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No. _____

IN THE

Supreme Court of the United States

ETHICON, INC. AND JOHNSON & JOHNSON,
Petitioners,

v.

JO HUSKEY AND ALLEN HUSKEY,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Section 510(k) of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360(k), requires the federal Food and Drug Administration ("FDA") to review medical devices for safety and efficacy before clearing them for marketing and sale. Under the 510(k) review process applicable to the "Class II" device at issue in this case, FDA clears the device as safe to market if the agency finds it to be "substantially equivalent" to a device already determined to be safe. The Fourth Circuit in this case, however, construed *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), as holding categorically that FDA's 510(k) review process does *not* encompass meaningful safety review. Applying that reading of *Lohr*, the Fourth Circuit held that FDA's 510(k) clearance of petitioners' device was irrelevant to its safety, and thus affirmed a district court ruling prohibiting petitioners from introducing evidence of FDA's 510(k) clearance to defend against respondents' claims that the device was unsafe.

The question presented is:

Whether the Fourth Circuit properly applied *Lohr* to hold that safety is irrelevant to FDA's 510(k) clearance of a medical device and that the device's manufacturer therefore may be barred from introducing evidence of 510(k) clearance in defense of a claim that the device is not reasonably safe.

PARTIES TO THE PROCEEDING AND RULE 29.6 STATEMENT

Petitioners are Ethicon, Inc. and Johnson & Johnson, defendants-appellants below. Ethicon, Inc. is a wholly-owned subsidiary of petitioner Johnson & Johnson, a publicly-held company.

Respondents are Jo Huskey and Allen Huskey, plaintiffs-appellees below.

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OPINIONS BELOW

The decision of the United States Court of Appeals for the Fourth Circuit is published at 848 F.3d 151 (4th Cir. 2017), and is reprinted in the Appendix to the Petition ("App.") at 1a-20a. The district court's order denying petitioners' motion for a new trial is unpublished but available at 2015 WL 4944339, and is reprinted at App. 34a-74a.

JURISDICTION

The court of appeals issued its decision on January 26, 2017. App. 1a. A timely petition for rehearing en banc was denied on February 22, 2017. *Id.* at 75a. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The relevant statutory provisions—21 U.S.C. §§ 360, 360c, 360e—are reprinted at Appendix F to the petition, App. 76a-153a.

STATEMENT OF THE CASE

A. Regulatory Background

"A fundamental precept of the FDCA is that any product regulated by the FDA—but not banned—must be safe for its intended use." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 142 (2000). Though safety review did not always apply to medical devices, it does today: any medical device authorized for sale by the FDA—including those cleared through FDA's 510(k) process, 21 U.S.C. § 360(k)—is first reviewed by the FDA for safety.

1. Congress enacted the Medical Device Amend-

ments ("MDA") to the FDCA in 1976 to ensure comprehensive federal oversight of the market for medical devices. *Medtronic Inc. v. Lohr*, 518 U.S. 470, 476-77 (1996). Prior to the MDA's enactment, regulation of that market was left largely to the states, *id.* at 476, although some devices—including petitioners' Prolene suture, which is a predicate for the device here at issue—were regulated under the federal framework applicable to drugs, C.A. App. 771.[1] That system changed with the MDA, which gave FDA regulatory jurisdiction over all "devices intended for human use," 21 U.S.C. § 360c(a)(1), and charged the FDA with determining whether "there is reasonable assurance of the safety and effectiveness" of those devices before they reach the market, *id.* § 393(b)(2)(C); *see id.* §§ 360c(a)(1)(A)-(C).

Under the MDA, a device's path to market is determined by its classification. *Lohr*, 518 U.S. at 477. Classification is determined by expert panels prescribed by the Act "to evaluate the safety and effectiveness of" medical devices and classify them according to the risks they pose. 21 U.S.C. § 360c(b)-(c). Low risk devices are designated Class I and are subject only to "general controls." *Id.* § 360c(a)(1)(A). Devices that pose intermediate risks—the overwhelming majority of devices—fall into Class II.[2]

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[1] All citations to "C.A. App." refer to petitioners' appendix in the Fourth Circuit. All citations to "DE" refer to district court docket entries in the underlying action.

[2] In some years, the figure is as high as 98%. *See* Jeffrey K. Shapiro, *Substantial Equivalence Premarket Review: the Right Approach for Most Medical Devices*, 69 Food & Drug L.J. 365, 365, 377 (2014).

Class II devices must pass through FDA's 510(k) "clearance" process, *id.* § 360c(a)(1)(B); *see id.* § 360(k), which requires the manufacturer to show that the device is "substantially equivalent" to a "predicate device" that is *already* marketed legally. *Id.* § 360c(i)(1)(A). Class III devices, finally, pose the greatest risks—"a potential unreasonable risk of illness or injury"—and are thus subject to a more elaborate "premarket approval" ("PMA") process. *Id.* § 360c(a)(1)(C). Thus, while FDA by regulation prohibits manufacturers of 510(k) "cleared" devices from marketing them as if they received FDA "approval" applicable to Class III devices, *see* 21 C.F.R. § 807.97, both regulatory pathways involve safety and effectiveness review. The specific pathway chosen by FDA simply reflects its determination of what type of review process is necessary "to provide reasonable assurance of the safety and effectiveness of the device." 21 U.S.C. § 360c(a)(1).

Although all Class III devices were supposed to go through the PMA process, the MDA contained two important exceptions. First, because "Congress realized that existing medical devices could not be withdrawn from the market while the FDA completed its PMA analysis for those devices," Congress included a "'grandfathering' provision which allow[ed] pre-1976 devices to remain on the market without FDA approval until such time as the FDA initiate[d] and complete[d] the requisite PMA." *Lohr*, 518 U.S. at 477-78 (citing 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1) (1995)). "Second, to prevent manufacturers of grandfathered devices from monopolizing the market while new devices clear[ed] the PMA

hurdle, and to ensure that improvements to existing devices [could] be rapidly introduced into the market," the Act also permitted new Class III devices to reach the market through the 510(k) pathway so long as they were substantially equivalent to pre-existing devices, *including those that were grandfathered*. *Id.* (citing 21 U.S.C. § 360e(b)(1)(B)); *see Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008). In other words, some devices were allowed to reach the market through the 510(k) process based on their substantial equivalence to grandfathered devices that had "never been formally reviewed under the MDA for safety or efficacy." *Lohr*, 518 U.S. at 493.

2. Since the MDA's enactment in 1976, there have been "far-reaching statutory and administrative changes in substantial equivalence review" under § 510(k). Shapiro, *supra*, at 393; *see* Ralph F. Hall & Michelle Mercer, *Rethinking* Lohr*: Does "SE" Mean Safe and Effective, Substantially Equivalent, or Both?*, 13 Minn. J.L. Sci. & Tech. 737, 754-55 (2012) ("One cannot simply talk about, or draw conclusions about, the 510(k) system as one system throughout time. Rather, one must consider the system as it existed at the time the particular 510(k) submission was reviewed by the FDA.").

Most important, in 1990, Congress enacted the Safe Medical Devices Act ("SMDA"), which "essentially rewrote the 510(k) process" to "impose[] more safety and effectiveness requirements on 510(k) medical devices." Hall & Mercer, *supra*, at 748; *see* Shapiro, *supra*, at 369 (enactment of SMDA was "watershed event" for 510(k) review). In particular, the SMDA defined the phrase "substantial equiva-

lence," 21 U.S.C. § 360c(i), and Congress closed the § 510(k) grandfathering loophole for Class III devices, mandating that FDA review all grandfathered Class III devices and either "downclassify" the device based on its history of safe and effective use or require it to go through Class III's PMA process. *See* Pub. L. No. 101-629, § 4, 104 Stat. 4511, 4515-17 (amending, *inter alia*, 21 U.S.C. §§ 360c(f)(4), 360e(i)); *see also* Ellen J. Flannery, *The Safe Medical Devices Act of 1990: An Overview*, 46 Food, Drug, Cosm. L.J. 129, 135-36 (1991); Hall & Mercer, *supra*, at 750. As a result, almost every Class II and Class III device that has reached the market since the SMDA's enactment has been cleared under § 510(k) based on its substantial equivalence to a device or devices already specifically reviewed by FDA for safety and efficacy.[3]

Thus, while the 510(k) review process may have been relatively lax in the early 1980s—when review was "completed in an average of only 20 hours," *Lohr*, 518 U.S. at 479—the process is nothing like that today, *see* Shapiro, *supra*, at 382; *see also* Emergo Group, *How long it takes the US FDA to clear medical devices via the 510(k) process* at 5 (Mar. 2017) (average traditional 510(k) review performed by FDA takes six months, as FDA "has become much more strict about clinical evidence and testing requirements, thus lengthening the overall

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[3] As of 2014, about two dozen grandfathered Class III device types had not been downclassified or received premarket approval, *see* Shapiro, *supra*, at 367 & n.21, 376, but none is relevant to this case.

path to clearance").[4]

3. The best evidence of how modern 510(k) reviews are actually conducted comes from FDA itself. FDA has emphasized time and again that when it undertakes a 510(k) review, it specifically evaluates "the issues of safety and effectiveness presented by the new device, and the regulatory controls necessary to address those issues." C.A. App. 611. As recently as January 2017, FDA reiterated that "principles of safety and effectiveness underlie the substantial equivalence determination in *every* 510(k) review."[5]

4. This Court has considered the 510(k) process in three prior cases.

a. In *Lohr*, the Court held that § 510(k) does not preempt state-law claims because it does not impose device-specific requirements. 518 U.S. at 493. The Court observed in passing that "the 510(k) process is focused on *equivalence*, not safety," *id.* (quotations and alteration omitted), which was accurate in *Lohr* because the Model 4011 pacemaker lead at issue—a Class III device—had been cleared based on its equivalence to a *device that had been grandfathered*, and thus had "never been formally reviewed . . . for safety or efficacy," *id.*

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[4] *Available at* https://www.emergogroup.com/resources/research/fda-510k-review-times-research.

[5] FDA, Public Health Interests and First Amendment Considerations Related to Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products, at 44, Docket No. FDA-2016-N-1149 (Jan. 17, 2017) (emphasis added).

b. In *Riegel*, the Court held that unlike the substantial equivalence standard for Class II devices, the PMA process for Class III devices does preempt certain state-law claims. 552 U.S. at 330. In contrasting the 510(k) and PMA processes, the Court repeated *Lohr*'s observation that 510(k) review focuses on equivalence rather than safety. *Id.* at 323.

c. And in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Court held that state-law fraud-on-the-FDA claims are preempted. *Id.* at 353. The Court's opinion in *Buckman* more accurately characterized the current FDA medical-device review process, explaining that "the exhaustive PMA and the more limited § 510(k) [i.e., substantial equivalence] processes" both "ensure . . . that medical devices are reasonably safe and effective." *Id.* at 349-50.

B. The TVT-O

This case concerns a Class II surgical mesh device called TVT-O. TVT-O and similar pelvic mesh devices are used to treat stress urinary incontinence ("SUI"), a chronic condition afflicting millions of women that causes involuntary leakage of urine during everyday activities like laughing, coughing, and sneezing.[6] TVT-O is considered by professional medical societies to be a "gold standard" treatment for SUI. C.A. App. 2309-10. It is composed of polymeric mesh knitted from filaments of Prolene, a proprietary brand of polypropylene.

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[6] Another family of pelvic mesh devices is used to treat pelvic organ prolapse.

TVT-O has a robust regulatory history.

1. That history begins with FDA's clearance of the Prolene suture in 1969 under its rigorous New Drug Application process—a process roughly equivalent to premarket approval now required for Class III medical devices. *See* C.A. App. 771-74.[7] As relevant to this case, when FDA approved the Prolene suture and its label, it reviewed the issue of degradation and rejected the proposition that degradation presented a clinically significant risk, if it even occurred at all. C.A. App. 776, 1122-28, 1201.

In 1990, after consulting with its General and Plastic Surgery Devices Panel, FDA "down classified" nonabsorbable polypropylene surgical sutures like Prolene from Class III to Class II, concluding that Class III's stringent controls were not needed to ensure the devices' "safety and effectiveness." 21 U.S.C. § 360c(a)(1)(B); *see* C.A. App. 778.

In 2003, FDA adopted a guidance for surgical sutures like Prolene as a Class II "special control" designed to provide additional "assurance of the safety and effectiveness" of these devices. 68 Fed. Reg. 32,983, 32,983 (June 3, 2003); *see* 21 U.S.C. § 360c(a)(1)(B).

2. Polymeric meshes—the umbrella category for

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[7] When the MDA was enacted in 1976, Prolene was treated as a "transitional device" under the MDA, 21 U.S.C. § 360j(*l*)(1), which meant that it was considered to have received premarket approval. *See* C.A. App. 777 ("Because the FDA had already approved PROLENE as safe and effective, and because it was the subject of an effective New Drug Application, it automatically had Pre-Market Approval.").

the TVT-O—also underwent rigorous panel review. When FDA first determined the proper regulatory classification for polymeric meshes, three different expert medical panels—Gastroenterology/Urology, Plastic Surgery, and Orthopedics—studied their safety and effectiveness and recommended that they be placed in Class II. *See* 47 Fed. Reg. 2810, 2817-18 (Jan. 19, 1982). That recommendation was based on polymeric mesh's "established history of safe and effective use" and "generally accepted satisfactory level of tissue compatibility." *Id.* at 2817. FDA agreed, and placed the devices in Class II. *See* 53 Fed. Reg. 23,856, 23,861 (June 24, 1988); 21 C.F.R. § 878.3300; C.A. App. 779-80.

3. In fall 1997, Ethicon submitted a 510(k) application for its Tension Free Vaginal Tape ("TVT") system—the predecessor of TVT-O and, like the latter, a surgical mesh device for the treatment of SUI. C.A. App. 780-81. Ethicon advised FDA that the device was composed of the same polypropylene strands as Prolene mesh and are used to fabricate the Prolene suture. *Id.* That material is the only part of the TVT intended to be left in a patient's body following a TVT surgical procedure. *Id.* FDA cleared TVT in January 1998, *id.* at 781. Upon clearance, FDA placed the device in Class II, and has monitored it ever since, *see* 21 C.F.R. § 803.1(a) (prescribing post-market reporting requirements "to protect the public health by helping to ensure that devices . . . are safe and effective for their intended use").

4. This regulatory history was integral to TVT-O's clearance. In November 2003, Ethicon submitted a 510(k) application for TVT-O based on its substan-

tial equivalence to TVT. While the new device had some modifications to facilitate its placement, those modifications "did not affect the intended use of the device or alter [its] fundamental scientific technology." C.A. App. 781. Critically, the Prolene mesh implant "remain[ed] unchanged"—the device is composed of the same polypropylene strands that comprise Prolene mesh and are used to fabricate the Prolene suture. *Id.* at 781-82. FDA cleared TVT-O, including its label advising that its mesh was not subject to degradation. *Id.* at 782.

5. In 2011, partly in response to the wave of pelvic mesh litigation, the FDA convened its Obstetrics & Gynecology Devices Advisory Committee to consider whether certain pelvic mesh products should be placed in Class III and whether pelvic mesh products for the treatment of SUI should be subject to more rigorous Class II controls, including a requirement for pre- or post-market clinical trials. *Id.* at 782, 1505, 1547-51. After reviewing the medical and scientific literature, considering medical device reports for all such devices over a period of years, and hearing testimony, the panel, on the recommendation of the FDA, agreed that neither pre- nor post-market clinical data was needed to substantiate the safety and effectiveness of devices like TVT-O. *Id.* at 1589. TVT-O remains in Class II to this day. *Id.* at 782.

C. Procedural History

1. This case is one of more than 60,000 cases from seven MDLs in the Southern District of West Virginia concerning pelvic mesh devices. *See Waynick v. Ethicon, Inc.*, 2017 WL 404659, at *1

(S.D. W. Va. Jan. 30, 2017). Respondent Jo Huskey and her husband filed suit directly in MDL 2327, asserting product-liability claims against petitioners under Illinois law alleging that TVT-O is not reasonably safe for its intended use. C.A. App. 54-60.

2. a. It is undisputed that regulatory evidence, including evidence of compliance with FDA standards, is legally relevant to respondents' Illinois-law claims. *See Moehle v. Chrysler Motors Corp.*, 443 N.E.2d 575, 578 (Ill. 1982) (even evidence of "antiquated or grossly minimal safety standards" is relevance and admissible); *Hatfield v. Sandoz-Wander, Inc.*, 464 N.E.2d 1105, 1109 (Ill. Ct. App. 1984) (trial court properly admitted evidence of compliance with FDA standards). Ethicon accordingly sought to introduce the undisputed fact that FDA had cleared TVT-O under § 510(k) as evidence in defending against respondents' claims that TVT-O is not reasonably safe.

Respondents moved to exclude the evidence of FDA's 510(k) clearance under Federal Rules of Evidence 402 and 403. According to respondents, "the FDA's 510(k) process is not related to product safety or efficacy," and hence Ethicon should be barred from citing TVT-O's 510(k) clearance as evidence of its safety and efficacy. DE 140. The district court agreed, App. 21a-29a, relying on its prior ruling in *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748 (S.D. W. Va. 2014), another case from the same MDL. *Lewis* in turn relied solely on this Court's decision in *Lohr*, construing *Lohr* as holding that "FDA's 510(k) clearance . . . does not speak to [a] device's safety or efficacy," thereby rendering the

510(k) clearance "irrelevant . . . and inadmissible under Rule 402." *Id.* at 755.

The court excluded from trial any reference to FDA's 510(k) clearance of TVT-O. The court went so far as to threaten "very large" sanctions if even a medical article including the letters "F-D-A" was introduced by accident. App. 32a-33a. Thus, in this trial on an FDA-regulated prescription-only medical device, the letters F-D-A were never uttered—not once.

b. Respondents took full advantage of the ruling. Respondents told the jury that TVT-O was "rushed to market," C.A. App. 3846, knowing petitioners could not answer the charge by truthfully explaining that TVT-O only got to market through FDA's 510(k) clearance process. Respondents also heavily emphasized that petitioners should be held liable for not performing clinical trials before marketing TVT-O, *id.*, again knowing that petitioners could not respond by arguing that *FDA does not require clinical trials* before marketing this Class II device, *see* 21 U.S.C. § 360c(a)(1)(B); *see also* C.A. App. 1547-51, 1589. Respondents further argued that Ethicon *knew* that TVT-O's mesh "degrades," C.A. App. 3875, and "is unsuitable for implantation," *id.* at 2240, yet again confident that Ethicon could not cite FDA's 510(k) clearance to explain accurately why they concluded that TVT-O was safe for use.

c. The jury returned a verdict in respondents' favor, awarding $3,070,000 to Mrs. Huskey and $200,000 to her husband.

d. Petitioners moved for a new trial based on the

district court's exclusion of 510(k) evidence. The district court reiterated its position that, "[i]n light of the Supreme Court's precedent [in *Lohr*] on the meaning and purpose of 510(k)," there is "little relevance in the fact that the TVT-O was cleared under this regulation." App. 70a. According to the district court, this Court in *Lohr* "held that compliance with 510(k) focuses on 'equivalence, not safety' and that products entering the market through the 510(k) process have 'never been formally reviewed for safety or efficacy.'" *Id.* (alteration omitted). "If 510(k) does not go to a product's safety or efficacy—the 'very subjects' of the plaintiffs' product liability claims," the court reasoned, "then evidence of Ethicon's compliance with 510(k) has no relevance to the state law claims in this case and was properly excluded by the court." *Id.* (internal citations and alterations omitted). Having concluded that evidence of 510(k) clearance had little or no probative value, the court also held that it was inadmissible under Rule 403. *Id.* at 71a-72a.

3. The court of appeals affirmed on the authority of its earlier decision in *Cisson v. C.R. Bard, Inc.*, 810 F.3d 913 (4th Cir. 2016), another bellwether case against a different manufacturer from the pelvic mesh MDLs. *See* App. 15a-17a. In *Cisson*, the Fourth Circuit upheld the exclusion of 510(k) evidence on the ground that, under *Lohr*, the 510(k) process speaks only "tangentially" about safety, if at all. *Id.* at 921-22; *see id.* at 920 ("the clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value"). In so doing, the *Cisson* court brushed

aside as "[b]ald assertions" FDA's own statements about how it conducts 510(k) reviews today. *Id.* at 921 (alteration in original).

The decision below invokes *Cisson* to emphasize that the 510(k) process "only *'tangentially'* examines the safety of the product going through [it]," App. 16a (quoting *Cisson*, 810 F.3d at 922 (emphasis added by decision below)). The decision likewise cites *Cisson* to confirm that the Fourth Circuit conclusively "reject[s]" *FDA's own view* that "510(k) compliance [is] highly probative of a product's safety." *Id.* On the basis of *Cisson*'s construction of *Lohr*, the Fourth Circuit affirmed the district court's ruling that Ethicon could not cite FDA's 510(k) clearance of TVT-O in defending against claims that TVT-O is unsafe. *Id.* at 16a-17a.

REASONS FOR GRANTING THE PETITION

This case presents a recurring question of exceptional importance, *viz.*, whether a medical-device manufacturer can be barred from citing FDA's 510(k) clearance of the device to defend against claims that the device is unsafe, on the ground that the 510(k) process has little or nothing to do with device safety.

This Court has addressed the 510(k) process in multiple decisions, but those decisions have unfortunately yielded a profound and entrenched misunderstanding of the 510(k) process among lower courts. This case starkly illustrates the enormous significance of this issue to products-liability litigation throughout the nation—the Fourth Circuit's incorrect understanding of the 510(k) process will be guid-

ing an MDL court's oversight of *scores of thousands* of product-liability trials involving FDA-regulated devices cleared under § 510(k).

The Fourth Circuit's error derives entirely from this Court's decision in *Lohr*, and the Fourth Circuit's misunderstanding of *Lohr* does not stand alone. To the contrary, courts have consistently "interpret[ed] *Lohr* as holding that the 510(k) process does not go to whether a product is safe and effective." *Lewis*, 991 F. Supp. 2d at 755 n.3; *see Cisson*, 810 F.3d at 920-21; *Mack v. Stryker Corp.*, 748 F.3d 845, 856 (8th Cir. 2014); *Smith v. Depuy Orthopaedics, Inc.*, 552 F. App'x 192, 193 n.1 (3d Cir. 2014); *Rodriguez v. Stryker Corp.*, 680 F.3d 568, 574 (6th Cir. 2012); *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1369 n.1 (11th Cir. 1999).

Although normally a circuit conflict is what motivates the exercise of certiorari jurisdiction, in this case it is the *absence* of a conflict that warrants certiorari: the consensus interpretation of *Lohr* and § 510(k) is unambiguously wrong as to non-grandfathered devices, but at this point will stand uncorrected without this Court's intervention. This Court can and does grant review in such circumstances. *See, e.g.*, *Skilling v. United States*, 561 U.S. 358, 377 (2010); *Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 169-70 (1994); *McNally v. United States*, 483 U.S. 350, 361 (1987). And because the lower courts' error derives from this Court's own precedent, the Court's intervention to resolve the problem is all the more justified. *See, e.g.*, *Trevino v. Thaler*, 133 S. Ct. 1911, 1916 (2013); *Shafer v. South Carolina*, 532 U.S. 36,

48 (2001); *Dolan v. City of Tigard*, 512 U.S. 374, 383 (1994); *United Gas Pipe Line Co. v. Memphis Light, Gas & Water Div.*, 358 U.S. 103, 109 (1958).

Certiorari is also warranted because this issue is of paramount importance. *See United States v. Article of Drug Bacto-Unidisk*, 394 U.S. 784, 791 (1969) (granting review where courts of appeals' interpretation "raised issues of importance in the administration of the [FDCA]"). The Fourth Circuit's decision will likely affect an extraordinary number of cases—fully 60,000 currently pending in the pelvic mesh MDLs. And given that the vast majority of medical devices reach the market through § 510(k), this recurring issue will likely affect an untold number of future product-liability cases as well.

The purely quantitative significance of the issue would be enough to justify certiorari, but there is a serious qualitative dimension as well. Under the lower court's understanding of *Lohr* and the 510(k) process, for a device manufacturer subject to suit for marketing an allegedly unsafe device, it is literally impossible to present a complete defense—the manufacturer cannot even begin to offer jurors the wholly truthful account of how the device actually got to market. Indeed, lay jurors unaware that the device was cleared by FDA may well infer that FDA thought the device was *unsafe*. *Cf. Old Chief v. United States*, 519 U.S. 172, 188 (1997). As much as this judicial misunderstanding of *Lohr* deprives device manufacturers of what is often their most important defense, it deprives *jurors* of information critical to the exercise of their authority to decide whether a device should be marketed at all—exactly

contrary to *Lohr*'s central lesson that *properly informed and instructed* juries can apply state law to make judgments about device safety.

The Court should grant certiorari to correct the consensus judicial misunderstanding of *Lohr* and clarify that the 510(k) process includes safety and efficacy review.

I. THE COURT SHOULD GRANT REVIEW TO CORRECT THE LOWER COURTS' MISINTERPRETATION OF *LOHR* AND CLARIFY THAT 510(k) REVIEW ENCOMPASSES DEVICE SAFETY

The Fourth Circuit's decision rests entirely on the fundamentally erroneous premise that 510(k) review "only *tangentially* examines the safety of the product going through the process." App. 16a (quotation marks omitted; emphasis in original). The same error affects almost every case involving § 510(k), and it flows directly from a gross misinterpretation of this Court's decision in *Lohr*.

A. *Lohr* Does Not Address The Current 510(k) Clearance Process For Non-Grandfathered Products

The Court in *Lohr* addressed the question whether FDA's 510(k) clearance process imposed on a device called a "pacemaker lead" a specific "requirement" that preempted state-law claims effectively seeking to impose different "requirements" through the guise of common-law tort standards. This Court rejected the preemption defense because the 510(k) process mainly addressed substantial equivalence to a pre-1976 device and thus did not impose any de-

vice-specific "requirements," but instead aimed only to "maintain the status quo." 518 U.S. at 493-94. In so holding, the Court observed that "the 510(k) process is focused on *equivalence*, not safety." *Id.* at 493 (quotations and alterations omitted).

