cycles of medical devices."[121] The NEST system will be designed to aggregate data from electronic health records, billing claims, and clinical registries, helping to close some of the gaps in data

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[116]GAO Report, *supra* note 12, at 26.

[117]*Id.*

[118]Noorchashm Interview, *supra* note 89.

[119]*Id.*

[120]Grady, *supra* note 45.

[121]*National Evaluation System for Health Technology (NEST)*, U.S. FOOD & DRUG ADMIN. (Feb. 15, 2018), https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhreports/ucm301912.htm.

collection that let issues like the damaging effects of power morcellators go undetected by FDA. Because it will include the use of barcodes and other means of tracking that automatically captures device data, it will be an "active" system, unlike the current passive approach. Though NEST may be only one small step towards to the comprehensive, active, and integrated data systems necessary to optimally ensure public health and safety, FDA's attention to the faults of its approach and the dedication of resources to the problem are promising signals of reform.

Thus, the current state of affairs seems relatively optimistic: the GAO identified a key deficiency that permitted damaging devices to reach and remain on the U.S. market, and FDA is actively working to fix the problem. However, there remains a set of fundamental gaps in public safety that are contributing to problems like the morcellation crisis. These lingering issues are located primarily on the clinical side of the medical device realm, rather than purely on the regulatory side. Unless these physician-side problems are also addressed, another problem like morcellation could be looming on the horizon.

V. PERSISTENT GAPS: BRIDGING THE CLINICAL/REGULATORY DIVIDE

While FDA is taking steps to address the reporting deficiencies that let the dangers of morcellation evade detection for decades, similar measures have not yet been taken to address problems in the behavior and training of physicians that also contributed to the morcellation crisis. These include the disconnect between the ethical and legal obligations of doctors with regard to their reporting of adverse events, as well as the siloed nature of the gynecological field, which has contributed to the development of problematic standards of care.

A. Physician Reporting Obligations

The American Medical Association Code of Medical Ethics contains a provision that explicitly obligates physicians to report adverse events resulting from the use of a drug or device to FDA. Opinion 8.8, entitled "Required Reporting of Adverse Events,"[122] states that "[a] physician who suspects that an adverse reaction to a drug or medical device has occurred has an ethical responsibility to . . . [c]ommunicate that information to the professional community through established reporting mechanisms . . . [and] promptly report serious adverse events . . . to the appropriate regulatory agency."[123] The Opinion further states that "[a]s the professionals who prescribe and monitor the use of drugs and medical devices, physicians are best positioned to observe and communicate about adverse events," and emphasizes that

[122] In previous editions of the American Medical Association Code of Medical Ethics, this opinion was known as Opinion 9.032 and entitled "Reporting Adverse Drug or Device Events." *See, e.g.*, AM. MED. ASSOC., CODE OF MEDICAL ETHICS OF THE AMERICAN MEDICAL ASSOCIATION 302–03 (2008) [hereinafter Opinion 9.032]. While the new version of the opinion uses slightly different wording, its substance is unchanged from that of its predecessor.

[123] *Opinion 8.8: Required Reporting of Adverse Events*, *in* AM. MED. ASSOC., CODE OF MEDICAL ETHICS OF THE AMERICAN MEDICAL ASSOCIATION 132, 132 (2017) [hereinafter Opinion 8.8]. Serious adverse events are those that result in "hospitalization, death, or medical or surgical intervention." *Id.* The previous version of the opinion referred to an "obligation" to report to FDA, while the new version instead describes an "ethical responsibility" and uses broader language that encompasses all relevant regulatory agencies. *Compare id. with* Opinion 9.032, *supra* note 122.

"[s]pontaneous reports of adverse events, especially rare or delayed effects or effects in vulnerable populations, are irreplaceable as a source of information about the safety of drugs and devices."[124] Recognizing the critical on-the-ground perspective of physicians, the American Medical Association thus places upon them the burden to immediately flag problems like the upstaging of cancer by power morcellators and requires that physicians bring such issues to the attention of regulators.

