

# Courts v. FDA: A Lesson from Pelvic Mesh Litigation on Relative Competence to Decide a Legal Question

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## ABSTRACT

The extent to which courts should defer to an administrative agency's interpretation of the law governing the agency is the subject of considerable debate. In that debate, judges have asserted that the judicial branch is the most competent branch to decide what the law is and that it need not defer to agency opinion.

In assessing relative competence, it is helpful to consider an instance in which, in multibillion dollar product liability litigation, the courts have made a fundamental, and in retrospect obvious, legal error which has led them to say, contrary to FDA's well-founded assurances of reasonable safety and effectiveness, that the FDA clearance process does not "go to" safety at all.

## INTRODUCTION

Recent calls to overrule "*Chevron* deference" have put into issue the relative competence of courts and agencies to decide legal questions. *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*,<sup>1</sup> and related cases,<sup>2</sup> require courts to defer to an agency's interpretation of ambiguities in the law the agency enforces. But to borrow from Chief Justice John Marshall, it is the province of the courts, not executive agencies, to "say what that law is."<sup>3</sup> Justice Neil Gorsuch, while on the Tenth Circuit, felt so strongly about overruling *Chevron* deference that he separately concurred to his own opinion so he could express himself freely on the issue.<sup>4</sup> More recently, Justice

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<sup>1</sup> *Chevron U.S.A., Inc. v. Nat. Res. Def. Council*, 467 U.S. 837 (1984) (addressing deference to agency interpretation of statutes).

<sup>2</sup> *Auer v. Robbins*, 519 U.S. 452 (1997) and *Kisor v. Wilkie*, 139 U.S. 2400 (2019) (addressing deference to agency interpretation of agency regulations); *United States v. Mead Corp.*, 533 U.S. 218, 232 (2001) (addressing deference to a non-binding agency guidance). For simplicity, this Article refers to deference as a "*Chevron*" problem or *Chevron* deference. The issue of judicial competence is relevant to each of the deference doctrines.

<sup>3</sup> *Marbury v. Madison*, 5 U.S. 137, 177 (1803) ("It is emphatically the province of the judicial department to say what the law is. Those who apply the rule to particular cases, must of necessity expound and interpret that rule. If two laws conflict with each other, the courts must decide on the operation of each.").

<sup>4</sup> *Gutierrez-Brizuela v. Lynch*, 834 F.3d 1142, 1149 (10th Cir. 2016) (Gorsuch, J., concurring) ("There's an elephant in the room with us today. We have studiously attempted to work our way around it and even left it unremarked. But the fact is *Chevron* and *Brand X* permit executive bureaucracies to swallow

Clarence Thomas dissented from the denial of certiorari in a case raising the question.<sup>5</sup> Other judicial opinions also take the view that the courts know best.<sup>6</sup> The Tenth Circuit recently did so in a federal drug law preemption case.<sup>7</sup> The rationale is that courts decide what the law is and can do so free from institutional bias.

Others are not so sure that courts know best.<sup>8</sup> Agencies deal with agency law issues on a daily basis and are most acutely aware of the consequences a legal interpretation may have. Agencies, and not courts, are politically accountable. And, by placing ambiguities in the legislation creating the agency, Congress may have intended to delegate the power to make and interpret regulations that clarify the ambiguities or fill in legislative gaps.<sup>9</sup> The danger is that generalist judges may “disrupt[] rational and predictable agency policymaking schemes” by “[e]xamining cases one by one at the behest of particular claimants” and so “taking a myopic view.”<sup>10</sup>

Which view will prevail remains to be seen. It is possible that the Supreme Court will return to the previously embraced multi-factor formula that made deference depend on context, such as whether private parties had relied on the agency’s legal interpretation and, if so, for how long.<sup>11</sup> The outcome of this contest will rest in part on future opinions about judicial competence to decide questions of agency law.

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huge amounts of core judicial and legislative power and concentrate federal power in a way that seems more than a little difficult to square with the Constitution of the framers’ design. Maybe the time has come to face the behemoth.”).

<sup>5</sup> *Baldwin v. United States*, 140 U.S. 690 (2020) (Thomas, J., dissenting from denial of certiorari).

<sup>6</sup> *Pereira v. Sessions*, 138 U.S. 2105, 2120 (2018) (Kennedy, J., concurring) (application of administrative deference may “suggest[] an abdication of the Judiciary’s proper role in interpreting federal statutes”); *Perez v. Mortg. Bankers Ass’n*, 575 U.S. 92, 119 (2015) (Thomas, J., concurring) (“[T]he judicial power, as originally understood, requires a court to exercise its independent judgment in interpreting and expounding upon the laws”); *Voices for Int’l Bus. & Educ., Inc. v. Nat’l Labor Relations Bd.*, 905 F.3d 770, 781 (5th Cir. 2018) (administrative deference may “mean[] collapsing these three separated government functions into a single entity”) (Ho, J., concurring); *Waterkeeper All. v. Env’t. Prot. Agency*, 853 F.3d 527, 539 (D.C. Cir. 2017) (Brown, J., concurring) (stating that “[a]n Article III renaissance is emerging against the judicial abdication performed in *Chevron’s* name”); *Egan v. Del. River Port Auth.*, 851 F.3d 263, 279 (3d Cir. 2017) (Jordan, J., concurring) (“The deference required by *Chevron* not only erodes the role of the judiciary, it also diminishes the role of Congress.”).

<sup>7</sup> *In re MDL 2700 Genentech Herceptin Trastuzumab Mktg. & Sales Practice Litig.*, 960 F.3d 1210, 1233–34 (10th Cir. 2020) (holding that a law was clear despite conflicts with agency position).

<sup>8</sup> *Decker v. Nw. Env’t. Def. Ctr.*, 568 U.S. 597, 621 (2013) (Scalia, J., concurring in part and dissenting in part) (with administrative deference, “[t]he country need not endure the uncertainty produced by divergent views of numerous district courts and courts of appeals as to what is the fairest reading of the regulation, until a definitive answer is finally provided, years later, by this Court”); *Negusie v. Holder*, 555 U.S. 511, 530 (2009) (Stevens, J., concurring in part and dissenting in part) (“The *Chevron* framework thus accounts for the different institutional competencies of agencies and courts: Courts are expert at statutory construction, while agencies are expert at statutory implementation.”); *Barnhart v. Walton*, 535 U.S. 212, 222 (2002) (Breyer, J.) (citing, among other things, the “related expertise of the Agency” as a justification for applying *Chevron* deference). See generally Cass Sunstein, *Chevron as Law*, 107 GEO. L.J. 1613, 1669–74 (2019) (arguing for “domestication”).

<sup>9</sup> See *Chevron U.S.A. Inc. v. Nat. Res. Def. Council.*, 467 U.S. 837, 843 (1984).

<sup>10</sup> CASS R. SUNSTEIN & ADRIAN VERMEULE, *LAW & LEVIATHAN: REDEEMING THE ADMINISTRATIVE STATE* 100–101 (2020).

<sup>11</sup> See *Nat’l Muffler Dealers Ass’n, Inc. v. United States*, 440 U.S. 472, 477 (1979) (called into doubt in *Mayo Found. for Med. Educ. & Research v. United States*, 562 U.S. 44, 54–55 (2011) (multifactor approach inconsistent with *Chevron*)). See also *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944).

One way to test assumptions about relative competence is to examine a specific conflict between an agency and the courts. A comparison of how an agency has described its action under its statutory mandate to the courts' description of that action can provide at least one concrete measurement of court competence to discern agency law.

For several decades, the U.S. Food and Drug Administration (FDA) has regulated the sale of polypropylene surgical mesh.<sup>12</sup> Surgeons first used it to treat abdominal hernias. Later, they employed it to reinforce the female pelvic floor. Beginning in 1996, manufacturers made specially cut mesh and tools that enabled methods of insertion through small cuts in the vagina that did not require open abdominal surgery. The first devices, mesh "slings," supported the urethra and prevented stress urinary incontinence.<sup>13</sup> When those devices proved successful, manufacturers offered specially cut flat mesh pieces that would surround the vagina to repair pelvic organ prolapse, a condition in which adjacent organs protrude into the vagina.<sup>14</sup>

Over the years, FDA received a number of medical device reports that associated the pelvic mesh devices with pain and other patient problems. After issuing a public health warning in 2008<sup>15</sup> and conducting an intensive medical panel review in 2011,<sup>16</sup> the agency treated the two kinds of devices differently.<sup>17</sup> FDA decided that, in general, the incontinence slings were safe and effective, while questions about the prolapse devices remained.<sup>18</sup> In 2019, it stopped the sale of some of the prolapse devices altogether.<sup>19</sup>

<sup>12</sup> See U.S. FOOD & DRUG ADMIN., OBSTETRICS & GYNECOLOGY DEVICES ADVISORY COMM. OF SEPT. 8–9, 2011, SURGICAL MESH FOR TREATMENT OF WOMEN WITH PELVIC ORGAN PROLAPSE AND STRESS URINARY INCONTINENCE: FDA EXECUTIVE SUMMARY 24, 68 (2011), <https://wayback.archive-it.org/7993/20170404140406/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/UCM270402.pdf> [<https://perma.cc/ZUS8-34CG>] [hereinafter FDA EXECUTIVE SUMMARY]. For all Non-FDA-Generated and FDA-Generated Meeting Materials, see U.S. FOOD & DRUG ADMIN., 2011 MEETING MATERIALS OF THE OBSTETRICS AND GYNECOLOGY DEVICES PANEL, <https://wayback.archive-it.org/7993/20170403223431/https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/ucm262488.htm> [<https://perma.cc/5QW5-N25E>] [hereinafter 2011 MEETING MATERIALS PAGE].

<sup>13</sup> See FDA EXECUTIVE SUMMARY, *supra* note 12, at 5.

<sup>14</sup> See *id.* at 5, 10–12.

<sup>15</sup> U.S. FOOD & DRUG ADMIN., FDA PUBLIC HEALTH NOTIFICATION: SERIOUS COMPLICATIONS ASSOCIATED WITH TRANSVAGINAL PLACEMENT OF SURGICAL MESH IN REPAIR OF PELVIC ORGAN PROLAPSE AND STRESS URINARY INCONTINENCE (2008), <http://www.amiform.com/web/documents-risques-op-coelio-vagi/fda-notifcation-about-vaginal-mesh.pdf> [<https://perma.cc/3TM9-VD4B>] [hereinafter 2008 FDA PUBLIC HEALTH NOTIFICATION].

<sup>16</sup> See FDA EXECUTIVE SUMMARY, *supra* note 12 (2011 summary of medical literature and adverse event reports for all pelvic mesh devices).

<sup>17</sup> *FDA's Activities: Urogynecologic Surgical Mesh*, U.S. FOOD & DRUG ADMIN. (Oct. 24, 2019), <https://www.fda.gov/medical-devices/urogynecologic-surgical-mesh-implants/fdas-activities-urogynecologic-surgical-mesh> [<https://perma.cc/3X55-3KPE>] [hereinafter *FDA's Activities: Urogynecologic Surgical Mesh*].

<sup>18</sup> U.S. FOOD & DRUG ADMIN., OBSTETRICS & GYNECOLOGY DEVICES ADVISORY COMM. OF SEPT. 8–9, 2011, SUMMARY OF THE OBSTETRICS & GYNECOLOGY DEVICES PANEL 1–3 (2011), <https://wayback.archiveit.org/7993/20170404140420/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/UCM271769.pdf> [<https://perma.cc/9GPW-D524>] [hereinafter PANEL SUMMARY].

<sup>19</sup> *FDA's Activities: Urogynecologic Surgical Mesh*, *supra* note 17.

The 2008 FDA public health notice triggered the filing of more than 104,800 lawsuits against the seven manufacturers of the devices.<sup>20</sup> The suits claimed that the devices were defective and that the manufacturers did not warn surgeons of the adverse events they caused.<sup>21</sup> The federal multidistrict litigation, or MDL, took place in West Virginia, while state mass tort proceedings went forward in New Jersey and Pennsylvania.<sup>22</sup> A dispute over attorneys' fees revealed that at least \$7 billion was paid by manufacturers in the federal MDL alone.<sup>23</sup>

One issue in the litigation was the relevance of FDA regulatory efforts to the tort claims.<sup>24</sup> At least eleven states have statutes that make regulatory compliance a defense to either compensatory or punitive damages, or both.<sup>25</sup> Under the common law, compliance with federal regulations evidences due care in making a product and can negate a claim that safety has been recklessly disregarded.<sup>26</sup>

As a result, multiple courts have been called on to decide whether the FDA regulation is a safety regulation relevant to the jury's decision. The litigation has produced opinions on the subject from the Fourth, Eleventh, and Seventh Circuits, as well as from the intermediate appellate court in Pennsylvania.<sup>27</sup>

The opinions of FDA and those of the courts stand in direct conflict. FDA has said that the method it has used to regulate mesh is sufficient "to provide a reasonable assurance of safety and effectiveness."<sup>28</sup> On the other hand, courts have dismissed this claim as nothing but a "[b]ald assertion[]" by FDA that does "little to alter the analysis."<sup>29</sup> And the courts' "analysis" has been that because FDA regulation does not "go to safety," regulatory evidence would so confuse the jury and waste court time that it should be excluded pursuant to Federal Rule of Evidence 403.<sup>30</sup> Consequently,

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<sup>20</sup> See Petition for Writ of Certiorari, *Katz v. Common Benefit Fee & Cost Comm.*, No. 19-984, 2020 WL 598609, at \*6 (U.S. Feb. 3, 2020).