In the specific context before the Court, that statement was unquestionably true: the pacemaker lead's 510(k) clearance *was* focused on equivalence, not safety—but *only* because the original (predicate) device had been grandfathered into FDA approval, i.e., it had "never been formally reviewed under the MDA for safety or efficacy." 518 U.S. at 493; *see Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1340 (11th Cir. 1995) (pacemaker lead "entered the market through the 510(k) process as the substantial equivalent of a device grandfathered into the Act").

Subsequent decisions of this Court confirm that *Lohr* was not making a categorical statement that 510(k) review excludes meaningful safety review. In *Brown & Williamson*, this Court explained that a "fundamental precept of the FDCA is that any product regulated by the FDA—but not banned—must be safe for its intended use." 529 U.S. at 143. The 510(k) process serves that objective for Class II devices, because by definition, the agency deems the special controls applicable to Class II devices to be "sufficient" "to provide reasonable assurance of the safety and effectiveness of the device." 21 U.S.C. § 360c(a)(B). What's more, a device type must undergo "formal medical review" by an expert classification panel to be placed in Class II in the first place. And in *Buckman*, a case that specifically addressed § 510(k), the Court further acknowledged

that *both* the PMA process *and* substantial equivalence review are designed to "ensure . . . that medical devices are reasonably safe and effective." 531 U.S. at 349-50.

The Court's comments in *Buckman* and *Brown & Williamson* accurately reflect the nature of 510(k) review. And they demonstrate that the comments in *Lohr* were limited to the narrow, anachronistic context in which they were made, i.e., clearance of a device based on a grandfathered predicate product that itself had not been subject to safety review.

B. Courts Have Erroneously Expanded *Lohr* Into A Categorical Holding That FDA's Current 510(k) Clearance Process Does Not Include Meaningful Safety Review

As exemplified by the decisions below, courts have drastically expanded *Lohr*'s scope by transforming its observation about 510(k) review of a device with a *grandfathered* predicate into a categorical description of the 510(k) process for *all* devices, ignoring the major subsequent changes to the statutory scheme.

1. The Fourth Circuit's decision in *Cisson* is a leading example of the confusion fomented by *Lohr*'s comments on the 510(k) process. *Cisson* holds that 510(k) evidence has virtually no probative value because it reads *Lohr* to hold that 510(k) clearance only "tangentially" relates to safety. 810 F.3d at 922. According to the Fourth Circuit, *Lohr* conclusively established that 510(k) "clearance rests *only* on whether the device is 'substantially equivalent to one

that existed before 1976,'" i.e., one that had been grandfathered into the Act. *Id.* at 921 (quoting *Lohr*, 518 U.S. at 493) (emphasis added)). The Fourth Circuit in this case applied *Cisson*'s construction of *Lohr* to affirm the exclusion of 510(k) evidence here, App. 15a-17a, based on a district court ruling that anticipated *Cisson*'s analysis and holding, *id.* 70a (510(k) evidence is of little or no probative value because *Lohr* "held that compliance with 510(k) focuses on 'equivalence, not safety' and that products entering the market through the 510(k) process have 'never been formally reviewed for safety or efficacy'"). Decisions from numerous other circuits have interpreted *Lohr* in the same way. *See supra* at 15.

2. The lower courts' interpretation of *Lohr* and the 510(k) process is unambiguously wrong. As already shown, the Fourth Circuit's reading of *Lohr* takes the Court's comments about the 510(k) process out of their narrow context. *See supra* at 17-19. *Lohr* only discussed the 510(k) process because of the MDA's grandfathering provisions, which allowed pre-1976 Class III devices to remain on the market and substantially equivalent devices to obtain clearance through § 510(k), rather than through the PMA process ordinarily required for Class III devices. The use of the 510(k) substantial equivalence process for Class III devices was a purely "transitional" issue specific to Class III devices that was "not relevant" to the 510(k) process "as applied to . . . Class II devices" like TVT-O. Shapiro, *supra*, at 367 n.21; *see id.* at 376.

As to Class II devices, it is not true that 510(k) clearance rests "only on whether the device is 'sub-

stantially equivalent to one that existed before 1976'" and thus was not formally reviewed for safety and efficacy. *Cisson*, 810 F.3d at 921 (quoting *Lohr*, 518 U.S. at 494). Under the SMDA, a Class II "device demonstrating substantial equivalence" *does not* have to have "a pre-1976 device as a predicate." Hall & Mercer, *supra*, at 749; *see* Shapiro, *supra*, at 369; *see also* 21 U.S.C. § 360c(i). Congress even closed the grandfathering loophole for Class III devices, requiring FDA to review *all* grandfathered Class III devices for safety and efficacy. Hall & Mercer, *supra*, at 750; Flannery, *supra*, at 135-36. In short, unlike the transitional Class III review process at issue in *Lohr*, a Class II device today is cleared through the 510(k) pathway based on its equivalence to predicate devices that FDA *has* reviewed for safety and efficacy.

TVT-O, for example, obtained clearance only after multiple formal medical reviews. First, FDA cleared TVT-O in 2003 based on its equivalence to TVT, a device FDA had cleared in 1998 and had monitored for five years. *See* C.A. App. 780-82; *supra* at 9. Second, TVT obtained clearance based in part on FDA's earlier clearance of Ethicon's polymeric Prolene suture, which FDA evaluated and approved under a process analogous to the rigorous premarket approval process for Class III devices. C.A. App. 771-74. Third, FDA put TVT-O in Class II, not Class III, based on the work of three different expert medical panels, which evaluated the safety and effectiveness of polymeric meshes. *See supra* at 8-9. Based on those evaluations, FDA concluded that these devices had an established history of safe and effective

use warranting Class II placement, *id.*; *see also Talley v. Danek Med., Inc.*, 179 F.3d 154, 161 (4th Cir. 1999) (reclassification from Class III into Class II means the product is "safe to market"); Shapiro, *supra*, at 374 (placement in Class I or II itself "should provide reasonable assurance of safety and effectiveness, because by statutory definition a Class I or Class II device type has such assurance subject to applicable postmarket controls")—a determination that also means that the device poses no "potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C)(ii)(II).

And these were not the only formal medical reviews either. In 2011, FDA convened its Obstetrics and Gynecology Devices Advisory Committee to reassess the safety and effectiveness of devices used to treat SUI and determine whether additional safeguards were necessary. C.A. App. 782. In preparation for that meeting, FDA "systematically evaluated the peer-reviewed scientific literature" and its own adverse-event database—which is composed of information collected through FDA's post-market monitoring program—and concluded that the safety and effectiveness of TVT-O and similar mesh devices for the treatment of SUI was well established. *Id.* 1513; *see id.* at 782, 1532; *see also id.* at 1592. The Committee agreed, and advised FDA that neither pre- nor post-market clinical studies were necessary. *Id.* at 1589. In March 2013, again based on its review of information collected from post-market monitoring, FDA reiterated these conclusions. *Id.* at 783, 1592.[8]

[8] None of this evidence, however, was presented to the jury because of the district court's ruling.

TVT-O remains in Class II to this day. *Id.* at 782.

Thus, while FDA's clearance of the pacemaker lead in *Lohr* did focus on equivalence rather than safety, because the predicate device *had never been reviewed for safety*, exactly the opposite was true for TVT-O: the device and its predicate products *were* formally reviewed for safety, and TVT-O was found to be substantially equivalent to those products. That determination is what matters under § 510(k): if FDA finds a device to be "substantially equivalent" to a predicate device already found to be safe, then FDA is finding the device itself to be safe. CA. App. 614.

FDA's own statements about its 510(k) process remove any remaining doubt that the process encompasses safety review. In FDA's view, the modern 510(k) system "requires [it] to determine the issues of safety and effectiveness presented by the new device, and the regulatory controls necessary to address those issues." C.A. App. 611. FDA reiterated that conclusion just months ago, emphasizing in January 2017 that "principles of safety and effectiveness underlie the substantial equivalence determination in *every* 510(k) review." *Supra* n.5.

The Fourth Circuit refused to credit FDA's consistent description of its own process, dismissing the agency's statements as "[b]ald assertions." App. 16a (quotations omitted; alteration in original). But the court of appeals cited no evidence indicating that FDA has been lying about the nature of its 510(k) review process. Nor did the court volunteer any speculation as to why the agency would do so. Given the absence of any basis for inferring that FDA has

falsely characterized its own process, its characterization must be accepted as a genuine statement of the agency's "body of experience and informed judgment." *Fed. Exp. Corp. v. Holowecki*, 552 U.S. 389, 399 (2008) (quotations omitted). FDA's statements are the best evidence of how its process operates.

* * * *

Courts "have erred in uncritically extrapolating *Lohr* to the present day, ignoring far-reaching statutory and administrative changes in substantial equivalence review." Shapiro, *supra* at 393; *see* Hall & Mercer, *supra*, at 754-55. *Lohr*'s analysis has little if any relevance to modern 510(k) clearance, which unquestionably encompasses safety and effectiveness review.

This Court should grant review to correct these errors and reconcile the Court's descriptions of FDA's 510(k) process with the modern statutory scheme.

II. THE PETITION PRESENTS A RECURRING QUESTION OF NATIONAL IMPORTANCE

A. The Issue Directly Affects Many Thousands Of Pending Cases And Will Directly Affect Many Thousands More In The Future

The lower courts' misinterpretation of *Lohr* and § 510(k) is not limited to the occasional erroneous exclusion of marginal evidence in a handful of cases. To the contrary, *Lohr* may be directly responsible for the wrongful exclusion of critical evidence in *tens of thousands of cases*—ample grounds for this Court to

grant review. *See, e.g.*, *United States v. Centennial Sav. Bank FSB*, 499 U.S. 573, 578 (1991) (granting review "in light of the significant number of pending cases concerning" the issue); *Maass v. Higgins*, 312 U.S. 443, 445 (1941) (granting review in the absence of a circuit conflict "because of the importance of the question and the number of pending cases in which it is presented").

This is a bellwether case from a cluster of MDLs in which "more than 60,000 cases [are] currently pending." *Waynick*, 2017 WL 404659, at *1. If the Fourth Circuit's decision is left undisturbed, it likely will be applied in *every* pending case to exclude 510(k) evidence on the ground that under *Lohr*, 510(k) review is irrelevant to safety. And there are still thousands more mesh-related cases pending in state courts around the country in which the same result will likely obtain unless this Court grants review in this federal case to clarify *Lohr*.

Nor is the issue limited to the current wave of mesh trials. The "majority of medical devices" make their way to market through the 510(k) process, *Talley v. Danek Med., Inc.*, 179 F.3d 154, 160 (4th Cir. 1999)—in some years, the number is as high as 98% percent, *see* Shapiro, *supra*, at 377. Consequently, the question whether 510(k) review encompasses a device's safety—and thus whether 510(k) evidence is admissible in a product-liability trial on 510(k)-cleared device—is going to be central to all device-safety litigation for the foreseeable future. *See, e.g.*, *In re Zimmer Nexgen Knee Implant Prods. Liab. Litig.*, 2015 WL 5145546, at *12-15 (N.D. Ill. Aug. 31, 2015) (excluding expert testimony on the 510(k)

process on the ground that *Lohr* established that "FDA's finding of substantial equivalence, as a matter of law, is not a safety determination"); *see also In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 2015 WL 7863032, at *6 (M.D. Ga. Dec. 3, 2015) (noting that "[o]ne of the recurring issues in this multi-district litigation that has perplexed the Court is whether evidence that Mentor's product was approved by the FDA during the 510(k) clearance process should be admitted" and holding, based on *Lohr*, that 510(k) clearance "has no bearing on the safety" of the product and thus that 510(k) evidence is inadmissible).

B. The Appellate Courts' Misreading Of *Lohr* Deprives Medical Device Manufacturers Of A Critical Defense In Products Liability Cases

The consistent misreading of *Lohr* deprives medical device manufacturers of what is often the best defense they have in products liability cases: their devices are safe because the expert federal regulator *determined* that they are safe. That regulatory determination may not be preemptive or conclusive as to the devices' safety, as *Lohr* holds, but it is certainly *relevant* to that question, by any definition. Yet juries cannot even consider FDA's expert viewpoint when making their own assessment of safety.

Plaintiffs of course exploit the exclusion of FDA 510(k) clearance evidence in ways that maximize unfairness to defendants and minimize the truthfinding function of jury trials. Like the plaintiffs here, plaintiffs commonly insist to juries that 510(k)-cleared products were "rushed to market," C.A. App.

3846, and that defendants should be held liable for not performing clinical trials, *id.* The lower court's misreading of *Lohr* leaves defendants essentially powerless to defend against these charges. A defendant cannot even provide jurors an accurate account of how a device actually got to market—jurors are, in effect, *intentionally misled* as to how and why devices become marketed. Nor can a defendant argue that it did not conduct clinical trials because FDA generally *does not require* clinical trials for Class II devices before marketing. 21 U.S.C. § 360c(a)(1)(B); *see* C.A. App. 1547-51, 1589 A properly informed and instructed jury might still find that the defendant should have conducted clinical trials, but FDA's process is unquestionably *relevant* to the jury's assessment of that issue.

Plaintiffs also often retain out-of-mainstream experts, knowing that the voice of the most important expert—the expert agency charged by Congress to determine whether on balance the device is safe—will never be heard. Here, for instance, respondents' expert opined that TVT-O's mesh degrades. C.A. App. 3875. Petitioners could not respond that FDA reviewed the issue of degradation, found the risk insignificant, and cleared TVT-O's label consistent with that determination. *Id.* at 776, 1122-28, 1201. Respondents' expert also pronounced TVT-O to be "unsuitable for implantation." *Id.* at 2240. And petitioners likewise could not respond that FDA found after multiple expert panel reviews that polymeric meshes like TVT-O have a "generally accepted satisfactory level of tissue compatibility." 47 Fed. Reg. at 2817.

The refusal to allow a manufacturer to defend itself with evidence of FDA's 510(k) clearance is especially glaring because jurors *expect* drugs and medical devices to be reviewed by FDA, and likely draw negative inferences from what they wrongly perceive to be FDA's silence. This Court has recognized that parties are entitled to "satisfy the jurors' expectations about what proper proof should be." *Old Chief*, 519 U.S. at 188. As noted by one of the only courts to allow jurors to hear FDA evidence, jurors in a medical-device case are "going to say what did the FDA say about this [device] because that's the world we live in. They want to know." C.A. App. 1602. The misunderstanding of *Lohr* that pervades the federal judicial system leaves that obvious question unanswered, inevitably fostering speculation among jurors that FDA did *not* clear the device they are evaluating.

The misreading of *Lohr* is harming the trial process in other ways. The Fourth Circuit now holds that because 510(k) review, per *Lohr*, supposedly has so little to do with safety, a manufacturer's "decision to pursue 510(k) clearance" actually cuts "in favor of punitive damages." *Cisson*, 810 F.3d at 922. But 510(k) clearance is not something the manufacturer of a Class II device "chooses" to do—it is *mandated by statute*. 21 U.S.C. § 360c(a)(1)(B). Nor does obtaining the only FDA permission available demonstrate egregious misconduct—just the opposite. *See* David. G. Owen & Mary J. Davis, 3 *Owen & Davis on Products Liability* § 26:33 ("a manufacturer or other product supplier is far from quasi-criminal in doing what the government explicitly permitted it or

required it to do"). And if 510(k) clearance really were a choice, manufacturers of Class II devices would be well advised to *forgo* 510(k) clearance in favor of the slower PMA process, taxing the FDA and depriving the public of the use of devices for which Congress determined the 510(k) process was "sufficient" "to provide reasonable assurance of the[ir] safety and effectiveness." 21 U.S.C. § 360c(a)(1)(B).

Finally, the Fourth Circuit's rule prevents juries from performing the very function the Court envisioned for them in *Lohr*, when it ruled that state-law tort claims are not preempted by the 510(k) process. It should go without saying that lay jurors can make reliable decisions about the safety and efficacy of medical devices *only* if they are fully informed and well instructed. And in a products liability trial, the medical benefits of a device are not directly represented. *See Riegel*, 552 U.S. at 325 ("A jury . . . sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court."). It is thus all the more important for lay jurors to consider evidence that the expert agency charged with evaluating those benefits determines that the device on balance promotes public health. *See* 21 U.S.C. § 393(b)(2)(C) (FDA's core mission is to "promote the public health by ensuring . . . the safety and effectiveness of devices"). Doctors consider TVT-O to be a "gold standard" device, and where a jury's verdict threatens the ability of other patients to receive the benefit of such a device or any device like it in the future, FDA's judgment should at least be considered. But because of the consensus interpretation of

Lohr, it will not, unless this Court corrects that error.

III. THIS CASE IS AN IDEAL VEHICLE FOR RESOLVING THE QUESTION PRESENTED

This case is a perfect vehicle for addressing whether district courts properly apply *Lohr* to exclude evidence that a device was cleared under § 510(k) on the ground that the 510(k) process does not address safety. The district court here applied *Lohr* to exclude Ethicon's 510(k) evidence—in fact, the court excluded *all* FDA evidence under penalty of sanctions—and the court of appeals affirmed on the basis of *Lohr*'s supposed holding that the 510(k) process "only *'tangentially'* examines the safety of the product going through [it]," App. 16a (quoting *Cisson*, 810 F.3d at 922, which in turn applied *Lohr*). The question whether *Lohr* actually justifies that characterization of FDA's 510(k) process is thus squarely presented on the facts and posture of this case. The Court should take this opportunity to prevent the misunderstanding of *Lohr* from misleading juries in scores of thousands of other pending and future medical-device products liability trials.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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May 23, 2017

APPENDIX

APPENDIX A - COURT OF APPEALS OPINION

PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 15-2118

JO HUSKEY; ALLEN HUSKEY,

Plaintiffs – Appellees,

v.

ETHICON, INC.; JOHNSON & JOHNSON,

Defendants – Appellants.

Appeal from the United States District Court for the Southern District of West Virginia, at Charleston. Joseph R. Goodwin, District Judge. (2:12-cv-05201; 2:12-md-02327)

Argued: December 8, 2016

Decided: January 26, 2017

Before MOTZ and DIAZ, Circuit Judges, and DAVIS, Senior Circuit Judge.

Affirmed by published opinion. Judge Motz wrote the opinion, in which Judge Diaz and Senior Judge Davis joined.

ARGUED: David B. Thomas, THOMAS COMBS & SPANN, PLLC, Charleston, West Virginia, for Appellants. Edward Anthony Wallace, WEXLER WALLACE LLP, Chicago, Illinois; Fidelma Louise Fitzpatrick, MOTLEY RICE LLC, Providence, Rhode Island, for Appellees. **ON BRIEF:** Charles C. Lifland, Los Angeles, California, Stephen D. Brody, David K. Roberts, O'MELVENY & MYERS LLP, Washington, D.C.; Philip J. Combs, THOMAS COMBS & SPANN, PLLC, Charleston, West Virginia; Christy D. Jones, BUTLER SNOW LLP, Ridgeland, Mississippi, for Appellants. Mark R. Miller, WEXLER WALLACE LLP, Chicago, Illinois; Jeffrey Kuntz, Adam Davis, WAGSTAFF & CARTMELL LLP, Kansas City, Missouri, for Appellees.

DIANA GRIBBON MOTZ, Circuit Judge:

After Jo Huskey experienced complications from the implantation of a transvaginal mesh medical device, she and her husband Allen Huskey filed this products liability action against Ethicon, Inc. and Johnson & Johnson (collectively "Ethicon"). Following a nine-day trial, the jury returned a general verdict for the Huskeys on their design defect, failure to warn, and loss of consortium claims. Ethicon now appeals the denial of its post-trial renewed motion for judgment as a matter of law or, in the alternative, for a new trial. The Huskeys offered sufficient evidence to sustain the jury's verdict and the district court committed no reversible error. Accordingly, we affirm.

I.

A.

In 2008, Mrs. Huskey began suffering symptoms of Stress Urinary Incontinence ("SUI"). In January 2011, after her condition had worsened, she discussed treatment options with her doctor, Dr. Gretchen Byrkit. By this time, Mrs. Huskey was regularly leaking urine while coughing, laughing, and sneezing, and she also experienced pain during intercourse. At Dr. Byrkit's suggestion, Mrs. Huskey agreed to have Dr. Byrkit surgically implant a medical device called the Tension-Free Vaginal Tape-Obturator ("TVT-O").

The TVT-O is a mid-urethral sling that uses a heavy-weight laser-cut mesh. Ethicon received clearance from the Food and Drug Administration ("FDA") to market the TVT-O in December 2003. Ethicon uses polypropylene for the TVT-O's mesh. The TVT-O was not the first mid-urethral sling Ethicon had manufactured; rather, it was a second-generation version of an earlier Ethicon device called the Gynecare TVT and is one of multiple slings that Ethicon has manufactured and sold.

On February 23, 2011, Dr. Byrkit performed Mrs. Huskey's implantation surgery. A few weeks later, Mrs. Huskey visited Dr. Byrkit's office for a post-operative check-up. At this visit, Dr. Byrkit examined Mrs. Huskey and found that some mesh on her right side had eroded. This eroded mesh caused Mrs. Huskey to experience pelvic pain.

On June 24, 2011, after various alternative treatments that Dr. Byrkit had recommended failed,

Mrs. Huskey agreed to have a second surgical operation to cover the exposed mesh. Dr. Byrkit performed this operation on June 29, 2011. Unfortunately, this operation was not successful and did not relieve Mrs. Huskey's pain. Dr. Byrkit then referred Mrs. Huskey to Dr. Sohail Siddique, a urogynecologist, for further treatment.

On November 18, 2011, Dr. Siddique performed surgery to excise Mrs. Huskey's mesh. He found that she had an infection and that the mesh on Mrs. Huskey's right side had completely eroded. He could not remove all the mesh because some had retracted behind Mrs. Huskey's pubic bone.

To this day, the remaining mesh and scar tissue from her operations cause Mrs. Huskey to experience severe pain, particularly when engaging in physical activity and sexual intercourse. Additionally, her SUI symptoms have returned. For the rest of her life, she will require medication for pain management; no surgical intervention can permanently cure her.

B.

On September 6, 2012, the Huskeys filed the operative Short Form Complaint in the Southern District of West Virginia in the instant multidistrict litigation, *In Re Ethicon Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2327. The Huskeys, Illinois residents, brought all of their claims under Illinois law. After the district court granted Ethicon partial summary judgment, five claims remained for trial: strict liability and negligent design defect; strict liability and negligent failure to warn; and Mr. Huskey's loss of consortium. Beyond actual

damages, Mrs. Huskey sought punitive damages for the substantive claims.

Trial began on August 22, 2014 and lasted nine days. The Huskeys presented their case, which consisted of testimony from thirteen witnesses and the introduction of numerous documents, over the first six trial days. At the conclusion of their case, Ethicon orally moved for judgment as a matter of law under Federal Rule of Civil Procedure 50(a). The court granted the motion as to Mrs. Huskey's claim for punitive damages but otherwise deferred ruling on the motion. Ethicon renewed its motion at the close of its case, and the court, again deferring a ruling, submitted the case to the jury.

The jury returned a unanimous general verdict for the Huskeys on all five claims. The jury awarded Mrs. Huskey $3.07 million in total damages, allocated between past expenses for medical care, previous pain and suffering, and future pain and suffering. The jury awarded Mr. Huskey an additional $200,000 for his loss of consortium.

After the jury returned its verdict, Ethicon again renewed its motion for judgment as a matter of law. In the alternative, Ethicon sought a new trial pursuant to Rule 59(a)(1)(A). The court issued a thorough written order denying the motion. *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2015 WL 4944339 (S.D. W. Va. Aug. 19, 2015). Ethicon subsequently noted this timely appeal.

II.

A.

Ethicon initially contends that the district court erred in denying it judgment as a matter of law. We review de novo the denial of Ethicon's motion. *Durham v. Jones*, 737 F.3d 291, 298 (4th Cir. 2013). A court "may grant judgment as a matter of law only if, viewing the evidence in a light most favorable to the non-moving party and drawing every legitimate inference in that party's favor, . . . the only conclusion a reasonable jury could have reached is one in favor of the moving party." *Saunders v. Branch Banking & Tr. Co. of Va.*, 526 F.3d 142, 147 (4th Cir. 2008). If, upon the conclusion of a party's case, "a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue," a court may grant a motion from the opposing party for judgment as a matter of law. Fed. R. Civ. P. 50(a). When the court defers ruling on such a motion, Rule 50(b) allows a party to renew it after the jury returns a verdict.

Ethicon moved for judgment as a matter of law on all five of the Huskeys' claims. As Ethicon's counsel conceded at oral argument, since the jury returned a general verdict, we can reverse the court's denial of Ethicon's motion only if the Huskeys failed, as a matter of law, to prove both their design defect and failure to warn claims. Given our resolution of the Huskeys' design defect claims, we need not discuss their failure to warn claims. Moreover, because their negligent design defect claim relies on the same facts and arguments as their strict liability design defect claim, we address

those claims together. Similarly, because it is wholly derivative of Mrs. Huskey's claims, we do not separately consider Mr. Huskey's loss of consortium claim. *See Blagg v. Ill. F.W.D. Truck & Equip. Co.*, 572 N.E.2d 920, 926 (Ill. 1991).

B.

To prevail on their design defect claims, the Huskeys had to demonstrate: 1) that a certain condition of the TVT-O resulted from Ethicon's design, 2) that this condition made the product unreasonably dangerous, 3) that the dangerous condition existed when Mrs. Huskey's TVT-O left Ethicon's control, and 4) that the dangerous condition in the TVT-O proximately caused harm to Mrs. Huskey. *See Mikolajczyk v. Ford Motor Co.*, 901 N.E.2d 329, 345 (Ill. 2008). Ethicon makes two arguments in support of its contention that the court erred in denying it judgment as a matter of law: 1) that the Huskeys failed to prove a specific flaw in the TVT-O's design -- as opposed to a general complication flowing from implantation, and 2) that comment k of the Restatement (Second) of Torts § 402A shields it from liability. We address these arguments in turn.

1.

The record belies Ethicon's assertion that the Huskeys failed to prove that a specific defect of the TVT-O's design caused harm to Mrs. Huskey. As the district court properly held, the Huskeys offered sufficient evidence for a reasonable jury to find that Ethicon's use of heavyweight polypropylene mesh in the TVT-O caused Mrs. Huskey's injuries.