Despite this acknowledgement by the medical profession of the critical perspective of physicians in identifying and reporting safety issues with devices and drugs, FDA's mandatory reporting requirements do not include physicians. The regulations cover device user facilities, manufacturers, importers, and distributors; in contrast, physicians are subject only to voluntary reporting.[125] Placing a legal obligation on doctors to report adverse events to FDA could hardly be considered an imposition on their ability to practice, given that they are already supposed to be subject to these requirements by the ethical code of their profession—particularly if such a requirement is paired with immunity from civil liability. Yet, as the morcellation crisis has demonstrated, doctors' ethical obligation alone has not been sufficient in prompting an adequate degree of such voluntary reporting. This scheme is permitting some of the most critical data points about the actual use and outcomes of medical devices, which would be invaluable in FDA's efforts to ensure public safety and keep dangerous devices off the market, remain uncaptured.

Legislation attempting to rectify this problem, the Medical Device Guardians Act, was introduced in the House of Representatives by a bipartisan effort in June 2016.[126] The bill sought to "codif[y] an existing mandate of the American Medical Association's Code of Medical Ethics, which recognizes that physicians are in the best position to identify and report unsafe devices," while facilitating reporting by "add[ing] physicians' reports to the list of groups, such as hospitals, already protected from having their reporting to the FDA used against them in a civil case."[127] Unfortunately, progress on that bill stalled after it was referred to the Subcommittee on Health within the House Committee on Energy and Commerce in April 2017.[128] One of the bill's champions, Rep. Louise Slaughter, passed away in March 2018.

A solution like the Medical Device Guardians Act is a critical measure in order to prevent the next device-related regulatory lapse. As the American Medical Association's standards clearly recognize, the necessary data is in the hands of doctors, who are positioned on the front lines of device use and are therefore best equipped to detect adverse events. Countless lives could have been saved if doctors

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[124]Opinion 8.8, *supra* note 123. The Opinion further clarifies that "[c]ases in which there is clearly a causal relationship between use of a drug and device and an adverse event, especially a serious event, will be rare." *Id.* Accordingly, "[p]hysicians need not be certain that there is such an event, or even that there is a reasonable likelihood of a causal relationship"; rather, the obligation to report arises upon a mere suspicion of a causal relationship. *Id.*

[125]21 C.F.R. § 803 (2017).

[126]Medical Device Guardians Act, H.R. 2163, 115th Cong. (2017).

[127]Press Release, Office of Congresswoman Louise M. Slaughter, Fitzpatrick, Slaughter Announce Package of Medical Device, FDA Reform Bills (June 8, 2016), https://louise.house.gov/media-center/press-releases/fitzpatrick-slaughter-announce-package-medical-device-fda-reform-bills.

[128]*See All Actions: H.R. 2163*, CONGRESS.GOV, https://www.congress.gov/bill/115th-congress/house-bill/2163/all-actions?overview=closed#tabs (last visited Mar. 1, 2018).

had reported upstaged cancers in their morcellation patients, even if they were not entirely certain of the causal link between the use of the device and the progression of the cancers. FDA's efforts to develop high-tech information capture systems to help address data gaps are admirable, but these complex undertakings are a mere drop in the bucket relative to the massive amount of information that could be unlocked and made accessible if physician reporting were to be successfully mobilized. As Dr. Noorchashm has observed:

These doctors are being trained and reimbursed using federal dollars; it's not too much to ask that if someone gets harmed, these individual physicians self-report to the FDA . . . People want have fancy newfangled barcodes and tracking of data, but it's as simple as: if Dr. Smith sees a problem, he should have a responsibility to report that.[129]

Dr. Noorchashm also pointed out that, while data capture systems like NEST will take years to develop and launch, allowing critical information to slip away in the meantime, a change in physicians' reporting obligations "could be implemented with immediacy — it just requires the political willpower to do it."[130] Unfortunately, that political willpower is currently lacking. Dr. Noorchashm attributes this lack of momentum in part to the fact that lobbyists have no interest in the Medical Device Guardians Act, while technology companies are eager to sell lucrative data integration systems to the government.[131] Those who have been harmed by devices like power morcellators are generally laypersons without the political clout or scientific expertise to speak forcefully on behalf of such legislation — and those who have been the most profoundly harmed are dead. Unless Capitol Hill can generate the motivation to make this much-needed change in the reporting requirements of doctors, FDA will never be fully empowered to keep the public safe from faulty medical devices.

