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DePaul Journal of Health Care Law

Volume 24
Issue 2 *2023*

Article 1

The Relevance of FDA Regulation in Medical Device Product Defect Cases

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INTRODUCTION

Product defect laws, which are creatures of state law, exist in an uneasy relationship with product safety regulation, which is a creature of federal law. In the case of medical device product design defect cases, a plaintiff alleges that a medical device is dangerous and that an individual who used it was injured because of the faulty design. The goal of the trial is to determine if the manufacturer is liable to the particular plaintiff. The Food and Drug Administration ("FDA), which regulates most medical devices, is also concerned with whether the medical devices are safe, but FDA regulators focus on the big picture, balancing the overall benefits to thousands versus the small risk of harm to a few. While some state's product defect laws ask juries to be mini regulators, balancing overall costs and benefits of a particular design, juries naturally focus on what happened to the individual in the case before them.

Federal regulators rely heavily on experts who work to develop consensus. They recognize that the data may not suggest a clear answer one way or the other. Juries in product cases are not experts. If they were, they would not qualify as jurors. Instead, they listen to competing experts who provide diametrically opposing points of view. Since most products present some risk, one side tries to convince them that any risks are quite limited and can be avoided altogether if people follow the warnings. The other side tries to convince them that the product is unreasonably dangerous, and the warnings are inadequate.

If the regulatory experts are uncertain, they usually extend their review in order to get more data. In some cases, the review may go one for years. If a juror is still uncertain after hearing the evidence, she cannot ask for more data or more time. She has to make a decision based on the information she has been given within tight time constraints.

Even though a juror is sometimes asked to think like a regulator, he invariably focuses on the specific history of the plaintiff in the individual case. If a single person is harmed, jurors are told that the product was unsafe even if the vast majority of users of the product suffered no adverse effects. Regulators may conclude a product is safe even if a small percentage of users suffer adverse consequences. This different perspective on the meaning of a "safe product" leads to fundamental differences in the evaluation of evidence.

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Given these differences in perspective, it is not surprising that federal regulators and state juries can look at the same product and reach different conclusions. It also tends to confuse courts and sometimes leads to surprising, and incorrect, results in judicial decision-making. Nevertheless, product defect law and federal safety regulation must coexist even though there are forces at work that push toward different conclusions. Should the fact that a device was subject to federal regulation have any impact on the jury's analysis? In some cases, federal law preempts state product defect claims, and the conflict never arises.[2] But short of preemption, should the jury even hear about the federal regulation? If the juries don't consider federal regulation at all, they do not get the benefit of what the premier experts in the country concluded about the safety of the product. Moreover, they may mistakenly conclude that the product manufacturers recklessly put a product on the market without any review whatsoever. But, if the court allows the defendant to tell the juries about what the federal regulators have done, the jury may not be able to make sense of it.

This article focuses on one of these situations -- state product defect cases involving medical devices cleared under Section 510(k) of the Food Drug and Cosmetic Act (the "FDA Act") and the FDA's process for allowing these devices to be marketed.[3] As discussed below, a number of courts have concluded that juries should not hear about FDA regulation in making factual findings regarding liability and damages. The reasoning of these courts – that the FDA's regulatory process is irrelevant, or even if it has some probative value, the probative value is substantially outweighed by other factors – deprives the jury of important information and potentially distorts the fact-finding process.

FDA regulation is complex. Asking a jury to consider the relevance of FDA regulation in a product defect case places a difficult burden on people who may never have heard of the FDA until the case began. On the other hand, juries in the United States are expected to make all kinds of decisions involving technical issues, and it would be a mistake to underestimate the ability of juries to make sense of these issues when litigants do a reasonable job of educating them and courts do a reasonable job of instructing them.[4]

What the FDA concludes about the safety of a product can be extremely relevant to juries in deciding whether to find there was a defective product and whether punitive damages are appropriate. On the other hand, because of the complexity of FDA regulation, it is important for courts to control how this evidence is presented to avoid overwhelming a jury, which already must deal with a number of complicated issues. This article shows how and when the 510(k) regulatory review is relevant. It also discusses how the FRE 403 standard for balancing

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[2] *See infra* notes 31-34 and accompanying text for a discussion on preemption in medical device product defect.

[3] Section 510(k) of the Act provides a process that the FDA uses to allow medical devices to be sold even though they are not subjected to a more extensive safety review called "premarket authorization" or PMA. Pub. L. No. 75-717, 52 Stat. 1040 (codified at 21 U.S.C. §360(k)); *see* U.S. FOOD & DRUG ADMIN., THE 510(K) PROGRAM: EVALUATING SUBSTANTIAL EQUIVALENCE IN PREMARKET NOTIFICATIONS [510(K)], GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2014) (https://www.fda.gov/media/82395/download) (hereinafter FDA 2014 GUIDANCE) (illustrating the 510(k) process throughout sec. II.B.).