First, Dr. Scott Guelcher, an associate professor of chemical engineering at Vanderbilt University and one of the Huskeys' expert witnesses, testified about the body's reaction to polypropylene and the consequences that ensue. He explained that "the body recognizes [the polypropylene mesh] as a foreign material, and . . . will continue to attack it in this way until it's removed or destroyed or it's gone." And Dr. Guelcher testified, based on his research, that "it's best to minimize the amount of polypropylene that's present in the mesh," because "the more polypropylene surface that's present, the greater those changes would be, [and] the more hazardous they could be."

Next, Dr. Bruce Rosenzweig, a urogynecologist and another of the Huskeys' expert witnesses, bolstered Dr. Guelcher's testimony. Dr. Rosenzweig testified that Ethicon used a heavyweight mesh and "[t]he more mesh there is in the pelvis, the more of a foreign body response." He explained that heavyweight mesh can lead to a foreign body response in an area near the inner thigh called the obturator space, and that these foreign bodies can "irritate the nerve [that passes nearby] and lead to pain."

Additionally, Dr. Brigitte Hellhammer, a former Ethicon employee, testified that she had no reason to believe that lightweight mesh could not effectively treat SUI. Dr. Hellhammer explained that one risk of implanting mesh devices in patients was that the mesh would shrink, and that the weight of the mesh helps determine the likelihood of shrinkage. Dr. Hellhammer testified to a generally-recognized understanding that lightweight mesh "would help in

reducing a foreign body response, inflammatory response, and would reduce the potentiation for scar plating."

Finally, Dr. Jerry Blaivas, a urologist and another expert witness for the Huskeys who had conducted a pelvic examination of Mrs. Huskey, testified that Mrs. Huskey had severe scarring and suffered from "chronic pelvic pain." Dr. Blaivas believed Mrs. Huskey's symptoms were "a reaction to the mesh" and that he did not "know of anything else that can cause . . . this particular constellation of symptoms."

Drawing all inferences in the Huskeys' favor, a reasonable jury could conclude from this expert testimony that Ethicon's use of a heavyweight quantity of polypropylene mesh in the TVT-O constituted a design defect that caused Mrs. Huskey's inflammation and pelvic pain.

2.

Ethicon next argues that an exception to strict liability found in comment k to § 402A of the Restatement (Second) of Torts, on which Illinois courts rely, nevertheless shields it from liability. *See Kirk v. Michael Reese Hosp. & Med. Ctr.*, 513 N.E.2d 387, 392 (Ill. 1987) (citing comment k in a recitation of applicable law).

Comment k, which is captioned "[u]navoidably unsafe products," recognizes that "some products . . ., in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." Restatement (Second) of Torts § 402A cmt. k (Am. Law Inst. 1965). Comment k recommends that such products, "with the

qualification that they are properly prepared and marketed, and proper warning is given," not trigger strict liability. *Id.* This is because "the marketing and the use of [unavoidably unsafe products] are fully justified, notwithstanding the unavoidable high degree of risk which they involve." *Id.* Such products, it explains, are neither "defective, nor . . . *unreasonably* dangerous." *Id.*

Although comment k notes that unavoidably unsafe products "are especially common in the field of drugs," *id.*, under Illinois law, courts determine "on a case by case basis" if a particular product falls within comment k, *Glassman v. Wyeth Labs., Inc.*, 606 N.E.2d 338, 342 (Ill. App. Ct. 1992). Whether a product is unavoidably unsafe is a question of fact on which the defendant bears the burden of proof. *Id.* at 343. If a reasonable jury could find that the TVT-O did not meet comment k's parameters, Ethicon's reliance on comment k fails.

Much of the trial evidence indicating that the use of heavyweight polypropylene mesh constituted a design defect also suggests that comment k provides Ethicon no defense. Specifically, the jury could reasonably infer from Dr. Guelcher's testimony that the greater quantity of mesh Ethicon used in the TVT-O, the greater the chance that a patient would experience an adverse foreign body response. The jury could also reasonably infer from Dr. Hellhammer's testimony that had Ethicon used lightweight mesh, the TVT-O would have remained effective and patients would have a reduced risk of an adverse foreign body response. Taken together, the expert testimony allowed the jury to infer that Ethicon could have designed the TVT-O with

lightweight mesh without sacrificing any performance. Consequently, the jury could reasonably conclude that the TVT-O was not unavoidably unsafe. Comment k does not shield Ethicon from liability.

III.

We next address Ethicon's contention that the district court should have granted it a new trial. Federal Rule of Civil Procedure 59(a)(1)(A) allows a court to grant a party's motion for a new trial if the verdict is contrary to the clear weight of the evidence, rests upon false evidence, or will cause a miscarriage of justice. *Minter v. Wells Fargo Bank, N.A.*, 762 F.3d 339, 346 (4th Cir. 2014).

We review a denial of a new trial for abuse of discretion. *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 375 (4th Cir. 2015). A court abuses its discretion if it relies on incorrect legal conclusions or clearly erroneous findings of fact. *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 161 (4th Cir. 2012). Moreover, we can reverse even without such errors "if we have 'a definite and firm conviction that the court below committed a clear error of judgment in the conclusion it reached upon a weighing of the relevant factors.'" *Id.* (quoting *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)).

Ethicon raises two grounds for a new trial. First, it contends that the district court improperly refused to instruct the jury on comment k. Next, it asserts that the court improperly excluded multiple pieces of evidence involving the FDA.

A.

We turn first to the comment k instruction. Ethicon argued at trial that comment k entitled it to "at a minimum, an appropriate jury instruction." After considering briefing and oral argument on the question, the district court declined to include the requested comment k instruction.[1] Instead, the court instructed the jury that it could find Ethicon liable on the design defect claim only if it found that the TVT-O was unreasonably dangerous. The court then defined an "unreasonably dangerous" product as one in which the "risk of danger inherent in the design outweighs the benefits of the design when the product is put to a use that is reasonably foreseeable considering the nature and function of the product."

We review the district court's refusal to provide Ethicon's proposed instruction for abuse of discretion. *Rowland v. Am. Gen. Fin., Inc.*, 340 F.3d 187, 191 (4th Cir. 2003). We evaluate the jury

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[1] Ethicon titled the instruction it requested "Inherent Risks," and the proposed instruction read:

> Some useful products are inherently dangerous and cannot be made safe for their intended and ordinary use. An example is a prescription drug. A prescription drug is not defective simply because it . . . has unavoidable side effects.
>
> Products that contain inherent dangers are not defectively designed or unreasonably dangerous so long as they are accompanied by proper directions and warning.
>
> If you find that the risks that allegedly injured Mrs. Huskey . . . were unavoidable, inherent risks of the product, and that the product was accompanied by proper directions and warnings, you should find that the product is not defective.

charge as a whole, and an instructional error warrants a new trial only if it fails to inform the jury of the controlling legal principles. *Id.* Any lack of clarity must prejudice the challenging party. *Id.*

Again, to show that a product falls within comment k's protection, *the defendant* must prove that a product's "marketing and . . . use . . . are fully justified, notwithstanding the unavoidable high degree of risk which [it] involve[s]." Restatement (Second) of Torts § 402A cmt. k. We can discern only one difference between comment k and the jury instruction the court gave.[2] That difference is the burden of proof, which of course shifts to the defendant for comment k. Even assuming that Ethicon had produced sufficient evidence to justify the issuance of a comment k instruction, we cannot hold that it suffered prejudice from the absence of that instruction. As the district court correctly observed, the failure to provide an instruction that shifts the burden to Ethicon would not likely have provided Ethicon with a more favorable outcome. Without any prejudice, the district court did not abuse its discretion in denying Ethicon a new trial on that basis.

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[2] Ethicon argues that the district court's actual instruction did not capture "the policy rationale underlying comment k," namely, that of encouraging medical innovations. This argument fails however, given that defendants must prove comment k's applicability "on a case by case basis." *Glassman*, 606 N.E.2d at 342.

B.

We next address Ethicon's evidentiary contentions. Ethicon posits that the district court's exclusion of four pieces of FDA evidence warrants a new trial. Those four pieces of evidence are: evidence of the TVT-O's compliance with the FDA's Section 510(k) evaluation process; evidence that a 2011 FDA Advisory Committee deemed mesh slings, including the TVT-O, safe and effective; a 2013 published guidance, which reported the Advisory Committee's conclusions; and the regulatory history of the Prolene suture, an Ethicon product that contains the same polypropylene as the TVT-O's mesh.

The court relied on Federal Rule of Evidence 403 in excluding this evidence. That Rule allows a court to exclude relevant evidence when its "probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. We review a decision to exclude evidence on this basis for abuse of discretion. *United States v. Davis*, 690 F.3d 226, 257 (4th Cir. 2012). Improper exclusion of evidence warrants a new trial only if it results in "a high probability that the error . . . affect[ed] the judgment." *Drakeford*, 792 F.3d at 375.

We will address each exclusion in turn. But before doing so, we consider whether Ethicon has waived any challenge pertaining to the latter three pieces of evidence. The Huskeys argue that Ethicon never sought to introduce these three pieces of

evidence, and that Ethicon thus cannot now rely on the exclusion of this evidence to gain a new trial. To the extent this accurately represents the proceedings below—a notion Ethicon strongly contests—the Huskeys have waived this argument.

Ethicon's memorandum in support of its post-trial motion contended that the exclusion of *all* of the evidence it invokes on appeal justified a new trial. The Huskeys' only response to this argument in their briefing was to incorporate by reference their pre-trial filing to exclude the 510(k) evidence. Nowhere did they contend that Ethicon had not sufficiently sought to introduce the other FDA evidence, or had otherwise waived its ability to assert that the exclusion of this evidence compelled a new trial. The Huskeys thus waived this argument by omitting it from their post-trial briefing. *Cf. United States v. Carthorne*, 726 F.3d 503, 509 n.5 (4th Cir. 2013) (holding that the Government "waived the waiver argument" when it failed to argue that plain error review applied to a particular appellate challenge). Having resolved this issue, we now examine the evidence in question.

1.

We begin with the evidence of the TVT-O's compliance with the 510(k) process. Under the Federal Food, Drug, and Cosmetic Act, a manufacturer seeking to market a new medical device may attempt to bypass the FDA's normal premarket approval process by submitting a "§ 510(k) notification." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996). The FDA then evaluates whether the new device is "'substantially equivalent'

to a pre-existing device." *Id.* If the FDA finds substantial equivalence, the new device "can be marketed without further regulatory analysis." *Id.* The district court refused to permit Ethicon to introduce evidence that it had cleared the 510(k) process and evidence explaining that process.

We recently held in *Cisson v. C.R. Bard, Inc. (In re C.R. Bard, Inc.)*, 810 F.3d 913, 919 (4th Cir. 2016), a bellwether case from a related MDL, that this same district judge did not abuse his discretion when he excluded evidence that the device in question had complied with the 510(k) process. We noted that the 510(k) process focuses mostly on the *equivalence* between the product in question and an older one, and only "*tangentially*" examines the safety of the product going through the process. *Id.* at 922 (emphasis added). We rejected the view that "[b]ald assertions by the FDA" as to 510(k) compliance are highly probative of a product's safety. *Id.* at 921. Given its limited probative value and the risk of confusing the jury by, inter alia, causing a battle of the experts over the robustness of the 510(k) process's safety examinations, we held that exclusion of the 510(k) compliance evidence was not improper. *Id.* at 921-22.

We see no reason to distinguish *Cisson* here. The information Ethicon sought to introduce would, at best, have had "tangential[]" relevance to the case. This relative lack of probative value, especially given a possible battle of experts over the 510(k) process, underscores the risks of confusion and wasted time that would follow the introduction of this evidence. Ethicon's effort to distinguish *Cisson* on the ground that the TVT-O's 510(k) compliance process actually

did focus heavily on safety would only amplify the risk, as the trial would then likely face a substantial diversion into just how rigorous those safety considerations were, how forthcoming Ethicon was to the FDA, and how robust the 510(k) process is. The district court did not abuse its discretion in excluding this evidence.

2.

We next address the FDA Advisory Committee evidence. In 2011, an Obstetrics and Gynecology Devices Advisory Committee (the "FDA Advisory Committee") conducted an examination of the "risks and benefits of surgical mesh . . . based on the published literature and adverse event data from" an FDA database, and noted that "[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 safety and effectiveness of these devices." FDA Advisory Committee, *Surgical Mesh for Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence: FDA Executive Summary* 1, 28 (2011). In 2013, the FDA issued a published guidance reiterating these conclusions.

While the district court did not permit Ethicon to present evidence as to the FDA's view of the underlying studies, it did permit Ethicon to introduce those studies themselves. The FDA did not use its own analysis of the TVT-O to reach a conclusion regarding the device's safety and efficacy. Rather, it simply opined on the work others had done. The underlying studies themselves enabled Ethicon to obtain most of the probative value from

the FDA Advisory Committee evidence without risking a usurpation of the *jury's* essential role in determining if the Huskeys had adequately proven their claims.

Additionally, the FDA's use of the 510(k) process to approve the TVT-O layers on another risk of introducing the FDA Advisory Committee evidence. As discussed above, the 510(k) process focuses on a particular device's equivalence to an older device. Thus, the FDA's only original conclusion regarding the TVT-O did not address its safety. This dynamic creates a potentially confusing disjunction for the jury between what the FDA deems other literature has to say about the TVT-O's safety and what the FDA itself found about the TVT-O's equivalence to an earlier device. This goes beyond the mere specter of too much jury deference to the FDA and tacks on the prospect of the jury misunderstanding the FDA Advisory Committee's actual conclusions. In these circumstances, therefore, the court did not abuse its discretion in excluding the FDA Advisory Committee evidence.

3.

Finally, we consider the evidence of the regulatory history of Prolene used in the Prolene sutures—the same polypropylene used in the TVT-O's mesh also makes up part of the Prolene suture. Ethicon wanted to introduce evidence that the FDA had approved the Prolene suture not only in an initial application, but also in over thirty subsequent New Drug Applications. Ethicon also sought to introduce evidence that the "FDA approved

language indicating that Prolene [in the suture] is not subject to degradation via tissue enzymes."

As the district court correctly explained, "evidence regarding the FDA process that the Prolene suture underwent . . . says little about the safety and effectiveness of *the final product*, the TVT-O." *Huskey*, 2015 WL 4944339, at *13 (emphasis added). The jury ultimately had to make a determination about the entire device that Mrs. Huskey received, not just a component of it. Introducing the evidence regarding Prolene sutures alone could quite plausibly cause a diversion into how similar and integral the Prolene sutures are to the TVT-O end product and the role that other components of the TVT-O might play in triggering foreign body responses or interacting with the Prolene sutures to mitigate safeguards against such responses. And that is to say nothing of the risk, also present with the FDA Advisory Committee evidence, that the jury might draw too strong a conclusion from the fact that the evidence of Prolene's safety comes from the FDA. These drawbacks underscore that the court acted within its discretion.

Moreover, even without the evidence of the regulatory history of the Prolene sutures, the court permitted Ethicon to introduce evidence of their robust safety record. On cross-examination, Ethicon's counsel elicited testimony from Dr. Guelcher that Prolene sutures have an identical chemical composition to the Prolene Ethicon uses in both its hernia meshes and in its TVT meshes to treat SUI. In that same line of questioning, Dr. Guelcher also acknowledged that his research

had uncovered no "problem[s] with polypropylene mesh." Ethicon was thus able to extract the same information that would have made up the core probative value of the Prolene suture's regulatory history without bringing in the potential negative effects of introducing that evidence. The court did not abuse its discretion in excluding evidence of that other product's regulatory history.

IV.

Accordingly, for the reasons set forth above, the judgment of the district court is

AFFIRMED.

APPENDIX B - MEMORANDUM OPINION AND ORDER GRANTING PLAINTIFFS' MOTION IN LIMINE NO. 1: TO EXCLUDE FDA 510(k) EVIDENCE

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

JO HUSKEY, et al.,

Plaintiffs,

v.

CIVIL ACTION NO. 2:12-cv-05201

ETHICON, INC., et al.,

Defendants.

MEMORANDUM OPINION AND ORDER

Before the court is the Plaintiffs' Motion in Limine No. 1: To Exclude FDA 510(k) Evidence [Docket 139]. For the reasons stated below, the motion is **GRANTED**.

I. Background

This is not the first time I am confronted with determining the admissibility of evidence relating to marketing clearance under the FDA's 510(k) process. *See, e.g.*, *Lewis v. Johnson & Johnson*, --- F. Supp. 2d. ---, No. 2:12-cv-04301, 2014 WL 152374, at *4-6 (S.D. W. Va. Jan. 15, 2014); *In re C. R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, MDL 2187,

2013 WL 3282926, at *2 (S.D. W. Va. June 27, 2013). In all previous cases, I excluded all evidence relating to the 510(k) process because it does not go to safety or efficacy of medical devices and because of the potential to mislead and confuse the jury.

In this case, the plaintiffs previously moved that I automatically extend my earlier 510(k) rulings to this case. I denied that motion and wrote that "I have not reviewed the admissibility of the 510(k) process in relation to Illinois law, and it has not been fully briefed here. It is conceivable—although difficult to imagine—that my ruling on this issue could differ *in this case*." *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2014 WL 1347372, at *1 (S.D. W. Va. Apr. 3, 2014). As the plaintiffs correctly point out, I sought briefing from the parties regarding how, if at all, Illinois law differed from that of Georgia and Texas, and how those differences affected the admissibility of the FDA's 510(k) process. Even so, Ethicon focused the majority of its briefing on extraneous issues, ultimately urging me to reconsider the bases for my earlier rulings. I do not address those issues here, and I decline to reconsider the bases for any of my prior rulings on admissibility of 510(k) evidence. I now hold that the evidence of the FDA's 510(k) process is **INADMISSIBLE** in this case.

II. Analysis

My reasoning for excluding evidence of the 510(k) process in general is fully set out in *Lewis*, 2014 WL 152374, at *2, 4-6. I will not rehash it here. I will simply describe relevant Illinois law and explain why evidence of the 510(k) process should be

excluded in this case.

A. Relevance under Illinois's Consumer-Expectation and Risk-Utility Tests

In order to recover on a product liability claim under Illinois law, a plaintiff must prove that the injury resulted from a condition of the product that was "unreasonably dangerous." *Mikolajczyk v. Ford Motor Co.*, 901 N.E.2d 329, 335 (Ill. 2008). A product may be unreasonably dangerous based on a defect in its design, manufacturing, or warnings. *Id.*; *Sollami v. Eaton*, 772 N.E.2d 215, 219 (Ill. 2002). A plaintiff may establish that a product is unreasonably dangerous using either the consumer-expectation test or the risk-utility test, or both. *Mikolajczyk*, 901 N.E.2d at 336.

Under the consumer-expectation test, "the plaintiff may introduce 'evidence that the product failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.'" *Mikolajczyk*, 901 N.E.2d at 336 (quoting *Lamkin v. Towner*, 563 N.E.2d 449, 457 (Ill. 1990)). The plaintiffs argue that because this test focuses on how "safely" an ordinary consumer expects a product to perform, evidence of 510(k) clearance is per se inadmissible. (*See* Pls.' Mot. in Limine [Docket 140], at 8). Ethicon does not respond to this argument, and I agree with the plaintiffs. Clearance to market under the 510(k) process does not relate to the safety of a product. Therefore, the 510(k) process is irrelevant and inadmissible under Federal Rule of Evidence 402 with respect to the consumer-expectation test.

In contrast to the consumer-expectation test,

"[t]he risk-utility test . . . is a multifactor analysis and [is] therefore[] much broader in scope[.]" *Mikolajczyk*, 901 N.E.2d at 352. Under this test, a plaintiff "may introduce evidence that the product's design proximately caused his injury. If the defendant thereafter fails to prove that on balance the benefits of the challenged design outweigh the risk of danger inherent in such designs, the plaintiff will prevail." *Mikolajczyk*, 901 N.E.2d at 336. (internal quotations omitted). Illinois courts consider a wide range of factors under the risk-utility test, including

> "the magnitude and probability of the foreseeable risks of harm, the instructions and warnings accompanying the product, and the nature and strength of consumer expectations regarding the product, including expectations arising from product portrayal and marketing," as well as "the likely effects of the alternative design on production costs; the effects of the alternative design on product longevity, maintenance, repair, and esthetics; and the range of consumer choice among products."

Id. at 352 (quoting Restatement (Third) of Torts: Product Liability § 2, cmt. f, at 23 (1998)).

The point of all these factors, however, is to assist the jury in determining whether the benefits of a product outweigh the product's "risk of danger." *Mikolajczyk*, 901 N.E.2d at 336. A plaintiff must prove that "the magnitude of the danger outweighs

the utility of the product, as designed." *Calles v. Scripto-Tokai Corp.*, 864 N.E.2d 249, 257 (Ill. 2007). A product's utility must be weighed against its "risk of harm" or "gravity of harm." *Id.* (quoting 63A Am. Jur. 2d *Products Liability* § 978, at 146-47 (1997)).

The plaintiffs argue that because the 510(k) process is not a safety standard, it does not factor into the jury's consideration of either the risk or utility of the product, and it is therefore irrelevant under the risk-utility test. (*See* Pls.' Mot. [Docket 140], at 9). Ethicon does not respond to this argument. The focus of the risk-utility test is on a product's risk of harm compared with the product's utility. The 510(k) process is irrelevant to this analysis because it does not relate to safety or efficacy of a product.

B. Regulatory Compliance

While ignoring the plaintiffs' arguments that the 510(k) process is irrelevant under the consumer-expectation and risk-utility tests, Ethicon contends that regulatory compliance is relevant to the plaintiff's claims. In support, Ethicon cites *Rucker v. Norfolk & W. Ry. Co.*, 396 N.E.2d 534 (1979), where the court held that evidence of compliance with then-existing federal standards was admissible in determining whether a railroad tank car was unreasonably dangerous. The tank car in question collided with a boxcar and exploded, killing a railroad employee. The tank car was manufactured before federal regulations required a "'headshield,' a protective device that would shield the car from damaging contact with other cars and objects." *Rucker*, 396 N.E.2d at 536. The court stated that:

> [E]vidence of compliance with Federal standards is relevant to the issue of whether a product is defective, as well as the issue of whether a defective condition is unreasonably dangerous, as GATX contends. If the product is in compliance with Federal standards, the finder of fact may well conclude that the product is not defective, thus ending the inquiry into strict liability. If a finding is entered that the product is defective, evidence of compliance becomes additionally relevant to the issue of whether the defective condition is unreasonably dangerous. The fact of compliance may indicate to the finder of fact that the defect is not unreasonably dangerous.

Id. at 536-37 (citation omitted).

Contrary to Ethicon's contentions, *Rucker* does not mean that compliance with *any* federal regulation is admissible. Rather, the regulation must relate to the safety or efficacy of a product. In fact, the court stated that "it would be reasonable to conclude that the purpose of the [headshield] regulations is to insure greater safety . . . ." *Id.* at 537. And just three years after *Rucker*, the Illinois Supreme Court explicitly stated that Rucker concerned the admissibility of *safety* regulations: "In *Rucker* . . . this court held that evidence of a product's compliance with governmental *safety* standards is relevant and admissible in a product liability case on the issues of whether the product is defective and whether a defect in the product is

unreasonably dangerous." *Moehle v. Chrysler Motors Corp.*, 443 N.E.2d 575, 577 (Ill. 1982) (emphasis added).

Ethicon also cites *Sosnowski v. Wright Med. Tech., Inc.*, 2012 WL 1030485 (N.D. Ill. Mar. 27, 2012). There, the court granted summary judgment to a medical device manufacturer after considering, among other things, evidence that the medical device received 510(k) clearance. *Sosnowski*, 2012 WL 1030485, at *3-4. In considering the "industry standards factor" under the risk-utility test, the court noted that the plaintiff did "not dispute that the defendant received clearance from the FDA to sell the [device]." *Id.* at 4. The court did not consider whether the 510(k) process relates to the safety of a product. The court merely noted that the plaintiff argued 510(k) clearance "does not involve rigorous review." *Id.* Further, the court did not consider whether the 510(k) process is admissible in spite of Federal Rules of Evidence 402 and 403. *Sosnowski* is therefore not on point.

None of the other cases cited by Ethicon stands for the proposition that compliance with *non-safety* regulations is relevant to whether a product is unreasonably dangerous. *See, e.g., Ruffiner v. Material Serv. Corp.*, 506 N.E.2d 581, 58-59 (Ill. 1987) (finding that standards for fixed ladders in factories and industrial plants were not relevant to plaintiff's claim that tugboat ladder was unreasonably dangerous, even though the standards were "animated by a concern for safety"); *Estate of Carey v. Hy-Temp Mfg. Inc.*, No. 82-c-7171, 1991 WL 161394, at *4 (N.D. Ill. Aug. 19, 1991) ("The jury shall be instructed as to the applicable law regarding

compliance with safety regulations. Accordingly, plaintiffs' motion to prevent defendants from arguing that compliance with safety regulations bars liability is inappropriate."); *Hatfield v. Sandoz-Wander, Inc.*, 464 N.E.2d 1105, 1109 (Ill. Ct. App – 1st Dist. 1984) (discussing admissibility of FDA approval process for prescription drugs).

C. Punitive Damages

Finally, Ethicon argues that evidence of regulatory compliance is relevant to the plaintiffs' claim for punitive damages. However, Ethicon fails to explain this argument or cite any controlling law in support. Ethicon simply states that its "briefs in support of summary judgment on punitive damages under the law of New Jersey and Georgia explain this." (Resp. in Opp. to Pls.' Mot. in Limine No. 1: To Exclude FDA 510(k) Evidence [Docket 190], at 6). Ethicon's brief under New Jersey law, the law that the parties agree controls punitive damages in this case, does not argue that regulatory compliance with non-safety standards is relevant to the punitive damages claim. Instead, that brief focuses on whether the New Jersey Products Liability Act precludes recovery of punitive damages in this case. That is a separate issue, which I will address separately.

Whether or not compliance with *non-safety* regulations is relevant to punitive damages in this case, I hold that 510(k) evidence is inadmissible because of its potential to confuse the issues and mislead the jury.