<sup>21</sup> See, e.g., *In re C.R. Bard, Inc.*, MDL No. 2187, Pelvic Repair Sys. Prod. Liab. Litig., 810 F.3d 912 (4th Cir. 2016) (claims for design defect and failure to warn).

<sup>22</sup> *Id.* See also Petition for Writ of Certiorari, *Katz v. Common Benefit Fee & Cost Comm.*, 2020 WL 598609, at \*7–9.

<sup>23</sup> Petition for Writ of Certiorari, *Katz v. Common Benefit Fee & Cost Comm.*, 2020 WL 598609, at \*7.

<sup>24</sup> See *infra*, Part IV.

<sup>25</sup> JAMES M. BECK & ANTHONY VALE, DRUG AND MEDICAL DEVICE PRODUCT LIABILITY DESKBOOK §§ 2.04[2] n.112, 11.01[1] n.1 (2019). See also James M. Beck, *Regulatory Compliance and Punitive Damages*, DRUG & DEVICE LAW (March 8, 2007), <https://www.druganddevicelawblog.com/2007/03/regulatory-compliance-and-punitive.html> [<https://perma.cc/UTX8-PAKJ>] (citing ARIZ. REV. STAT. § 12-701; FLA. STAT. § 768.1256; IND. CODE § 34-20-5-1; KAN. STAT. ANN. § 60-3304(a); MICH. COMP. LAWS § 600.2946(4); N.J. STAT. ANN. § 2A:58C-4; N.C. GEN. STAT. § 99B-6(b)(4); N.D. CENT. CODE § 28-01.3-09; TENN. CODE ANN. § 29-28-104; TEX. REV. CIV. PRAC. & REM. C. §82.007; and UTAH CODE ANN. §78-15-6).

<sup>26</sup> RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY: PRODUCTS LIABILITY § 4 (1998).

<sup>27</sup> See *infra*, Part IV.

<sup>28</sup> U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF, THE 510(K) PROGRAM: EVALUATING SUBSTANTIAL EQUIVALENCE IN PREMARKET NOTIFICATIONS 7 (2014), <https://www.fda.gov/media/82395/download> [<https://perma.cc/T7SH-ZLST>] [hereinafter FDA 2014 GUIDANCE].

<sup>29</sup> See, e.g., *In re C.R. Bard, Inc.*, MDL No. 2187, Pelvic Repair Sys. Prod. Liab. Litig., 810 F.3d 912, 921 (4th Cir. 2016).

<sup>30</sup> *Id.* at 921–22. The exclusion of evidence of the method FDA has used to clear the mesh devices has not been universal. Recently, a New Jersey appellate court found FDA evidence admissible in a pelvic

juries have imposed both compensatory and punitive damages on manufacturers without ever being told that the manufacturers, before marketing, had submitted their devices to FDA for review and had passed that review.

Whether FDA's regulation of mesh "goes to safety" is a proposition that is relatively easy to test. The Supreme Court has recently held that the meaning of FDA "agency action" is "a legal one for the judge, not a jury."<sup>31</sup> The bones of the FDA story are found in statutes and regulations. The details are fleshed out in the pages of the Federal Register, and in the 2011 medical panel deliberations that can be seen on FDA's website.<sup>32</sup> For that reason, the question as to whether FDA's efforts "go to safety" is a pure question of law.

As explained in this Article, the courts have gotten the answer wrong. The "examination of cases one by one" has in fact produced a "myopic view." Mesmerized by a legally irrelevant and factually obsolete Supreme Court precedent, courts have misunderstood the manner in which FDA has regulated not only mesh but also other devices FDA has classified as presenting only moderate risks.

Not only does FDA regulation of these devices "go to safety," but safety and effectiveness are the only things it "goes to." "Reasonable assurance" of "safety and effectiveness" is what Congress has told FDA to ensure, and what FDA says it has done, in ways both favorable and, in some cases, unfavorable to mesh devices. The bottom line is that there is simply no basis for refusing to give the manufacturers of these devices whatever benefit regulatory compliance entitles them to under state law.

But once the first courts to consider the question in mesh litigation got it wrong, subsequent courts have been unwilling to give a different answer. Ironically, courts have adhered to precedent while at the same time refusing to give FDA any credit for its own similar process, which depends in part on its history with "predicate" devices.

The failure of the courts to answer correctly such a basic question of federal regulatory law in litigation of this magnitude strongly suggests that, with questions of federal administrative law, courts do indeed need help, especially in cases where the agency is not a party. If they cannot correctly apply the plain words of a statute that mandates "reasonable assurance" of safety and effectiveness, then there is all the more reason to question their ability to address the ambiguities to which the *Chevron* doctrine is addressed.

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mesh case. *Hrymoc v. Ethicon, Inc.*, No. A-1083-18, 2021 WL 787039 (N.J. Super. Ct. App. Div. March 2, 2021). One early hip implant decision found evidence of the use of that method more probative than prejudicial. *McCracken v. DePuy Orthopaedics Inc.*, No. 11 DP 20485, 2013 WL 12141334, at \*5 (N.D. Ohio July 26, 2013). More recently, courts in IVC filter cases have allowed defendants to offer FDA clearance evidence, but with erroneous limiting instructions. *Nolen v. C.R. Bard Inc.*, No. 3:19-CV-0799, 2021 WL 1264539, at \*8 (M.D. Tenn. April 6, 2021); *Keen v. C.R. Bard*, 480 F. Supp. 3d 646, 650–52 (E.D. Pa. 2020) (citing *In re Bard IVC Filters Prod. Liab. Litig.*, 289 F. Supp. 3d 1045, 1047 (D. Ariz. 2018)). Other decisions required that the whole FDA story be told. Where a defendant disobeyed an in limine order and told the jury that a prolapse device had been cleared by FDA, the plaintiffs were allowed to point out that the device had been taken off the market after the surgery, *Scott v. C.R. Bard, Inc.*, 180 Cal. Rptr. 3d 479, 494–95 (Cal. Ct. App. 2014), and where a defendant was allowed to prove clearance of prolapse device, the appellate court reversed a defense verdict because the plaintiff had not been allowed to introduce post-surgery letters from FDA about the decision to stop selling the device, *Albright v. Bos. Sci. Corp.*, 58 N.E.3d 360, 371–72 (Mass. App. Ct. 2016).

<sup>31</sup> *Merck Sharp & Dohme Corp. v. Albrecht*, 139 U.S. 1668, 1679 (2019).

<sup>32</sup> *FDA's Activities: Urogynecologic Surgical Mesh*, *supra* note 17; 2011 MEETING MATERIALS PAGE, *supra* note 12.

## I. CONGRESS HAS TOLD FDA TO CLASSIFY AND TO REGULATE MEDICAL DEVICES TO PROVIDE “REASONABLE ASSURANCE” OF SAFETY AND EFFECTIVENESS

The framework of FDA’s regulation of medical devices is set out in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301, et seq., as amended by the Medical Device Amendments Act of 1976, 21 U.S.C. §§ 360c–360k, 379, 379a; 42 U.S.C. § 3512, and the Safe Medical Devices Act of 1990, 21 U.S.C. §§ 360l, 383, along with other amendments and agency regulations.<sup>33</sup>

In the FDA regulatory scheme, some requirements apply to all devices, some apply to certain types of devices, and some apply to particular, individual devices.

**All devices.** For all devices, manufacturers must register with FDA, list devices with FDA, observe quality design and manufacturing process standards, and report any incident which “reasonably suggests” a device “may have caused or contributed” to a death or serious injury.<sup>34</sup>

Other general requirements give FDA the power to ban any device that presents an “unreasonable and substantial risk of illness or injury” or whose labeling is substantially deceptive.<sup>35</sup> In addition, Congress amended the medical device reporting requirements in 1990 to require reporting not only by manufacturers, but also by hospitals and others who use devices—a doubling-up designed to provide an “audit” of manufacturer reporting efforts.<sup>36</sup>

**Types of devices.** Federal law also requires either some form of FDA review before the device is marketed or an exemption from that review. The kind of review depends on the type of device. Because something like 1,700 different types of medical devices currently exist, Congress created a “triage” system that assesses the risks of each device type and dictates a corresponding level of premarket review.

Risk levels are indicated by the classification that FDA gives the device. In § 519 of the Act, Congress instructed FDA to convene panels of independent experts to classify all types of devices into one of three categories according to the risk the device presented. The statute says the panels must be “qualified by training and experience to evaluate the safety and effectiveness of the device[s]” and should consist of “members with adequately diversified expertise in such fields as clinical and administrative

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<sup>33</sup> The history of statutory changes to the Medical Device Act of 1976 is treated in more detail in 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 (2012) (recounting the statutory history and reform efforts); 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, 904–05 (2008) (reciting statutory history).

<sup>34</sup> 21 U.S.C. §§ 360(b) (2018) (registration), 360j(f) (“good manufacturing practice”), 360i (reports to FDA when information “reasonably suggests” device “may have caused or contributed to” a “serious injury”) (2020). See also 21 C.F.R. § 803.3(c) (2012) (report if injury “may have been attributed to” device) (2015).

<sup>35</sup> 21 U.S.C. § 360f (2018). See §§ 352(a)(1), (f), (s) (2010) (misbranding); 21 C.F.R. §§ 801.5, 801.109 (2012). See also Peter Barton Hutt, *A History of Government Regulation of Adulteration and Misbranding of Medical Devices*, 44 FOOD DRUG COSM. L.J. 99 (1989).

<sup>36</sup> 21 U.S.C. § 360(b) (2018) (“user facility” reports). See H.R. REP. NO. 101-808 (1990), reprinted in 1990 U.S.C.C.A.N. 6305, 6313–14 (“an important audit tool for assessing reporting by manufacturers”).

medicine, engineering, biological and physical sciences, and other related professions,” as well as nonvoting representatives of consumer and manufacturer interests.<sup>37</sup> When a panel makes a classification decision, that decision is published in the Federal Register and, after public notice and comment, FDA promulgates a regulation classifying devices by type.<sup>38</sup>

The statute explicitly states that devices are to be classified so that a corresponding level of premarket review provides “reasonable assurance of safety and effectiveness” for the devices in each class.<sup>39</sup> The separate classifications “allow more FDA resources to be directed to the review of devices which present the greatest benefits or risks.”<sup>40</sup> The three classes are:

- Class I contains the lowest risk devices for which only general controls are needed to ensure safety and effectiveness.<sup>41</sup> A tongue depressor is a Class I device.
- Class II includes devices that might require a special control, such as a guidance specifying what a premarket review submission should contain.<sup>42</sup> Surgical mesh is a Class II device.
- Class III includes the riskiest devices, including devices that “present a potential unreasonable risk of illness or injury.”<sup>43</sup> Devices posing such risks are not the only Class III devices, but all devices that pose those risks must be in Class III and not any other class. Cardiac pacemakers are Class III devices.

For each classification, Congress generally has specified a type or types of review.

- Today, almost all Class I and many Class II devices are exempt from premarket review.<sup>44</sup>
- If not exempt, Class I and Class II devices can be sold only after the manufacturer submits a “510(k)” notice to FDA that

<sup>37</sup> 21 U.S.C. § 360c(b)(2) (2018). *See also* 21 C.F.R. § 14.1(b)(5) (2020).

<sup>38</sup> 21 U.S.C. § 360c(d)(1). This is the process for pre-1976 device types. In more recent years, novel device types are used as a template for a de novo classification, and this can be done by order without issuing a regulation.

<sup>39</sup> 21 U.S.C. §§ 360c(a)(1)(A), (B), (C). *See* Food & Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 134 (2000) (“[r]egardless of which category FDA chooses, there must be a ‘reasonable assurance of the safety and effectiveness of the device’”).

<sup>40</sup> 136 CONG. REC. S17456-01 (daily ed. Oct. 27, 1990); H.R. REP. NO. 101-808, at 28 (1990), *reprinted in* 1990 U.S.C.C.A.N. 6305. The author is indebted to Jeffrey K. Shapiro for the description of device classification as a form of triage. *See* Jeffrey K. Shapiro, *Substantial Equivalence Premarket Review: The Right Approach for Most Medical Devices*, 69 FOOD & DRUG L.J. 365, 372 (2014).

<sup>41</sup> 21 U.S.C. § 360c(a)(1)(A).

<sup>42</sup> 21 U.S.C. § 360c(a)(1)(B).

<sup>43</sup> 21 U.S.C. § 360c(a)(1)(C)(ii)(II). Devices which are “purported or 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” are also in Class III. *Id.* § 360c(a)(1)(C)(ii)(I) (this would include implantable devices that have not been placed in Class I or II).