[4] Luther T. Munford, *Courts v. FDA: A Lesson from Pelvic Mesh Litigation on Relative Competence to Decide a Legal Question*, 76 FOOD & DRUG L. J. 6 (2021); *see SRI Int'l v. Matsushita Elec. Corp. Am.*, 775 F.2d 1107, 1127 (9th Cir. 1985) (explaining jury members' level of legal comprehension); *see also* Goldberg, *supra* note 1.

probative value against unfair prejudice, juror confusion, etc., should be applied in a way that allows the jury to hear about the 510(k) process in way that is understandable and useful.

Before I discuss what juries should hear, it is helpful to set out some background on the following: 1) the different conceptions of safety itself; 2) the role of preemption; 3) the FDA's 510(k) review process; 4) Federal Rules of Evidence 401 through 403, which deal with relevance and admissibility; and 5) the questions juries are typically asked to decide in these types of cases. Once the background is set, we can get a better picture of what jurors should hear.

II. WHAT IS A SAFE PRODUCT?

At the core of the difference between regulatory and tort law perspectives is a different conception of safety. Regulators focus on the net social impact of a product: Is the overall benefit to society from a product greater than the risks? Almost all products present some risk, but these largely stem from misuse. No one would seriously argue that sharp knives are defective because they can result in severing an artery. Drugs and medical devices present a different question because they can cause harm even though they are used according to the FDA's labeling requirements and accepted medical protocols. What the FDA may conclude is a "safe" product still may result in an adverse reaction in a small percentage of users.

An example is the FDA's assessment of surgical mesh. Plastic surgical mesh has been regulated by the FDA for several decades. It can be used to treat two types of conditions -- pelvic-organ prolapse (POP) and stress urinary incontinence (SUI). POP occurs when the pelvic muscles that separate the vagina from the pelvic organs begin to weaken. As a result, these organs press up against the vaginal wall. Implanting vaginal mesh is a treatment option that involves inserting a polypropylene mesh through the vagina and anchoring it to the muscle wall to reinforce its integrity. SUI is also due to a weakening of the muscle wall that supports the pelvic organ. In this case, a leakage of urine results.[5]

The FDA reviewed the use of surgical mesh in both these situations and eventually came to different conclusions about their safety and effectiveness.[6] An FDA medical advisory panel concluded in 1982 that surgical mesh should be classified as a Class II device, meaning that it did not present such a serious risk of that required it be placed in Class III, which is reserved for devices that present more significant risks.[7] In making that determination, the FDA considered a number of factors.[8]

A decade later, however, the FDA had received a sufficient number of adverse reports about surgical mesh that it issued a public health notice regarding the use of mesh for both conditions.[9] It issued an update in 2011 based on an extensive review of evidence.

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[5] *Hrymoc v. Ethicon, Inc.*, 249 A.3d 191, 197-98 (N.J. Super. Ct. App. Div. 2021); *see Huskey v. Ethicon, Inc.*, 848 F.3d 151, 161-62 (4th Cir. 2017); *Cisson v. C.R. Bard, Inc.*, 810 F.3d 913, 930-31 (4th Cir. 2016).

[6] *See* Munford, *supra* note 4, at 19-20 (discussing the process of review).

[7] The FDA system for classification is discussed below in section II.A. *See supra* note 3 and accompanying text.

[8] *See* Munford, *supra* note 4, 19 (explaining medical devices were cleared by the FDA due to a "medical panel recommendation . . . medical device reports . . . FDA kn[owledge] about other, similar devices . . . [and[510(k) notice for the device itself").

[9] *See id*. at 20.

Subsequent staff analysis concluded that there was sufficient information to confirm the safety and effectiveness of the product to treat incontinence patients, while the use for vaginal prolapse raised serious concerns.[10] Ultimately, the FDA retained the lower risk Class II classification for the use for incontinence but reclassified the use for vaginal prolapse as Class II and finally in 2019 ordered manufacturers to stop selling the product for that use.[11]

While the FDA concluded that the use of surgical mesh to treat incontinence was safe and effective, it relied upon studies showing that 4% of patients suffered from erosion of tissue around the mesh and 5% suffered from pain.[12] In other words, what the FDA viewed as safe and effective was not literally "safe" for a small percentage of users. That is the nature of complex medical devices.

An SUI patient in the small group that suffered adverse effects could make a claim that the mesh was defective. How the claim would be treated under state law would depend in part on whether the state's product defect law takes into account a balancing of the benefits and costs of a particular design.[13] Whatever the state's law, a juror, encouraged by plaintiff's counsel, is likely to focus on what happened to the plaintiff in the case before her. Even if the state's product defect law calls for an overall social balancing, the juror may decide that the harm to a particular plaintiff requires a remedy even if the product meets some abstract test of overall social utility. If the juror concludes that the adverse impact on a very small percentage of patients means the product is defective, it has the practical effect of making medical devices much more expensive and may even create an incentive for a manufacturer to withdraw the product from the market.