III. Conclusion

In short, Ethicon has not identified any cases,

statutes, or other authorities indicating that 510(k) clearance, which focuses on equivalence, not safety, is relevant in determining whether a product is unreasonably dangerous under the law applicable to this case. And, to the extent that authorities identified by Ethicon *do* indicate relevance, I again **FIND** that evidence of the 510(k) process is inadmissible under Federal Rule of Evidence 403 because of its potential to confuse the issues and mislead the jury. For these reasons, the Plaintiffs' Motion in Limine No. 1: To Exclude FDA 510(k) Evidence [Docket 139] is **GRANTED**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: May 12, 2014

s/Joseph R. Goodwin
JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

APPENDIX C - BENCH RULING BARRING ALL MENTION OF "FDA"

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA AT CHARLESTON

JO HUSKEY AND ALLAN HUSKEY,	:	
Plaintiffs,	:	Case Number
v.	:	2:12-cv-05201
ETHICON, INC., ET AL.,	:	
Defendants.	:	

TRANSCRIPT OF TRIAL - DAY SEVEN
SEPTEMBER 02, 2014

BEFORE THE HONORABLE JOSEPH R. GOODWIN,
UNITED STATES DISTRICT JUDGE

Court Reporter: Carol Farrell, CRR, RMR, CCP, RPR (304)347-3188
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rolland.crr@gmail.com

Proceedings recorded by machine stenography; transcript produced by computer.

[34]

A. I have.

Q. And have you analyzed yourself explants of humans --

A. I have.

Q. -- who have had Prolene polypropylene?

A. Yes, sir.

Q. And have you reviewed the work of others of explants of Prolene polypropylene?

A. I have.

Q. Have you ever found in research in a controlled experiment a decrease in molecular weight in explanted Prolene polypropylene?

A. No.

Q. And what does that tell you as a polymer scientist if there's no decrease in molecular weight in Prolene polypropylene?

A. If there is no decrease in molecular weight, there's no degradation of the polypropylene, in this case, Prolene.

Q. Have you also reviewed work by Ethicon studying Prolene polypropylene?

A. I have.

MR. THOMAS: May I approach, Your Honor?

THE COURT: You may.

BY MR. THOMAS:

Q. Dr. Thames, I've handed you what's been marked as Defendants' Exhibit 23228, titled "Seven-Year Dog Study."

[35]

A. Yes, sir.

Q. Have you reviewed that in connection with your work in this case?

A. I have.

MR. THOMAS: Your Honor, I'd offer this exhibit into evidence.

THE COURT: May I see you at sidebar just one second?

(The following occurred at sidebar.)

THE COURT: This appears to be about a 50-page exhibit. Is counsel for the defendants representing to me that the initials FDA or the Federal Drug Administration appears nowhere in this document?

MR. THOMAS: Not to my knowledge, Your Honor.

THE COURT: I'm asking you if you're making that affirmative representation? I'm not -- it's happened twice. I will take a ten-minute break if you want to look through it, or if you want to go on to something else. Otherwise, if it's in here, I'm going to sanction you if it is, a very large amount of money, if it's introduced by accident.

MR. THOMAS: I understand, Your Honor.

THE COURT: So what do you want to do? Do you want to take a break and look at it?

MR. THOMAS: Yes, I do, Your Honor.

THE COURT: All right.

(Sidebar concluded.)

[36]

THE COURT: Ladies and gentlemen, I think that we've done very well. We haven't had to take very many unscheduled breaks. This is a time when we have to take one.

Ten-minute break -- make it 15, and we'll look and see how the morning goes. Do a 15-minute break.

I hope you enjoy that healthy stuff that's back in the jury room. And I'll call you back when we're ready.

Court stands in recess.

(The jury left the courtroom at 10:03 a.m.)

(A recess was taken at 10:03 a.m.)

(The jury entered the courtroom at 10:22 a.m.)

THE COURT: Okay. Mr. Thomas.

APPENDIX D - MEMORANDUM OPINION AND ORDER DENYING PETITIONERS' RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW OR, IN THE ALTERNATIVE, FOR A NEW TRIAL

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

JO HUSKEY, et al.,

Plaintiffs,

v.

CIVIL ACTION NO. 2:12-cv-05201

ETHICON, INC., et al.,

Defendants.

MEMORANDUM OPINION & ORDER

Pending before this court is Defendants Ethicon, Inc. & Johnson & Johnson's Renewed Motion for Judgment as a Matter of Law or, in the Alternative, for a New Trial ("Motion") [Docket 437]. The plaintiffs have responded [Docket 439], making the matter ripe for decision. For the reasons stated below, the Motion is **DENIED**.

I. Background

This case was the first bellwether jury trial within the Ethicon, Inc. MDL, MDL 2327. At

present, the Ethicon, Inc. MDL is the largest MDL in the country, containing over 26,000 individual cases. The Judicial Panel on Multidistrict Litigation assigned the Ethicon, Inc. MDL to this court, along with six other MDLs concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). More than 70,000 cases are currently pending in the MDLs. Jo and Allen Huskey ("the plaintiffs") filed this particular action against Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon"), alleging injuries associated with implantation of the TVT Obturator System ("TVT-O"), a polypropylene-based, transvaginal mesh product manufactured by Ethicon to treat SUI.

Mrs. Huskey's implantation surgery was performed by Dr. Gretchen Byrkit on February 23, 2011. (Statement of Undisputed Facts Regarding Jo Huskey's Medical History & Condition [Docket 215] ¶ 25). At a post-operative visit on March 9, 2011, Dr. Byrkit examined Mrs. Huskey and noticed eroded mesh on the right side of the vagina. (Id. ¶ 27). The erosion persisted over the next few months and caused Mrs. Huskey to experience painful sexual intercourse. (*Id.* ¶ 28). When revision surgery did not resolve the mesh erosion, Dr. Byrkit referred Mrs. Huskey to Dr. Sohail Siddique, who had specific experience with mesh erosion. (*Id.* ¶¶ 28–29).

Dr. Siddique met with Mrs. Huskey on August 29, 2011. (*Id.* ¶ 30). Mrs. Huskey complained of pelvic pain and dyspareunia (pain with sexual intercourse). (*Id.*). After examining Mrs. Huskey, Dr. Siddique observed the exposed mesh and recommended excision, though he noted that due to

the placement of the mesh in the obturator space, he could not remove it all. (*Id.* ¶¶ 30–31). Dr. Siddique performed the excision surgery on November 18, 2011. (*Id.* ¶ 33). He ultimately removed six centimeters of mesh from what he described as a "chronically infected space" and left the portions that were retracted around the pubic bone. (*Id.*). Mrs. Huskey's pain returned after the excision surgery, and steroid injections, though successful at first, have provided minimal relief. (*Id.* ¶ 36).

Since removal of the sling, Mrs. Huskey continues to have constant pelvic and vaginal pain that is exacerbated by physical activity. (*Id.* ¶ 41). She has also experienced recurrence of SUI, pain in her bladder, dyspareunia, and sacroiliac joint pain. (*Id.* ¶¶ 39–41). Attributing these injuries to the TVT-O, Mrs. Huskey and her husband filed suit against Ethicon on September 6, 2012. (*See generally* Short Form Compl. [Docket 1]). Trial began on August 25, 2014. After nine days of trial, the plaintiffs ultimately presented four claims to the jury: strict liability for defective design; strict liability for failure to warn; negligence; and loss of consortium. (*See* Verdict Form [Docket 402]).[1] The jury returned a verdict in favor of the plaintiffs on all claims. In so doing, the jury awarded $3,070,000 in compensatory damages to Mrs. Huskey, in addition to $200,000 to Mr. Huskey for loss of consortium. (*Id.*)

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[1] The court dismissed the plaintiffs' other claims upon a motion for summary judgment. (*See* Mem. Op. & Order (Mots. for Summ. J.) [Docket 272]).

At the conclusion of the plaintiffs' case, Ethicon orally moved for judgment as a matter of law on each claim pursuant to Federal Rule of Civil Procedure 50(a). (Trial Tr. (Aug. 29, 2014) [Docket 388], at 94:15–18). I granted the motion in part with respect to the issue of punitive damages and deferred ruling on the remaining claims. (*Id.* at 114:18–115:3). Then, at the close of its case, Ethicon renewed its Rule 50(a) motion for judgment as a matter of law, and I again deferred ruling. (Trial Tr. (Sept. 4, 2014) [Docket 428], at 78:24–25). I now consider Ethicon's post-verdict renewed motion for judgment as a matter of law pursuant to Rule 50(b), along with its alternative motion for a new trial under Rule 59(a)(1)(A).[2]

II. Renewed Motion for Judgment as a Matter of Law

A. Legal Standard

Pursuant to Federal Rule of Civil Procedure 50(a), a court may grant judgment as a matter of law "[i]f a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue." Fed. R. Civ. P. 50(a). When considering a party's motion for judgment as a matter of law, the court must "view the evidence in the light most favorable" to the non-moving party and "draw all reasonable inferences in his favor without weighing the evidence or assessing

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[2] The governing substantive law, as I have previously held in this case, is that of Illinois. (*See* Mem. Op. & Order (Mots. for Summ. J.) [Docket 272], at 5).

the witnesses' credibility." *Baynard v. Malone*, 268 F.3d 228, 234–35 (4th Cir. 2001). Judgment as a matter of law is inappropriate if a reasonable jury could find in favor of the non-moving party. *Id.* at 235. On the other hand, a court may grant judgment as a matter of law if the "evidence presented supports only one reasonable conclusion as to the verdict." *Bank of Montreal v. Signet Bank*, 193 F.3d 818, 831 (4th Cir. 1999).

Rule 50 also states that "[i]f the court does not grant a motion for judgment as a matter of law made under Rule 50(a), the court is considered to have submitted the action to the jury subject to the court's later deciding the legal questions raised by the motion." Fed. R. Civ. P. 50(b). After the matter is submitted to the jury, the Rules allow a movant to file a renewed motion for judgment as a matter of law. *Id.* "When a jury verdict has been returned, judgment as a matter of law may be granted only if, viewing the evidence in a light most favorable to the non-moving party (and in support of the jury's verdict) and drawing every legitimate inference in that party's favor, the only conclusion a reasonable jury could have reached is one in favor of the moving party." *Int'l Ground Transp. v. Mayor & City Council of Ocean City, Md.*, 475 F.3d 214, 218–19 (4th Cir. 2007).

While courts should not simply rubber stamp a jury's verdict, judgment as a matter of law is a remedy to be applied sparingly and only in the most extraordinary circumstances. 9B Charles Wright & Arthur Miller, *Federal Practice and Procedure* § 2524 (3d ed. 2008); *see also, e.g., Sawyer v. Asbury*, 861 F. Supp. 2d 737, 743–44 (S.D. W. Va. 2012)

(submitting the case to the jury despite "deep concerns" but granting post-verdict motion for judgment as a matter of law where video evidence contradicted trial testimony). Put simply, a court "may not disturb the [jury] verdict where there was sufficient evidence for a reasonable jury to find in the non-movant's favor." *Dotson v. Pfizer, Inc.*, 558 F.3d 284, 292 (4th Cir. 2009).

B. Discussion

I decline to disturb the jury's verdict in this case because, as explained below, a reasonable jury could find in favor of the plaintiffs on each of their claims. The evidence on the defective design claim is particularly strong and is capable of upholding the verdict on its own. Thus, I begin there before turning to Ethicon's Motion regarding the plaintiffs' other theories of liability.

a. Design Defect

Illinois requires a plaintiff to prove five factors to succeed on a strict liability claim under a theory of design defect: "(1) a condition of the product as a result of [] design, (2) that made the product unreasonably dangerous, (3) and that existed at the time the product left the defendant's control, and (4) an injury to the plaintiff, (5) that was proximately caused by the condition." *Mikolajczyk v. Ford Motor Co.*, 901 N.E.2d 329, 345 (Ill. 2008), *opinion modified on denial of reh'g* (Dec. 18, 2008). The second element, that the condition made the product "unreasonably dangerous," can be proven through either the consumer-expectations test or the risk-utility test. *Id.* at 351–52. The consumer-expectations test "is a single-factor test" that asks

the jury to determine "whether the product is unsafe when put to a use that is reasonably foreseeable considering its nature and function." *Id.* at 352. In contrast, the risk-utility test is a "multifactor analysis" that integrates consumer expectations along with "a broad range" of other factors, such as the "magnitude and probability of the foreseeable risks of harm[;] the instructions and warnings accompanying the product[;] the likely effects of an alternative design on production costs; the effects of the alternative design on product longevity, maintenance, repair, and esthetics; and the range of consumer choice among products." *Id.* (citing Restatement (Third) of Torts: Prods. Liab. § 2 cmt. f (1998)).

Which of these two tests should be charged to the jury depends on the evidence presented by the parties at trial:

> [W]hen the evidence presented by either or both parties supports the application of this integrated [risk-utility] test, an appropriate instruction is to be given at the request of either party. If, however, both parties' theories of the case are framed entirely in terms of consumer expectations, including those based on advertising and marketing messages, and/or whether the product was being put to a reasonably foreseeable use at the time of the injury, the jury should be instructed only on the consumer-expectation test.

Id. Here, the parties presented evidence pertinent to both the consumer-expectations test and the risk-utility test. Therefore, I instructed the jury in accordance with the integrated test set forth in the Illinois Pattern Civil Jury Instructions, which provide as follows: "When I use the expression 'unreasonably dangerous,' I mean that the risk of danger inherent in the design outweighs the benefits of the design when the product is put to a use that is reasonably foreseeable considering the nature and function of the product." *See* Ill. Pattern Civ. Jury Instructions § 400.06A.[3]

Ethicon states three reasons for why it is entitled to judgment as a matter of law on the plaintiffs' design defect claim. First, Ethicon contends that comment k of the Restatement (Second) of Torts ("Restatement") § 402A applies to this case and acts as a bar to the plaintiffs' design defect claim. Second, Ethicon asserts that no reasonable juror could find that the TVT-O is unreasonably dangerous. And third, in Ethicon's view, the

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[3] Specifically, I instructed the jury as follows: "A product is unreasonably dangerous when the risk of danger inherent in the design outweighs the benefits of the design when the product is put to a use that is reasonably foreseeable considering the nature and function of the product." (Trial Tr. (Sept. 4, 2014) [Docket 428], at 222:1–5). This was the instruction proposed by both parties. (*See* Pls.' Resp. to the Court's Questions Regarding Cmt. k & the Significance of "Standard of Care" Test. on Pls.' Design Defect Claims [Docket 391], at 5–6 ("Plaintiffs propose that the Illinois Pattern Instructions relating to the risk-utility test should be followed in this case."); Defs.' Proposed Jury Instructions [Docket 349], at 11 (quoting Ill. Pattern Civ. Jury Instructions § 400.06A)).

plaintiffs were required to show that a *specific* design defect caused Mrs. Huskey's injuries and failed to do so.

i. Comment k

Comment k provides an exemption to strict liability for products that can be categorized as "[u]navoidably unsafe." Restatement § 402A cmt. k. According to comment k, such products, when "properly prepared and accompanied by proper directions and warning," are not "defective[,] nor [are they] *unreasonably* dangerous." *Id.* (emphasis in original). The comment illustrates by example: the "unavoidable high degree of risk" presented by the rabies vaccine is "fully justified," given that "the disease itself invariably leads to a dreadful death." *Id.* Manufacturers of products like this—when the product has been properly prepared, marketed, and labeled—are "not to be held to strict liability for unfortunate consequences attending their use, merely because [they] have undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk." *Id.*

I recently wrote at length on the purpose and import of comment k, concluding that comment k is, in essence, nothing more than another name for the risk-utility test. *See Mullins v. Ethicon, Inc.*, __ F. Supp. 3d __, at *4–9 (S.D. W. Va. 2015), *available* at 2015 WL 4635573. Thus, in the states that have adopted a form of the risk-utility test, comment k is a "redundant," "useless relic" reflective of an era from decades past, when courts relied exclusively on the consumer-expectations test in product liability

cases. *Id.* at *8. My reasoning in *Mullins* is apropos to the matter at hand. Because Illinois already provides for a risk-utility test, see *Mikolajczyk*, 901 N.E.2d at 347, the analysis set forth by comment k adds nothing to Ethicon's defense. In fact, Illinois's interpretation of comment k burdens Ethicon with proving the TVT-O is unavoidably unsafe. *See Glassman v. Wyeth Labs., Inc.*, 606 N.E.2d 338, 342 (Ill. App. Ct. 1992) ("[A] defendant has the burden to demonstrate that a product comes under comment k's protection."). To do this, Ethicon must show that the risks of the TVT-O, no matter how high, are "fully justified" (i.e., outweighed) by the "apparent[] useful[ness] and desirab[ility]" (i.e., utility) of the TVT-O. Restatement § 402A cmt. k.

Illinois courts, which apply comment k on a "case by case basis," have identified products that could possibly satisfy this standard. *Glassman*, 606 N.E.2d at 342. In *Glassman*, for example, the court explained that

> [a]n oral contraceptive is an apparently useful and desirable product, and comment k should apply to a particular oral contraceptive if the conditions of comment k are met, *i.e.*, the product is unavoidably unsafe and is properly prepared, and there are adequate directions and warnings.

Id. The court concluded, however, that the defendant–manufacturer had not shown, as a matter of law, that the oral contraceptive was unavoidably unsafe, and as a result, summary judgment under comment k was not proper. *Id.* at 343. Ethicon

suffers from the same shortcomings here.

On the one hand, Ethicon presented evidence that the TVT-O is an improvement over other types of SUI treatments, such as anterior repairs or open abdominal procedures. Dr. David Robinson, former Worldwide Medical Director at Ethicon, testified that unlike these latter invasive procedures, which carry risks of bleeding, infection, and recurrence, the TVT-O results in fewer postoperative complications and has a shorter recovery time. (Robinson Dep. Tr. [Docket 415-3], at 1149:20–1150:11; 1151:10–16;[4] *see also* Trial Tr. (Sept. 3, 2014) [Docket 427], at 66:10–12; 75:11–20 (testimony by Dr. Christina Pramudji that the TVT-O procedure, which requires a small incision, allows for faster recovery and is a better alternative to the invasive abdominal procedures)). In addition, Ethicon offered evidence that the TVT-O is considered the "gold standard" or "the best that [physicians] have to offer at the time to a patient." (Robinson Dep. Tr. [Docket 415-3], at 1152:8–23).

But the plaintiffs also produced significant evidence on the TVT-O's risks. Dr. Bruce Rosenzweig, a urogynecologist and expert witness in this case, testified that polypropylene mesh can "degrade," "shrink and contract," "deform," and result in "chronic foreign body reaction and chronic inflammation." (Trial Tr. (Aug. 26, 2014) [Docket 385], at 32:15–18). He further explained that these problems cannot always be resolved by removing the

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[4] Video of Dr. Robinson's deposition testimony was played for the jury during the trial. (*See* Trial Tr. (Aug. 27, 2014) [Docket 386], at 96:20–97:10).

mesh because there can be "scarring," "nerve irritation," and "residual mesh left in various areas that you can't get out, such as in muscle." (*Id.* at 32:21–23). Dr. Rosenzweig concluded that, in his opinion, the TVT-O's "risks outweigh its benefits." (*Id.* at 35:4–13). Urologist and expert witness Dr. Jerry Blaivas agreed, opining that symptoms of pain and dyspareunia "persist," even if the visible exposed mesh is removed. (Trial Tr. (Aug. 28, 2014) [Docket 387], at 171:17–25; 200:7–17). The jury heard evidence indicating that these risks posed by the TVT-O could have been avoided, or at least reduced, in several ways. (*See, e.g.*, Trial Tr. (Aug. 25, 2014) [Docket 384], at 145:8–18 (testimony by Dr. Scott Guelcher that "minimiz[ing] the amount of polypropylene that's present in the mesh" can lessen the foreign body reaction); Trial Tr. (Aug. 26, 2014) [Docket 385], at 67:4–68:16 (testimony by Dr. Rosenzweig that laser-cut mesh, such as that used in the TVT-O, is "stiffer" than mechanical-cut mesh, which can result in "further irritat[ion of] nerves and muscles"); *id.* at 40:22–41:6; 49:13–15:52:20–23 (testimony by Dr. Rosenzweig that the insertion of mesh near the obturator space is "inappropriate" and "especially concerning" due to nerves and muscles in that area that can be irritated by the foreign body reaction)).[5]

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[5] Ethicon argues that the existence of alternative products and treatments for SUI does not preclude application of comment k. (Defs.' Mem. in Supp. [Docket 438], at 10 ("[C]omment k protect[s] manufacturers of desirable and useful products, . . . even if the benefits could be obtained with another product[.]" (quoting *Glassman*, 606 N.E.2d at 342))). The testimony recounted here, however, does not go to the

From this evidence, a reasonable jury could conclude that the high risks of the TVT-O are not justified by the benefits, and as a result, the TVT-O cannot, as a matter of law, qualify as an unavoidably unsafe product. Ethicon, having failed to meet its burden, cannot save itself from the jury's verdict on design defect by appealing to comment k's exemption.

Before moving on, I quickly address Ethicon's briefing related to the interaction between comment k and product warnings. Ethicon contends that "the comment k inquiry consists of two independent steps": first, whether the product is unavoidably unsafe, and second, whether the product was properly prepared and accompanied by proper warning. (Defs.' Reply [Docket 440], at 9–10). This reading of comment k is overbroad. Once a product has been deemed unavoidably unsafe (the benefits outweigh the risks), comment k immunizes it from a design defect claim. Alternatively, if a product is not deemed to be unavoidably unsafe (the benefits do not outweigh the risks), which was the finding in this case, comment k has no effect. In either case, the comment k inquiry ends upon determination that the product is or is not unavoidably unsafe.

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existence of alternative *treatments* for SUI but instead presents evidence of alternative *design* decisions that Ethicon could have made to avoid the risks posed by the TVT-O. This evidence is key to the availability of comment k as a defense. "After all, a product is not *unavoidably* unsafe if it could be made safer through a reasonable alternative design." *Mullins*, __ F. Supp. 3d at *7 n.9; *see also Grundberg v. Upjohn Co.*, 813 P.2d 89, 92 (Utah 1991) ("The purpose of comment k is to protect from strict liability products that cannot be designed more safely.").

Ethicon's second step is not part of the analysis. Rather, the second step goes to the strict liability claims of failure to warn and manufacturing defect, which are separate and distinct from a claim of design defect.[6]

ii. Unreasonably Dangerous

Next, Ethicon argues that it is entitled to judgment on the design defect claim because no reasonable juror could conclude that the TVT-O is unreasonably dangerous. Again, determining unreasonable dangerousness in this case called for application of the risk-utility test. *See supra* at 5–6. The jury must weigh the utility of the design against the "risk of harm created," and "[i]f the likelihood and gravity of harm outweigh the benefits and utilities of the product, the product is unreasonably dangerous." *Calles v. Script-Tokai Corp.*, 864 N.E.2d 249, 257 (Ill. 2007) (internal citations omitted). This analysis is no different than that required to determine applicability of comment k. Therefore, I can dispose of Ethicon's argument in the same way I

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[6] Comment k mentions the need for "proper[] preparation" and "proper warning[s]" only to emphasize that even if a product is unavoidably unsafe, and thereby immune from a design defect claim, it can still be the subject of a warning defect or manufacturing defect claim. *See* Dan B. Dobbs et al., 2 *The Law of Torts* § 461 (2d ed. 2011) ("Manufacturing flaws and warning defects d[o] not obtain Comment k's dispensation."). Put differently, "comment k excepts unavoidably unsafe products from strict liability only to the extent that the plaintiff alleges a design defect; comment k's immunity from strict liability does not extend to strict liability claims based on manufacturing flaw or an inadequate warning." *Grundberg*, 813 P.2d at 92.

did in the previous section. In short, while Ethicon produced evidence of the TVT-O's usefulness and benefits, *see supra* at 8, the plaintiffs countered with evidence of the TVT-O's high risks of injury and how Ethicon could have mitigated those risks through alternative designs, *see supra* at 9. Taking the evidence as a whole and viewing it in the light most favorable to the plaintiffs, it is clear that reasonable persons could balance the risks and benefits against Ethicon. As a result, I cannot displace the jury's verdict on these grounds. *See Duke v. Uniroyal Inc.*, 928 F.2d 1413, 1417 (4th Cir. 1991) ("[If] a reasonable jury could return a verdict in favor of the plaintiffs, the court must defer to the judgment of the jury.").

iii. Non-Specific Defect

Finally, Ethicon argues that the plaintiffs did not establish the causation element of their design defect claim. In particular, Ethicon asserts that the plaintiffs were required to prove that a specific defect in the TVT-O caused Mrs. Huskey's injuries, but they failed to do so. As an initial matter, courts in Illinois "have generally held that a plaintiff need not pinpoint the specific defect in a product in order to recover under strict liability." *Doyle v. White Metal Rolling & Stamping Corp.*, 618 N.E.2d 909, 915–16 (Ill. App. Ct. 1993). But here, the plaintiffs did identify several specific defects in the TVT-O. Furthermore, they provided evidence that these defects proximately caused Mrs. Huskey's injuries,

at least in part.[7]

Proximate cause can be established either by direct evidence or by circumstantial evidence. *Stojkovich v. Monadnock Bldg.*, 666 N.E.2d 704, 709 (Ill. App. Ct. 1996); *see also Olson v. Williams All Seasons Co.*, 974 N.E.2d 914, 921 (Ill. App. Ct. 2012) ("[P]roximate cause can be sufficiently established by circumstantial evidence when an inference can reasonably be drawn from it."). Circumstantial evidence is evidence "from which a [factfinder] may infer other connected facts which usually and reasonably follow, according to the common experience of mankind." *Id.* (quoting *Housh v. Swanson*, 869 N.E.2d 321, 323 (Ill. App. Ct. 1990)). When a plaintiff relies on circumstantial evidence, she must show that the evidence "support[s] an inference which is reasonable and probable, not merely possible." *Stojkovich*, 666 N.E.2d at 709. She does not have to show, however, that the circumstantial evidence "exclude[s] all other possible inferences." *Id.* Put simply, "[i]f as a matter of ordinary experience a particular act or omission might be expected, under the circumstances, to produce a particular result, and that result in fact has followed, the conclusion may be permissible that the causal relation exists." *Id.* at 710 (quoting W. Keaton, *Prosser & Keeton on Torts* § 41, at 270 (5th ed. 1984)).

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[7] "It is well settled that a defendant need not be the *only* cause to be held liable for an injury; rather, it is sufficient that the defendant is *a* cause." *Voykin v. Estate of DeBoer*, 733 N.E.2d 1275, 1279 (Ill. 2000) (emphasis in original).