B. Deficiencies in Gynecological Training and Practice

While the absence of mandatory physician reporting requirements affects all fields equally, another clinical-side gap that may have contributed to the morcellation crisis is specific to gynecology. The training requirements and residency structure for the obstetrics and gynecology (OB-GYN) specialty have come under fire for failing to adequately prepare physicians for practice, particularly with regard to surgical skills. Relative to other specialties, OB-GYN trainees generally spend a reduced amount of time training in surgery, and almost no time cross-training in general surgical disciplines.[132] As Drs. Sarah L. Cohen and Emily Hinchcliff observed in *Contemporary Ob-Gyn*, "The adequacy of surgical training in ob/gyn is a real concern. This is in part related to the increasing breadth of required education, which accompanies medical and technological advances in the field. In addition, clinical experience is on the decline with work-hour limitations and concerns regarding limited surgical case volume."[133] Reflecting these concerns, the Contemporary

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[129] Noorchashm Interview, *supra* note 89.

[130] *Id.*

[131] *Id.*

[132] *See, e.g.*, Noorchashm, *supra* note 18.

[133] Sarah L. Cohen & Emily Hinchcliff, *Is Surgical Training in Ob-Gyn Residency Adequate?*, CONTEMPORARY OB-GYN (July 22, 2016), http://contemporaryobgyn.modernmedicine.com/news/surgical-training-obgyn-residency-adequate?page=0,1.

OB/GYN 2015 Labor Force Reader Survey found that the notion that "we are training poorly prepared ob/gyns who are not capable of handling a variety of clinical problems, and who are not truly surgically independent and competent when they finish residency" was part of "an increasingly common concern about the adequacy of surgical training during residency."[134]

Numerous studies investigating the adequacy of OB-GYN residency training have demonstrated these deficiencies. A 2015 study of four OB-GYN subspecialties published in *Obstetrics and Gynecology*, the official publication of the American College of Obstetricians and Gynecologists, found that "[o]nly 20% of first-year fellows were able to independently perform a vaginal hysterectomy, 46% an abdominal hysterectomy, and 34% basic hysteroscopic procedures," concluding that "[g]raduating residents may be underprepared for advanced subspecialty training, necessitating an evaluation of the current structure of resident and fellow curriculum."[135] In another study, an analysis of case log reports found a decreasing amount of surgical experience in OB-GYN residencies, which "raises [the] concern that graduating residents may not have sufficient exposure to all the surgical approaches. Even in the area of laparoscopy, residents self-reported a low level of competency in most advanced procedures upon graduation."[136] Similarly, a survey specific to the sub-field of gynecologic oncology demonstrated insufficient surgical skills of incoming fellows, who were not prepared to function independently in the operating room at the outset of their fellowships.[137] That study concluded that "general Ob/Gyn residency is ineffective in preparing fellows for advanced training in gynecologic oncology and should prompt a revision of the goals and objectives of resident education to correct these deficiencies."[138]

This inadequate residency structure, including the lack of cross-disciplinary training, may have led to a siloed approach to surgery that permitted the development of a standard of care that would not have been considered permissible in other disciplines. As one thoracic surgeon at Temple University put it, "[I]n general surgery and in chest surgery, we would never morcellate. We do everything we can to remove specimens intact. It goes against surgical principles to chop something up inside a body cavity."[139] A more interdisciplinary approach to surgical training in the OB-GYN specialty may have discouraged the kind of thinking that led power morcellator use to become widespread despite the possibility of undetected cancers in women undergoing surgery for the removal of uterine fibroids.