One way to solve the problem of jurors focusing on the specific plaintiff, while regulators focus on overall social balancing, is for Congress to preempt state law claims if the regulators have concluded a product is "safe." As discussed below, the Supreme Court has concluded that product defect claims for products that have undergone 510(k) review are not preempted.[14] Whether that decision was correct is debatable. A narrower question is whether the juries should hear about the 510(k) review at all. As I discuss below, many courts have mistakenly concluded that evidence of 510(k) review is irrelevant, or even if relevant, is too confusing for jurors to understand. Doing so has the practical effect of undercutting the big picture regulatory perspective in favor of a narrow definition of safety that focus on harm to a particular person.

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[10] *Id.* at 20-21; *see also Huskey v. Ethicon, Inc.*, 848 F.3d 151,154 (4th Cir. 2017).
[11] *See* Munford, *supra* note 4, 21-22.
[12] *Id.* at 21; *see* U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY AND/OR FOR FDA REVIEWERS/STAFF AND/OR COMPLIANCE, GUIDANCE FOR THE PREPARATION OF A PREMARKET NOTIFICATION APPLICATION FOR A SURGICAL MESH (1999) (https://www.fda.gov/media/71828/download) (hereinafter FDA 1999 GUIDANCE).
[13] State product defect laws vary in their definition of unsafe products. *See infra* sec. III. The MDA and Preemption articulating the relevant state law. *See generally* J. Joseph Tanner & Lexi C. Fuson, *Survey of Recent Developments in Indiana Product Liability Law*, 52 INDIANA L. REV. 793, 800 (2019) (citing *Jeffrods v. BP Prods. N. Am., Inc*., No. 2:15-CV-55-TLS, 2018 WL 3819251, at *7 (N.D. Ind. Aug. 10, 2018) (quoting W*hitthead v. Gen. Motors Corp.*, 58 F.3d 1200, 1206 (7th Cir, 1995) (stating "In this defect design scenario, a jury must compare costs and benefits between the Model 110 and a crane with the Plaintiff's alternative designs.").
[14] *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, 741 (2012); Tanner, *supra* note 13, at 807 (attributing the court's decision in *Lohr* that the claims were not preempted to the 510(k) clearance process).

III. THE FDA'S 510(K) CLEARANCE PROCESS

Medical devices have been marketed in the United States since at least the nineteenth century. While the safety and effectiveness of those devices improved markedly over time, there were still too many dangerous and ineffective devices on the market well into the middle of the twentieth century. A study group on medical devices called the "Cooper Committee," which was convened by the Secretary of what was then called the Department of Health, Education and Welfare, published a report concerning and documenting thousands of injuries and several hundred deaths and recommended a special regulatory regime for medical devices.[15] As a result of these and other developments, Congress amended the FDA Act with the Medical Devices Amendments (MDA) in 1976.[16] The MDA created the 510(k) process, which has come to be the way most Part II devices come to market.[17]

The MDA and Device Classifications

In order to implement the new regulatory regime, the MDA created a three-tiered system based on the FDA's assessment of risk. Products were divided into Class I devices, products with simple designs such as bandages and tongue depressors. These were subject to very basic controls such as a prohibition on misbranding. Class I devices were also subject to recall if one of them turned out to be dangerous. Class III devices were subjected to the most stringent controls, including a rigorous Pre-Market Approval (PMA) review requiring clinical data of safety and effectiveness.[18]

Class II devices were placed in the middle. They are more complex than Class I devices and require more than the "general controls" that are adequate for Class I devices, but they are viewed as sufficiently safe and effective that they require only "special controls," such as performance standards, post market surveillance, and special warning labels. However, they do not raise the more difficult regulatory issues presented by more complex Class III devices. Most medical devices fall into Class II.[19] A fundamental difference in the regulatory approach to Class II and Class III products because of their different degrees of risk is that the 510(k) standard is comparative, and the Class III standard relies on an independent review of safety and effectiveness.[20] However, the goal of both processes to make sure a product is safe and effective.

Imposing product safety regulation on an industry which is already selling thousands of devices presents a difficult problem. Does Congress abruptly ban the sale of these products until

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[15] *See* COMPTROLLER GENERAL, FEDERAL REGULATION OF MEDICAL DEVICES, H.R. DOC. NO. 83-53, at 20-24 (1976) (describing the negative results of the study); *see also Medical Devices, A Legislative Plan: Hearing on H.R. 5545 Before the Subcomm. on Pub. Health& Env't Comm. on Interest & Foreign Com.* (statement of Theodore Cooper, M.D., Assistant Secretary for Health) (referencing the study conducted by the Cooper Committee and reporting its findings).

[16] Pub. L. 94-295, 90 Stat. 539 (1976).

[17] *Id.*; *see* Lohr, *supra* note 14, at 752-53.