The plaintiffs' design defect claim focused on four alleged defects: (1) the tendency of the polypropylene material to erode; (2) the use of laser-cut mesh; (3) the placement of the TVT-O in the obturator space; and (4) the use of heavyweight mesh in the TVT-O. I **FIND** that the plaintiffs demonstrated sufficient circumstantial evidence to support proximate causation for at least one of these defects such that a reasonable jury could find in their favor on the design defect claim.

For example, with respect to the alleged defect of using heavyweight mesh, Dr. Scott Guelcher, a chemical engineer and expert witness, testified that because polypropylene is particularly susceptible to oxidation, (Trial Tr. (Aug. 25, 2014) [Docket 384], at 115:10–21), the foreign body response can "lead to changes in the polypropylene structure." (*Id.* at 104:11–15). After elaborating on these changes, Dr. Guelcher concluded that the more polypropylene surface present in the body, the "greater [these] changes would be [and] the more hazardous they could be." (*Id.* at 145:8–15). In other words, the foreign body response to polypropylene is "elevated" when more polypropylene is present. (*Id.* at 103:1–7). Dr. Rosenzweig explained that the TVT-O is made of a heavyweight mesh (Prolene mesh), meaning that "there is more mesh in the pelvic floor." (Trial Tr. (Aug. 26, 2015) [Docket 385], at 39:23–40:8). Like Dr. Guelcher, Dr. Rosenzweig opined that "[t]he more mesh there is in the pelvis, the more of a foreign body response." (*Id.* at 40:10–11). In turn, the foreign body response causes pain, "redness," "irritation," and "inflammation." (*Id.* at 40:12–19). Dr. Rosenzweig ultimately concluded

that the TVT-O "is unsuitable for implantation into the human body for SUI treatment" because the product is "made from a heavyweight mesh." (*Id.* at 35:21–23).

Dr. Blaivas provided specific causation testimony to connect the effects of heavyweight mesh to Mrs. Huskey's injuries. He explained that his examination of Mrs. Huskey revealed "chronic[] inflammation" and "chronic pelvic pain," which he believes was caused by the body's reaction to the mesh. (Trial Tr. (Aug. 28, 2014) [Docket 387], at 153:8–14; 156:10–15; 160:22–161:5). Indeed, Dr. Blaivas does not know of any other cause for "this particular constellation of symptoms." (*Id.* at 173:6–11). Although Dr. Blaivas did not directly state that the heavyweight condition of the TVT-O proximately caused Mrs. Huskey's chronic inflammation and pain, a jury could readily reach this inference, taking Drs. Guelcher, Rosenzweig, and Blaivas's testimony as a whole. Such an inference would be reasonable and probable.[8] It is therefore sufficient to establish circumstantial proof of proximate causation, even if other logical inferences could have been drawn from the doctors' testimony. *See Mort v. Walter*, 457 N.E.2d 18, 21

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[8] The same inference could reasonably be made with respect to the other three defects alleged by the plaintiffs, namely, the erosion of polypropylene, the use of laser-cut mesh, and the placement in the obturator space. But I need not address the evidence presented on these defects because, as explained above, a reasonable jury could find in favor of the plaintiffs based on the heavyweight-mesh theory of design defect.

(Ill. 1983) ("[T]he use of circumstantial evidence is not limited to those instances in which the circumstances support only one logical conclusion. Instead, circumstantial evidence will suffice whenever an inference may be reasonably be drawn.").

Because a reasonable jury could find that the risks of the TVT-O outweigh the benefits and that the heavyweight condition of the TVT-O caused Mrs. Huskey's injuries, I must **DENY** Ethicon's Motion with respect to the plaintiffs' design defect claim.

b. Failure to Warn

A manufacturer has a duty to warn of a product's "dangerous propensities" for which "there is unequal knowledge with respect to the risk of harm." *Salerno v. Innovative Surveillance Tech., Inc.*, 932 N.E.2d 101, 109–10 (Ill. App. Ct. 2010). To recover in a strict product liability action under a theory of failure to warn, the plaintiff must prove that the defendant–manufacturer failed to disclose an unreasonably dangerous propensity of the product, which resulted in injury to her. *See Mikolajczyk v. Ford Motor Co.*, 901 N.E.2d 329, 335 (Ill. 2008), *opinion modified on denial of reh'g* (Dec. 18, 2008); *see also Woodill v. Parke Davis & Co.*, 402 N.E.2d 194, 196 (Ill. 1980) ("It is well recognized that a failure to warn of a product's dangerous propensities may serve as the basis for holding a manufacturer or seller strictly liable in tort."). In the case of prescription medical devices, Illinois applies the learned intermediary doctrine, which directs the manufacturer's duty to warn to the prescribing

physician rather than the ultimate consumer or patient. *See Hansen v. Baxter Healthcare Corp.*, 764 N.E.2d 35, 42 (Ill. 2002). The medical device manufacturer, however, need not warn about "risks already known to the medical community." *Id.*

In light of these principles, the plaintiffs' burden at trial was to show that Ethicon failed to warn Dr. Byrkit about a dangerous condition of the TVT-O, not already known to the medical community, and that the lack of warning proximately caused Mrs. Huskey's complained-of injuries. Ethicon's Motion homes in on the causation element of the failure to warn claim, arguing that the plaintiffs did not prove (1) that Dr. Byrkit would have changed her decision to implant the TVT-O had she been adequately warned or (2) that Dr. Byrkit relied on the Instructions for Use ("IFU") for the TVT-O when treating Mrs. Huskey.

i. Physician's Change in Decision

With respect to the first argument, Ethicon contends that because Dr. Byrkit testified that she "would use the TVT-O again" for a patient with the same symptoms as Mrs. Huskey, the lack of warning could not have caused Mrs. Huskey's alleged injuries. (Defs.' Mem. in Supp. [Docket 438], at 3–4 (quoting Byrkit Dep. Tr. [Docket 413-20], at 279:1–10)). Ethicon's argument rests on the assumption that Illinois law requires a plaintiff to show, as part of her prima facie case, that the physician would have changed her prescribing decision had the manufacturer provided an adequate warning. As several federal district courts have observed, however, "the Supreme Court of Illinois has not

spoken on this issue clearly." *Giles v. Wyeth, Inc.*, 500 F. Supp. 2d 1063, 1066 (S.D. Ill. 2007); *see also, e.g., Mason v. Smithkline Beecham Corp.*, No. 05-1252, 2010 WL 2697173, at *9 (C.D. Ill. July 7, 2010) ("The Illinois Supreme Court has not determined what elements a plaintiff must prove in order to prevail on the issue of proximate causation in a failure-to-warn case.").

There is considerable reason for this court to believe, based on the holdings of other federal district courts, that the Supreme Court of Illinois would not agree with Ethicon's interpretation of the law and would adopt the heeding presumption for failure to warn claims. Under the heeding presumption, a court presumes that warnings, if given, will be heeded and followed by the learned intermediary. Applying this presumption "relieves the plaintiff of her burden" of proving that her prescribing physician would have acted differently under adequate warnings. *Giles*, 500 F. Supp. 2d at 1069. A number of federal cases involving Illinois law have employed this analysis. *See id.* (predicting that the Supreme Court of Illinois would adopt a rebuttable heeding presumption in cases involving the learned intermediary doctrine); *Rutz v. Novartis Pharm. Corp.*, No. 12-cv-0026-MJR, 2012 WL 6569361, at *7 (S.D. Ill. Dec. 17, 2012) (holding that "the heeding presumption is a natural result of or corollary to the learned intermediary doctrine" and as a result, "if [a physician] were considered a learned intermediary, there is a presumption that he would have heeded an adequate warning about [a particular risk]"); *Erikson v. Baxter Healthcare, Inc.*, 151 F. Supp. 2d 952, 970 (N.D. Ill. 2001) ("[T]he

plaintiffs are entitled at this stage to a presumption that a learned intermediary would have heeded the warnings given. . . . [W]hat a physician might or might not have done had he been adequately warned is not an element the plaintiff must prove as part of her case."); *Noyola v. Johnson & Johnson*, No. 85 C 2184, 1986 WL 14657, at *4 (N.D. Ill. Dec. 16, 1986) ("What a physician might or might not have done had he been adequately warned is not an element plaintiff must prove as part of her case.").

I find these cases informative and well-reasoned. However, I do not need to predict whether the Supreme Court of Illinois would follow suit because the plaintiffs presented sufficient evidence at trial demonstrating that Dr. Byrkit would have acted differently had she been warned about the TVT-O's increased risks for active women:

> Q: If you had been told that it shouldn't be implanted in women who are active, actively exercising, fit women, if you had been told that it shouldn't be implanted in those women, would you still have implanted it in Jo Huskey?
>
> A: I don't think I would.

(Byrkit Dep. Tr. [Docket 413-20], at 96:2–7).[9]

Ethicon argues that Dr. Byrkit's testimony is inconsequential because the plaintiffs "offered no

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[9] Video of Dr. Byrkit's deposition testimony was played for the jury during the trial. (*See* Trial Tr. (Aug. 26, 2014) [Docket 385], at 168:21–22).

evidence that would support [the] contraindication" that the TVT-O should not be implanted in active women. (Defs.' Mem. in Supp. [Docket 438], at 4). This argument overlooks several pieces of key evidence presented at trial. First, the plaintiffs admitted notes from a meeting Ethicon had with co-inventor of the TVT-O, Professor Jean de Leval, where Professor de Leval pointed out that the "presence of tape in the adductors" can contribute to pain, particularly in "young, active and/or sportive patients." (Pls.' Ex. 13036 [Docket 412-7], at 1).

Then, Dr. Rosenzweig testified that when tape is placed inside the adductor muscles (as it is in the TVT-O surgery), the body's reaction to it can irritate the obturator nerve, resulting in both thigh pain and groin pain. (*See* Trial Tr. (Aug. 26, 2014) [Docket 385], at 52:20–23, 54:24–55:7). In his experience, this pain can last "much longer" than is indicated by the IFU, which states that patients might experience "transient leg pain lasting 24 to 48 hours." (*Id.* at 81:7–14). According to Dr. Rosenzweig, the IFU's failure to explain the risks of extended leg pain is one example of its inadequacy. (*Id.* at 77:22–84:1, 85:4–6). He also emphasized that an IFU must provide information on the patients the product is "contraindicated for," that is, "who should not get the device." (*Id.* at 75:14–19).

Expert testimony from Dr. Blaivas put Dr. Rosenzweig's testimony into context. He explained that due to the high "propensity for causing groin and thigh pain," the TVT-O operation is not preferred for "physically active" women like Mrs. Huskey. (Trial Tr. (Aug. 28, 2014) [Docket 387], at 219:8–12). The jury also heard evidence

that Mrs. Huskey experienced such pain, which increased with physical activity. (Trial Tr. (Aug. 27, 2015) [Docket 386], at 80:9–20 (testimony from Gretchen Dean, Mrs. Huskey's former physical therapist, that Mrs. Huskey was complaining of "right sacroiliac pain [that] would sometimes go . . . down her leg," and "activity increased her symptoms")).

From this evidence and expert testimony, a reasonable jury could conclude that the IFU was inadequate in that it lacked a contraindication for the type of pain that active women can experience, and that Dr. Byrkit would not have implanted the TVT-O in Mrs. Huskey had she been aware of such a contraindication.[10] Accordingly, judgment as a matter of law is not appropriate on this basis.

ii. Reliance and Awareness of Risks

Ethicon's next attack on proximate causation relates to Dr. Byrkit's knowledge of the IFU and the TVT-O's risks. First, Ethicon argues that the allegedly inadequate IFU could not have caused Mrs. Huskey's injuries because the plaintiffs have

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[10] Illinois requires expert testimony to substantiate a failure to warn claim in cases where the duty to warn is to a prescribing physician. *See N. Trust Co. v. Upjohn Co.*, 572 N.E.2d 1030, 1038 (Ill. App. Ct. 1991). Ethicon argues that the plaintiffs did not meet this requirement because they "failed to adduce expert testimony that the TVT-O should not be used in active women." (Defs.' Reply [Docket 440], at 5). I disagree. As demonstrated above, Drs. Rosenzweig and Blaivas's testimony, when taken together, provide the expert testimony needed for the jury to conclude that the IFU for the TVT-O lacked a necessary contraindication.

not produced any evidence that Dr. Byrkit relied on the IFU in treating Mrs. Huskey. During her deposition, Dr. Byrkit gave conflicting testimony on this matter. Twice, she testified that she read the IFU before performing the implantation surgery on Mrs. Huskey. (Byrkit Dep. Tr. [Docket 413-20], at 31:15–18; 67:5–11). But later on, she testified that the last time she read the IFU was when she first began using the TVT-O to treat SUI. (*Id.* at 206:6–9). The jury is tasked with sorting out Dr. Byrkit's testimony and judging her credibility. *See Int'l Ground Transp. v. Mayor & City Council of Ocean City, Md.*, 475 F.3d 214, 221 (4th Cir. 2007) ("[The court] may not substitute [its] judgment for that of the jury or make credibility determinations."). Thus, because there is evidence in the record from which a reasonable jury could infer that Dr. Byrkit relied on the IFU in treating Mrs. Huskey, I must defer to the verdict on this point.

Ethicon also contends that it is entitled to judgment because Dr. Byrkit was "well aware of the risk of pain associated with the TVT-O procedure." (Defs.' Mem. in Supp. [Docket 438], at 5). In Illinois, a manufacturer's duty to warn does not extend to risks "already known by those to be warned." *Proctor v. Davis*, 682 N.E.2d 1203, 1211 (Ill. App. Ct. 1997)). Here, although Dr. Byrkit indicated that she understood that the risks of pain associated with the TVT-O ranged "from mild to severe [and] from temporary to permanent," (Byrkit Dep. Tr. [Docket 413-20], at 148:13–17), a reasonable jury could infer from her testimony that she was unaware of several other types of risks posed by the TVT-O. For instance, Dr. Byrkit had no knowledge of

contraindications for active patients, (*id.* at 94:3–95:5), nor did she know that the mesh itself could cause infection, (*id.* at 85:22–86:5). Similarly, Dr. Byrkit seemed unaware of any relationship between the amount of mesh material in the implant and the risk of complications. (*See id.* at 120:24–121:3 ("[I] would expect potentially less mesh could result in less potential complication. But I don't know that for certain.")). These risks were developed by expert testimony at trial. *See supra* at 17–18 (contraindications for active patients); (Trial Tr. (Aug. 26, 2014) [Docket 385], at 32:13–18 (testimony by Dr. Rosenzweig on complications caused by mesh); Trial Tr. (Aug. 25, 2014) [Docket 384], at 103:1–7 (testimony by Dr. Scott Guelcher on the effect "more mesh" has on the body)).

Giving the plaintiffs the "benefit of all inferences," I **FIND** that a reasonable jury could return a verdict in their favor on the failure to warn claim. *Duke v. Uniroyal Inc.*, 928 F.2d 1413, 1417 (4th Cir. 1991). Therefore, Ethicon's Motion on this cause of action is **DENIED**.

c. Negligence

The plaintiffs' negligence claim centered on two theories, negligent design and negligent failure to warn. In its Motion, Ethicon simply argues that the "negligence claim is based on the same facts and duties as the strict-liability design-defect and warning claims and thus fails for the same reasons." (Defs.' Mem. in Supp. [Docket 438], at 17).

Under Illinois law, "the key question in a negligent-design case is whether the manufacturer exercised reasonable care in designing the product."

Jablonski v. Ford Motor Co., 955 N.E.2d 1138, 1154 (Ill. 2011). This analysis "is essentially identical" to the risk-utility balancing test used for strict liability claims. *Id.* at 1155. Indeed, the Supreme Court of Illinois has said that any distinction between the claims of negligent design and strict liability for design defect "is mere semantics." *Id.* Accordingly, the same reasoning applied to Ethicon's Motion regarding design defect applies to the claim of negligent design, and Ethicon's Motion is **DENIED**. *See supra* at 5–14.

The difference between strict liability and negligence for a failure to warn claim is slightly more pronounced, the former focusing on the *industry's* knowledge and the latter focusing on the *particular defendant's* knowledge. *See Werckenthein v. Bucher Petrochemical Co.*, 618 N.E.2d 902, 908 (Ill. App. Ct. 1993) ("[S]trict liability for failure to warn requires evidence of the industry's knowledge of the product's dangerous propensity, and it turns on the nature of the product and the adequacy of the warning; negligence focuses on the particular defendant's knowledge and conduct."); *see also Baltus v. Weaver Div. of Kidde & Co.*, 557 N.E.2d 580, 585 (Ill. App. Ct. 1990) (stating that "the distinction between claims in negligence and strict liability lies in the fault concept"). For purposes of Ethicon's Motion, however, the result is the same. The plaintiffs presented sufficient evidence on Ethicon's knowledge of dangerous propensities of the TVT-O and failure to warn about those propensities such that a reasonable jury could conclude that Ethicon was negligent. (*See, e.g.*, Pls.' Ex. 13036 [Docket 412-7], at 1 (notes from a meeting between

Ethicon and Professor de Leval held on January 23, 2009, demonstrating Ethicon's knowledge that the "presence of tape in the adductors" can contribute to pain, particularly in "young, active and/or sportive patients")). Accordingly, Ethicon's Motion regarding negligent failure to warn is **DENIED**.

d. Loss of Consortium

The jury awarded $200,000 to Mr. Huskey for his loss of consortium claim, which arose from his wife's claims against Ethicon. (Verdict Form [Docket 402]). Seeing no argument otherwise, I **FIND** that Mr. Huskey's loss of consortium claim survives along with his wife's claims. *See, e.g.*, *Blagg v. Ill. F.W.D. Truck & Equip. Co.*, 572 N.E.2d 920, 924 (Ill. 1991) (explaining that a loss of consortium action is "predicated on the claim of the directly injured spouse," and the basis for recovery "is interference with the continuance of a healthy and happy marriage and injury to the conjugal relation"). Ethicon's Motion on this point is therefore **DENIED**.

e. Preemption

Ethicon's final basis for judgment as a matter of law rests on the doctrine of preemption. In short, Ethicon argues that because the Prolene suture component of the TVT-O has satisfied the FDA's premarket approval process, the plaintiffs' claims are preempted to the extent they concern mesh degradation. I thoroughly addressed this argument at the summary judgment stage. (*See generally* Mem. Op. & Order (Mots. for Summ. J.) [Docket 272]). I concluded that "[p]reemption is based on FDA premarket approval of a medical device, not its component parts." (*Id.* at 22). As a result, the fact

that the Prolene suture underwent premarket approval "is irrelevant" to the preemption of claims concerning the TVT-O, which has only received approval under the FDA's less-stringent 510(k) process. (*Id.*). I see no reason to deviate from this ruling. Therefore, I **ADOPT** it here and **FIND** that preemption is not warranted in this case. Ethicon's Motion based on the doctrine of preemption is **DENIED**.[11]

III. Motion for a New Trial

Having denied Ethicon's Renewed Motion for Judgment as a Matter of Law in its entirety, I now turn to Ethicon's Motion for a New Trial.

A. Legal Standard

Rule 59 allows a court to grant a new trial "for any reason for which a new trial has heretofore been granted in an action at law in federal court." Fed. R. Civ. P. 59(a)(1)(A). The Fourth Circuit has set forth a three-prong standard to govern Rule 59 motions:

> [I]t is the duty of the judge to set aside the verdict and grant a new trial, if he is of the opinion that (1) the verdict is against the clear weight of the evidence, or (2) is based upon evidence which is false, or (3) will result in a miscarriage of justice, even though there may be substantial evidence which would prevent the direction of a verdict.

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[11] For additional discussion on this issue, *see Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, 2014 WL 6674424 (S.D. W. Va. Nov. 24, 2014).

Atlas Food Sys. & Servs., Inc. v. Crane Nat'l Vendors, Inc., 99 F.3d 587, 594 (4th Cir. 1996) (internal citations and brackets omitted). When considering a motion for a new trial, the "crucial inquiry," particularly when employing the third prong, is "whether an error occurred in the conduct of the trial that was *so grievous* as to have rendered the trial unfair." *Bristol Steel & Iron Works v. Bethlehem Steel Corp.*, 41 F.3d 182, 186 (4th Cir. 1994) (emphasis added).

The decision to grant or deny a new trial "is within the sound discretion of the trial court." *Cline v. Wal-Mart Stores, Inc.*, 144 F.3d 294, 301 (4th Cir. 1998). Moreover, the discretion bestowed under Rule 59 "should be exercised sparingly." *United States v. Arrington*, 757 F.2d 1484, 1486 (4th Cir. 1985); *see also United States v. Perea*, 458 F.2d 535, 536 (10th Cir. 1972) ("A motion for a new trial is generally not regarded with favor, and is granted only with *great caution*." (emphasis added)). Below, I conclude that Ethicon has fallen far short of clearing the high bar set by Rule 59.

B. Discussion

Ethicon asserts three grounds for a new trial: (1) the jury's findings were against the clear weight of the evidence; (2) the court should have given the jury an instruction based on comment k; and (3) several of the court's evidentiary rulings prejudiced Ethicon.

a. Verdict Against the Clear Weight of the Evidence

When ruling on a motion for a new trial based on the sufficiency of the evidence, the court enjoys

"wider" discretion than when ruling on a motion for judgment as a matter of law. *McCracken v. Richmond, F. & P. R. Co.*, 240 F.2d 484, 488 (4th Cir. 1957). In the latter instance, the court must view the evidence in the light most favorable to the non-moving party and resolve any conflict on the non-movant's behalf. If there is substantial evidence in support of the plaintiff's case, the court may not direct a verdict against her, "even though [it] may not believe [her] evidence or may think that the weight of the evidence is on the other side." *Id.* (quoting *Garrison v. United States*, 62 F.2d 41, 42 (4th Cir. 1932)). On a motion for a new trial, however, the court must exercise its "independent judgment after a weighing of all the evidence and any other pertinent factors" and "determin[e] whether the verdict was against the clear weight of the evidence or would result in a miscarriage of justice." *Williams v. Nicols*, 266 F.2d 389, 393 (4th Cir. 1959). In any event, the court may not "reweigh the evidence and set aside the jury verdict merely because the jury could have redrawn different inferences or conclusions or because judges feel that other results are more reasonable." *Lee v. Adrales*, 778 F. Supp. 904, 907 (W.D. Va. 1991) (citation omitted); *see also* 6A J. Moore, *Moore's Federal Practice* ¶ 59.08[5] (stating that the court should "abstain from interfering with the verdict unless it is quite clear that the jury has reached a seriously erroneous result"). Applying this less-stringent standard to the case at bar, I do not believe that Ethicon has made the required showing to warrant a new trial.

First, Ethicon insists that the evidence on the

failure to warn claim "conclusively disproved" any causal link between an inadequacy in the TVT-O's IFU and Dr. Byrkit's decision to use the product. (Defs.' Mem. in Supp. [Docket 438], at 19). As the discussion above makes clear, this is not the case. Although Dr. Byrkit testified that she would use the TVT-O again, she also conveyed a lack of awareness about several of the specific risks associated with the TVT-O, including the risks to active women. *See supra* at 19. Then, she confirmed that had she known of the contraindication for active women, she would not have performed the implantation surgery on Mrs. Huskey. *See supra* at 16–17. Furthermore, Dr. Byrkit testified to relying on other sources of information *in addition* to the TVT-O's IFU, not exclusive of it. (*See* Byrkit Dep. Tr. [Docket 413–20], at 31:15–18 ("Q: What about the Instructions for Use, would you have read the Instructions For Use before you implanted the product? A: Yes.")). While Dr. Byrkit's testimony may be imprecise at times, when considered as a whole, it supports a finding of proximate causation. As a result, I **FIND** that the jury's verdict on the failure to warn claim is aligned with the clear weight of the evidence.

I reach the same conclusion for the design defect claim and negligence claim. The plaintiffs presented a wide array of expert testimony that demonstrated the high risks of the TVT-O and the injuries that can result from its use. *See supra* at 9. In addition, the plaintiffs presented compelling evidence indicating that Mrs. Huskey experienced such injuries from certain conditions of the TVT-O. *See supra* at 13. The jury also heard evidence indicating that Ethicon knew about the risks associated with the TVT-O.

See supra at 20–21. Ethicon's proof on the TVT-O's benefits, though also persuasive, was not overwhelming or incontrovertible. Thus, considering the case in its entirety, I do not find the jury's verdict to be erroneous.

Absent such a finding, Ethicon's Motion on this issue must be **DENIED**.

b. Jury Instruction on Comment k

Ethicon next argues that it is entitled to a new trial because the court did not instruct the jury on comment k. A district court is accorded "'much discretion' to fashion the charge" to the jury. *Noel v. Artson*, 641 F.3d 580, 586 (4th Cir. 2011) (quoting *Teague v. Bakker*, 35 F.3d 978, 985 (4th Cir. 1994)). The Fourth Circuit Court of Appeals has held that a court abuses its discretion in declining to give an instruction proposed by a party "only when the requested instruction (1) was correct; (2) was not substantially covered by the court's charge to the jury; and (3) dealt with some point in the trial so important, that failure to give the requested instruction seriously impaired that party's ability to make its case." *Id.* at 586–87 (internal quotation marks omitted).

Above, I found that the principles of comment k are already embodied in Illinois's risk-utility test, which was charged to the jury in this case. *See supra* at 6. Ethicon disagrees and argues that the court's instruction on the risk-utility test does not cover "the special risk-benefit considerations that govern prescription-only medical devices like TVT-O." (Defs.' Mem. in Supp. [Docket 438], at 20). Specifically, Ethicon argues, an instruction about

comment k was necessary to inform the jury that any inherent risks in the TVT-O do not necessarily make it unreasonably dangerous.

I find that the general risk-utility test can fully and adequately account for a product's "inherent risks."[12] A knife, for example, makes many tasks simpler but can also cause injury. The risk of causing injury is inherent to the knife's design—it would be very difficult, or even impossible, to make a knife that does not cut human skin yet cuts other materials effectively. Similarly, gasoline, which carries the risk of explosion, also has great utility, allowing for efficient transportation of goods and persons. Even a fondue pot has inherent risks. *See Rock v. Oster Corp.*, 810 F. Supp. 665, 667 (D. Md. 1991) (acknowledging the inherent risk of a hot fondue pot being tipped over in application of the risk-utility test). The general risk-utility test works well for these products, allowing the jury to account for their utility as well as their risks, inherent or otherwise. The TVT-O is not unique simply because it is a prescription medical device. Rather, the medical benefits and side effects are factors for the jury to consider in weighing the product's risks against its utility.[13]

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[12] In fact, the instruction to the jury specifically directed the jurors to consider the TVT-O's inherent risks of danger. (See Trial Tr. (Sept. 4, 2014) [Docket 428], at 222:1–5).