<sup>44</sup> *See* Shapiro, *supra* note 40, at 372.

establishes that the device is substantially equivalent in safety and effectiveness to a Class I or Class II device already on the market legally, known as a “predicate” device. If FDA agrees, it “clears” the device for sale.<sup>45</sup>

- If a device type has been placed in Class III, then the device can be sold only if the manufacturer gains premarket “approval” from FDA based on independent evidence of the safety and effectiveness of the device.<sup>46</sup> “Valid scientific evidence,” which includes “well-controlled investigations,” is required.<sup>47</sup> The approval will come with device-specific requirements for labeling and design.<sup>48</sup> The word “approval” in FDA law is reserved for these possibly high-risk Class III devices.<sup>49</sup>

**Individual devices.** From this scheme, several conclusions emerge with respect to the marketing of an individual Class II medical device.

First, while a 510(k) notice, whose contents are regulated by statute and regulation, need only establish equivalence to an existing legally marketed Class I or II device, the placement of the device in either of those classes is itself a determination that the device does not “present a potential unreasonable risk of illness or injury” that would require it to be in Class III. In other words, the classification itself is a safety determination.

Second, if a device is implanted in the body, as mesh is, the classification panel can put the device type in Class II only if it determines that Class III approval is “not necessary to provide reasonable assurance of safety and effectiveness.”<sup>50</sup>

Third, to show substantial equivalence to a classified predicate device, offering some evidence of safety and effectiveness is necessary. The evidence is usually performance data to show equivalent performance. FDA will also take into account any negative medical device report history. The House Report to the 1990 bill said FDA was only authorized to place a device in Class II if FDA made a “determination . . . that such classification is appropriate and will provide adequate assurance of the device’s safety and effectiveness”<sup>51</sup> and that FDA must “consider the

<sup>45</sup> 21 U.S.C. § 360(k) (2018); 21 C.F.R. § 807.100 (2010) (FDA action on premarket notification). Novel device types can also enter the market through a de novo classification process.

<sup>46</sup> 21 U.S.C. § 360e (2018).

<sup>47</sup> 21 U.S.C. §§ 360c(a)(3)(B)–(D) (2018).

<sup>48</sup> See *Riegel v. Medtronic*, 552 U.S. 312, 323 (2008) (discussing premarket approval requirements).

<sup>49</sup> 21 U.S.C. § 360e (2018); 21 C.F.R. § 807.97 (2010). See also *infra* notes 212–26 and accompanying text (explaining that FDA permission to market after review of a submission is required for both “cleared” and “approved” devices, and that use of words “clearance” and “approval” is a matter of labeling the type of review, not characterizing its substance, which in each case is to determine reasonable assurance of safety and effectiveness).

<sup>50</sup> 21 U.S.C. §§ 360c(c)(2)(C), (d)(2)(B) (2018).

<sup>51</sup> H.R. REP. NO. 101-808, at 28, *reprinted in* 1990 U.S.C.C.A.N. 6305, 6322 (“the statute does not authorize the FDA to place a device in class I or class II without a determination by the FDA that such classification is appropriate and will provide adequate assurance of the device’s safety and effectiveness”). See S. REP. NO. 101-513, at 35 (1990) (controls may be used to “provide the requisite assurance of the safety and effectiveness of a Class II device”); 136 CONG. REC. S17456-01 (daily ed. Oct. 27, 1990) (Class II placement to ensure “safety and effectiveness”).



safety and effectiveness of a device when determining whether such a device is substantially equivalent to a predicate device.”<sup>52</sup>

FDA has said that it considers safety and effectiveness when determining equivalence.<sup>53</sup> As stated in a 2014 guidance, FDA believes that its classification system coupled with its 510(k) substantial equivalence determination is sufficient “to provide a reasonable assurance of safety and effectiveness” for a device.<sup>54</sup> This sufficiency has been especially true since the 1990 amendments: “[t]oday, the 510(k) process is more like a miniature premarket approval than it had been from 1976 to the time of the 1990 amendments.”<sup>55</sup> A 2009 GAO study found that in every case where FDA found the new device had a different indication or technological characteristics that could affect safety or effectiveness, it examined performance data to determine equivalence.<sup>56</sup>

Fourth, because Class II 510(k) “cleared devices” are devices that do not present an “unreasonable risk,” they are, at the very least, just as safe as the more risky Class III “approved” devices, even though the “approved” devices usually get a much more rigorous agency scrutiny at the time of clearance.

This point is frequently misunderstood. FDA’s placement of a device in Class II is based on an assessment of the device’s relative safety. FDA considers those devices to be so safe that the more rigorous “approval” process is not needed and, in fact, is not allowed because that process is the exclusive province of more risky Class III devices.<sup>57</sup>

But, at the end of the day, the same “reasonable assurance” safety standard applies to all devices. The temptation to conclude that Class III devices are safer because they are the only ones “approved” has caused a great deal of confusion.<sup>58</sup>

In fact, as Jeffrey K. Shapiro has pointed out, the record of recalls suggests that devices cleared using 510(k) are, on average, safer than FDA “approved” Class III devices based on independent evidence. Serious recalls are not common.<sup>59</sup> However, from 2005 to 2009, for example, the proportion of all serious recalls was significantly *lower* for Class II 510(k) “cleared” devices than it was for Class III “approved” devices.<sup>60</sup> Cleared devices were 98% of the devices receiving premarket review but

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<sup>52</sup> H.R. REP. NO. 101-808, at 25. *See also infra* notes 209–11 and accompanying text (citing descriptions of equivalence as being a determination of equivalent safety and effectiveness).

<sup>53</sup> FDA 2014 GUIDANCE, *supra* note 28, at 3.

<sup>54</sup> *Id.*

<sup>55</sup> JAMES T. O’REILLY & KATHARINE A. VAN TASSEL, 2 FOOD AND DRUG ADMIN. § 18.22 (4th ed. 2019). *See also* Flaherty, *supra* note 33, at 915 (“pseudo safety and effectiveness review” and “mini-PMA”).

<sup>56</sup> U.S. GOV’T ACCOUNTABILITY OFFICE, MEDICAL DEVICES: FDA SHOULD TAKE STEPS TO ENSURE THAT HIGH-RISK DEVICE TYPES ARE APPROVED THROUGH THE MOST STRINGENT PREMARKET REVIEW PROCESS (2009), <https://www.gao.gov/products/GAO-09-190> [<https://perma.cc/Q52F-VXN5>] (performance data examined and used to judge equivalence).

<sup>57</sup> 21 U.S.C. § 360c(a)(1)(C) (2010). *See also* 21 C.F.R. § 860.10 (2010). Of course, a device type that is in Class III because it is implantable and has not yet been classified into Class I or Class II could also be one that does not present a potential unreasonable risk.

<sup>58</sup> 21 U.S.C. § 360c(a)(1)(A), (B), (C) (requiring “reasonable assurance” for each class). *See also infra* notes 214–225 and accompanying text (addressing confusion over meaning of word “approval”).

<sup>59</sup> Shapiro, *supra* note 40, at 389–91.

<sup>60</sup> *Id.* at 390 (approved devices are responsible for a disproportionate number of serious recalls).

were responsible for only 71% of all serious recalls, while approved devices, 2% of the total, were responsible for 19% of the serious recalls.<sup>61</sup>

## II. FOR TRANSITIONAL PURPOSES ONLY, CONGRESS IN 1976 ALLOWED AN EXCEPTION FOR DEVICES THAT HAD NOT YET BEEN CLASSIFIED

While this sketch is sufficient to explain the manner in which FDA has regulated pelvic mesh, it is not sufficient to explain the mistakes the courts have made in describing what FDA has done. Those mistakes arise from a different use of 510(k).

The different use was not the normal use that Congress intended to be permanent and that was used to clear pelvic mesh. Rather, Congress intended this different use to be both transitional and temporary.

The transitional use was to last for each device type only until the § 519 medical panels had classified the device type.<sup>62</sup> The length of that period would depend on how quickly the panels reached the device type. For some device types, however, the period lasted more than a decade.<sup>63</sup>

The transitional process did not require the normal safety finding. In the normal process, clearance of a Class II device required a finding of equivalence to another Class II device, i.e., one that did not present a “potential unreasonable risk” that would require classification in Class III.<sup>64</sup> That finding of equivalence is necessarily a safety finding. The transitional process did not require any such showing. It allowed clearance based on equivalence to a device lawfully sold in 1976, when the device act became law. That clearance was allowed until the relevant device types were classified.

The transitional method is found in the section of the statute that distinguishes clearance of new devices whose type “is to be classified” from the clearance of devices of a type that “has been classified.”<sup>65</sup> If a device type “is to be classified,” then until it was classified, and only then, it could be cleared for sale if the manufacturer established in a 510(k) notice that the device was equivalent to a device lawfully marketed before 1976.

Congress wanted to allow devices being sold in 1976, before premarket review existed, to continue to be sold even though they had not yet been reviewed. Congress also wanted to allow new devices that would compete with them. So, pending classification, Congress allowed marketing if the manufacturer established equivalence to a device being lawfully sold in 1976. That equivalence was some indication of safety. Devices sold before 1976 had always been subject to general

<sup>61</sup> *Id.* at 390.

<sup>62</sup> See 21 U.S.C. § 360c(f)(1)(A)(i) (equivalence to 1976 device only allowed for devices which are “to be” classified”).

<sup>63</sup> See Shapiro, *supra* note 40, at 367–68 (a few types still not classified in 2014).

<sup>64</sup> 21 U.S.C. § 360c(a)(1)(C)(ii)(II).

<sup>65</sup> 21 U.S.C. § 360c(f)(1)(A)(i) allows clearance based on equivalence to a device:

(I) which was introduced . . . into commerce for commercial distribution before [1976] and **which is to be classified** pursuant to subsection (b), or (II) which was not introduced or delivered before such date and **has been classified** in class I or II . . .

(emphasis added).

controls concerning labeling and safety.<sup>66</sup> Continued lawful sale and use of a device over a period of time provided some assurance of safety and effectiveness. That assurance somewhat strengthened when the statute was amended to require additional adverse event reporting. In fact, in 1990 when Congress chastised FDA for its delay in classifying devices and attempted to impose deadlines, a Senate Committee report conceded that “the premarket notification program [510(k)] has proved to be a reasonable screen for identifying unsafe or ineffective devices.”<sup>67</sup> But still, equivalence to a pre-1976 device was equivalence to a device of a type whose safety and effectiveness had never been reviewed by a medical panel.

An example of transitional use from 1982 was at issue in the Supreme Court’s only 510(k) case, *Medtronic, Inc. v. Lohr*.<sup>68</sup> The type of device, a pacemaker lead, had not yet been classified.<sup>69</sup> No medical panel had yet reviewed the device type.<sup>70</sup> For that reason, it was automatically treated as a Class III device pending “reclassification” of its device type by a medical panel.<sup>71</sup> Not only had the type not been reviewed by a medical panel, but also, in 1982, all that had to happen before the device was sold was that the manufacturer had to file a 510(k) notice with FDA.<sup>72</sup> In those early days, marketing was allowed if FDA did not affirmatively act to stop it. Thus, the device at issue in *Lohr* was marketed solely on FDA’s brief review of the manufacturer’s claim of equivalence to a pre-1976 device.<sup>73</sup>

*Lohr* was a case about preemption, not premarket review. In passing, however, the *Lohr* Court said the device in question had been “grandfathered,” its clearance was based on “equivalence, not safety,” and it had “never been formally reviewed under the MDA for safety or efficacy.”<sup>74</sup> For good measure, it cited an FDA calculation indicating that, before Congress strengthened 510(k) review and required FDA clearance before marketing in 1990, a 510(k) review on average took twenty hours, while a premarket review took 1,200 hours.<sup>75</sup>

As it turned out, the “transitional” process outlined in *Lohr* lasted for a very long time. Because of the delays in device type classification and the invention of new types, FDA continued to use 510(k) to clear presumptively “high risk” Class III devices based on equivalence to pre-1976 devices whose type had never been reviewed by a medical panel. In fact, during the first decade of the 1976 Medical Device Act,

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<sup>66</sup> See *supra* notes 34–36 and accompanying text.

<sup>67</sup> See S. REP. NO. 101-513, at 15 (1990).

<sup>68</sup> *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

<sup>69</sup> *Id.* at 480.

<sup>70</sup> *Id.* at 478 n.3 (FDA has taken action “which may lead the FDA to reclassify or initiate the PMA process”).

<sup>71</sup> 21 U.S.C. § 360c(c)(2)(C).

<sup>72</sup> *Lohr*, 518 U.S. at 478–79. See also *infra* notes 214–25 and accompanying text.

<sup>73</sup> *Id.* at 490.

<sup>74</sup> *Id.* at 493.

<sup>75</sup> *Id.* at 478–79. The twenty-hour figure applied to individual device review did not take into account time spent classifying device types, and it applied to review before 1990 when Congress first defined substantial equivalence and required FDA clearance orders before a device could be sold. See Jeffrey K. Shapiro, *Is the 510(k) Process as Worthless as the Federal Courts Seem to Believe*, FDA LAW BLOG (July 11, 2017), <http://www.fdalawblog.net/2017/07/is-the-510k-process-as-worthless-as-the-federal-courts-seem-to-believe/> [<https://perma.cc/ZP7W-454M>] (discussing post-1982 changes to 510(k) review and obsolescence of twenty-hour estimate).