[18] The 510(k) regulatory scheme is described in *In re C.R. Bard, Inc.*, 810 F.3d 913, 920-21 (4th Cir 2016) 920-21 and FDA 2014 GUIDANCE, *supra* note 3.

[19] *See Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1004-05 (7th Cir. 2020) (noting Class II distinction has a "reasonable assurance of safety"). *See generally*, FDA 2014 GUIDANCE, *supra* note 3, at 2-4.

[20] FDA 2014 GUIDANCE, *supra* note 3, at 6.

they are reviewed, thereby depriving the public of products that for the most part are working well, perhaps for long period? Or should it create a system that requires a review of the most dangerous products and deals with the others as best it can? Practical considerations and practical politics make the answer obvious. We would expect Congress to do exactly what it did -- create a transitional process that kept most products on the market while presuming that the FDA would review these products as soon as possible.

The MDA created a transitional system to avoid the problem of barring existing medical devices from the market. It allowed all devices that were on the market prior to 1976 to remain on the market until such time as they could be reviewed. As for new devices, the MDA provided that a post-1976 device could be cleared to be marketed if it was substantially equivalent to a pre-1976 device.[21] There was considerable logic in this policy, since requiring a more rigorous review for a virtually identical product already on the market would leave the incumbent devices in a monopoly or near-monopoly position. The downside of the policy is that, if the original device is flawed or even dangerous, an equivalent device is likely to be, too.

If the predicate device was not subject to safety review at all, clearance based solely on equivalence to the predicate says little or nothing about how safe the product is. On the other hand, if there was consideration of safety, but short of a full-blown PMA, the 510(k) review still says a lot of about safety. In fact, after the transition use of 510(k) approval, the process ensured a much more extensive safety review. A good example is the review of surgical mesh discussed earlier.[22] The FDA did not simply allow vaginal mesh to be put on the market and forget about it. There was an ongoing process designed to gather information about the safety and effectiveness of the product. [23] Moreover, the review ultimately culminated in a different conclusion about the safety of surgical mesh for incontinence and for vaginal prolapse.[24] The FDA's conclusions were reached after a far more extensive review of evidence that is possible in a truncated trial of a product defect claim.

The 1976 Act was not Congress's last effort at strengthening FDA review of medical devices. In 1990, it enacted the Safe Medical Device Act (SDMA), which converted the 510(k) for a limited "equivalence" determination to a more in-depth review of not only equivalence but, depending on the circumstances, safety and effectiveness issues.[25] The SDMA requires that manufacturers include in their 510(k) application a summary of all adverse safety and

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[21] *See* FDA 2014 GUIDANCE, *supra* note 3, at 6-7 (defining the statutory standard for substantial equivalence); Munford, *supra* note 4, at 15 (outlining the transition policy).

[22] *See supra* notes 6-8 and accompanying text.

[23] *See* 47 Fed. Reg. 2810 (Jan. 19, 1982) and 53 Fed. Reg. 23856 (June 24, 1988). Throughout the 1980s, panels within the FDA came together to "recommend that FDA place all 'surgical mesh' in Class II" since there may be risks associated with the product. Furthermore, the FDA went "adopted a regulation classifying surgent mesh in Class II" since "[s]ome regulation might be needed." Finally, after extensive research and further testing of the product, the FDA Guidance document of 1999 solidified the market requirements. Munford, *supra* note 4, at 18-19. *See generally* Jordan Bauman, *The Déjà Vu Effect: Evaluation of United States Medical Device Legislation, Regulation, and the Food and Drug Administration's Contentious 510(k) Program*, 62 FOOD & DRUG L. J. 337, 341- 42 (2012) (highlighting the impact of the Medical Device Amendments of 1976 on the FDA's approval process).

[24] *Id.*

[25] *See* FDA 2014 GUIDANCE, *supra* note 3, at 4; Brief for AdvaMed as Amici Curiae at 5-7, *Mary McGinnis v. C. R. Bard, Inc.*, 2017 WL 10744315 (N.J. Super. L) (No. A-001083-19T1).

effectiveness data for the product.[26] In addition, the FDA may request the manufacturer to submit the adverse event data.[27] The FDA's regulation implementing the MDMA provides that the submitter must include any safety and effectiveness data from testing.[28]

The FDA also periodically reviews products that can serve as predicates and can preclude their use if there have been safety and effectiveness concerns.[29] Thus, there is a process for bringing to the attention of the FDA new information that a product previously thought to be safe and effective may not be.[30] That is exactly what state product defect laws expect of manufacturers. They should keep up with the latest information on their product and take steps if new information suggests it is more dangerous than previously thought.

In addition to what the 510(k) process shows about the safety of a product, it almost always has a lot to say about the actions and the mindset of the manufacturers that submit their products for 510(k) review. For example, if a manufacturer complied with FDA requirements in putting a product on the market, that compliance may be relevant in determining whether the manufacturer was reckless or in bad faith and, therefore, subject to punitive damages. On the other hand, if a manufacturer deliberately short-circuited or ignored the process, that is relevant in most states' approaches to punitive damages.[31]

When courts are deciding the admissibility of 510(k) review, it is necessary to examine the actual review process that occurred when a product came to market. Was it the transitional review envisioned by the FDA to last only for a short period, or was it a more significant safety review that Congress envisioned would eventually occur? Part of the difficulties the courts have had is distinguishing between products that were subject only to the transitional process and those that were subject to the later more extensive review.