[13] Ethicon's interpretation of comment k as a remedy to the "clash between medical-malpractice and product-liability law," (Defs.' Mem. in Supp. [Docket 438], at 21–22), is unpersuasive and has no effect on this ruling. Ethicon argues that a product cannot meet the standard of care for physicians—the TVT-O is

The cases Ethicon cites in support of its position are easily distinguishable. In *Ortho Pharmaceutical Corp. v. Heath*, the Supreme Court of Colorado held that the defendant "was entitled to an instruction based on the comment k defense." 722 P.2d 410, 416 (Colo. 1986), *overruled in part on other grounds by Armentrout v. FMC Corp.*, 842 P.2d 175 (Colo. 1992). This holding makes sense, given that the lower court had also failed to give an instruction on the general risk-utility test, which the Supreme Court of Colorado found to be reversible error. *Id.* at 415. *Mele v. Howmedica, Inc.* involved a similar situation. 808 N.E.2d 1026 (Ill. App. Ct. 2004). The Appellate Court of Illinois, First District, held that the lower court should have instructed the jury on the risk-utility test. *Id.* at 1045–46. It also held that the lower court "erroneously excluded evidence of the

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considered the "gold standard" by some physician groups—and, at the same time, be deemed unreasonably dangerous. But, with a closer look, this seeming conflict is resolved not by comment k but by recognizing the difference between the standard of care for physicians and the standard of care for manufacturers. The former is based on the customs of medical professionals in a particular community. *See* Dan B. Dobbs et al., 2 *The Law of Torts* § 292 (2d ed. 2011) ("[T]he 'standard' in medical cases is conceived of as the specific procedure or medical conduct that the relevant medical community considered to be acceptable at the time of the alleged negligence."). The latter turns on conformity with the "design standards of the industry." *Anderson v. Hyster Co.*, 385 N.E.2d 690, 692 (Ill. 1979). Conceivably, therefore, a doctor whose sole wrong was using a product later found to be defectively designed would not be liable for medical malpractice so long as doctors in his or her community also routinely used the product.

product's benefits and risks," which would go to the question of unreasonable dangerousness under the risk-utility test, as well as the comment k defense. *Id.* at 1042. Unlike these cases, I instructed the jury on the risk-utility test. The jury found that the TVT-O's risks outweigh its utility. A duplicative instruction—not to mention, one that would have reversed the burden onto Ethicon, *see Glassman v. Wyeth Labs., Inc.*, 606 N.E.2d 338, 343 (Ill. App. Ct. 1992)—is unlikely to have changed this outcome.

Because the principles of comment k were substantially covered in the court's instructions on the risk-utility test, there is no cause for a new trial based on the jury charge. Ethicon's Motion on this point is **DENIED**.

c. Evidentiary Rulings

Ethicon's last argument for a new trial concerns this court's evidentiary rulings. The Supreme Court has stated that "alleged substantial errors in admission or rejection of evidence" may warrant a new trial. *Montgomery Ward & Co. v. Duncan*, 311 U.S. 243, 251 (1940). To succeed on this theory, Ethicon must demonstrate that the alleged evidentiary errors were "*substantial*." *Id.* (emphasis added); *see also Creekmore v. Maryview Hosp.*, 662 F.3d 686, 693 (4th Cir. 2011) (holding that the court will not set aside a judgment on this basis "unless justice so requires or a party's substantial rights are affected"). As explained below, none of Ethicon's arguments—taken individually or together—convey the substantial error required to secure a new trial.

i. Exclusion of FDA Evidence

Ethicon argues that this court's exclusion of the

TVT-O's clearance under the FDA's 510(k) process, along with other FDA-related evidence, was prejudicial and entitles Ethicon to a new trial. I have addressed this argument multiple times throughout the course of these MDLs, each time reaching the same conclusion: the modest probative value of such evidence is substantially outweighed by the risk of unfair prejudice, specifically, the risk of confusing and misleading the jury. *See, e.g., Cisson v. C. R. Bard, Inc.*, __ F. Supp. 3d __, at *3–5 (S.D. W. Va. 2015), *available at* 2015 WL 566959; *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 754 (S.D. W. Va. 2014); *Sanchez v. Boston Scientific Corp. (Sanchez I)*, No. 2:12-cv-05762, 2014 WL 4059214, at *15 (S.D. W. Va. Aug. 18, 2014).

Federal Rule of Evidence 401 provides that evidence is relevant if "it has a tendency to make a fact more or less probable than it would be without the evidence." Fed. R. Evid. 401. In light of the Supreme Court's precedent on the meaning and purpose of 510(k), I see little relevance in the fact that the TVT-O was cleared under this regulation. In *Medtronic, Inc. v. Lohr*, the Supreme Court held that compliance with 510(k) focuses on "equivalence, not safety" and that products entering the market through the 510(k) process have "never been formally reviewed [for] safety or efficacy." 518 U.S. 470, 493 (1996). If 510(k) does not go to a product's safety and efficacy—the "very subjects" of the plaintiffs' products liability claims, *Riegel v. Medtronic, Inc.*, 552 U.S 312, 322 (2008)—then evidence of Ethicon's compliance with 510(k) has no relevance to the state law claims in this case and was properly excluded by the court. *See* Fed. R.

Evid. 402 ("Irrelevant evidence is not admissible."). In a similar vein, evidence regarding the FDA process that the Prolene suture underwent, which this court excluded, says little about the safety and effectiveness of the final product, the TVT-O. *See Lewkut v. Stryker Corp.*, 724 F. Supp. 2d 648, 656 (S.D. Tex. 2010) ("To require that a distinction be drawn between the approval process of the individual components of a system and the system itself, would, it seems, add a level of complication to the medical device approval process not anticipated by Congress, the FDA, or medical device manufacturers.").

Even if evidence on FDA rules and regulations had some relevance to this case, the balancing test set forth in Federal Rule of Evidence 403 nevertheless forecloses Ethicon's argument in favor of a new trial. Rule 403 provides that a court "may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. In previous cases, I explained how FDA evidence succumbs to this rule:

> Jurors are likely to believe that FDA enforcement relates to the validity of the plaintiffs' state law tort claims, which it does not. [Furthermore,] the jury may attach undue significance to an FDA determination, and [] alleged shortcomings in FDA procedures are not probative to a state law products liability claim.

Lewis, 991 F. Supp. 2d at 754–55 (internal quotations omitted); *see also Sanchez v. Boston Scientific Corp. (Sanchez II)*, No. 2:12-cv-05762, 2014 WL 4851989, at *35 (S.D. W. Va. Sept. 29, 2014) ("[T]estimony about the requirements of the FDCA, which are not at issue in this case, could lead to more confusion about [the state law claims] than enlightenment."). Additionally, admitting FDA evidence might have provoked the parties to engage in a time-consuming mini-trial on whether Ethicon in fact complied with its regulations. In short, because going down the road of federal regulatory schemes—which do not concern any of the state law claims at issue—would risk confusing and misleading the jury, this court was correct in excluding FDA evidence.

ii. Rulings on Expert Testimony

Ethicon also disputes this court's rulings regarding the testimony of two expert witnesses. First, Ethicon contends that the court improperly overruled objections to Dr. Blaivas's testimony about the risks of mesh devices known to the medical community and about alternative devices used to treat pelvic disorders. I disagree. Dr. Blavias's testimony on pelvic surgeons' general knowledge of risks is not speculative, given that Dr. Blaivas, as a urologist who performs mesh explant surgeries, belongs to that medical community. Moreover, the scope of the medical community's knowledge affects the plaintiffs' failure to warn claim. *See Hansen v. Baxter Healthcare Corp.*, 764 N.E.2d 35, 42 (Ill. 2002) (explaining that "a prescription medical device manufacturer need not provide a warning of risks already known to the medical community."). And

Dr. Blaivas's testimony about other medical devices was a proper question for redirect-examination intended to clarify the meaning of the term "gold standard," which Ethicon had raised during cross-examination. *See United States v. Wiley*, 846 F.2d 150, 156 (2d Cir. 1988) ("Redirect examination may be used to rebut false impressions that arise from cross-examination, . . . and the scope of such an examination is a matter confided to the district court's discretion[.]").

Second, Ethicon argues that the court incorrectly and prejudicially excluded Dr. Pramudji's opinion that Mrs. Huskey may suffer from interstitial cystitis. Prior to trial, I excluded this opinion because it had no support in the record. Mrs. Huskey was never diagnosed with interstitial cystitis, despite having been examined by multiple physicians. (*See* Mem. Op. & Order (*Daubert* Mots.) [Docket 271], at 48–49). Ethicon did not produce any support for such a diagnosis at trial either. Therefore, the court's exclusion of Dr. Pramudji's testimony, which had no reliable basis, was proper under Federal Rule of Evidence 702. *See* Fed. R. Evid. 702 (allowing expert opinion testimony only if the opinion "is the product of reliable principles and methods").

Whether these evidentiary rulings were correct or not, Ethicon has provided no persuasive argument that they resulted in a miscarriage of justice such that it is entitled to a new trial. Therefore, Ethicon's Motion on this point is **DENIED**.

IV. Conclusion

Ethicon has asked this court to discard the jury's

unanimous decision and direct a verdict in its favor pursuant to Rule 50(b), which allows for a directed verdict only if no reasonable jury could find in the plaintiffs' favor. Alternatively, Ethicon has asked for a new trial pursuant to Rule 59, which allows for a do-over only if a grievous error occurred that rendered the trial unfair. Both courses of action require the court to desert the jury's verdict, and consequently, neither should be taken lightly. Indeed, the remedies of a directed verdict or a new trial should be applied only in exceptional circumstances. Ethicon has failed to show that such circumstances exist here. Thus, applying the hesitancy and caution that a district court must employ in these circumstances, I **DENY** Ethicon's Renewed Motion for Judgment as a Matter of Law or, in the Alternative, for a New Trial ("Motion") [Docket 437].

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: August 19, 2015

/s/Joseph R. Goodwin
JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

APPENDIX E - ORDER DENYING PETITIONERS' PETITION FOR REHEARING EN BANC

FILED: February 22, 2017

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 15-2118
(2:12-cv-05201)
(2:12-md-02327)

JO HUSKEY; ALLEN HUSKEY

Plaintiffs - Appellees

v.

ETHICON, INC.; JOHNSON & JOHNSON

Defendants - Appellants

O R D E R

The court denies the petition for rehearing and rehearing en banc. No judge requested a poll under Fed. R. App. P. 35 on the petition for rehearing en banc.

Entered at the direction of the panel: Judge Motz, Judge Diaz, and Senior Judge Davis.

For the Court

/s/ Patricia S. Connor, Clerk

APPENDIX F - STATUTORY PROVISIONS INVOLVED

21 U.S.C. § 360

(a) Definitions

As used in this section-

(1) the term "manufacture, preparation, propagation, compounding, or processing" shall include repackaging or otherwise changing the container, wrapper, or labeling of any drug package or device package in furtherance of the distribution of the drug or device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user; and

(2) the term "name" shall include in the case of a partnership the name of each partner and, in the case of a corporation, the name of each corporate officer and director, and the State of incorporation.

(b) Annual registration

(1) During the period beginning on October 1 and ending on December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs shall register with the Secretary the name of such person, places of business of such person, all such establishments, the unique facility identifier of each such establishment, and a point of contact e-mail address.

(2) During the period beginning on October 1 and ending on December 31 of each year, every person

who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a device or devices shall register with the Secretary his name, places of business, and all such establishments.

(3) The Secretary shall specify the unique facility identifier system that shall be used by registrants under paragraph (1). The requirement to include a unique facility identifier in a registration under paragraph (1) shall not apply until the date that the identifier system is specified by the Secretary under the preceding sentence.

(c) New producers

Every person upon first engaging in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices in any establishment which he owns or operates in any State shall immediately register with the Secretary-

(1) with respect to drugs, the information described under subsection (b)(1); and

(2) with respect to devices, the information described under subsection (b)(2)..[1]

(d) Additional establishments

Every person duly registered in accordance with the foregoing subsections of this section shall immediately register with the Secretary any additional establishment which he owns or operates in any State and in which he begins the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices.

(e) Registration number; uniform system for identification of devices intended for human use

The Secretary may assign a registration number to any person or any establishment registered in accordance with this section. The Secretary may also assign a listing number to each drug or class of drugs listed under subsection (j). Any number assigned pursuant to the preceding sentence shall be the same as that assigned pursuant to the National Drug Code. The Secretary may by regulation prescribe a uniform system for the identification of devices intended for human use and may require that persons who are required to list such devices pursuant to subsection (j) shall list such devices in accordance with such system.

(f) Availability of registrations for inspection

The Secretary shall make available for inspection, to any person so requesting, any registration filed pursuant to this section; except that any list submitted pursuant to paragraph (3) of subsection (j) and the information accompanying any list or notice filed under paragraph (1) or (2) of that subsection shall be exempt from such inspection unless the Secretary finds that such an exemption would be inconsistent with protection of the public health.

(g) Exclusions from application of section

The foregoing subsections of this section shall not apply to-

(1) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing

prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail;

(2) practitioners licensed by law to prescribe or administer drugs or devices and who manufacture, prepare, propagate, compound, or process drugs or devices solely for use in the course of their professional practice;

(3) persons who manufacture, prepare, propagate, compound, or process drugs or devices solely for use in research, teaching, or chemical analysis and not for sale;

(4) any distributor who acts as a wholesale distributor of devices, and who does not manufacture, repackage, process, or relabel a device; or

(5) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that registration by such classes of persons in accordance with this section is not necessary for the protection of the public health.

In this subsection, the term "wholesale distributor" means any person (other than the

manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.

(h) Inspections

(1) In general

Every establishment that is required to be registered with the Secretary under this section shall be subject to inspection pursuant to section 374 of this title.

(2) Biennial inspections for devices

Every establishment described in paragraph (1), in any State, that is engaged in the manufacture, propagation, compounding, or processing of a device or devices classified in class II or III shall be so inspected by one or more officers or employees duly designated by the Secretary, or by persons accredited to conduct inspections under section 374(g) of this title, at least once in the 2-year period beginning with the date of registration of such establishment pursuant to this section and at least once in every successive 2-year period thereafter.

(3) Risk-based schedule for drugs

The Secretary, acting through one or more officers or employees duly designated by the Secretary, shall inspect establishments described in paragraph (1) that are engaged in the manufacture, preparation, propagation, compounding, or

processing of a drug or drugs (referred to in this subsection as "drug establishments") in accordance with a risk-based schedule established by the Secretary.

(4) Risk factors

In establishing a risk-based schedule under paragraph (3), the Secretary shall inspect establishments according to the known safety risks of such establishments, which shall be based on the following factors:

(A) The compliance history of the establishment.

(B) The record, history, and nature of recalls linked to the establishment.

(C) The inherent risk of the drug manufactured, prepared, propagated, compounded, or processed at the establishment.

(D) The inspection frequency and history of the establishment, including whether the establishment has been inspected pursuant to section 374 of this title within the last 4 years.

(E) Whether the establishment has been inspected by a foreign government or an agency of a foreign government recognized under section 384e of this title.

(F) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

(5) Effect of status

In determining the risk associated with an establishment for purposes of establishing a risk-based schedule under paragraph (3), the Secretary shall not consider whether the drugs manufactured, prepared, propagated, compounded, or processed by such establishment are drugs described in section 353(b) of this title.

(6) Annual report on inspections of establishments

Beginning in 2014, not later than February 1 of each year, the Secretary shall make available on the Internet Web site of the Food and Drug Administration a report regarding-

(A)(i) the number of domestic and foreign establishments registered pursuant to this section in the previous calendar year; and

(ii) the number of such domestic establishments and the number of such foreign establishments that the Secretary inspected in the previous calendar year;

(B) with respect to establishments that manufacture, prepare, propagate, compound, or process an active ingredient of a drug or a finished drug product, the number of each such type of establishment; and

(C) the percentage of the budget of the Food and Drug Administration used to fund the inspections described under subparagraph (A).

(i) Registration of foreign establishments

(1) Every person who owns or operates any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States shall, through electronic means in accordance with the criteria of the Secretary-

(A) upon first engaging in any such activity, immediately submit a registration to the Secretary that includes-

(i) with respect to drugs, the name and place of business of such person, all such establishments, the unique facility identifier of each such establishment, a point of contact e-mail address, the name of the United States agent of each such establishment, the name of each importer of such drug in the United States that is known to the establishment, and the name of each person who imports or offers for import such drug to the United States for purposes of importation; and

(ii) with respect to devices, the name and place of business of the establishment, the name of the United States agent for the establishment, the name of each importer of such device in the United States that is known to the establishment, and the name of each person who imports or offers for import such device to the United States for purposes of importation; and

(B) each establishment subject to the requirements of subparagraph (A) shall

thereafter register with the Secretary during the period beginning on October 1 and ending on December 31 of each year.

(2) The establishment shall also provide the information required by subsection (j).

(3) The Secretary is authorized to enter into cooperative arrangements with officials of foreign countries to ensure that adequate and effective means are available for purposes of determining, from time to time, whether drugs or devices manufactured, prepared, propagated, compounded, or processed by an establishment described in paragraph (1), if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 381(a) of this title.

(4) The Secretary shall specify the unique facility identifier system that shall be used by registrants under paragraph (1) with respect to drugs. The requirement to include a unique facility identifier in a registration under paragraph (1) with respect to drugs shall not apply until the date that the identifier system is specified by the Secretary under the preceding sentence.

(j) Filing of lists of drugs and devices manufactured, prepared, propagated and compounded by registrants; statements; accompanying disclosures

(1) Every person who registers with the Secretary under subsection (b), (c), (d), or (i) shall, at the time of registration under any such subsection, file with the Secretary a list of all drugs and a list of all devices and a brief statement of the basis for believing that each device included in the list is a device rather than a drug (with each drug and device

in each list listed by its established name (as defined in section 352(e) of this title) and by any proprietary name) which are being manufactured, prepared, propagated, compounded, or processed by him for commercial distribution and which he has not included in any list of drugs or devices filed by him with the Secretary under this paragraph or paragraph (2) before such time of registration. Such list shall be prepared in such form and manner as the Secretary may prescribe and shall be accompanied by-

(A) in the case of a drug contained in the applicable list and subject to section 355 or 360b of this title, or a device intended for human use contained in the applicable list with respect to which a performance standard has been established under section 360d of this title or which is subject to section 360e of this title, a reference to the authority for the marketing of such drug or device and a copy of all labeling for such drug or device;

(B) in the case of any other drug or device contained in an applicable list-

(i) which drug is subject to section 353(b)(1) of this title, or which device is a restricted device, a copy of all labeling for such drug or device, a representative sampling of advertisements for such drug or device, and, upon request made by the Secretary for good cause, a copy of all advertisements for a particular drug product or device, or

(ii) which drug is not subject to section 353(b)(1) of this title or which device is

not a restricted device, the label and package insert for such drug or device and a representative sampling of any other labeling for such drug or device;

(C) in the case of any drug contained in an applicable list which is described in subparagraph (B), a quantitative listing of its active ingredient or ingredients, except that with respect to a particular drug product the Secretary may require the submission of a quantitative listing of all ingredients if he finds that such submission is necessary to carry out the purposes of this chapter;

(D) if the registrant filing a list has determined that a particular drug product or device contained in such list is not subject to section 355 or 360b of this title, or the particular device contained in such list is not subject to a performance standard established under section 360d of this title or to section 360e of this title or is not a restricted device a brief statement of the basis upon which the registrant made such determination if the Secretary requests such a statement with respect to that particular drug product or device; and

(E) in the case of a drug contained in the applicable list, the name and place of business of each manufacturer of an excipient of the listed drug with which the person listing the drug conducts business, including all establishments used in the production of such excipient, the unique

facility identifier of each such establishment, and a point of contact e-mail address for each such excipient manufacturer.

(2) Each person who registers with the Secretary under this section shall report to the Secretary, with regard to drugs once during the month of June of each year and once during the month of December of each year, and with regard to devices once each year during the period beginning on October 1 and ending on December 31, the following information:

(A) A list of each drug or device introduced by the registrant for commercial distribution which has not been included in any list previously filed by him with the Secretary under this subparagraph or paragraph (1) of this subsection. A list under this subparagraph shall list a drug or device by its established name (as defined in section 352(e) of this title), and by any proprietary name it may have and shall be accompanied by the other information required by paragraph (1).

(B) If since the date the registrant last made a report under this paragraph (or if he has not made a report under this paragraph, since February 1, 1973) he has discontinued the manufacture, preparation, propagation, compounding, or processing for commercial distribution of a drug or device included in a list filed by him under subparagraph (A) or paragraph (1); notice of such discontinuance, the date of such discontinuance, and the identity (by

established name (as defined in section 352(e) of this title) and by any proprietary name) of such drug or device.

(C) If since the date the registrant reported pursuant to subparagraph (B) a notice of discontinuance he has resumed the manufacture, preparation, propagation, compounding, or processing for commercial distribution of the drug or device with respect to which such notice of discontinuance was reported; notice of such resumption, the date of such resumption, the identity of such drug or device (each by established name (as defined in section 352(e) of this title) and by any proprietary name), and the other information required by paragraph (1), unless the registrant has previously reported such resumption to the Secretary pursuant to this subparagraph.

(D) Any material change in any information previously submitted pursuant to this paragraph or paragraph (1).

(3) The Secretary may also require each registrant under this section to submit a list of each drug product which (A) the registrant is manufacturing, preparing, propagating, compounding, or processing for commercial distribution, and (B) contains a particular ingredient. The Secretary may not require the submission of such a list unless he has made a finding that the submission of such a list is necessary to carry out the purposes of this chapter.

(4) The Secretary shall require persons subject to this subsection to use, for purposes of this subsection, the unique facility identifier systems

specified under subsections (b)(3) and (i)(4) with respect to drugs. Such requirement shall not apply until the date that the identifier system under subsection (b)(3) or (i)(4), as applicable, is specified by the Secretary.

(k) Report preceding introduction of devices into interstate commerce

Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least ninety days before making such introduction or delivery, report to the Secretary or person who is accredited under section 360m(a) of this title (in such form and manner as the Secretary shall by regulation prescribe)-

(1) the class in which the device is classified under section 360c of this title or if such person determines that the device is not classified under such section, a statement of that determination and the basis for such person's determination that the device is or is not so classified, and

(2) action taken by such person to comply with requirements under section 360d or 360e of this title which are applicable to the device.

A notification submitted under this subsection that contains clinical trial data for an applicable device clinical trial (as defined in section 282(j)(1) of title 42) shall be accompanied by the certification required under section 282(j)(5)(B) of such title. Such

certification shall not be considered an element of such notification.

(l) Exemption from reporting requirements

(1) A report under subsection (k) is not required for a device intended for human use that is exempted from the requirements of this subsection under subsection (m) or is within a type that has been classified into class I under section 360c of this title. The exception established in the preceding sentence does not apply to any class I device that is intended for a use which is of substantial importance in preventing impairment of human health, or to any class I device that presents a potential unreasonable risk of illness or injury.

(2) Not later than 120 calendar days after December 13, 2016, and at least once every 5 years thereafter, as the Secretary determines appropriate, the Secretary shall identify, through publication in the Federal Register, any type of class I device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness. Upon such publication-

(A) each type of class I device so identified shall be exempt from the requirement for a report under subsection (k); and

(B) the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.

(m) List of exempt class II devices; initial and final determinations by Secretary; publication in Federal Register

(1) The Secretary shall-

(A) not later than 90 days after December 13, 2016, and at least once every 5 years thereafter, as the Secretary determines appropriate-

(i) publish in the Federal Register a notice that contains a list of each type of class II device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness; and

(ii) provide for a period of not less than 60 calendar days for public comment beginning on the date of the publication of such notice; and

(B) not later than 210 calendar days after December 13, 2016, publish in the Federal Register a list representing the Secretary's final determination with respect to the devices contained in the list published under subparagraph (A).

(2) Beginning on the date that is 1 calendar day after the date of publication of the final list under paragraph (1)(B), the Secretary may exempt a class II device from the requirement to submit a report under subsection (k), upon the Secretary's own initiative or a petition of an interested person, if the Secretary determines that such report is not necessary to assure the safety and effectiveness of the device. The Secretary shall publish in the Federal Register notice of the intent of the Secretary to exempt the device, or of the petition, and provide a 60-calendar-day period for public comment. Within 120 days after the issuance of the notice in the

Federal Register, the Secretary shall publish an order in the Federal Register that sets forth the final determination of the Secretary regarding the exemption of the device that was the subject of the notice. If the Secretary fails to respond to a petition within 180 days of receiving it, the petition shall be deemed to be granted.

(3) Upon the publication of the final list under paragraph (1)(B)-

(A) each type of class II device so listed shall be exempt from the requirement for a report under subsection (k); and

(B) the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.

(n) Review of report; time for determination by Secretary

(1) The Secretary shall review the report required in subsection (k) and make a determination under section 360c(f)(1) of this title not later than 90 days after receiving the report.

(2)(A) Not later than 18 months after July 9, 2012, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report regarding when a premarket notification under subsection (k) should be submitted for a modification or change to a legally marketed device. The report shall include the Secretary's interpretation of the following terms: "could significantly affect the safety or effectiveness of the device", "a significant change or modification in

design, material, chemical composition, energy source, or manufacturing process", and "major change or modification in the intended use of the device". The report also shall discuss possible processes for industry to use to determine whether a new submission under subsection (k) is required and shall analyze how to leverage existing quality system requirements to reduce premarket burden, facilitate continual device improvement, and provide reasonable assurance of safety and effectiveness of modified devices. In developing such report, the Secretary shall consider the input of interested stakeholders.

(B) The Secretary shall withdraw the Food and Drug Administration draft guidance entitled "Guidance for Industry and FDA Staff-510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device", dated July 27, 2011, and shall not use this draft guidance as part of, or for the basis of, any premarket review or any compliance or enforcement decisions or actions. The Secretary shall not issue-

> (i) any draft guidance or proposed regulation that addresses when to submit a premarket notification submission for changes and modifications made to a manufacturer's previously cleared device before the receipt by the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate of the report required in subparagraph (A); and
>
> (ii) any final guidance or regulation on that topic for one year after date of receipt

of such report by the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate.