510(k) cleared 80% of all devices and, as late as 2011, twenty-five device types had still not been classified.<sup>76</sup> This not-so-temporary extended “transitional” process caused substantial public criticism of the agency.<sup>77</sup>

That criticism culminated in a 2011 report by the Institute of Medicine of the National Academies which borrowed *Lohr*'s conclusion that the 510(k) program was about equivalence, not safety.<sup>78</sup> As a subsequent analysis put it, the report “uncritically extrapolated *Lohr* to the present day.”<sup>79</sup> In fact, the report relied on *Lohr* so completely that it offered no empirical support for its belief that the program shortchanged safety. The report admits this lack of support. It says it was not suggesting that “any medical devices cleared through the 510(k) clearance process and currently on the market are unsafe or ineffective.”<sup>80</sup> It mentioned the device classification process but failed to see how this process made *Lohr* distinguishable. It even faulted the classification process because FDA panels classified device types rather than individual devices.<sup>81</sup> The report thus missed the knowledge FDA gains from the regulation of other devices of the same type, the efficiency that results from FDA's focus on changes in a new device that might render it unsafe, and the predictability that clearance of predicate devices provides designers of new devices.<sup>82</sup>

In any event, the important distinction is that the transitional use of 510(k) was a short cut that is ultimately irrelevant when examining the intended use of 510(k). The intended use was to clear devices based on equivalence to devices in device types that § 519 medical panels had placed in either Class I or Class II, i.e., under subparagraph II of 21 U.S.C. § 360c(f)(1)(A)(i) (“class I or class II”), not under subparagraph I (devices introduced before 1976). As Shapiro also said, “[s]ubstantial equivalence review is intended for Class I and Class II devices, not Class III.”<sup>83</sup> Equivalence to devices that do not “present a potential unreasonable risk,” which would put them in Class III, is a safety determination that is both legally and factually distinct from the 510(k) transitional use at issue in *Lohr*.

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<sup>76</sup> INSTITUTE OF MEDICINE, *MEDICAL DEVICES AND THE PUBLIC'S HEALTH: THE FDA 510(k) CLEARANCE PROCESS AT 35 YEARS* 13, 100 (2011) [hereinafter IOM 2011].

<sup>77</sup> See, e.g., Michael VanBuren, *Closing the Loopholes in the Regulation of Medical Devices: The Need for Congress to Reevaluate Medical Device Regulation*, 17 HEALTH MATRIX 441, 460 (2007) (criticism of Class III “loophole”); U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-09-190, *MEDICAL DEVICES: FDA SHOULD TAKE STEPS TO ENSURE THAT HIGH-RISK DEVICE TYPES ARE APPROVED THROUGH THE MOST STRINGENT PREMARKET REVIEW PROCESS* (2009) (twenty device types had not been classified, and so devices presumed to be in Class III were still being cleared using 510(k)); IOM 2011, *supra* note 76, at 6 (criticizing use of pre-1976 predicates and questioning decisions made on basis of device type); Mayo B. Alao, *Thirty-Eight Years and Counting: The FDA's Misuse of the 510(k) Notification Process and Consequent Under-Regulation of Implantable Medical Devices*, 8 ST. LOUIS U. J. HEALTH L. & POL'Y 347, 349 (2015) (citing “safety concerns that have resulted from FDA's treatment of pre-amendment devices”).

<sup>78</sup> IOM 2011, *supra* note 76, at 5–6, 190–91.

<sup>79</sup> Shapiro, *supra* note 40, at 388.

<sup>80</sup> IOM 2011, *supra* note 76, at 193.

<sup>81</sup> *Id.* at 5–6, 191.

<sup>82</sup> See Shapiro, *supra* note 40, at 384–86.

<sup>83</sup> Shapiro, *supra* note 40, at 390.

### III. FDA CLASSIFIED AND REGULATED PELVIC MESH TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS

In 1982, FDA's General and Plastic Surgery Devices Panel, its Orthopedic Device Classification Panel, and its Gastroenterology and Urology Device Classification Panel, all created pursuant to § 519, recommended that FDA place all "surgical mesh" in Class II.<sup>84</sup> The panels complied with the statute's requirements and gave a "full statement of reasons" for not placing mesh in Class III: both metallic and polymeric mesh had "an established history of safe and effective use" and "premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device."<sup>85</sup> Infection and implant rejection were identified as potential risks.<sup>86</sup> The panel cited six published medical articles, two of which examined the use of polypropylene mesh, in support of its recommendation.<sup>87</sup>

After public comment, in 1988, FDA adopted a regulation classifying surgical mesh in Class II.<sup>88</sup> It agreed that "the biocompatibility of the materials now being used in these devices has been established through their successful use for a number of years" but added that, because of questions about long-term biocompatibility, mesh should not be in Class I.<sup>89</sup> Some regulation might be needed.

In 1999, FDA issued a "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh."<sup>90</sup> The guidance required that a mesh 510(k): (1) summarize the information regarding safety and effectiveness that provided the basis for determining substantial equivalence; (2) give test results to demonstrate biocompatibility; and (3) describe the product.<sup>91</sup> The biocompatibility tests were to include tests for cytotoxicity and other toxicity.<sup>92</sup> The description of the product was to include mesh thickness, weave characteristics, pore size, mesh density, and tensile strength.<sup>93</sup> The 510(k) notice was also to provide package labeling and inserts with a statement of the intended use of the device, contraindications, warnings, precautions, directions for use if necessary, and product claims.<sup>94</sup>

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<sup>84</sup> General and Plastic Surgery Devices; General Provisions and Classification of 54 Devices, 47 Fed. Reg. 2810 (Jan. 19, 1982) (to be codified at 21 C.F.R. pt. 878).

<sup>85</sup> *Id.*; 21 U.S.C. §360c(d)(2)(B) (2018).

<sup>86</sup> General and Plastic Surgery Devices, 47 Fed. Reg., *supra* note 84.

<sup>87</sup> *Id.*

<sup>88</sup> General and Plastic Surgery Devices; General Provisions and Classifications of 51 Devices, 53 Fed. Reg. 23,856 (June 24, 1988) (to be codified at 21 C.F.R. pt. 878); 21 C.F.R. § 878.3300.

<sup>89</sup> General and Plastic Surgery Devices, 53 Fed. Reg., *supra* note 88.

<sup>90</sup> U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY AND/OR FOR FDA REVIEWERS/STAFF AND/OR COMPLIANCE, GUIDANCE FOR THE PREPARATION OF A PREMARKET NOTIFICATION APPLICATION FOR A SURGICAL MESH (1999), <https://www.fda.gov/media/71828/download> [<https://perma.cc/EK5Y-BPQX>] [hereinafter FDA 1999 GUIDANCE].

<sup>91</sup> *Id.* at 1–4.

<sup>92</sup> *Id.* at 4.

<sup>93</sup> *Id.*

<sup>94</sup> *Id.* at 5.

Relying on this foundation, mesh manufacturers created specially cut “minimally invasive” surgical mesh devices packaged with tools that allowed the mesh to be inserted in the body through the vagina without an open abdominal incision.<sup>95</sup> Pursuant to the statutory scheme, these devices were cleared based on:

- The 1982 medical panel recommendation, adopted by FDA in 1988, that surgical mesh had an established history of safe and effective use,<sup>96</sup> and so should be placed in Class II, not Class III.<sup>97</sup> In other words, that it did not present a potential unreasonable risk that would require placement in Class III.<sup>98</sup>
- What FDA knew about the Class II predicate surgical mesh devices based not only on the 510(k) for each device but also on medical device reports its manufacturer and others had made to FDA any time an adverse event was even associated with the use of the predicate.<sup>99</sup>
- What FDA knew about other, similar devices, whether or not they were specifically listed as predicates.<sup>100</sup>
- The 510(k) notice for the device itself which, either independently or by incorporation of information from predicate devices, satisfied each element of FDA’s 1999 guidance for new devices.<sup>101</sup>

However, a decade after the first pelvic mesh devices were cleared, the medical device reporting system alerted FDA to problems with the devices. In 2008, FDA issued a public health notice warning of “serious complications associated with transvaginal placement of surgical mesh in repair of pelvic organ prolapse and stress

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<sup>95</sup> See FDA EXECUTIVE SUMMARY, *supra* note 12, at 10, 27.

<sup>96</sup> General and Plastic Surgery Devices, 47 Fed. Reg. 2810, *supra* note 84.

<sup>97</sup> General and Plastic Surgery Devices, 53 Fed. Reg. 23,856, *supra* note 88.

<sup>98</sup> 21 U.S.C. § 360c(a)(1)(C)(ii)(II).

<sup>99</sup> See Flaherty, *supra* note 33, at 923 (“Court decisions discrediting the 510(k) process have often misinterpreted and misunderstood the process by failing to give proper credit to the leveraging of predicate device clinical history offered by the substantial equivalence process.”). A 2018 article critical of the use of 510(k) to clear surgical mesh implied that all mesh was ultimately cleared based on 1976 predicates and so missed this point completely. See Nasim Zargar & Andrew Carr, *The Regulatory Ancestral Network of Surgical Meshes*, PLOS ONE (June 19, 2018), <https://doi.org/10.1371/journal.pone.0197883> [<https://perma.cc/7Y6V-HE6F>]. Not only did the article ignore the 1982 medical panel recommendation concerning the safety of mesh, but it also gave no credit to FDA’s ability to track the performance of surgical mesh using the medical device reporting system. *Id.* It mentioned the 2011 medical panel review of mesh but failed to take it into account. *Id.* It also overlooked the fact that “recall” of a mesh used as a predicate might have been due to a temporary manufacturing error and not a design flaw. *Id.*; see also *supra* note 34 (association, not causation, is test for reporting adverse events).

<sup>100</sup> See 21 C.F.R. § 807.87(j)(2) (requiring 510(k) submitter to provide summary of problems “associated with the type of device being compared”).

<sup>101</sup> FDA 1999 GUIDANCE, *supra* note 90.

urinary incontinence.”<sup>102</sup> The notice listed problems such as erosion of tissue around the mesh, infection, pain, and recurrence of prolapse or incontinence.<sup>103</sup>

In July 2011, FDA issued an “update” on the safety and effectiveness of transvaginal placement of mesh to treat pelvic organ prolapse.<sup>104</sup> No mention was made of the use of mesh to treat incontinence. The update discussed 1,503 medical device reports of adverse events, said FDA was evaluating the relevant literature, and encouraged surgeons to place the mesh through the abdomen rather than the vagina when treating prolapse.<sup>105</sup> The update also announced that FDA’s § 519 Obstetrics and Gynecology Devices Panel would meet in September to consider the safety and effectiveness of all pelvic mesh.<sup>106</sup>

That panel, which the statute calls a “classification panel,” served as an “advisory committee” to FDA.<sup>107</sup> When the panel met in September of 2011, it had nineteen members, including thirteen medical doctors, several PhDs, and consumer and manufacturer representatives. Panel members came from institutions that included the Cleveland Clinic, Harvard, Stanford, the Mayo Clinic, the National Institutes of Health, and FDA. The panel heard from and questioned more than forty-six witnesses over two days.<sup>108</sup>

The panel had before it an eighty-page Executive Summary prepared by FDA staff.<sup>109</sup> The summary drew on FDA’s database of adverse event reports and found that FDA had received 2,874 reports in the past three years for the 168 pelvic mesh devices cleared using 510(k).<sup>110</sup> In preparing the summary, the staff examined 260 medical studies that compared one type of surgery against another.<sup>111</sup> In the summary’s text, the staff footnoted and cited forty publications from medical journals.<sup>112</sup> Both the

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<sup>102</sup> 2008 FDA PUBLIC HEALTH NOTIFICATION, *supra* note 15.

<sup>103</sup> *Id.*

<sup>104</sup> U.S. FOOD & DRUG ADMIN., UPDATE ON SERIOUS COMPLICATIONS ASSOCIATED WITH TRANSVAGINAL PLACEMENT OF SURGICAL MESH FOR PELVIC ORGAN PROLAPSE: FDA SAFETY COMMUNICATION (2011), <https://www.burgsimpson.com/wp-content/uploads/2018/03/FDA-safety-communication-pelvic-mesh.pdf> [<https://perma.cc/S4BW-L4TJ>] [hereinafter 2011 FDA UPDATE].

<sup>105</sup> *Id.*; see also FDA EXECUTIVE SUMMARY, *supra* note 12, at 24, 68.

<sup>106</sup> 2011 FDA UPDATE, *supra* note 104; 21 U.S.C. § 360c(e) (2020) (“classification panel” to meet when reclassification considered).

<sup>107</sup> 21 U.S.C. § 360c(b); 21 U.S.C. § 360c(e) (2020).