<u>The MDA and Preemption</u>

The MDA contains a preemption provision that was intended to preclude state laws that upset the MDA's regulatory regime.[32] Section 360k of the Act preempts "any

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[26] *See* Pub. L. No. 101-629, 104 Stat. 4511 (1990); *see also* FDA 2014 GUIDANCE, *supra* note 3, at 30-32 (recommending the identification of adverse events).

[27] *See supra* notes 25-26 and accompanying text.

[28] 21 CFR § 807.92 (1994) (listing the requirements for the "content and format of a 510(k) summary" including "a discussion of the safety or effectiveness data").

[29] The FDA will take action to eliminate the use of a 510(k) cleared device as a predicate when it raises safety concerns. For example, the FDA may pursue reclassification (from Class II to Class III) and issue a call for Premarket Approval applications when it determines that a device type should be regulated as high risk because general and special controls are not sufficient to assure its safety and effectiveness. This process eliminates the use of previously cleared 510(k)s as legal predicates. Since Congress enacted the Medical Device Amendments in 1976, the FDA has eliminated the use of 1,758 devices as predicates in the 510(k) process. Of these, 1,477 (84%) have been eliminated since 2012. *See e.g.*, U.S. FOOD & DRUG ADMIN., THE SPECIAL 510(K) PROGRAM GUIDANCE FOR INDUSTRY AND FOOD & DRUG ADMIN STAFF (2018) (https://www.fda.gov/media/116418/download) (hereinafter FDA 2018 GUIDANCE).

[30] 21 U.S.C. 360c (a)(1)(B) (requiring Class II devices to be subject to "postmarket surveillance"); *see also* FDA 2014 GUIDANCE, *supra* note 3, at 2 (clarifying that since the Safe Medical Devices Act of 1990, Class II devices can be subject to review after they are on the market).

[31] *See e.g.*, *infra* sec. V. Instructions for Punitive Damages.

[32] 21 U.S.C. § 360k(a) (1976).

requirement…which is different from, or in addition to, any requirement [under the Act] which relates to the safety or effectiveness of the device…" 21 U.S.C. § 360k(a)(1), (2). As many industries have discovered, it is notoriously difficult for Congress to preempt state law claims with a level of precision that courts require. Most Members of Congress (and their staff) are caught in a dilemma. If they use language that is too general, a court years later may parse the language and conclude that Congress should have spoken more explicitly. If the language is too specific, a court may conclude that certain specific situations were not expressly mentioned.

Whatever the actual Congressional intent in enacting the preemption provisions of the MDA, the Supreme Court went in different directions for Class III devices that require pre- market approvals and Class II devices that are subject to 510(k) review. In *Riegel v. Medtronic*, Inc., the Supreme Court held that a state law product defect claim involving a Class III device was preempted.[33] The Court emphasized the thoroughness of the PMA process and concluded that a state product defect law as applied to a product that had gone through such a process added a new "requirement" that Congress prohibited.[34]

On the other hand, in *Medtronic, Inc. v. Lohr*, the Court found that Class II products that had only gone through the FDA's 510(k) process were not subject to the same rigorous safety review and, therefore, state product defect claims were not preempted.[35] *Lohr* set the stage for later lower court decisions about the relevance of the 510(k) process. While the *Lohr* Court did not expressly address the issue of admissibility of the 510(k)-review process, its comments about the 510(k) process convinced many lower courts that it was irrelevant when it came time for juries to decide whether a product is defective.[36] As I discuss below, the *Lohr* decision has had a significant and unfortunate impact on how the lower courts treat evidence about the 510(k) process.

IV. COURT DECISIONS

A review of a number of appellate decisions shows a lack of understanding of the 510(k) process and a strong tendency to place too little value on the regulatory approach to an evaluation of safety. In this section, I examine three cases, two decisions by the Fourth Circuit and one by the New Jersey Superior Court.[37] The Fourth Circuit decisions excluded 510(k) evidence and the New Jersey court held it should have been admitted. In my view, the Fourth Circuit cases reflected

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[33] *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 329-30 (2008) (arguing state requirements can only be preempted under MDA "to the extent that they are 'different from, or in addition to' the requirements imposed by federal law," and providing a damages remedy is not an addition to).

[34] *Id.* at 316 ("Congress stepped in with the passage of the Medical Device Amendments of 1976(MDA) . . . which swept back some state obligations and imposed a regime of detailed federal oversight.").