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[134] *Id.*

[135] S.R. Guntupalli et al., *Prepardness of Obstetrics and Gynecology Residents for Fellowship Training*, 126 OBSTETRICS & GYNECOLOGY 559, 559 (2015).

[136] Cohen & Hinchcliff, *supra* note 133 (first citing E.E. Washburn et al., *Trends in Reported Resident Surgical Experience in Hysterectomy*, 21 J. MINIMALLY INVASIVE GYNECOLOGY 1067–70 (2014); then citing J.I. Einarsson et al., *Perceived Proficiency in Endoscopic Techniques Among Senior Obstetrics and Gynecology* Residents, 8 J. AM. ASSOC. GYNECOLOGIC LAPAROSCOPISTS 158–64 (2002)).

[137] David W. Doo et al., *Preparedness of Ob/Gyn Residents for Fellowship Training in Gynecologic Oncology*, 12 GYNECOLOGIC ONCOLOGY REPS. 55, 55 (2015).

[138] *Id.*

[139] Matthew Bin Han Ong, *Harvard Physician Whose Cancer Was Spread Through Morcellation Seeks to Revamp FDA Regulation of Medical Devices*, CANCER LETTER (July 4, 2014), www.ohsu.edu/xd/education/schools/school-of-medicine/departments/basic-science-departments/cell-and-developmental-biology/upload/CL40-27-1.pdf.

Furthermore, these concerns regarding the training of gynecologists and the isolated perspective that may result from it could help to explain why so many of the dangerous medical devices that have harmed consumers have been related to women's health and gynecological issues. Besides power morcellators, two of the most notorious device-related disasters involve transvaginal surgical mesh[140] and sterilization coils.[141] Interdisciplinary surgical training may have shaped a different understanding regarding whether these devices were safe to place within women's bodies.

Another factor potentially contributing to the disproportionate number of medical device safety failures in gynecology is the critical data lapses that have historically characterized the women's health field.[142] For years, women were excluded from clinical trials and women's issues were not the focus of technological and medical innovation.[143] While successful feminist movements in women's healthcare have helped to alleviate these inequalities,[144] the legacy of that exclusion shapes the landscape today: in the morcellation context, for example, the tests that might be able to detect hidden sarcomas in women who are candidates for uterine fibroid surgery have not been developed, while the studies that pointed to the risk of these undetected cancers were not robust enough to have garnered attention prior to the introduction of morcellators into mainstream gynecological practice. Against this backdrop, developing strong interdisciplinary training and deep surgical expertise is especially critical for gynecologists.

There are several possible actions that could prompt change to the structure of training in gynecology and help protect women in the future. One suggestion is for courts to take a broader view of the applicable standard of care in medical malpractice cases. The relevant standard of care varies significantly across jurisdictions, but the practice within a specific specialty is generally the point of reference for determining duty in medical malpractice suits.[145] This approach entrenches dangerously isolated thinking by shielding from liability doctors within a specialty who have agreed upon a standard of care that would be considered unacceptable by other specialties. Where one specialty has, because of substandard

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[140] *See, e.g.*, Obstetrical and Gynecological Devices; Reclassification of Surgical Mesh for Transvaginal Pelvic Organ Prolapse Repair, 81 Fed. Reg. 353, 354 (Jan. 5, 2016) (codified at 21 C.F.R. pt. 884) (ordering transvaginal surgical mesh to be reclassified from Class II to Class III because "general controls and special controls together are not sufficient to provide reasonable assurance of safety and effectiveness for this device, and these devices present a potential unreasonable risk of illness or injury"); *see also* Lennox, *supra* note 34, at 1367–68.

[141] *See, e.g.*, *Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization: Guidance for Industry and Food and Drug Administration Staff*, U.S. FOOD & DRUG ADMIN. (Oct. 31, 2016), https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM488020.pdf (requiring a boxed warning for the Essure permanent sterilization coil devices after a wave of adverse event reports).