<sup>108</sup> U.S. FOOD & DRUG ADMIN., OBSTETRICS & GYNECOLOGY DEVICES ADVISORY COMM. OF SEPT. 8–9, 2011, PANEL ROSTER, OB/GYN DEVICES PANEL OF THE MEDICAL DEVICES PANEL MEETING (2011), <https://wayback.archive-it.org/7993/20170404140403/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/UCM270778.pdf> [<https://perma.cc/ZYE8-LG2Y>]. See also U.S. FOOD & DRUG ADMIN., OBSTETRICS & GYNECOLOGY DEVICES ADVISORY COMM. OF SEPT. 8–9, 2011, MEETING TRANSCRIPTS (2011), <https://wayback.archive-it.org/7993/20170404140421/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricandGynecologyDevices/UCM275043.pdf> [<https://perma.cc/W85H-MWT8>] (September 8<sup>th</sup> transcript), <https://wayback.archive-it.org/7993/20170404140426/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/UCM275061.pdf> [<https://perma.cc/R3Z2-EEQJ>] (September 9<sup>th</sup> transcript).

<sup>109</sup> FDA EXECUTIVE SUMMARY, *supra* note 12.

<sup>110</sup> *Id.* at 6, 56.

<sup>111</sup> *Id.* at 58.

<sup>112</sup> *Id.* at 48–51.

summary and the classification panel, as well as FDA, analyzed slings to treat incontinence separately from the transvaginal insertion of mesh to treat prolapse.<sup>113</sup>

With respect to the incontinence slings, FDA’s staff summary said a “substantial number of quality clinical trials, as well as systematic reviews, have been published for the first-generation minimally invasive slings that provide evidence of the safety and effectiveness of these devices.”<sup>114</sup> The summary listed the adverse events reported to FDA in order of frequency. It cited comparative studies for the proposition that slings were just as effective as open abdominal surgery, but operating time and hospital stays were shorter.<sup>115</sup> Other articles showed that, at studies of up to five years, only 4% of sling patients suffered from erosion of tissue around the sling and an average of 5% suffered from pain.<sup>116</sup>

Agreeing with FDA staff, the § 519 classification panel found, based on the evidence at the hearing, that “the safety and effectiveness of [the traditional slings] is well-established” and recommended that FDA retain them in Class II.<sup>117</sup>

FDA subsequently kept the incontinence slings in Class II, expressly endorsed their safety and effectiveness, and declared that problems with the slings were not specific to any one brand.<sup>118</sup> Incontinence slings remain on the market today and are regarded by gynecological surgeons as being the gold standard treatment for stress urinary incontinence.<sup>119</sup>

FDA’s staff summary and ultimately FDA reached a very different conclusion with respect to the use of pelvic mesh inserted through the vagina to treat pelvic organ prolapse, a use first introduced in 2005. The summary said most studies had judged the effectiveness of treatment, and not the frequency of adverse events. It cited a higher rate of resurgery compared to abdominal surgery or vaginal surgery without mesh.<sup>120</sup> Some comparative studies reported worse outcomes, especially if the type of prolapse

<sup>113</sup> See, e.g., *id.* at 10, 27.

<sup>114</sup> *Id.* at 28.

<sup>115</sup> *Id.* at 33, 35; *id.* at 6, fig.1 (Considering sixty-two stress urinary incontinence “SUI” devices (seven single incision), forty-three pelvic organ prolapse “POP” devices, sixteen devices for both.); *id.* at 13, 28 (reviewing 2,874 Medical Device Reports, filed from 2008 to 2010, and 1,371 of these were for SUI, 1,503 for POP); *id.* at 58 (examining 925 studies from medical journals from 1996 to 2011).

<sup>116</sup> *Id.* at 39.

<sup>117</sup> PANEL SUMMARY, *supra* note 18, at 2. The slings FDA endorsed were “full length” slings, not “mini-slings,” which it found in 2013 lacked a sufficient record of safety and effectiveness. FDA did not, however, reclassify them. They are no longer made.

<sup>118</sup> *Considerations about Surgical Mesh for SUI*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/urogynecologic-surgical-mesh-implants/considerations-about-surgical-mesh-sui> [<https://perma.cc/MH88-7ADC>] [hereinafter *Considerations about Surgical Mesh for SUI*] (last updated Apr. 16, 2019). Although this publication describes its content as current as of April 16, 2019, it was initially published in 2013. See, e.g., *Carlino v. Ethicon, Inc.*, 208 A.3d 92, 111 n.24 (Pa. Super. Ct. 2019), *reargument denied* (June 12, 2019) (referring to “FDA’s 2013 Publication”). After another classification panel hearing, FDA reclassified the instruments used to implant mesh into Class II and subjected them to special controls. 21 C.F.R. § 884.4910.

<sup>119</sup> See AM. UROGYNECOLOGIC SOC’Y & SOC’Y OF URODYNAMICS, FEMALE PELVIC MED. & UROGENITAL RECONSTRUCTION, POSITION STATEMENT: MESH MIDURETHRAL SLINGS FOR STRESS URINARY INCONTINENCE 2 (2018), [https://www.augs.org/assets/1/6/AUGS-SUFU\\_MUS\\_Position\\_Statement.pdf](https://www.augs.org/assets/1/6/AUGS-SUFU_MUS_Position_Statement.pdf) [<https://perma.cc/KU7W-GQBZ>] [hereinafter, AUGS POSITION STATEMENT] (polypropylene mesh midurethral slings “remain a leading treatment option and current gold standard for stress incontinence surgery”; 99% of AUGS members use them).

<sup>120</sup> FDA EXECUTIVE SUMMARY, *supra* note 12, at 18.



were taken into account.<sup>121</sup> The staff summary doubted whether there was adequate evidence of the safety and effectiveness of mesh implanted through the vagina, but it reached the opposite conclusion if the mesh were implanted through the abdomen.<sup>122</sup> The medical classification panel again agreed with the staff and endorsed this distinction.<sup>123</sup>

FDA ultimately agreed. It retained in Class II mesh implanted through the abdomen to treat prolapse.<sup>124</sup> After further studies, however, in 2016 FDA reclassified the vaginal insertion prolapse devices as Class III devices and in 2019 ordered manufacturers to stop selling them.<sup>125</sup>

#### IV. COURTS, HOWEVER, DECIDED THAT THIS FDA REGULATION OF MESH DID NOT “GO TO” SAFETY

FDA’s 2008 public health notice triggered an avalanche of lawyer advertising for litigation against pelvic mesh manufacturers. The federal courts created the largest collection of multidistrict litigation cases in history and sent it to the Southern District of West Virginia for resolution. Consolidated case dockets were also created in New Jersey and Pennsylvania. In these cases, one issue was whether defendants could offer evidence of compliance with FDA regulations as a defense to either compensatory or punitive damages, or both.

**Cisson 2016.** The 510(k) admissibility issue first came before a pelvic mesh court in the West Virginia Multidistrict Litigation, or *Cisson*.<sup>126</sup> Both before trial and at trial in defense of the punitive damages claim, the defendant sought to tell the jury that its prolapse mesh product had been cleared by FDA before it was sold.<sup>127</sup> The district court excluded the evidence.<sup>128</sup> Relying solely on *Lohr*, the court cited the language from that decision quoted above and concluded that because 510(k) clearance was only about “equivalence,” it does not “go to whether the product is safe and effective.”<sup>129</sup>

On appeal, the defendant complained that the district court had deprived it of a regulatory defense under Georgia law to both compensatory and punitive damages.<sup>130</sup> The Fourth Circuit recognized the defenses but held that the district court had not abused its discretion in excluding all the evidence that would support them.<sup>131</sup>

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<sup>121</sup> *Id.* at 21.

<sup>122</sup> *Id.* at 24.

<sup>123</sup> PANEL SUMMARY, *supra* note 18, at 2.

<sup>124</sup> 21 C.F.R. § 878.3300 (2020).

<sup>125</sup> See 21 C.F.R. § 884.5980 (2020); 21 C.F.R. § 878.3300. The astute reader will recognize that what FDA did was, in effect, to order doctors to stop inserting mesh through the vagina because FDA decided insertion through the abdomen was safer. Apparently, no argument was made that this was an improper FDA incursion into the practice of medicine. 21 U.S.C. § 396 (2018).

<sup>126</sup> *Cisson v. C.R. Bard, Inc.*, 86 F. Supp. 3d 510 (S.D.W. Va. 2015), *aff’d sub nom. In re C.R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2187, 810 F.3d 913 (4th Cir. 2016) (citing 2013 pre-trial ruling).

<sup>127</sup> *Id.* at 514.

<sup>128</sup> *Id.*

<sup>129</sup> *Id.* at 514–15.

<sup>130</sup> *In re C.R. Bard, Inc.*, 810 F.3d at 917–18.

<sup>131</sup> *Id.* at 921–22, 932.

Looking to *Lohr*, it dismissed the idea that the “regulatory framework safeguards consumer safety.”<sup>132</sup> Even though the device’s FDA classification controls the method of premarket review, the Fourth Circuit said 510(k) “allows some medical devices to avoid the strict safety testing requirements imposed” by the 1976 Act, “so long as the device is ‘substantially equivalent’ to a pre-1976 device already in use at that time.”<sup>133</sup> This process, the court said, operates “to exempt devices from rigorous safety review procedures.”<sup>134</sup>

The Fourth Circuit thus not only got the facts wrong—mesh devices were cleared based on equivalence to *post-1976 classified and regulated* Class II devices—but it turned the statutory scheme upside down. Congress reserved the “rigorous safety review procedures” for Class III devices that may present a “potential unreasonable risk of illness or injury.”<sup>135</sup> Devices, even after approval, are not in Class III because they are safer. Devices may be in Class III because they are more risky and FDA believes more evidence was needed to justify them. And FDA’s initial placement of pelvic mesh devices in Class II was based on FDA’s belief of a “reasonable assurance of safety and effectiveness” without more “rigorous safety procedures” because the devices did not pose a potential “unreasonable risk” that would require them to be in Class III. The same “reasonable assurance” standard applies to all devices once the device type is classified.<sup>136</sup>

Going further astray, the Fourth Circuit wrongly assumed that the manufacturer, not FDA, had chosen the 510(k) review path, and so said the manufacturer had made a “choice to minimize the burden of compliance, potentially cutting in favor of punitive damages.”<sup>137</sup> But the manufacturer did not choose the review path. FDA chose it when it placed all surgical mesh in Class II in 1988. Class II devices must be cleared using 510(k) and are not eligible for the premarket approval “path.”

An analogy to an emergency room triage further illustrates the court’s error. Patients who come to an emergency room present a variety of medical problems. Those diagnosed with moderate problems may be given medicine and sent home. Those with serious injuries are sent to the operating room. This example parallels Congress’ decision to have medical panels classify devices so that devices that present moderate risks can be cleared using 510(k) and regulated while devices that may present unreasonable risks must be cleared using the more extensive premarket approval process.

No one would ever say that a patient who was sent home was sicker than the patient who went to the operating room just because the patient who was sent home was given a less “rigorous” treatment. But that is exactly the kind of reasoning the Fourth Circuit used. By looking only at FDA’s “treatment” of the individual device, i.e., 510(k) review, and failing to take into account FDA’s initial “diagnosis,” or classification of risk, the court completely misjudged the regulatory process.

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<sup>132</sup> *Id.* at 920. *See also id.* at 922 (calling clearance “something less than a safety requirement”).

<sup>133</sup> *Id.*

<sup>134</sup> *Id.*

<sup>135</sup> 21 U.S.C. § 360c(a)(1)(C)(ii)(II).

<sup>136</sup> *See* 21 U.S.C. §§ 360c(a)(1)(A)–(C) (requiring “reasonable assurance” for each classification); *see also supra* note 58 and accompanying text.

<sup>137</sup> *In re C.R. Bard, Inc.*, 810 F.3d at 922.

Reinforcing its error, the Fourth Circuit wrongly added that “the clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value” to a finding of design defect.<sup>138</sup> But the cases cited do not support this erroneous statement. Only two of the five cited cases addressed the exclusion of evidence, and they excluded evidence that FDA had *refused* to grant permission to market a device, not evidence that it had *cleared* a device using 510(k).<sup>139</sup>

The evidentiary value of a refusal is different from the evidentiary value of a clearance. A device is cleared only if reasonable assurance of safety exists. By contrast, FDA may refuse to clear a device for safety reasons or for reasons other than safety. For example, the device may be a new type of device that has no predicate.<sup>140</sup> If that is the reason, the refusal to clear is irrelevant to safety. Also, because FDA’s standards are more protective of consumers than tort law standards, admitting evidence of adverse FDA action against a manufacturer may be unfairly prejudicial.<sup>141</sup> FDA can take adverse action if injuries are somehow associated with the use of a device,<sup>142</sup> while tort law standards are more demanding and require causation.

The Fourth Circuit also dismissed FDA’s 2014 guidance which said that 510(k) clearance was sufficient to provide a “reasonable assurance of safety and effectiveness.”<sup>143</sup> The Fourth Circuit said that, whatever this meant, it had not prevented the Supreme Court from ruling as it did in *Lohr*, and that “[b]ald assertions by the FDA do little to alter the analysis.”<sup>144</sup> In fact, “reasonable assurance” was not at issue in *Lohr* because no medical panel had ever classified the device in question, and so the statutory conditions for “reasonable assurance” were not present.<sup>145</sup> Also, the “assertions” in the 2014 guidance were not “bald”—they were FDA’s interpretation of the statutes and regulations it administers and on which it relied in the guidance. “Reasonable assurance” is statutory language.<sup>146</sup>

The Fourth Circuit ultimately held that the district court did not abuse its discretion in avoiding a “mini-trial” about the strengths and weaknesses of the 510(k) process

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<sup>138</sup> *Id.* at 920.