[35] *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 498-99, 503 (1996)

> The Lohrs' theory is supported by the FDA regulations, which provide that state requirements are pre-empted "only" when the FDA has established 'specific counter part regulations or . . . other specific requirements applicable to a particular device.' 21 CFR §808.1(d) (1995). They further note that the statue is not intended to pre-empt '[s]tate and local requirements.'

[36] *Id.* at 471 (finding the focus of the 510(k) process is on equivalence but not safety); *see Riegel v. Medtronic, Inc*., 552 U.S. 3, 322 (2008) (citing to the court's discussion in *Lohr* rejecting "manufacturer's contention that 510(k) approval imposed device-specific requirements").

[37] *See Eghnayem v. Boston Sci. Corp.*, 873 F.3d 1304, 1319-21 (11th Cir. 2017) (utilizing the holding from *Cisson* to affirm the lower court's decision); *Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1020-21 (7th Cir. 2020).

a misunderstanding of the FDA 510(k) process and an unwillingness to consider the practical effects of preventing juries from learning about it. The New Jersey court, on the other hand, took a creative approach to dealing with the evidence in light of the actual way the trial proceeded and the impact on the jury of withholding the information.

The Fourth Circuit Cases

In *Cisson v. C.R. Bard, Inc.*, the Fourth Circuit Court of Appeals affirmed the District Court's exclusion of evidence that the product (vaginal surgical mesh) had been cleared to be marketed by the FDA's 510(k) process.[38] There were two fundamental mistakes in the court's analysis. First, the court apparently thought that the device was cleared to be marketed solely based on equivalence to a pre-1976 device that itself had not been subject to a safety review.[39] As discussed above, if that was the extent of the equivalence determination, it says little about the safety of the device. However, the device was cleared based in part on equivalence to a post- 1976 device, which was the subject of an FDA medical advisory panel review.[40] It is true that the FDA ultimately concluded that the vaginal mesh product should be removed from the market.[41] However, had the jury heard evidence about the FDA's review, culminating in that determination, it would have heard the entire story, including the FDA's final determination.[42]

The Fourth Circuit did not reach the question whether the 510(k) process was completely irrelevant under FRE 402, but only affirmed a ruling by the district court that the evidence presented "substantial dangers of misleading the jury and confusing the issues."[43] Moreover, the court pointed out that it would only reverse the district court for abuse of discretion in making such a ruling under "the most 'extraordinary of circumstances…'"[44] Thus, it seems unlikely that the court would have found error if the district court had admitted the evidence.

A more significant and troubling aspect of the decision was to affirm the decision of the district court to exclude any consideration by the jury in its determination about the appropriateness of punitive damages. The court reasoned that the manufacturer's decision to pursue 510(k) clearance was a "choice to minimize the burden of compliance, potentially cutting in favor of punitive damages."[45] Perhaps the jury would have viewed the evidence that way, perhaps not. But surely the decision to use 510(k) review, which was the method prescribed by

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[38] 810 F.3d 913, 930-32 (4th Cir. 2016).
[39] *Id.* at 920; *see also* Munford, *supra* note 4, at 13.
[40] *See* Munford, *supra* note 4 at 15.
[41] U.S. Food & Drug Admin., FDA Takes Action to Protect Women's Health, Orders Manufacturers of Surgical Mesh Intended for Transvaginal Repair of Pelvic Organ Prolapse to Stop Selling all Devices, FDA News Release (April 16, 2019) (https://www.fda.gov/news-events/press-announcements/fda-takes-action-protect-womens-health-orders-manufacturers-surgical-mesh-intended-transvaginal#:~:text=The%20U.S.%20Food%20and%20Drug,products%20in%20the%20U.S.%20immediately) (halting the distribution of vaginal mesh devices since manufactures have not "demonstrated a reasonable assurance of safety and effectiveness for these devices").
[42] *See* Munford, *supra* note 4**.**
[43] *See Cisson*, 810 F.3d 913, 922 (4th Cir. 2016).
[44] *Id.* at 920.
[45] *Id.* at 917. The manufacturers used the review process that Congress had provided for their particular situation. To suggest that the manufacturer evaded a review that Congress did not conclude was necessary is elevating theory far above practical reality. *See* Munford, *supra* note 4, at 23.

Congress and the only practical way the product could have been marketed, was something that the jury could easily have understood. To say that it was so confusing that it was better that the jury should never hear about it seems entirely unpersuasive. That is particularly true when, as the court itself note, FRE 403 is a rule that generally favors admissibility.[46]

Not long after *Cisson*, the Fourth Circuit decided *Huskey v. Ethicon, Inc.*, and reached the same result.[47] The *Huskey* court relied primarily on *Cisson* and did not discuss the exclusion of 510(k) evidence extensively.[48] The case is notable for three reasons. First, the court's instruction to the jury regarding the finding a defect was based on the regulator's perspective of balancing the benefits of the product to the population as a whole compared to the risks to the few.[49] While the defendant claimed that the court erred by not giving an instruction based on comment k of the Second Restatement of Torts, the actual instruction given by the court was more favorable to the defendant since it put the burden on the plaintiff to show that the risk of danger in the product outweighs the benefits of the design.[50] In contrast, comment k puts the burden of proof on the defendant.[51] The court's recognition that a regulatory-like balancing was needed makes it even clearer that the jury should have known about the 501(k) process.