[142] *See, e.g.*, Anita Holdcroft, Editorial, *Gender Bias in Research: How Does it Affect Evidence Based Medicine?*, 100 J. ROYAL SOC'Y MED. 2–3 (2007).

[143] *See, e.g.*, Pat Milmoe McCarrick, *Gender Issues in Health Care*, 5 KENNEDY INST. ETHICS J. 61, 61–64 ("For many years, men have been the usual participants in health care research, with the result that findings in normal men became the standard for all populations." *Id.* at 62).

[144] *See generally* MICHELLE MURPHY, SEIZING THE MEANS OF REPRODUCTION: ENTANGLEMENTS OF FEMINISM, HEALTH, AND TECHNOSCIENCE (2012).

[145] *See* B. Sonny Bal, *An Introduction to Medical Malpractice in the United States*, 467 CLINICAL ORTHOPAEDICS & RELATED RES. 339, 342 (2009).

training, developed an irresponsible standard of care, courts should be willing to look outside the specific field's standards in determining negligence. Over time, this shift could prompt the field to seek more interdisciplinary training and incorporate viewpoints from other fields.

A more direct solution to the training deficiency, proposed by Dr. Noorchashm, is to bring a lawsuit against the Accreditation Council for Graduate Medical Education (ACGME), the body responsible for accrediting graduate medical training programs, alleging negligent design of the residency program in gynecology.[146] Such a lawsuit would face an uphill battle in court, especially in establishing the causation element of a tort claim. However, as Dr. Noorchashm has demonstrated through his successes in eliciting a swift regulatory response to the morcellation issue, sometimes the publicity associated with such a move may be sufficient to drive change.

VI. CONCLUSION

The story of how power morcellators reached the U.S. market, became a common tool in gynecological surgeries for more than two decades despite harming hundreds of women, eventually came to the attention of FDA, and ultimately were nearly eliminated is a narrative of many threads. It is the story of how an individual patient and her family, engaged in dedicated activism, can bring about pervasive change and save untold lives. It is the story of how FDA, when empowered with the necessary information to make decisions about the safety of devices, can move swiftly and decisively to protect the public. Yet it is also the story of how dozens of studies telling of the risks of a medical device could go unheeded for years, leading to a profound underestimation of the danger involved; of physicians interacting with patients on the front line of care, able to observe the deleterious impacts of a device and under an ethical obligation to report them, yet failing to do so; and of an entire field of medicine that is receiving what some have labeled insufficient training in surgery and cross-disciplinary studies, leading to the development of inadequate standards of care that have put women at risk.

The challenge of balancing the speed of technological innovation with the need to protect the public is thus a multi-faceted one, and it requires a multi-faceted solution. The 510(k) process has many virtues, most significantly that it serves as a robust pathway for bringing potentially life-saving innovations to the market. But it cannot stand alone in ensuring patient safety, and it was never intended to do so. FDA is working to improve its postmarket surveillance and data collection, and those efforts are promising. In today's world of technological advancement and hyperconnectivity, nobody should lose her life because the data that could have saved it was not accessible. However, improved data collection will never be sufficient unless doctors fulfill their ethical obligation by reporting adverse events, and unless training programs for doctors are reformed to eliminate dangerous silos that may permit unsafe devices to continue to be used. A holistic approach enlisting both FDA and physicians in efforts to ensure the safety of new technology can

[146] *See* Noorchashm Interview, *supra* note 89; Am. Patient Def. Union, *A Formal Public Complaint to the Accreditation Council for Graduate Medical Education: Surgical Training in Gynecology Is Dangerously Deficient*, MEDIUM (Oct. 4, 2017), https://medium.com/@patientdefenseunion/a-formal-public-complaint-to-the-accreditation-council-for-graduate-medical-education-surgical-15ba074817e6.

ultimately lead to an optimal balance between the promise and the danger of innovation.