<sup>139</sup> *See id.* at 920–22 (citing the cases cited here). Two of the five cases were preemption cases, not evidence cases. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322 (2008) (approval of Class III device triggers express preemption); *Duval v. Bristol-Myers-Squibb, Co.*, 103 F.3d 324, 330 (4th Cir. 1996) (denying preemption because §510(k) clearance based on pre-1976 device imposed no requirements). Another concerned the interplay between 510(k) and HEW regulations. *Almy v. Sebelius*, 679 F.3d 297, 308 (4th Cir. 2012) (not arbitrary and capricious for HHS to require proof of safety and effectiveness beyond 510(k) clearance to justify Medicare reimbursement). Two cases excluded evidence of the failure to get 510(k) clearance, not the grant of 510(k) clearance. *Rodriguez v. Stryker Corp.*, 680 F.3d 568, 574 (6th Cir. 2012) (FDA denial of §510(k) clearance for lack of a predicate was not a statement that device was unsafe); *Talley v. Danek Med., Inc.*, 179 F.3d 154, 160 (4th Cir. 1999) (because off-label uses are not illegal, failure to get approval for a Class III use before selling a Class II device was not negligence per se).

<sup>140</sup> *See Rodriguez v. Stryker Corp.*, 680 F.3d 568, 574 (6th Cir. 2012) (FDA denial of §510(k) clearance for lack of a predicate was not a statement that device was unsafe).

<sup>141</sup> *See Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1201 (5th Cir. 2002).

<sup>142</sup> *See supra* note 34, citing 21 U.S.C. § 360i(a)(1) (adverse event report required if information “reasonably suggests” that device “may have caused or contributed” to an injury).

<sup>143</sup> *In re C.R. Bard., Inc.*, 810 F.3d at 921.

<sup>144</sup> *Id.*

<sup>145</sup> *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475–80 (1996).

<sup>146</sup> 21 U.S.C. § 360c(a)(1)(B).

and whether the defendant had made all necessary disclosures to FDA.<sup>147</sup> It said the district court could properly avoid “hours, and possibly days, of complex testimony about regulatory compliance” which “could lead jurors to erroneously conclude that regulatory compliance proved product safety.”<sup>148</sup>

That conclusion was itself error. Their original clearance and placement in Class II was evidence of safety. The only “complex testimony” would have been about the transitional device problems discussed in *Lohr*. Those problems are irrelevant and should be inadmissible in a case that was not about a transitional device. It is true, however, that because *Cisson* was a prolapse device case, the plaintiff could have been entitled to counter with evidence of FDA’s 2012 statement that the safety of vaginally implanted prolapse devices had not been adequately demonstrated. But the defendant had apparently chosen to run that risk in order to use regulatory compliance to avoid punitive damages.

In excluding all FDA evidence, the Fourth Circuit also misused Federal Rule of Evidence 403 not just to exclude a piece of evidence, but to wipe out an entire defense. Where state law makes regulatory compliance relevant, evidence of that compliance is direct evidence needed to prove the defense, and Rule 403 does not afford a district court discretion to exclude all evidence that support the defense.<sup>149</sup>

**Huskey 2017.** The Fourth Circuit next addressed the 510(k) question in *Huskey v. Ethicon, Inc.*<sup>150</sup> While the regulatory issues in *Cisson* were clouded by the prolapse device in question being a type questioned by FDA after 2011, the FDA record in *Huskey* was not so blemished. The device at issue in *Huskey* was an incontinence sling of a type whose safety and effectiveness were endorsed by the § 519 classification committee in 2011 and by FDA itself in 2013 and today.<sup>151</sup>

But the Fourth Circuit again upheld the exclusion of FDA evidence.<sup>152</sup> With respect to the 510(k) clearance of the device at issue in 2003, the court again disparaged 510(k) as an “attempt to bypass FDA’s normal premarket approval process,” which only “tangentially” examines safety, and added that the trial judge could properly avoid a trial over “how rigorous those safety considerations were.”<sup>153</sup> Again, it mistakenly assumed the 1982 clearance in *Lohr* accurately represented the clearance process. It did not examine the evidence as to how the mesh sling at issue in the case was actually cleared in 2003.

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<sup>147</sup> *In re C.R. Bard., Inc.*, 810 F.3d at 921–22.

<sup>148</sup> *Id.* at 922.

<sup>149</sup> See KENNETH W. GRAHAM, JR., FEDERAL PRACTICE AND PROCEDURE (WRIGHT & MILLER) § 5214.2 (2d ed. updated Apr. 2020) (direct evidence “has the highest possible probative value and therefore cannot be ‘substantially outweighed’ by any of the possible harms”); *United States v. 0.161 Acres of Land*, 837 F.2d 1036, 1042 (11th Cir. 1988) (abuse of discretion to exclude evidence “undeniably probative of a central issue in the case”). See also *Musgrave v. Breg*, No. 2:09-cv-01029, 2011 WL 4620767, at \*3 (S.D. Ohio Oct. 3, 2011) (“Plaintiffs may argue about what it means, but they cannot keep the jury from hearing the fact that FDA cleared a general indication for use for the Pain Care 3200, and that [the manufacturer] understood that general clearance to include orthopedic and intra-articular uses. The Court concludes that the probative value of this evidence is not substantially outweighed by the danger of confusion of the issues or misleading the jury.”).

<sup>150</sup> *Huskey v. Ethicon, Inc.*, 848 F.3d 151 (4th Cir. 2017), cert. denied 138 S.Ct. 107 (2017).

<sup>151</sup> See *supra* Part III.

<sup>152</sup> *Huskey*, 848 F.3d at 160–62.

<sup>153</sup> *Id.* at 160–61.

With respect to the conclusions of the 2011 FDA “Advisory Committee” that sling devices were safe and effective, the court said that FDA “simply opined on the work of others” and that Ethicon was allowed to introduce the “underlying studies” and so was not prejudiced.<sup>154</sup> Again, this was untrue. The 2011 deliberations not only relied on the literature, but they also relied on an FDA staff evaluation of the literature, a staff evaluation of medical device reports to FDA, testimony of forty-six witnesses, and the personal experience of nineteen expert advisory committee members.<sup>155</sup>

The Fourth Circuit believed that only an evaluation of literature was involved because it made a factual mistake. It wrongly thought one line in the FDA staff report about medical literature was the Advisory Committee’s conclusion.<sup>156</sup> The Advisory Committee’s conclusion that the devices were safe and effective was, however, in a different document and was not limited to an opinion about literature.<sup>157</sup>

Going further, the Fourth Circuit said exclusion was necessary to avoid “risking a usurpation of the *jury’s* essential role” in determining if the plaintiffs had proven their case.<sup>158</sup> The court bolstered this conclusion with a belief that FDA’s 510(k) clearance in 2003 “did not address the [device’s] safety,” and clearance was the only thing that FDA “itself” had determined.<sup>159</sup> Thus, the jury, it said, might give “too much jury deference to the FDA.”<sup>160</sup>

Almost none of this was correct, either. State law made regulatory evidence relevant for the jury’s consideration.<sup>161</sup> The clearance in 2003 placed the device in Class II and so was a safety determination. It did in this way “address safety.” And even if that were not the case, both the Advisory Committee in 2011 and FDA in 2013 made independent safety determinations.<sup>162</sup> They kept Class II status for the incontinence devices like the one in issue and endorsed their safety and effectiveness. FDA’s 2013 statement even said that the brand of sling did not have any effect on the number of adverse event reports it received.<sup>163</sup> In other words, it was incorrect and untrue to say the only thing FDA “itself” had done was to clear the device in 2003 using 510(k).

The court also missed the importance of the 2011 proceedings to the “minitrial” argument. Because FDA and the Advisory Committee considered the full regulatory record for 168 devices developed over more than twenty years, along with extensive medical literature, any argument about what any individual manufacturer had provided FDA at the time of initial 510(k) clearance was factually irrelevant, and any argument

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<sup>154</sup> *Id.* at 161.

<sup>155</sup> *See supra* Part III.

<sup>156</sup> *Huskey*, 848 F.3d at 161 (quoting pre-hearing staff summary).

<sup>157</sup> *See* PANEL SUMMARY, *supra* note 18.

<sup>158</sup> *Huskey*, 848 F.3d at 161 (emphasis in original).

<sup>159</sup> *Id.*

<sup>160</sup> *Id.*

<sup>161</sup> *Moehle v. Chrysler Motors Corp.*, 443 N.E. 2d 575, 578 (Ill. 1982) (jury should be allowed to weigh safety standards evidence with proper instructions); *Strum v. DePuy Orthopaedics, Inc.*, No. 2011 L 009352, 2013 WL 3184765, at 1 (Ill. Cir. Ct. Mar. 8, 2013) (denying motion in limine to exclude references to FDA).

<sup>162</sup> *See supra* Part III.

<sup>163</sup> *Id.*

about clearance based on equivalence to devices sold in 1976 was both legally and factually irrelevant.<sup>164</sup>

**Eghnayem 2017.** The Eleventh Circuit became the next court to address the issue of FDA admissibility when it reviewed an appeal from four consolidated MDL cases.<sup>165</sup> The MDL judge remanded these cases to Florida but then was himself appointed as the trial judge in *Eghnayem v. Boston Scientific Corp.*<sup>166</sup> At trial, the jury found in favor of plaintiffs treated with a mesh device used to cure prolapse.<sup>167</sup> The defendant appealed one of the judgments.<sup>168</sup> The defendant complained on appeal that it had not been allowed to tell the jury that FDA had cleared the device for sale in 2008.<sup>169</sup>

Like the Fourth Circuit, the Eleventh Circuit wrongly assumed that the only way FDA provided “reasonable assurance” of safety and effectiveness was through the premarket approval process and that pre-1976 devices “were allowed to remain on the market until FDA initiates and completes” premarket approval.<sup>170</sup>

That has never been correct. Pre-1976 devices were allowed to remain on the market pending classification, which might or might not have ultimately resulted in an approval requirement.<sup>171</sup> And the normal and intended permanent use of 510(k), as well as its use in mesh cases, was to clear Class I and Class II devices based on Class I and Class II predicates, not devices with pre-1976 equivalents.<sup>172</sup>

Continuing, the Eleventh Circuit agreed with the district court that 510(k) cleared devices had “never been formally reviewed . . . for safety and efficacy.”<sup>173</sup> It quoted the obsolete twenty-hours of review figure from *Lohr*.<sup>174</sup> It added that exclusion was proper because 510(k) “does not go to a product’s safety and efficacy—the very subject of the plaintiffs’ product liability claims,” and said “510(k) is not a safety regulation.”<sup>175</sup> Adopting *Cisson*’s statement about the weight of authority, *Eghnayem* said the jury might be misled into thinking that “general federal regulatory compliance, not state tort liability, was the core issue.”<sup>176</sup> The court failed to mention the Florida statute that expressly makes regulatory compliance a defense in a product liability case.<sup>177</sup>

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<sup>164</sup> In *Huskey*, the Fourth Circuit acted “as if the 510(k) program had not changed since 1982.” See Shapiro, *supra* note 40.

<sup>165</sup> *Eghnayem v. Bos. Sci. Corp.*, 873 F.3d 1304, 1310–11 (11th Cir. 2017).

<sup>166</sup> *Id.*

<sup>167</sup> *Id.* at 1311–12.

<sup>168</sup> *Id.* at 1310.

<sup>169</sup> *Id.* at 1311.

<sup>170</sup> *Id.* at 1317.

<sup>171</sup> See *supra* Part II.

<sup>172</sup> *Id.*

<sup>173</sup> *Eghnayem*, 873 F.3d at 1317 (quoting *Riegel v. Medtronic*, 552 U.S. 312, 323 (2008) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 494 (1996))).

<sup>174</sup> *Id.* (quoting *Lohr*, 518 U.S. at 479). See *supra* notes 74–75 and accompanying text (twenty-hour figure obsolete).

<sup>175</sup> *Id.* at 1318.

<sup>176</sup> *Id.*

<sup>177</sup> FLA. STAT. § 768.1256:

Significantly, in a footnote, the Eleventh Circuit rejected as raised too late the defendant's argument that *Lohr* could be distinguished because FDA had determined that the device at issue was "substantially equivalent to a post-1976 device that may have undergone formal safety review, as opposed to a pre-1976 Class III device which had not."<sup>178</sup>

**Campbell 2018.** The Fourth Circuit then briefly revisited the issue in *Campbell v. Boston Scientific Corp.*, an appeal from judgments based on implantation of another incontinence sling of the same general type as the one before the court in *Huskey*.<sup>179</sup> The court treated *Cisson* and *Huskey* as controlling on the issue, even though the *Campbell* defendant expressly argued that facts concerning FDA's clearance of the incontinence device were not comparable to the facts in *Lohr*:

The manufacturer in *Huskey* attempted to distinguish *Cisson* based on the specifics of each product's regulatory compliance processes, but we rejected this argument, reasoning that focusing on these details "would only amplify the risk" of "confusion and wasted time."