Second, the court greatly understated the significance of the actual 510(k) process that occurred for the product at issue. The court referred to the fact that the 510(k) process only "tangentially" examined the safety of the product.[52] In fact, the FDA's review of mesh products, which began in 1982 and culminated in a decision to withdraw the vaginal mesh product from the market in 2019 was quite extensive.[53] Third, the safety of the product at issue, mesh for incontinence procedures, was expressly determined by the FDA to be supported by the evidence after an extensive review.[54]

The *Huskey* court was concerned about the potential for the jury to be confused by the complexity and technical aspects of the 510(k)-review process. In one of the more ironic statements in the opinion, the court suggested that, because the process was extensive and complex, it would be even more confusing for the jury.[55] In other words, the opinion seemed to

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[46] *Cisson*, 810 F.3d at 920.
[47] 848 F.3d 151, 161-62 (4th Cir. 2017)
[48] *Id.* at 160-61.
[49] *Id.* at 159 (explaining the jury instruction shifted the "burden of proof" off of the defendant as compared to comment k).
[50] *Id.*
[51] RESTATEMENT (SECOND) OF TORTS § 402A cmt. k. (AM. L. INST. 1965) (emphasizing the challenge of ensuring complete safety leading to consumers taking on a "known but apparently reasonable risk"); *see Huskey* 848 F.3d 151, 158-59 n. 1-2 (discussing the jury instruction that *Ethicon* wanted to provide); *Products Liability and Section 402A of the Restatement of Torts*, 55 GEO. L. J. 286, 303 (1966) (articulating the impact of comment k).
[52] *Huskey*, 848 F.3d at 160.
[53] *See* Munford, *supra* note 4, at 7-8.
[54] *See* U.S. FOOD & DRUG ADMIN., OBSTETRICS & GYNECOLOGY DEVICES ADVISORY COMM. OF SEPT. 8-9, 2011, SURGICAL MESH FOR TREATMENT OF WOMEN WITH PELVIC ORGAN PROLAPSE AND STRESS URINARY INCONTINENCE: FDA EXECUTIVE SUMMARY 24, 68 (2011) (https://www.fda.gov/files/medical%20devices/published/Urogynecologic-Surgical-Mesh--Update-on-the-Safety-and-Effectiveness-of-Transvaginal-Placement-for-Pelvic-Organ-Prolapse-%28July-2011%29.pdf) (hereinafter FDA Comm 2011).
[55] *Huskey*, 848 F.3d at 161 ("[The defendant's] effort to distinguish *Cisson* on the ground that the [510(k) review] actually did focus heavily on safety would only amplify the risk [of confusing the jury], as the trial court would then

suggest that the more time the FDA spent on a complicated safety review, the more difficult it was to understand. Therefore, the best approach was simply to ignore it. That elevates the risk of juror confusion over the probative value itself, which is the balance that FRE expressly rejects.

A Different Approach

In *Hrymoc v. Ethicon, Inc.,* the Superior Court of New Jersey dealt with an appeal of a jury finding of liability in two related vaginal mesh product defect cases.[56] The jury awarded punitive damages in both cases.[57] Both trial courts had excluded evidence of the 510(k) review.[58] The appellate court found that "the total disallowance of such proof had the patent capacity to deprive defendants of a fair trial, most poignantly with respect to the state of mind and venal conduct that underlie the punitive damages award."[59]

The defendants in both the New Jersey cases had attempted to introduce evidence about the FDA's review of the mesh products, including ordering the defendants themselves to make an extensive submission to the agency.[60] The trial courts in both cases concluded that the 510(k) review was only about substantial equivalence and not about safety.[61] As in *Cisson* and *Huskey,* both trial courts were concerned about the complexity of the evidence and how it might confuse jurors, including the potential for a "mini-trial" about the strengths and weaknesses of the process.[62]

The practical realities of what the jury hears and how it is likely to react are central to coming up with fair instructions. The *Ethicon* case is instructive. In that case, plaintiffs prevailed on a pre-trial motion to exclude evidence of 510(k) clearance of the allegedly defective process.[63] Even though the manufacturer was not required to conduct a clinical trial and even though it submitted all the required information to the FDA, plaintiff's counsel suggested that the manufacturer was not only reckless but perhaps pulling a fast one in bringing the product to market.[64]

The practical effect of the trial courts' approach, however, was to allow plaintiffs' counsel to imply that the defendants had ignored an obligation to have the products reviewed for safety.[65] Among other things, plaintiff's counsel in both the opening statement and summation stated that clinical studies were "clearly required," that the jury never heard "why a study wasn't done, why it wasn't necessary," and that defendant should be punished with punitive damages so that it would

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likely face a substantial diversion into just how rigorous those safety considerations were, how forthcoming [the defendant] was the FDA, and how robust the 510(k) process is."