(C) The Food and Drug Administration guidance entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device", dated January 10, 1997, shall be in effect until the subsequent issuance of guidance or promulgation, if appropriate, of a regulation described in subparagraph (B), and the Secretary shall interpret such guidance in a manner that is consistent with the manner in which the Secretary has interpreted such guidance since 1997.

(o) Reprocessed single-use devices

(1) With respect to reprocessed single-use devices for which reports are required under subsection (k):

(A) The Secretary shall identify such devices or types of devices for which reports under such subsection must, in order to ensure that the device is substantially equivalent to a predicate device, include validation data, the types of which shall be specified by the Secretary, regarding cleaning and sterilization, and functional performance demonstrating that the single-use device will remain substantially equivalent to its predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification. Within six months after October 26, 2002, the Secretary shall publish in the Federal

Register a list of the types so identified, and shall revise the list as appropriate. Reports under subsection (k) for devices or types of devices within a type included on the list are, upon publication of the list, required to include such validation data.

(B) In the case of each report under subsection (k) that was submitted to the Secretary before the publication of the initial list under subparagraph (A), or any revision thereof, and was for a device or type of device included on such list, the person who submitted the report under subsection (k) shall submit validation data as described in subparagraph (A) to the Secretary not later than nine months after the publication of the list. During such nine-month period, the Secretary may not take any action under this chapter against such device solely on the basis that the validation data for the device have not been submitted to the Secretary. After the submission of the validation data to the Secretary, the Secretary may not determine that the device is misbranded under section 352(o) of this title or adulterated under section 351(f)(1)(B) of this title, or take action against the device under section 331(p) of this title for failure to provide any information required by subsection (k) until (i) the review is terminated by withdrawal of the submission of the report under subsection (k); (ii) the Secretary finds the data to be acceptable and issues a letter; or (iii) the Secretary determines that the

device is not substantially equivalent to a predicate device. Upon a determination that a device is not substantially equivalent to a predicate device, or if such submission is withdrawn, the device can no longer be legally marketed.

(C) In the case of a report under subsection (k) for a device identified under subparagraph (A) that is of a type for which the Secretary has not previously received a report under such subsection, the Secretary may, in advance of revising the list under subparagraph (A) to include such type, require that the report include the validation data specified in subparagraph (A).

(D) Section 352(o) of this title applies with respect to the failure of a report under subsection (k) to include validation data required under subparagraph (A).

(2) With respect to critical or semi-critical reprocessed single-use devices that, under subsection (l) or (m), are exempt from the requirement of submitting reports under subsection (k):

(A) The Secretary shall identify such devices or types of devices for which such exemptions should be terminated in order to provide a reasonable assurance of the safety and effectiveness of the devices. The Secretary shall publish in the Federal Register a list of the devices or types of devices so identified, and shall revise the list as appropriate. The exemption for each device or type included on the list is

terminated upon the publication of the list. For each report under subsection (k) submitted pursuant to this subparagraph the Secretary shall require the validation data described in paragraph (1)(A).

(B) For each device or type of device included on the list under subparagraph (A), a report under subsection (k) shall be submitted to the Secretary not later than 15 months after the publication of the initial list, or a revision of the list, whichever terminates the exemption for the device. During such 15-month period, the Secretary may not take any action under this chapter against such device solely on the basis that such report has not been submitted to the Secretary. After the submission of the report to the Secretary the Secretary may not determine that the device is misbranded under section 352(o) of this title or adulterated under section 351(f)(1)(B) of this title, or take action against the device under section 331(p) of this title for failure to provide any information required by subsection (k) until (i) the review is terminated by withdrawal of the submission; (ii) the Secretary determines by order that the device is substantially equivalent to a predicate device; or (iii) the Secretary determines by order that the device is not substantially equivalent to a predicate device. Upon a determination that a device is not substantially equivalent to a predicate

device, the device can no longer be legally marketed.

(C) In the case of semi-critical devices, the initial list under subparagraph (A) shall be published not later than 18 months after the effective date of this subsection. In the case of critical devices, the initial list under such subparagraph shall be published not later than six months after such effective date.

(D) Section 352(o) of this title applies with respect to the failure to submit a report under subsection (k) that is required pursuant to subparagraph (A), including a failure of the report to include validation data required in such subparagraph.

(E) The termination under subparagraph (A) of an exemption under subsection (l) or (m) for a critical or semi-critical reprocessed single-use device does not terminate the exemption under subsection (l) or (m) for the original device.

(p) Electronic registration and listing

(1) In general

Registrations and listings under this section (including the submission of updated information) shall be submitted to the Secretary by electronic means unless the Secretary grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting such waiver.

(2) Electronic database

Not later than 2 years after the Secretary specifies a unique facility identifier system under subsections (b) and (i), the Secretary shall maintain an electronic database, which shall not be subject to inspection under subsection (f), populated with the information submitted as described under paragraph (1) that-

(A) enables personnel of the Food and Drug Administration to search the database by any field of information submitted in a registration described under paragraph (1), or combination of such fields; and

(B) uses the unique facility identifier system to link with other relevant databases within the Food and Drug Administration, including the database for submission of information under section 381(r) of this title.

(3) Risk-based information and coordination

The Secretary shall ensure the accuracy and coordination of relevant Food and Drug Administration databases in order to identify and inform risk-based inspections under subsection (h).

(q) Reusable medical devices

(1) In general

Not later than 180 days after December 13, 2016, the Secretary shall identify and publish a list of reusable device types for which reports under subsection (k) are required to include-

(A) instructions for use, which have been validated in a manner specified by the Secretary; and

(B) validation data, the types of which shall be specified by the Secretary;

regarding cleaning, disinfection, and sterilization, and for which a substantial equivalence determination may be based.

(2) Revision of list

The Secretary shall revise the list under paragraph (2),[3] as the Secretary determines appropriate, with notice in the Federal Register.

(3) Content of reports

Reports under subsection (k) that are submitted after the publication of the list described in paragraph (1), for devices or types of devices included on such list, shall include such instructions for use and validation data.

21 USC § 360c

(a) Classes of devices

(1) There are established the following classes of devices intended for human use:

(A) Class I, General Controls.-

(i) A device for which the controls authorized by or under section 351, 352, 360, 360f, 360h, 360i, or 360j of this title or any combination of such sections are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

(ii) A device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but because it-

(I) is not 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, and

(II) does not present a potential unreasonable risk of illness or injury,

is to be regulated by the controls referred to in clause (i).

(B) Class II, Special Controls.-A device which cannot be classified as a class I device because the general controls by

themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 360(k) of this title), recommendations, and other appropriate actions as the Secretary deems necessary to provide such assurance. For a device that is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall examine and identify the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness and describe how such controls provide such assurance.

(C) Class III, Premarket Approval.-A device which because-

(i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and (II) cannot be classified as a class II device because insufficient information exists to determine that the special controls described in subparagraph (B)

would provide reasonable assurance of its safety and effectiveness, and

(ii)(I) is 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, or

(II) presents a potential unreasonable risk of illness or injury,

is to be subject, in accordance with section 360e of this title, to premarket approval to provide reasonable assurance of its safety and effectiveness.

If there is not sufficient information to establish a performance standard for a device to provide reasonable assurance of its safety and effectiveness, the Secretary may conduct such activities as may be necessary to develop or obtain such information.

(2) For purposes of this section and sections 360d and 360e of this title, the safety and effectiveness of a device are to be determined-

(A) with respect to the persons for whose use the device is represented or intended,

(B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and

(C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

(3)(A) Except as authorized by subparagraph (B), the effectiveness of a device is, for purposes of this section and sections 360d and 360e of this title, to be

determined, in accordance with regulations promulgated by the Secretary, on the basis of well-controlled investigations, including 1 or more clinical investigations where appropriate, by experts qualified by training and experience to evaluate the effectiveness of the device, from which investigations it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device.

(B) If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A))-

> (i) which is sufficient to determine the effectiveness of a device, and
>
> (ii) from which it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device,

then, for purposes of this section and sections 360d and 360e of this title, the Secretary may authorize the effectiveness of the device to be determined on the basis of such evidence.

(C) In making a determination of a reasonable assurance of the effectiveness of a device for which an application under section 360e of this title has been submitted, the Secretary shall consider whether the extent of data that otherwise would be required for approval of the application with respect

to effectiveness can be reduced through reliance on postmarket controls.

(D)(i) The Secretary, upon the written request of any person intending to submit an application under section 360e of this title, shall meet with such person to determine the type of valid scientific evidence (within the meaning of subparagraphs (A) and (B)) that will be necessary to demonstrate for purposes of approval of an application the effectiveness of a device for the conditions of use proposed by such person. The written request shall include a detailed description of the device, a detailed description of the proposed conditions of use of the device, a proposed plan for determining whether there is a reasonable assurance of effectiveness, and, if available, information regarding the expected performance from the device. Within 30 days after such meeting, the Secretary shall specify in writing the type of valid scientific evidence that will provide a reasonable assurance that a device is effective under the conditions of use proposed by such person.

(ii) Any clinical data, including one or more well-controlled investigations, specified in writing by the Secretary for demonstrating a reasonable assurance of device effectiveness shall be specified as result of a determination by the Secretary that such data are necessary to establish device effectiveness. The Secretary shall consider, in consultation with the applicant, the least burdensome appropriate means of evaluating device effectiveness that would have a reasonable likelihood of resulting in approval.

(iii) For purposes of clause (ii), the term "necessary" means the minimum required information that would support a determination by the Secretary that an application provides

reasonable assurance of the effectiveness of the device.

(iv) Nothing in this subparagraph shall alter the criteria for evaluating an application for premarket approval of a device.

(v) The determination of the Secretary with respect to the specification of valid scientific evidence under clauses (i) and (ii) shall be binding upon the Secretary, unless such determination by the Secretary could be contrary to the public health.

(b) Classification panels

(1) For purposes of-

(A) determining which devices intended for human use should be subject to the requirements of general controls, performance standards, or premarket approval, and

(B) providing notice to the manufacturers and importers of such devices to enable them to prepare for the application of such requirements to devices manufactured or imported by them,

the Secretary shall classify all such devices (other than devices classified by subsection (f)) into the classes established by subsection (a). For the purpose of securing recommendations with respect to the classification of devices, the Secretary shall establish panels of experts or use panels of experts established before May 28, 1976, or both. Section 14 of the Federal Advisory Committee Act shall not apply to the duration of a panel established under this paragraph.

(2) The Secretary shall appoint to each panel established under paragraph (1) persons who are qualified by training and experience to evaluate the safety and effectiveness of the devices to be referred to the panel and who, to the extent feasible, possess skill in the use of, or experience in the development, manufacture, or utilization of, such devices. The Secretary shall make appointments to each panel so that each panel shall consist of members with adequately diversified expertise in such fields as clinical and administrative medicine, engineering, biological and physical sciences, and other related professions. In addition, each panel shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry. Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this chapter may be a member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

(3) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, but not at rates exceeding the daily equivalent of the rate in effect for grade GS–18 of the General Schedule, for each day so engaged, including traveltime; and while so serving away from their homes or regular places of business each member may be allowed travel expenses (including per diem

in lieu of subsistence) as authorized by section 5703 of title 5, for persons in the Government service employed intermittently.

(4) The Secretary shall furnish each panel with adequate clerical and other necessary assistance.

(5)(A) Classification panels covering each type of device shall be scheduled to meet at such times as may be appropriate for the Secretary to meet applicable statutory deadlines.

(B) When a device is specifically the subject of review by a classification panel, the Secretary shall-

(i) ensure that adequate expertise is represented on the classification panel to assess-

(I) the disease or condition which the device is intended to cure, treat, mitigate, prevent, or diagnose; and

(II) the technology of the device; and

(ii) provide an opportunity for the person whose device is specifically the subject of panel review to provide recommendations on the expertise needed among the voting members of the panel.

(C) For purposes of subparagraph (B)(i), the term "adequate expertise" means that the membership of the classification panel includes-

(i) two or more voting members, with a specialty or other expertise clinically relevant to the device under review; and

(ii) at least one voting member who is knowledgeable about the technology of the device.

(D) The Secretary shall provide an annual opportunity for patients, representatives of patients, and sponsors of medical device submissions to provide recommendations for individuals with appropriate expertise to fill voting member positions on classification panels.

(6)(A) Any person whose device is specifically the subject of review by a classification panel shall have-

(i) the same access to data and information submitted to a classification panel (except for data and information that are not available for public disclosure under section 552 of title 5) as the Secretary;

(ii) the opportunity to submit, for review by a classification panel, information that is based on the data or information provided in the application submitted under section 360e of this title by the person, which information shall be submitted to the Secretary for prompt transmittal to the classification panel; and

(iii) the same opportunity as the Secretary to participate in meetings of the panel, including, subject to the discretion of the panel chairperson, by designating a representative who will be provided a time during the panel meeting to address the panel for the purpose of correcting misstatements of fact or providing clarifying information, and permitting the person or representative to call on experts within the person's organization to address such specific issues in the time provided.

(B)(i) Any meeting of a classification panel with respect to the review of a device shall-

(I) provide adequate time for initial presentations by the person whose device is specifically the subject of such review and by the Secretary; and

(II) encourage free and open participation by all interested persons.

(ii) Following the initial presentations described in clause (i), the panel may-

(I) pose questions to a designated representative described in subparagraph (A)(iii); and

(II) consider the responses to such questions in the panel's review of the device.

(7) After receiving from a classification panel the conclusions and recommendations of the panel on a matter that the panel has reviewed, the Secretary shall review the conclusions and recommendations, shall make a final decision on the matter in accordance with section 360e(d)(2) of this title, and shall notify the affected persons of the decision in writing and, if the decision differs from the conclusions and recommendations of the panel, shall include the reasons for the difference.

(8) A classification panel under this subsection shall not be subject to the annual chartering and annual report requirements of the Federal Advisory Committee Act.

(9) The Secretary shall classify an accessory under this section based on the intended use of the accessory, notwithstanding the classification of any

other device with which such accessory is intended to be used.

(c) Classification panel organization and operation

(1) The Secretary shall organize the panels according to the various fields of clinical medicine and fundamental sciences in which devices intended for human use are used. The Secretary shall refer a device to be classified under this section to an appropriate panel established or authorized to be used under subsection (b) for its review and for its recommendation respecting the classification of the device. The Secretary shall by regulation prescribe the procedure to be followed by the panels in making their reviews and recommendations. In making their reviews of devices, the panels, to the maximum extent practicable, shall provide an opportunity for interested persons to submit data and views on the classification of the devices.

(2)(A) Upon completion of a panel's review of a device referred to it under paragraph (1), the panel shall, subject to subparagraphs (B) and (C), submit to the Secretary its recommendation for the classification of the device. Any such recommendation shall (i) contain (I) a summary of the reasons for the recommendation, (II) a summary of the data upon which the recommendation is based, and (III) an identification of the risks to health (if any) presented by the device with respect to which the recommendation is made, and (ii) to the extent practicable, include a recommendation for the assignment of a priority for the application of the requirements of section 360d or 360e of this title to a device recommended to be classified in class II or class III.

(B) A recommendation of a panel for the classification of a device in class I shall include a recommendation as to whether the device should be exempted from the requirements of section 360, 360i, or 360j(f) of this title.

(C) In the case of a device which has been referred under paragraph (1) to a panel, and which-

(i) is intended to be implanted in the human body or is purported or represented to be for a use in supporting or sustaining human life, and

(ii)(I) has been introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or

(II) is within a type of device which was so introduced or delivered before such date and is substantially equivalent to another device within that type,

such panel shall recommend to the Secretary that the device be classified in class III unless the panel determines that classification of the device in such class is not necessary to provide reasonable assurance of its safety and effectiveness. If a panel does not recommend that such a device be classified in class III, it shall in its recommendation to the Secretary for the classification of the device set forth the reasons for not recommending classification of the device in such class.

(3) The panels shall submit to the Secretary within one year of the date funds are first appropriated for the implementation of this section their recommendations respecting all devices of a type introduced or delivered for introduction into

interstate commerce for commercial distribution before May 28, 1976.

(d) Panel recommendation; publication; priorities

(1) Upon receipt of a recommendation from a panel respecting a device, the Secretary shall publish in the Federal Register the panel's recommendation and a proposed regulation classifying such device and shall provide interested persons an opportunity to submit comments on such recommendation and the proposed regulation. After reviewing such comments, the Secretary shall, subject to paragraph (2), by regulation classify such device.

(2)(A) A regulation under paragraph (1) classifying a device in class I shall prescribe which, if any, of the requirements of section 360, 360i, or 360j(f) of this title shall not apply to the device. A regulation which makes a requirement of section 360, 360i, or 360j(f) of this title inapplicable to a device shall be accompanied by a statement of the reasons of the Secretary for making such requirement inapplicable.

(B) A device described in subsection (c)(2)(C) shall be classified in class III unless the Secretary determines that classification of the device in such class is not necessary to provide reasonable assurance of its safety and effectiveness. A proposed regulation under paragraph (1) classifying such a device in a class other than class III shall be accompanied by a full statement of the reasons of the Secretary (and supporting documentation and data) for not classifying such device in such class and an identification of the risks to health (if any) presented by such device.

(3) In the case of devices classified in class II and devices classified under this subsection in class III

and described in section 360e(b)(1) of this title the Secretary may establish priorities which, in his discretion, shall be used in applying sections 360d and 360e of this title, as appropriate, to such devices.

(e) Classification changes

(1)(A)(i) Based on new information respecting a device, the Secretary may, upon the initiative of the Secretary or upon petition of an interested person, change the classification of such device, and revoke, on account of the change in classification, any regulation or requirement in effect under section 360d or 360e of this title with respect to such device, by administrative order published in the Federal Register following publication of a proposed reclassification order in the Federal Register, a meeting of a device classification panel described in subsection (b), and consideration of comments to a public docket, notwithstanding subchapter II of chapter 5 of title 5. The proposed reclassification order published in the Federal Register shall set forth the proposed reclassification, and a substantive summary of the valid scientific evidence concerning the proposed reclassification, including-

(I) the public health benefit of the use of the device, and the nature and, if known, incidence of the risk of the device;

(II) in the case of a reclassification from class II to class III, why general controls pursuant to subsection (a)(1)(A) and special controls pursuant to subsection (a)(1)(B) together are not sufficient to provide a reasonable assurance of safety and effectiveness for such device; and

(III) in the case of reclassification from class III to class II, why general controls pursuant to subsection (a)(1)(A) and special controls pursuant to subsection (a)(1)(B) together are sufficient to provide a reasonable assurance of safety and effectiveness for such device.

(ii) An order under this subsection changing the classification of a device from class III to class II may provide that such classification shall not take effect until the effective date of a performance standard established under section 360d of this title for such device.

(B) Authority to issue such administrative order shall not be delegated below the Director of the Center for Devices and Radiological Health, acting in consultation with the Commissioner.

(2) By an order issued under paragraph (1), the Secretary may change the classification of a device from class III-

(A) to class II if the Secretary determines that special controls would provide reasonable assurance of the safety and effectiveness of the device and that general controls would not provide reasonable assurance of the safety and effectiveness of the device, or

(B) to class I if the Secretary determines that general controls would provide reasonable assurance of the safety and effectiveness of the device.

(f) Initial classification and reclassification of certain devices

(1) Any device intended for human use which was not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, is classified in class III unless-

(A) the device-

(i) is within a type of device (I) which was introduced or delivered for introduction into interstate commerce for commercial distribution before such date and which is to be classified pursuant to subsection (b), or (II) which was not so introduced or delivered before such date and has been classified in class I or II, and

(ii) is substantially equivalent to another device within such type;

(B) the Secretary in response to a petition submitted under paragraph (3) has classified such device in class I or II; or

(C) the device is classified pursuant to a request submitted under paragraph (2).

A device classified in class III under this paragraph shall be classified in that class until the effective date of an order of the Secretary under paragraph (2) or (3) classifying the device in class I or II.

(2)(A)(i) Any person who submits a report under section 360(k) of this title for a type of device that has not been previously classified under this chapter, and that is classified into class III under paragraph (1), may request, after receiving written notice of such a classification, the Secretary to classify the device.

(ii) In lieu of submitting a report under section 360(k) of this title and submitting a request for classification under clause (i) for a device, if a person determines there is no legally marketed device upon which to base a determination of substantial equivalence (as defined in subsection (i)), a person may submit a request under this clause for the Secretary to classify the device.

(iii) Upon receipt of a request under clause (i) or (ii), the Secretary shall classify the device subject to the request under the criteria set forth in subparagraphs (A) through (C) of subsection (a)(1) within 120 days.

(iv) Notwithstanding clause (iii), the Secretary may decline to undertake a classification request submitted under clause (ii) if the Secretary identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence under paragraph (1), or when the Secretary determines that the device submitted is not of low to moderate risk or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

(v) The person submitting the request for classification under this subparagraph may recommend to the Secretary a classification for the device and shall, if recommending classification in class II, include in the request an initial draft proposal for applicable special controls, as described in subsection (a)(1)(B), that are necessary, in conjunction with general controls, to provide reasonable assurance of safety and effectiveness and a description of how the special controls provide such assurance. Any such request shall describe the

device and provide detailed information and reasons for the recommended classification.

(B)(i) The Secretary shall by written order classify the device involved. Such classification shall be the initial classification of the device for purposes of paragraph (1) and any device classified under this paragraph shall be a predicate device for determining substantial equivalence under paragraph (1).

(ii) A device that remains in class III under this subparagraph shall be deemed to be adulterated within the meaning of section 351(f)(1)(B) of this title until approved under section 360e of this title or exempted from such approval under section 360j(g) of this title.

(C) Within 30 days after the issuance of an order classifying a device under this paragraph, the Secretary shall publish a notice in the Federal Register announcing such classification.

(3)(A) The Secretary may initiate the reclassification of a device classified into class III under paragraph (1) of this subsection or the manufacturer or importer of a device classified under paragraph (1) may petition the Secretary (in such form and manner as he shall prescribe) for the issuance of an order classifying the device in class I or class II. Within thirty days of the filing of such a petition, the Secretary shall notify the petitioner of any deficiencies in the petition which prevent the Secretary from making a decision on the petition.

(B)(i) Upon determining that a petition does not contain any deficiency which prevents the Secretary from making a decision on the petition, the Secretary may for good cause shown refer the petition to an appropriate panel established or authorized to be

used under subsection (b). A panel to which such a petition has been referred shall not later than ninety days after the referral of the petition make a recommendation to the Secretary respecting approval or denial of the petition. Any such recommendation shall contain (I) a summary of the reasons for the recommendation, (II) a summary of the data upon which the recommendation is based, and (III) an identification of the risks to health (if any) presented by the device with respect to which the petition was filed. In the case of a petition for a device which is intended to be implanted in the human body or which is purported or represented to be for a use in supporting or sustaining human life, the panel shall recommend that the petition be denied unless the panel determines that the classification in class III of the device is not necessary to provide reasonable assurance of its safety and effectiveness. If the panel recommends that such petition be approved, it shall in its recommendation to the Secretary set forth its reasons for such recommendation.

(ii) The requirements of paragraphs (1) and (2) of subsection (c) (relating to opportunities for submission of data and views and recommendations respecting priorities and exemptions from sections 360, 360i, and 360j(f) of this title) shall apply with respect to consideration by panels of petitions submitted under subparagraph (A).

(C)(i) Within ninety days from the date the Secretary receives the recommendation of a panel respecting a petition (but not later than 210 days after the filing of such petition) the Secretary shall by order deny or approve the petition. If the Secretary approves the petition, the Secretary shall

order the classification of the device into class I or class II in accordance with the criteria prescribed by subsection (a)(1)(A) or (a)(1)(B). In the case of a petition for a device which is intended to be implanted in the human body or which is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall deny the petition unless the Secretary determines that the classification in class III of the device is not necessary to provide reasonable assurance of its safety and effectiveness. An order approving such petition shall be accompanied by a full statement of the reasons of the Secretary (and supporting documentation and data) for approving the petition and an identification of the risks to health (if any) presented by the device to which such order applies.

(ii) The requirements of paragraphs (1) and (2)(A) of subsection (d) (relating to publication of recommendations, opportunity for submission of comments, and exemption from sections 360, 360i, and 360j(f) of this title) shall apply with respect to action by the Secretary on petitions submitted under subparagraph (A).

(4) If a manufacturer reports to the Secretary under section 360(k) of this title that a device is substantially equivalent to another device-

(A) which the Secretary has classified as a class III device under subsection (b),

(B) which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990, and

(C) for which no final regulation requiring premarket approval has been

promulgated under section 360e(b) of this title,

the manufacturer shall certify to the Secretary that the manufacturer has conducted a reasonable search of all information known or otherwise available to the manufacturer respecting such other device and has included in the report under section 360(k) of this title a summary of and a citation to all adverse safety and effectiveness data respecting such other device and respecting the device for which the section 360(k) report is being made and which has not been submitted to the Secretary under section 360i of this title. The Secretary may require the manufacturer to submit the adverse safety and effectiveness data described in the report.

(5) The Secretary may not withhold a determination of the initial classification of a device under paragraph (1) because of a failure to comply with any provision of this chapter unrelated to a substantial equivalence decision, including a finding that the facility in which the device is manufactured is not in compliance with good manufacturing requirements as set forth in regulations of the Secretary under section 360j(f) of this title (other than a finding that there is a substantial likelihood that the failure to comply with such regulations will potentially present a serious risk to human health).

(g) Information

Within sixty days of the receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under this chapter, the Secretary shall provide such person a

written statement of the classification (if any) of such device and the requirements of this chapter applicable to the device.

(h) Definitions

For purposes of this section and sections 351, 360, 360d, 360e, 360f, 360i, and 360j of this title

(1) a reference to "general controls" is a reference to the controls authorized by or under sections 351, 352, 360, 360f, 360h, 360i, and 360j of this title,

(2) a reference to "class I", "class II", or "class III" is a reference to a class of medical devices described in subparagraph (A), (B), or (C) of subsection (a)(1), and

(3) a reference to a "panel under section 360c of this title" is a reference to a panel established or authorized to be used under this section.

(i) Substantial equivalence

(1)(A) For purposes of determinations of substantial equivalence under subsection (f) and section 360j(l) of this title, the term "substantially equivalent" or "substantial equivalence" means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device-

(i) has the same technological characteristics as the predicate device, or

(ii)(I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical

> or scientific data if deemed necessary by the Secretary or a person accredited under section 360m of this title, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the predicate device.