...

[The manufacturer] faults both *Cisson* and *Huskey* for failing to address the distinction between clearance based on a predicate device that was grandfathered in when the process was created and clearance based on a predicate device that itself received a thorough safety evaluation. But this argument, in fact, closely mirrors the argument we rejected in *Huskey*. Admitting the evidence would invite a battle of experts regarding the exact meaning of 510(k) approval in these circumstances, and would risk the same jury confusion we feared in *Cisson*.<sup>180</sup>

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(1) In a product liability action brought against a manufacturer or seller for harm allegedly caused by a product, there is a rebuttable presumption that the product is not defective or unreasonably dangerous and the manufacturer or seller is not liable if, at the time the specific unit of the product was sold or delivered to the initial purchaser or user, the aspect of the product that allegedly caused the harm:

(a) Complied with federal or state codes, statutes, rules, regulations, or standards relevant to the event causing the death or injury;

(b) The codes, statutes, rules, regulations, or standards are designed to prevent the type of harm that allegedly occurred; and

(c) Compliance with the codes, statutes, rules, regulations, or standards is required as a condition for selling or distributing the product.

(2) In a product liability action as described in subsection (1), there is a rebuttable presumption that the product is defective or unreasonably dangerous and the manufacturer or seller is liable if the manufacturer or seller did not comply with the federal or state codes, statutes, rules, regulations, or standards which:

(a) Were relevant to the event causing the death or injury;

(b) Are designed to prevent the type of harm that allegedly occurred; and

(c) Require compliance as a condition for selling or distributing the product.

(3) This section does not apply to an action brought for harm allegedly caused by a drug that is ordered off the market or seized by the Federal Food and Drug Administration.

<sup>178</sup> *Eghnayem*, 873 F.3d at 1318 n.3.

<sup>179</sup> *Campbell v. Bos. Sci. Corp.*, 882 F.3d 70 (4th Cir. 2018).

<sup>180</sup> *Id.* at 77 (citing *Huskey v. Ethicon, Inc.*, 848 F.3d 151, 160–61 (4th Cir. 2017)).

*Huskey*, however, never mentioned that the device in question had been placed in Class II based on equivalence to a Class II predicate that had received a “safety evaluation.” As stated above, *Huskey* made this mistake because it wrongly assumed that the device at issue had been cleared based on an unregulated 1976 predicate that no medical panel had ever addressed. *Huskey* simply provided no basis for *Campbell*’s conclusion on that critical point. And *Huskey* also provided no basis for a battle of experts because criticism based on *Lohr* is legally and factually irrelevant to the method by which mesh devices were actually cleared.

**Carlino 2019.** The next appellate court to address the issue was the Superior Court of Pennsylvania in another incontinence sling case, *Carlino v. Ethicon, Inc.*<sup>181</sup> The decision followed *Eghnayem* in assuming that only the approval process provided reasonable assurance of safety and that 510(k) applied to devices only until they were subject to approval.<sup>182</sup> Relying on *Lohr*, the court wrongly concluded that substantial equivalence did not review the design of the device, only took twenty hours, and focused on equivalence, not safety.<sup>183</sup> After quoting from *Cisson* and *Huskey*, the court noted that the incontinence sling in question had been cleared as a Class II device in 1997.<sup>184</sup> But the court did not attribute any significance to the classification and said it was “at most, marginally relevant to whether [the device] is safe” and should not be allowed to confuse the jury.<sup>185</sup>

The court then turned to FDA’s 2013 statement, based on the 2011 hearing, that “[T]he safety and effectiveness of multi-incision slings is well-established in clinical trials that followed patients for up to one year. Longer follow-up data is available in the literature, but there are fewer of these long-term studies compared to studies with one year follow-up.”<sup>186</sup> The Superior Court said the trial court had discretion to exclude this evidence, even in a punitive damages case, because the plaintiff complained about pain after the one-year period, and “what made up this ‘literature’ and ‘data’” on which FDA relied “was anyone’s guess.”<sup>187</sup> The Superior Court thus failed to take into account the 2011 FDA Executive Summary compiled by FDA staff which gave medical device report data, listed the frequency of adverse events, reported on studies that lasted up to five years, and footnoted forty medical articles that supported FDA’s conclusions.<sup>188</sup>

**Kaiser 2020.** When the Seventh Circuit addressed the issue in *Kaiser v. Johnson & Johnson*, a pelvic mesh case where both compensatory and punitive damages were awarded, the court recognized that the mesh device was cleared based on equivalence to Class II devices, not pre-1976 devices, but misunderstood and even misrepresented FDA’s decisions.<sup>189</sup>

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<sup>181</sup> *Carlino v. Ethicon, Inc.*, 208 A.3d 92 (Pa. Super. Ct. 2019), *reargument denied* (June 12, 2019).

<sup>182</sup> *Id.* at 108.

<sup>183</sup> *Id.* at 109 (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 497 (1996)).

<sup>184</sup> *Id.* (citing *Huskey*, 848 F.3d; *In re C.R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2187, 810 F.3d 913 (4th Cir. 2016)).

<sup>185</sup> *Id.* at 110–11.

<sup>186</sup> *Id.* at 111 (quoting *Considerations about Surgical Mesh for SUI*, *supra* note 118).

<sup>187</sup> *Id.* at 112.

<sup>188</sup> See FDA EXECUTIVE SUMMARY, *supra* note 12, at 48–51.

<sup>189</sup> *Kaiser v. Johnson & Johnson*, 947 F.3d 996 (7th Cir. 2020).



The Seventh Circuit recognized that, as a matter of statutory construction, FDA's placement of a device in Class II means that FDA has found a reasonable assurance of the device's safety and effectiveness.<sup>190</sup> But the Seventh Circuit ultimately held such classification to be irrelevant for several mistaken reasons.

First, the Seventh Circuit overlooked that, under the statute, placement in Class II is itself a finding that the device does not "present a potential unreasonable risk of illness or injury" that would require the device to be in Class III.<sup>191</sup>

Second, the court said it was "hard to draw inferences about a device's safety without knowing what concerns triggered its Class II designation and what special controls FDA thought were necessary."<sup>192</sup> The court thus failed to take into account the 1982 medical panel opinion found in the Federal Register, quoted above,<sup>193</sup> and seriously misinterpreted FDA's 1988 classification decision.<sup>194</sup> That misinterpretation led the Seventh Circuit to imply wrongly that FDA had not established a reasonable assurance of safety and effectiveness for surgical mesh. It attributed to FDA the statement that "due to 'insufficient evidence of safety and effectiveness,' FDA assigned these surgical meshes to Class II."<sup>195</sup> It then later paraphrased this finding as a warning that the "surgical meshes in the 1988 rulemaking—did not come with a reasonable assurance of safety."<sup>196</sup>

But this description is dead wrong. FDA in 1988 did find a "reasonable assurance" and there was no contrary "finding." Under the statute, the only way FDA could put surgical mesh, which is implantable, in Class II was if it found that Class III treatment "was not necessary to provide reasonable assurance of safety and effectiveness" and gave a "full statement of the reasons" for its decision.<sup>197</sup> FDA did both of those things.

FDA's statements quoted by the court were in response to a comment which argued that surgical mesh was so safe it did not present any risk at all and should be in Class I.<sup>198</sup> FDA said it was putting surgical mesh in Class II "to control the risks to health of infection and foreign body reaction which may lead to implant rejection."<sup>199</sup> That decision was consistent with the subsequent 1999 guidance which required that a surgical mesh 510(k) provide evidence on the materials used and their toxicity.

When FDA said "insufficient evidence of safety and effectiveness is available at this time," it added "to support classifying surgical mesh *into class I*."<sup>200</sup> The Seventh Circuit left out the latter phrase and so took the earlier phrase out of context. What FDA was saying was that, if mesh were in Class I, there would not be reasonable

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<sup>190</sup> *Id.* at 1003.

<sup>191</sup> *Id.* at 1003. See 21 U.S.C. § 360c(a)(1)(C)(ii)(II).

<sup>192</sup> *Id.* at 1004.

<sup>193</sup> General and Plastic Surgery Devices; General Provisions and Classification of 54 Devices, 47 Fed. Reg. 2810 (Jan. 19, 1982) (to be codified at 21 C.F.R. pt. 878).

<sup>194</sup> See General and Plastic Surgery Devices; General Provisions and Classifications of 51 Devices, 53 Fed. Reg. 23,856 (June 24, 1988) (to be codified at 21 C.F.R. pt. 878); 21 C.F.R. § 878.3300.

<sup>195</sup> Kaiser, 947 F.3d 996 at 1006.

<sup>196</sup> *Id.* at 1018.

<sup>197</sup> 21 U.S.C. § 360c(d)(2)(B) (2020).

<sup>198</sup> General and Plastic Surgery Devices, 53 Fed. Reg.

<sup>199</sup> *Id.*

<sup>200</sup> *Id.* (emphasis added).

assurance, so FDA was putting mesh into Class II so there would be reasonable assurance.<sup>201</sup>

Further evidence that FDA in no way doubted that Class II treatment was sufficient is found in FDA's simultaneous declaration that, with respect to the device group to which mesh belonged, FDA "has determined that the probable benefit to health from proper use of these devices outweighed an[y] likelihood of illness or injury resulting from their use."<sup>202</sup>

Third, the Seventh Circuit, in commenting that it did not know "what special controls the FDA thought necessary,"<sup>203</sup> overlooked that the statute does not require that special controls actually exist for Class II devices. The statute merely requires information to establish special controls if FDA chooses to do so.<sup>204</sup> The 1988 FDA statement the opinion quoted expressly recognized that a performance standard, later called a special control, was not necessary for Class II placement.<sup>205</sup> And FDA did, in 1999, issue a guidance for surgical mesh 510(k)s.

Fourth, the Seventh Circuit, apparently after consulting the FDA website, criticized what it called "piggybacking," i.e., clearance of a device based on equivalence to an existing device which in turn may have been cleared based on equivalence to yet another device.<sup>206</sup> The court said it could "not make out a clear" picture of that history,<sup>207</sup> and the device in question's "connection to these meshes [reviewed in 1982 and 1988] is attenuated."<sup>208</sup>

But there is nothing mysterious about the process. Every predicate was, necessarily, a Class II mesh, and each predicate was at all relevant times subject to the medical device reporting system, another critical fact that the Seventh Circuit overlooked.

Fifth, the Seventh Circuit wrongly assumed that a claim that a device had the "same technological characteristics" as a predicate device was not a claim about safety and effectiveness. It thus said that the manufacturer, by asserting that characteristics were the same, "never claimed that [the device] was as safe as its proposed predicates."<sup>209</sup>

But under the statute, a claim that a device has the same technological characteristics is a claim of no "significant change in the materials, design, energy source or other features of the device," and "significance" is assessed in terms of safety and effectiveness.<sup>210</sup> That is a universally recognized safety claim.<sup>211</sup>

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<sup>201</sup> *Id.*

<sup>202</sup> General and Plastic Surgery Devices, 53 Fed. Reg.

<sup>203</sup> *Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1004 (7th Cir. 2020).

<sup>204</sup> 21 U.S.C. § 360c(a)(1)(B).

<sup>205</sup> General and Plastic Surgery Devices, 53 Fed. Reg.

<sup>206</sup> *Kaiser*, 947 F.3d at 1005.

<sup>207</sup> *Id.* at 1006.

<sup>208</sup> *Id.* at 1018.

<sup>209</sup> *Id.*

<sup>210</sup> See 21 U.S.C. § 360c(i)(1)(A) (denial of "different technological characteristics" means there is no "significant change in the materials, design, energy source or other features"); 21 C.F.R. § 807.81(a)(3)(i) (defining significant change in another context in terms of effect on safety and effectiveness).

<sup>211</sup> As the Institute of Medicine put it, the equivalence determination is a finding that the device is "as safe and effective as its predicate." IOM 2011, *supra* note 76, at 91. See FDA 2014 GUIDANCE, *supra* note 28, at 7 ("safety and effectiveness factor into both parts of FDA's [equivalence] review"); Shapiro, *supra* note 40, at 369 ("at least as safe and effective as the predicate device"), 374–75, 377–82.

Finally, the Seventh Circuit also mistakenly gave an ordinary meaning to a word that in FDA law only has a technical meaning. The court found it significant that the regulations<sup>212</sup> prohibit calling compliance with 510(k) notice regulations “approval.”<sup>213</sup> The court implied that the word “approval” here carried its ordinary meaning, which is to “give formal or official sanction to” something.<sup>214</sup> But it does not. It is simply a reference to the method used to grant permission to market Class III devices.<sup>215</sup>

A surgical mesh device cannot be sold without 510(k) clearance from FDA.<sup>216</sup> That is giving “formal or official sanction” to marketing.<sup>217</sup> If “approval” were given its ordinary meaning, then 510(k) clearance would be “approval.”

The only way to make sense of the regulation is to conclude that the word “approval” is used in its technical sense. “Approval” is the label the statute gives to the method FDA uses to grant permission to market Class III devices.<sup>218</sup> It does not use that method when it clears a Class I or Class II and so it would be misleading to suggest that it does. But clearance and classification into Class II is certainly a grant of “official sanction” to the sale of the device.

Support for this distinction between ordinary and technical meanings is found in the history of the regulation. The regulation prohibits the use of the word “approval” only with respect to what the manufacturer does, which is to comply with 510(k) regulations. In 1977, when the regulation prohibiting the use of the word “approval” to describe 510(k) clearance was adopted,<sup>219</sup> a manufacturer could market a device after filing a 510(k) notice so long as FDA did not affirmatively act to stop the sale.<sup>220</sup> So, it was literally true at that time that no “formal or official sanction” was required.

But all this changed. In 1990, Congress first defined “substantial equivalence” as something FDA had to find “by order.”<sup>221</sup> In 1992, FDA by regulation prohibited the sale of a device before it issued “an order declaring a device substantially equivalent.”<sup>222</sup> In 1997, Congress required FDA to make a determination within ninety

<sup>212</sup> 21 C.F.R. § 807.97 (2021) (cannot give “impression of approval of a device” because of “compliance with premarket notification regulations”).

<sup>213</sup> *Kaiser*, 947 F.3d at 1018.

<sup>214</sup> WEBSTER’S NEW COLLEGIATE DICTIONARY 56 (1977).

<sup>215</sup> 21 U.S.C. § 360e.

<sup>216</sup> 21 U.S.C. §360(n)(1); 21 C.F.R. §807.100(a)(5) (“Until the applicant receives an order declaring a device substantially equivalent, the applicant may not proceed to market the device.”).

<sup>217</sup> See *Noln v. C.R. Bard, Inc.*, 2021 WL 1264539, at \*8 (M.D.Tenn., Apr. 6, 2021) (if term “approval” is limited to “use in ordinary speech, however, it seems clear that authorization to market a product pursuant to the §510(k) process is, in fact, a form of “approval”).

<sup>218</sup> 21 U.S.C. § 360e (“Premarket approval”).

<sup>219</sup> See 21 C.F.R. § 807.97; Establishment Registration and Premarket Notification Procedures, 42 Fed. Reg. 42520 (Aug. 23, 1977) (to be codified at 21 C.F.R. pts. 20, 25, 807, 809).

<sup>220</sup> See *Bauman*, *supra* note 33, at 343 (“If FDA agreed or failed to respond prior to the expiration of this 90 day period, the device could enter the market.”); Rodney R. Munsey, *Trends and Events in FDA Regulation Over the Last Fifty Years*, 50 FOOD & DRUG L.J. 163, 169, 173 (1995).

<sup>221</sup> Safe Medical Devices Act of 1990, Pub. L. 101-629, § 12(a), 104 Stat. 4511(1990) (“substantial equivalence” means “the secretary by order has found”), codified at 21 U.S.C. § 360c(i)(1). See *Munsey*, *supra* note 220, at 173.

<sup>222</sup> 21 C.F.R. § 807.100 (“FDA action on premarket notification”); Medical Devices; Procedures for Premarket Notification, Premarket Approval, Classification, Performance Standards Establishment, Banning Devices, and Availability of Regulatory Hearings, 57 Fed. Reg. 58400 (Dec. 10, 1992) (to be

days of receiving a 510(k).<sup>223</sup> These changes expressly required “formal or official sanction” for marketing, and in fact a 1990 House Report even gave the heading “PREMARKET APPROVAL” to its discussion of 510(k) clearance.<sup>224</sup>

In other words, the regulation could not have been intended to mean that FDA’s action in issuing a clearance order could not be called “approval” in the ordinary sense because those orders did not even exist in 1977 when the regulation was adopted. In fact, the only thing the regulation prohibits calling “approval” is what the manufacturer does to comply with premarket notification regulations.<sup>225</sup>

For these reasons, the only way to make sense today of the regulation restricting use of the word “approval” is to give that word a purely technical meaning that restricts it to the process used to conduct premarket review for the most risky Class III devices.<sup>226</sup> The regulation does not in any way impeach the conclusion that, when FDA classifies a Class II device, and grants permission to market it, that is “approval in the ordinary sense of the word, and also is a determination that there is the same “reasonable assurance” of its safety that the statute requires for Class III devices.

## V. ARE COURTS COMPETENT TO DECLARE AGENCY LAW?

These decisions raise serious questions as to the competence of courts, adjudicating common law cases “one-by-one,” to decide questions of agency law, especially where the agency itself is not a party. They thus caution against too facile an abandonment of the principle of deference to an agency’s interpretation of the statutes it administers. The Fourth Circuit in *Cisson* made a serious error when it disregarded what it called “[b]ald assertions by the FDA” that FDA’s 510(k) clearance decisions provide reasonable assurance of safety and effectiveness.<sup>227</sup> The “assertions” were in a non-binding guidance,<sup>228</sup> but they were FDA’s reasonable reading of the statute it administers. The statute says FDA procedures provide that assurance,<sup>229</sup> the regulations say they provide that assurance,<sup>230</sup> FDA’s guidance says they provide that assurance,<sup>231</sup> and statistics even demonstrate that “cleared” devices may be, on average, safer than “approved” ones.<sup>232</sup>

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codified at 21 C.F.R. pts. 16, 807, 814, 860, 861, 895) (“The section also codifies in § 807.100 the requirement in section 12 of the SMDA that a device for which a premarket notification is pending may not be marketed until the applicant receives an order from FDA declaring the device to be substantially equivalent.”).

<sup>223</sup> Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 209, 111 Stat. 2296 (1997).

<sup>224</sup> See H.R. REP. NO. 101-808 (1990), reprinted in 1990 U.S.C.C.A.N. 6305, 6331 (discussing 510(k) review under heading of “PREMARKET APPROVAL”).

<sup>225</sup> See *supra* note 212.

<sup>226</sup> 21 U.S.C. § 360e.

<sup>227</sup> *In re C.R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2187, 810 F.3d 913, 921 (4th Cir. 2016).

<sup>228</sup> See FDA 2014 GUIDANCE, *supra* note 28.

<sup>229</sup> 21 U.S.C. § 360c(a)(1)(A)–(C).

<sup>230</sup> 21 C.F.R. § 860.3(c)(1)–(3).

<sup>231</sup> FDA 2014 GUIDANCE, *supra* note 28.

<sup>232</sup> See *supra* notes 59–61 and accompanying text.

It was the Fourth Circuit which mistakenly made a “bald assertion,” i.e., that the outdated dictum in *Lohr* trumped FDA’s accurate description of its regulatory process. And once the Fourth Circuit got things wrong, other appellate courts fell in line without independently analyzing what the Fourth Circuit had said.<sup>233</sup>

The courts adhered to what they believed were their own precedents, even though they had the power to reconsider questions of law and the ability to take into consideration regulatory facts not previously considered. Transfixed by *Lohr*, they took language that described the 1982 grandfathering of an unclassified device in *Lohr* and applied it to a situation that could not be more different, i.e., FDA’s retention of incontinence mesh devices in Class II in 2011 after an extensive study of medical device reports and medical literature. And they did so in the context of applying Federal Rule of Evidence 403, which is supposed to so depend on the circumstances of the particular case that “a decision in one case should not be used as precedent in another.”<sup>234</sup>

The great irony is that the courts, while adhering to their own “precedents,” disparaged the very similar system Congress established for FDA, which relies on “predicates.” Just as a court is normally charged with comparing the facts of a new case to the holding of an old one, FDA is charged with comparing the characteristics of a new device to the characteristics of an old one.<sup>235</sup> Just as a court has the ability to consider how a “precedent” has been treated over time, FDA has the ability through the medical device reporting system to gain information about the safety history of the “predicate” and other devices like it, at least in so far as adverse events have been reported. Courts deferred to their own erroneous precedents while condemning FDA’s sensible reliance on what it knew about predicate devices, something the Seventh Circuit derided as “piggybacking” by FDA.<sup>236</sup>

It is not the purpose of this Article to judge the merits of FDA’s conclusions about pelvic mesh against the courts’ conclusions, with one exception. FDA drew a very careful distinction between the use of mesh slings to treat incontinence and the insertion of mesh through the vagina to treat prolapse.<sup>237</sup> The incontinence slings remain on the market and are considered by surgeons to be a gold standard treatment.<sup>238</sup> Less than a dozen cases report a surgeon being accused of having committed malpractice for implanting an incontinence sling.<sup>239</sup> On the other hand, the transvaginal prolapse devices are no longer made.

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<sup>233</sup> The only decision in the universe of mesh MDL federal cases which reaches a different conclusion is a district court decision on remand in *Winebarger v. Boston Scientific Corp.*, 2015 WL 5567578, 7 (W.D. N.C. Sept. 22, 2015) (evidence of clearance may be admissible with limiting instruction). However, recently an intermediate New Jersey appellate court has rejected federal precedents and found FDA evidence admissible in a pelvic mesh case. *Hrymoc v. Ethicon, Inc.*, No. A-1083-18, 2021 WL 787039 (N.J. Super. Ct. App. Div. March 2, 2021).

<sup>234</sup> 22A KENNETH W. GRAHAM, JR., FEDERAL PRACTICE AND PROCEDURE § 5224.1, at nn. 7, 9 (Wright & Miller eds., 2d ed. 2020).

<sup>235</sup> This analogy is taken from Shapiro, *supra* note 40, at 382–83, 387.

<sup>236</sup> See *Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1005 (7th Cir. 2020).

<sup>237</sup> See FDA EXECUTIVE SUMMARY, *supra* note 12, at 10, 27.

<sup>238</sup> See AUGS POSITION STATEMENT, *supra* note 119, at 2.

<sup>239</sup> A Westlaw search in Allstates and Allfeds for mesh cases with a malpractice key number reported since the 2008 public health notice, Date (aft 1-1-2008) & 198Hk6! 198Hk7! 198Hk8! & mesh & incontinence, yields six decisions. Typically, the malpractice claims are joined to product liability claims against the mesh manufacturer in an attempt to defeat removal to federal court. In a medical malpractice

The courts, however, have not made this distinction. If FDA evidence had been admitted, perhaps the court results would have been different. If a jury were told that FDA, after the extensive 2011 review, had endorsed the safety and effectiveness of the full length incontinence slings, the juries might have agreed that they were not defective. That would not have helped the manufacturers in the transvaginal prolapse device cases, but those devices are no longer made.

If juries had heard FDA evidence and found no defect in the incontinence slings, the courts would not be faced with an odd and disturbing spectacle. That spectacle is that, while the courts have punished makers of the sling devices, the medical profession so thoroughly disbelieves and disregards what the courts have found that it regards the use of the slings as being the “gold standard” treatment for incontinence.<sup>240</sup>

Finally, it is beyond the scope of this Article to assign fault for the courts’ failure to understand a reasonably simple FDA regulatory process. All of the actors—FDA, judges, lawyers, critics of FDA, and even the news media—played a role. The thesis here is that the mistakes the courts made are possible even in a judicial proceeding, or series of proceedings, in which \$7 billion is at stake. In fact, the size of the case may make error more likely because in multidistrict litigation, the hydraulic pressure of case management discourages trial judge reconsideration and encourages appellate court affirmance.

The management of the MDL has been criticized,<sup>241</sup> and it is noteworthy that a New Jersey appellate court in a non-MDL pelvic mesh case has recently disagreed with the MDL appellate decisions and reversed a multi-million dollar judgment because the trial court refused to admit FDA evidence.<sup>242</sup>

The ultimate lesson in the *Chevron* debate over deference is that courts should listen to agencies whose conduct and expertise are at issue, or at least ask for their help. That help has never been sought in these cases despite the requests of counsel who have asked the courts to seek that help. In our constitutional system, it will always be the courts who, at the end of the day, decide what the law is. But, as Justice Robert Jackson said, finality and infallibility should not be confused.<sup>243</sup> The voice of the agency should be heard and heeded.

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action, however, a surgeon can use the “two schools of thought” defense to establish that the surgeon was not negligent because a substantial body of medical opinion supports the use of the incontinence sling. *See Jones v. Chidester*, 610 A.2d 964, 969 (Pa. 1992).

<sup>240</sup> *See* AUGS POSITION STATEMENT, *supra* note 119, at 2.

<sup>241</sup> James M. Beck, *New Jersey Rejects Bogus Exclusion of FDA Device Clearance Evidence*, DRUG & DEVICE LAW (Mar. 4, 2021), <https://www.druganddeviceblog.com/2021/03/new-jersey-rejects-bogus-exclusion-of-fda-device-clearance-evidence.html> [<https://perma.cc/74ST-TFWA>] (calling exclusion of FDA evidence a “settlement tool”).

<sup>242</sup> *Hrymoc v. Ethicon, Inc.*, No. A-1083-18, 2021 WL 836854, \*1, \*21–32 (N.J. Super. Ct. App. Div. Mar. 2, 2021).

<sup>243</sup> *Brown v. Allen*, 344 U.S. 443, 540 (1953) (Jackson, J., concurring in result only).