(B) For purposes of subparagraph (A), the term "different technological characteristics" means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device.

(C) To facilitate reviews of reports submitted to the Secretary under section 360(k) of this title, the Secretary shall consider the extent to which reliance on postmarket controls may expedite the classification of devices under subsection (f)(1) of this section.

(D)(i) Whenever the Secretary requests information to demonstrate that devices with differing technological characteristics are substantially equivalent, the Secretary shall only request information that is necessary to making substantial equivalence determinations. In making such request, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and request information accordingly.

(ii) For purposes of clause (i), the term "necessary" means the minimum required information that would support a determination of substantial equivalence between a new device and a predicate device.

(iii) Nothing in this subparagraph shall alter the standard for determining substantial equivalence between a new device and a predicate device.

(E)(i) Any determination by the Secretary of the intended use of a device shall be based upon the proposed labeling submitted in a report for the device under section 360(k) of this title. However, when determining that a device can be found substantially equivalent to a legally marketed device, the director of the organizational unit responsible for regulating devices (in this subparagraph referred to as the "Director") may require a statement in labeling that provides appropriate information regarding a use of the device not identified in the proposed labeling if, after providing an opportunity for consultation with the person who submitted such report, the Director determines and states in writing-

(I) that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device; and

(II) that such use could cause harm.

(ii) Such determination shall-

(I) be provided to the person who submitted the report within 10 days from the date of the notification of the Director's concerns regarding the proposed labeling;

(II) specify the limitations on the use of the device not included in the proposed labeling; and

(III) find the device substantially equivalent if the requirements of subparagraph (A) are met and if the

labeling for such device conforms to the limitations specified in subclause (II).

(iii) The responsibilities of the Director under this subparagraph may not be delegated.

(F) Not later than 270 days after November 21, 1997, the Secretary shall issue guidance specifying the general principles that the Secretary will consider in determining when a specific intended use of a device is not reasonably included within a general use of such device for purposes of a determination of substantial equivalence under subsection (f) or section 360j(l) of this title.

(2) A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.

(3)(A) As part of a submission under section 360(k) of this title respecting a device, the person required to file a premarket notification under such section shall provide an adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request by any person.

(B) Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such device is substantially equivalent to another device.

(j) Training and oversight of least burdensome requirements

(1) The Secretary shall-

(A) ensure that each employee of the Food and Drug Administration who is involved in the review of premarket submissions, including supervisors, receives training regarding the meaning and implementation of the least burdensome requirements under subsections (a)(3)(D) and (i)(1)(D) of this section and section 360e(c)(5) of this title; and

(B) periodically assess the implementation of the least burdensome requirements, including the employee training under subparagraph (A), to ensure that the least burdensome requirements are fully and consistently applied.

(2) Not later than 18 months after December 13, 2016, the ombudsman for any organizational unit of the Food and Drug Administration responsible for the premarket review of devices shall-

(A) conduct an audit of the training described in paragraph (1)(A), including the effectiveness of such training in implementing the least burdensome requirements;

(B) include in such audit interviews of persons who are representatives of the device industry regarding their experiences in the device premarket review process, including with respect to the application of least burdensome concepts to premarket review and decisionmaking;

(C) include in such audit a list of the measurement tools the Secretary uses to assess the implementation of the least burdensome requirements, including under paragraph (1)(B) and section 360g–1(a)(3) of this title, and may also provide feedback on the effectiveness of such tools in the implementation of the least burdensome requirements;

(D) summarize the findings of such audit in a final audit report; and

(E) within 30 calendar days of completion of such final audit report, make such final audit report available-

(i) to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives; and

(ii) on the Internet website of the Food and Drug Administration.

21 USC § 360e

(a) General requirement

A class III device-

(1) which is subject to an order issued under subsection (b) (or a regulation promulgated under such subsection prior to July 9, 2012); or

(2) which is a class III device because of section 360c(f) of this title,

is required to have, unless exempt under section 360j(g) of this title, an approval under this section of an application for premarket approval or, as applicable, an approval under subsection (c)(2) of a report seeking premarket approval.

(b) Order to require premarket approval

(1) In the case of a class III device which-

(A) was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976; or

(B) is (i) of a type so introduced or delivered, and (ii) is substantially equivalent to another device within that type,

the Secretary shall by administrative order following publication of a proposed order in the Federal Register, a meeting of a device classification panel described in section 360c(b) of this title, and consideration of comments from all affected stakeholders, including patients, payors, and providers, notwithstanding subchapter II of chapter 5 of title 5, require that such device have an

approval under this section of an application for premarket approval. Authority to issue such administrative order shall not be delegated below the Director of the Center for Devices and Radiological Health, acting in consultation with the Commissioner.

(2) A proposed order required under paragraph (1) shall contain-

(A) the proposed order;

(B) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved application for premarket approval and the benefit to the public from use of the device;

(C) opportunity for the submission of comments on the proposed order and the proposed findings; and

(D) opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

(3) After the expiration of the period for comment on a proposed order and proposed findings published under paragraph (2), consideration of comments submitted on such proposed order and findings, and a meeting of a device classification panel described in section 360c(b) of this title, the Secretary shall (A) issue an administrative order under paragraph (1) and publish in the Federal Register findings on the matters referred to in paragraph (2)(B), or (B) publish a notice terminating the proceeding for the issuance of the administrative order together with the reasons for such termination. If a notice of

termination is published, the Secretary shall (unless such notice is issued because the device is a banned device under section 360f of this title) initiate a proceeding under section 360c(e) of this title to reclassify the device subject to the proceeding terminated by such notice.

(c) Application for premarket approval

(1) Any person may file with the Secretary an application for premarket approval for a class III device. Such an application for a device shall contain-

(A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;

(B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device;

(D) an identifying reference to any performance standard under section 360d of this title which would be applicable to any aspect of such device if it were a class II device, and either adequate information to show that such aspect of such device fully meets such performance standard or

adequate information to justify any deviation from such standard;

(E) such samples of such device and of components thereof as the Secretary may reasonably require, except that where the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of one or more such devices readily available for examination and testing;

(F) specimens of the labeling proposed to be used for such device;

(G) the certification required under section 282(j)(5)(B) of title 42 (which shall not be considered an element of such application); and

(H) such other information relevant to the subject matter of the application as the Secretary, with the concurrence of the appropriate panel under section 360c of this title, may require.

(2)(A) Any person may file with the Secretary a report seeking premarket approval for a class III device referred to in subsection (a) that is a reprocessed single-use device. Such a report shall contain the following:

(i) The device name, including both the trade or proprietary name and the common or usual name.

(ii) The establishment registration number of the owner or operator submitting the report.

(iii) Actions taken to comply with performance standards under section 360d of this title.

(iv) Proposed labels, labeling, and advertising sufficient to describe the device, its intended use, and directions for use.

(v) Full reports of all information, published or known to or which should be reasonably known to the applicant, concerning investigations which have been made to show whether or not the device is safe or effective.

(vi) A description of the device's components, ingredients, and properties.

(vii) A full description of the methods used in, and the facilities and controls used for, the reprocessing and packing of the device.

(viii) Such samples of the device that the Secretary may reasonably require.

(ix) A financial certification or disclosure statement or both, as required by part 54 of title 21, Code of Federal Regulations.

(x) A statement that the applicant believes to the best of the applicant's knowledge that all data and information submitted to the Secretary are truthful and accurate and that no material fact has been omitted in the report.

(xi) Any additional data and information, including information of the type required in paragraph (1) for an application under such paragraph, that the Secretary determines is necessary to determine whether there is reasonable assurance of

safety and effectiveness for the reprocessed device.

(xii) Validation data described in section 360(o)(1)(A) of this title that demonstrates that the reasonable assurance of the safety or effectiveness of the device will remain after the maximum number of times the device is reprocessed as intended by the person submitting such report.

(B) In the case of a class III device referred to in subsection (a) that is a reprocessed single-use device:

(i) Subparagraph (A) of this paragraph applies in lieu of paragraph (1).

(ii) Subject to clause (i), the provisions of this section apply to a report under subparagraph (A) to the same extent and in the same manner as such provisions apply to an application under paragraph (1).

(iii) Each reference in other sections of this chapter to an application under this section, other than such a reference in section 379i or 379j of this title, shall be considered to be a reference to a report under subparagraph (A).

(iv) Each reference in other sections of this chapter to a device for which an application under this section has been approved, or has been denied, suspended, or withdrawn, other than such a reference in section 379i or 379j of this title, shall be considered to be a reference to a device for which a report under subparagraph (A) has been approved, or has been denied, suspended, or withdrawn, respectively.

(3) Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary-

(A) may on the Secretary's own initiative, or

(B) shall, upon the request of an applicant unless the Secretary finds that the information in the application which would be reviewed by a panel substantially duplicates information which has previously been reviewed by a panel appointed under section 360c of this title,

refer such application to the appropriate panel under section 360c of this title for study and for submission (within such period as he may establish) of a report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation. Where appropriate, the Secretary shall ensure that such panel includes, or consults with, one or more pediatric experts.

(4)(A) Prior to the submission of an application under this subsection, the Secretary shall accept and review any portion of the application that the applicant and the Secretary agree is complete, ready, and appropriate for review, except that such requirement does not apply, and the Secretary has discretion whether to accept and review such portion, during any period in which, under section 379j(h) of this title, the Secretary does not have the authority to collect fees under section 379j(a) of this title.

(B) Each portion of a submission reviewed under subparagraph (A) and found acceptable by the

Secretary shall not be further reviewed after receipt of an application that satisfies the requirements of paragraph (1), unless a significant issue of safety or effectiveness provides the Secretary reason to review such accepted portion.

(C) Whenever the Secretary determines that a portion of a submission under subparagraph (A) is unacceptable, the Secretary shall, in writing, provide to the applicant a description of any deficiencies in such portion and identify the information that is required to correct these deficiencies, unless the applicant is no longer pursuing the application.

(5)(A) In requesting additional information with respect to an application under this section, the Secretary shall consider the least burdensome appropriate means necessary to demonstrate a reasonable assurance of device safety and effectiveness.

(B) For purposes of subparagraph (A), the term "necessary" means the minimum required information that would support a determination by the Secretary that an application provides a reasonable assurance of the safety and effectiveness of the device.

(C) For purposes of this paragraph, the Secretary shall consider the role of postmarket information in determining the least burdensome means of demonstrating a reasonable assurance of device safety and effectiveness.

(D) Nothing in this paragraph alters the standards for premarket approval of a device.

(d) Action on application for premarket approval

(1)(A) As promptly as possible, but in no event later than one hundred and eighty days after the

receipt of an application under subsection (c) (except as provided in section 360j(l)(3)(D)(ii) of this title or unless, in accordance with subparagraph (B)(i), an additional period as agreed upon by the Secretary and the applicant), the Secretary, after considering the report and recommendation submitted under paragraph (2) of such subsection, shall-

(i) issue an order approving the application if he finds that none of the grounds for denying approval specified in paragraph (2) of this subsection applies; or

(ii) deny approval of the application if he finds (and sets forth the basis for such finding as part of or accompanying such denial) that one or more grounds for denial specified in paragraph (2) of this subsection apply.

In making the determination whether to approve or deny the application, the Secretary shall rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness, if the proposed labeling is neither false nor misleading. In determining whether or not such labeling is false or misleading, the Secretary shall fairly evaluate all material facts pertinent to the proposed labeling.

(B)(i) The Secretary may not enter into an agreement to extend the period in which to take action with respect to an application submitted for a device subject to a regulation promulgated under subsection (b) unless he finds that the continued availability of the device is necessary for the public health.

(ii) An order approving an application for a device may require as a condition to such approval that the sale and distribution of the device be restricted but only to the extent that the sale and distribution of a device may be restricted under a regulation under section 360j(e) of this title.

(iii) The Secretary shall accept and review statistically valid and reliable data and any other information from investigations conducted under the authority of regulations required by section 360j(g) of this title to make a determination of whether there is a reasonable assurance of safety and effectiveness of a device subject to a pending application under this section if-

(I) the data or information is derived from investigations of an earlier version of the device, the device has been modified during or after the investigations (but prior to submission of an application under subsection (c)) and such a modification of the device does not constitute a significant change in the design or in the basic principles of operation of the device that would invalidate the data or information; or

(II) the data or information relates to a device approved under this section, is available for use under this chapter, and is relevant to the design and intended use of the device for which the application is pending.

(2) The Secretary shall deny approval of an application for a device if, upon the basis of the information submitted to the Secretary as part of the

application and any other information before him with respect to such device, the Secretary finds that-

(A) there is a lack of a showing of reasonable assurance that such device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

(B) there is a lack of a showing of reasonable assurance that the device is effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

(C) the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or installation of such device do not conform to the requirements of section 360j(f) of this title;

(D) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

(E) such device is not shown to conform in all respects to a performance standard in effect under section 360d of this title compliance with which is a condition to approval of the application and there is a lack of adequate information to justify the deviation from such standard.

Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to place such application in approvable form (which measures may include further research by the applicant in accordance with one or more protocols prescribed by the Secretary).

(3)(A)(i) The Secretary shall, upon the written request of an applicant, meet with the applicant, not later than 100 days after the receipt of an application that has been filed as complete under subsection (c), to discuss the review status of the application.

(ii) The Secretary shall, in writing and prior to the meeting, provide to the applicant a description of any deficiencies in the application that, at that point, have been identified by the Secretary based on an interim review of the entire application and identify the information that is required to correct those deficiencies.

(iii) The Secretary shall notify the applicant promptly of-

> (I) any additional deficiency identified in the application, or
>
> (II) any additional information required to achieve completion of the review and final action on the application,

that was not described as a deficiency in the written description provided by the Secretary under clause (ii).

(B) The Secretary and the applicant may, by mutual consent, establish a different schedule for a meeting required under this paragraph.

(4) An applicant whose application has been denied approval may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such denial, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g), and any interested person may obtain review, in accordance with paragraph (1) or (2) of

subsection (g), of an order of the Secretary approving an application.

(5)(A)(i) A supplemental application shall be required for any change to a device subject to an approved application under this subsection that affects safety or effectiveness, unless such change is a modification in a manufacturing procedure or method of manufacturing and the holder of the approved application submits a written notice to the Secretary that describes in detail the change, summarizes the data or information supporting the change, and informs the Secretary that the change has been made under the requirements of section 360j(f) of this title.

(ii) The holder of an approved application who submits a notice under clause (i) with respect to a manufacturing change of a device may distribute the device 30 days after the date on which the Secretary receives the notice, unless the Secretary within such 30-day period notifies the holder that the notice is not adequate and describes such further information or action that is required for acceptance of such change. If the Secretary notifies the holder that a supplemental application is required, the Secretary shall review the supplement within 135 days after the receipt of the supplement. The time used by the Secretary to review the notice of the manufacturing change shall be deducted from the 135-day review period if the notice meets appropriate content requirements for premarket approval supplements.

(B)(i) Subject to clause (ii), in reviewing a supplement to an approved application, for an incremental change to the design of a device that affects safety or effectiveness, the Secretary shall approve such supplement if-

(I) nonclinical data demonstrate that the design modification creates the intended additional capacity, function, or performance of the device; and

(II) clinical data from the approved application and any supplement to the approved application provide a reasonable assurance of safety and effectiveness for the changed device.

(ii) The Secretary may require, when necessary, additional clinical data to evaluate the design modification of the device to provide a reasonable assurance of safety and effectiveness.

(e) Withdrawal and temporary suspension of approval of application

(1) The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from a panel or panels under section 360c of this title, and after due notice and opportunity for informal hearing to the holder of an approved application for a device, issue an order withdrawing approval of the application if the Secretary finds-

(A) that such device is unsafe or ineffective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

(B) on the basis of new information before him with respect to such device, evaluated together with the evidence available to him when the application was approved, that there is a lack of a showing of reasonable assurance that the device is safe or effective under the conditions of use

prescribed, recommended, or suggested in the labeling thereof;

(C) that the application contained or was accompanied by an untrue statement of a material fact;

(D) that the applicant (i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 360i(a) of this title, (ii) has refused to permit access to, or copying or verification of, such records as required by section 374 of this title, or (iii) has not complied with the requirements of section 360 of this title;

(E) on the basis of new information before him with respect to such device, evaluated together with the evidence before him when the application was approved, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such device do not conform with the requirements of section 360j(f) of this title and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

(F) on the basis of new information before him, evaluated together with the evidence before him when the application was approved, that the labeling of such device, based on a fair evaluation of all material facts, is false or misleading in any

particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or

(G) on the basis of new information before him, evaluated together with the evidence before him when the application was approved, that such device is not shown to conform in all respects to a performance standard which is in effect under section 360d of this title compliance with which was a condition to approval of the application and that there is a lack of adequate information to justify the deviation from such standard.

(2) The holder of an application subject to an order issued under paragraph (1) withdrawing approval of the application may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such withdrawal, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g).

(3) If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a device under an approved application would cause serious, adverse health consequences or death, the Secretary shall by order temporarily suspend the approval of the application approved under this section. If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw such application.

(f) Product development protocol

(1) In the case of a class III device which is required to have an approval of an application submitted under subsection (c), such device shall be considered as having such an approval if a notice of completion of testing conducted in accordance with a product development protocol approved under paragraph (4) has been declared completed under paragraph (6).

(2) Any person may submit to the Secretary a proposed product development protocol with respect to a device. Such a protocol shall be accompanied by data supporting it. If, within thirty days of the receipt of such a protocol, the Secretary determines that it appears to be appropriate to apply the requirements of this subsection to the device with respect to which the protocol is submitted, the Secretary-

(A) may, at the initiative of the Secretary, refer the proposed protocol to the appropriate panel under section 360c of this title for its recommendation respecting approval of the protocol; or

(B) shall so refer such protocol upon the request of the submitter, unless the Secretary finds that the proposed protocol and accompanying data which would be reviewed by such panel substantially duplicate a product development protocol and accompanying data which have previously been reviewed by such a panel.

(3) A proposed product development protocol for a device may be approved only if-

(A) the Secretary determines that it is appropriate to apply the requirements of

this subsection to the device in lieu of the requirement of approval of an application submitted under subsection (c); and

(B) the Secretary determines that the proposed protocol provides-

(i) a description of the device and the changes which may be made in the device,

(ii) a description of the preclinical trials (if any) of the device and a specification of (I) the results from such trials to be required before the commencement of clinical trials of the device, and (II) any permissible variations in preclinical trials and the results therefrom,

(iii) a description of the clinical trials (if any) of the device and a specification of (I) the results from such trials to be required before the filing of a notice of completion of the requirements of the protocol, and (II) any permissible variations in such trials and the results therefrom,

(iv) a description of the methods to be used in, and the facilities and controls to be used for, the manufacture, processing, and, when relevant, packing and installation of the device,

(v) an identifying reference to any performance standard under section 360d of this title to be applicable to any aspect of such device,

(vi) if appropriate, specimens of the labeling proposed to be used for such device,

(vii) such other information relevant to the subject matter of the protocol as the Secretary, with the concurrence of the appropriate panel or panels under section 360c of this title, may require, and

(viii) a requirement for submission of progress reports and, when completed, records of the trials conducted under the protocol which records are adequate to show compliance with the protocol.

(4) The Secretary shall approve or disapprove a proposed product development protocol submitted under paragraph (2) within one hundred and twenty days of its receipt unless an additional period is agreed upon by the Secretary and the person who submitted the protocol. Approval of a protocol or denial of approval of a protocol is final agency action subject to judicial review under chapter 7 of title 5.

(5) At any time after a product development protocol for a device has been approved pursuant to paragraph (4), the person for whom the protocol was approved may submit a notice of completion-

(A) stating (i) his determination that the requirements of the protocol have been fulfilled and that, to the best of his knowledge, there is no reason bearing on safety or effectiveness why the notice of completion should not become effective, and (ii) the data and other information upon which such determination was made, and

(B) setting forth the results of the trials required by the protocol and all the information required by subsection (c)(1).

(6)(A) The Secretary may, after providing the person who has an approved protocol and opportunity for an informal hearing and at any time prior to receipt of notice of completion of such protocol, issue a final order to revoke such protocol if he finds that-

(i) such person has failed substantially to comply with the requirements of the protocol,

(ii) the results of the trials obtained under the protocol differ so substantially from the results required by the protocol that further trials cannot be justified, or

(iii) the results of the trials conducted under the protocol or available new information do not demonstrate that the device tested under the protocol does not present an unreasonable risk to health and safety.

(B) After the receipt of a notice of completion of an approved protocol the Secretary shall, within the ninety-day period beginning on the date such notice is received, by order either declare the protocol completed or declare it not completed. An order declaring a protocol not completed may take effect only after the Secretary has provided the person who has the protocol opportunity for an informal hearing on the order. Such an order may be issued only if the Secretary finds-

(i) such person has failed substantially to comply with the requirements of the protocol,

(ii) the results of the trials obtained under the protocol differ substantially from the results required by the protocol, or

(iii) there is a lack of a showing of reasonable assurance of the safety and effectiveness of the device under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.

(C) A final order issued under subparagraph (A) or (B) shall be in writing and shall contain the reasons to support the conclusions thereof.

(7) At any time after a notice of completion has become effective, the Secretary may issue an order (after due notice and opportunity for an informal hearing to the person for whom the notice is effective) revoking the approval of a device provided by a notice of completion which has become effective as provided in subparagraph (B) if he finds that any of the grounds listed in subparagraphs (A) through (G) of subsection (e)(1) of this section apply. Each reference in such subparagraphs to an application shall be considered for purposes of this paragraph as a reference to a protocol and the notice of completion of such protocol, and each reference to the time when an application was approved shall be considered for purposes of this paragraph as a reference to the time when a notice of completion took effect.

(8) A person who has an approved protocol subject to an order issued under paragraph (6)(A) revoking such protocol, a person who has an approved protocol

with respect to which an order under paragraph (6)(B) was issued declaring that the protocol had not been completed, or a person subject to an order issued under paragraph (7) revoking the approval of a device may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such order, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g).

(g) Review

(1) Upon petition for review of-

(A) an order under subsection (d) approving or denying approval of an application or an order under subsection (e) withdrawing approval of an application, or

(B) an order under subsection (f)(6)(A) revoking an approved protocol, under subsection (f)(6)(B) declaring that an approved protocol has not been completed, or under subsection (f)(7) revoking the approval of a device,

the Secretary shall, unless he finds the petition to be without good cause or unless a petition for review of such order has been submitted under paragraph (2), hold a hearing, in accordance with section 554 of title 5, on the order. The panel or panels which considered the application, protocol, or device subject to such order shall designate a member to appear and testify at any such hearing upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this requirement does not preclude any other member of the panel or panels from appearing and testifying at any such hearing. Upon

completion of such hearing and after considering the record established in such hearing, the Secretary shall issue an order either affirming the order subject to the hearing or reversing such order and, as appropriate, approving or denying approval of the application, reinstating the application's approval, approving the protocol, or placing in effect a notice of completion.

(2)(A) Upon petition for review of-

(i) an order under subsection (d) approving or denying approval of an application or an order under subsection (e) withdrawing approval of an application, or

(ii) an order under subsection (f)(6)(A) revoking an approved protocol, under subsection (f)(6)(B) declaring that an approved protocol has not been completed, or under subsection (f)(7) revoking the approval of a device,

the Secretary shall refer the application or protocol subject to the order and the basis for the order to an advisory committee of experts established pursuant to subparagraph (B) for a report and recommendation with respect to the order. The advisory committee shall, after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation, together with all underlying data and information and a statement of the reasons or basis for the recommendation. A copy of such report shall be promptly supplied by the Secretary to any person who petitioned for such referral to the advisory committee.

(B) The Secretary shall establish advisory committees (which may not be panels under section 360c of this title) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional backgrounds, except that the Secretary may not appoint to such a committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this chapter. Members of an advisory committee (other than officers or employees of the United States), while attending conferences or meetings of their committee or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent for grade GS–18 of the General Schedule for each day (including traveltime) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 for persons in the Government service employed intermittently. The Secretary shall designate the chairman of an advisory committee from its members. The Secretary shall furnish each advisory committee with clerical and other assistance, and shall by regulation prescribe the procedures to be followed by each such committee in acting on referrals made under subparagraph (A).

(C) The Secretary shall make public the report and recommendation made by an advisory committee with respect to an application and shall by order,

stating the reasons therefor, either affirm the order referred to the advisory committee or reverse such order and, if appropriate, approve or deny approval of the application, reinstate the application's approval, approve the protocol, or place in effect a notice of completion.

(h) Service of orders

Orders of the Secretary under this section shall be served (1) in person by any officer or employee of the department designated by the Secretary, or (2) by mailing the order by registered mail or certified mail addressed to the applicant at his last known address in the records of the Secretary.

(i) Revision

(1) Before December 1, 1995, the Secretary shall by order require manufacturers of devices, which were introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and which are subject to revision of classification under paragraph (2), to submit to the Secretary a summary of and citation to any information known or otherwise available to the manufacturer respecting such devices, including adverse safety or effectiveness information which has not been submitted under section 360i of this title. The Secretary may require the manufacturer to submit the adverse safety or effectiveness data for which a summary and citation were submitted, if such data are available to the manufacturer.

(2) After the issuance of an order under paragraph (1) but before the date that is 2 years after July 9, 2012, the Secretary shall issue an administrative order following publication of a proposed order in the Federal Register, a meeting of a device classification

panel described in section 360c(b) of this title, and consideration of comments from all affected stakeholders, including patients, payors, and providers, notwithstanding subchapter II of chapter 5 of title 5, for each device-

(A) which the Secretary has classified as a class III device, and

(B) for which no administrative order has been issued under subsection (b) (or no regulation has been promulgated under such subsection prior to July 9, 2012),

revising the classification of the device so that the device is classified into class I or class II, unless the administrative order issued under this paragraph requires the device to remain in class III. In determining whether to revise the classification of a device or to require a device to remain in class III, the Secretary shall apply the criteria set forth in section 360c(a) of this title.

(3) The Secretary shall, as promptly as is reasonably achievable, but not later than 12 months after the effective date of the order requiring a device to remain in class III, establish a schedule for the issuance of an administrative order under subsection (b) for each device which is subject to the order requiring the device to remain in class III.