[56] 249 A.3d 191 (2021).

[57] *Id.* at 196.

[58] *Id.*

[59] *Id.*

[60] *Id.* at 204.

[61] *Id.* at 205.

[62] *Id.* at 208.

[63] *Id.* at 205.

[64] *Id.* at 191. As the court noted, ~~in,~~ "Many jurors in our present society would naturally expect that the FDA would have some involvement in the regulation of a new medical product being implanted in patients." 249 A.3d at 212.

[65] *Id.* at 211-12.

do "clinical studies."[66] The court commented that, in its view, these arguments were not inappropriate, but the defendants should have been able to respond to them and explain the FDA review that was conducted.[67] Preventing the jury from hearing the steps that the manufacturer took to comply with regulatory requirements is most egregious in connection with the award of punitive damages.[68]

The approach of the appellate court in *Ethicon* was to take into account not only the strict issue of relevance but the practical realities of what went on in the courtroom.[69] Its suggestions for instructions are worth noting. "Rather than adopt a categorical ban, we believe the more reasoned approach is for our courts to explore whether a limited amount of 510(k) information, through a well-crafted stipulation or a modest presentation of evidence from both sides, along with a cautionary instruction from the judge, could help assure a fair trial."[70] The court specifically suggested:

- Imposing reasonable limits on the number of witnesses and the amount of time expended on the subject of 510(k) clearance;
- The court explaining to the jury the basic differences between Class II "substantial equivalency" clearance and PMA review;
- The court explaining the FDA's statements cautioning the public that 510(k) review is not "official approval" and the extent of the safety review involved.
- Allowing limited admission of some helpful FDA documents
- Limiting the use of demonstrative aids.
- Restricting the use of misleading arguments related to the FDA.[71]

IV. THE FEDERAL RELEVANCE RULES

The first two Federal Rules on relevance are straightforward. FRE 402 sets out the basic rule – evidence must be relevant to be admissible and all relevant evidence is admissible unless there is something else in the federal rules or in some other law that says otherwise. In other words, relevance is a necessary, but not sufficient, qualification for admissibility.[72]

FRE 401 defines relevance to mean evidence makes a fact that is of consequence more likely. FRE 401 does not place a minimum standard by which the probability goes up (or down). An increase in the probability from 10% to 20% satisfies the test just as an increase from 10% to

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[66] *Id.*
[67] *Id.* at 212 ("[D]efendants should have been permitted to try to counter them by allowing the jurors to at least know about the 510(k) clearance process and the fact that the FDA did not require such clinical studies.").
[68] *Id.* at 211-12 ("The inherent unfairness of the situation as it unfolded is perhaps most pronounced in connection with the punitive damages aspect of the cases.").
[69] For another opinion suggesting a guided approach to jury consideration of this type of evidence, *see In re Bard IVC Filter Prods. Liab. Litigation*, 289 F.Supp.3d 1045, 1047-48 (D. Ariz. 2018).
[70] *Hrymoc*, 249 A.3d at 213.
[71] *Id.* at 213-14 (listing what judges could do to "clarify for the jurors" what the FDA actually conducted and concluded).
[72] FED. R. EVID. 402, Notes of Advisory Comm. on Proposed Rules.

90%.[73] A determination by experts at the FDA that a product is safe clearly meets this test if the question is whether a product is, in fact, safe. On the other hand, if the experts at the FDA did not say anything at all about safety, their opinion does not make the fact of safety more likely. However, the FDA review may increase the likelihood of some other consequential fact, for example, that the manufacturer did what the law required before marketing the product. That may be of consequence to the proceeding if the jury is determining whether punitive damages should be imposed because the manufacturer was reckless or in bad faith.[74]

FRE 403 operates as a screen on evidence that has passed the permissive 401 test by establishing an additional, more demanding balancing test. FRE 403 introduces the concept of "probative value," which is a measure of how much the likelihood of a consequential fact changes because of the evidence.[75] If it changes very little, the evidence has low probative value. If it changes a lot, the probative value is high. For example, in a murder trial, eyewitness testimony by a credible witness who testifies he saw the defendant shoot the victim has high probative value. Testimony that places the defendant in the same city where the murder occurred has low probative value.

Under the rule, the probative value is to be balanced against the possibility that the evidence has other negative consequences on the jury or on the proceeding itself. Under the 403 balancing the test, the court may (not must) exclude the evidence if these negative consequences, e.g., unfair prejudice, confusing the jury, or wasting time "substantially" outweigh the probative value. The inclusion of the word "substantially" means the rule is heavily weighted toward admitting any evidence that has probative value. Thus, it is frequently said that FRE 403 favors admission. [76] It was the application of this balancing test and the consideration of possible negative consequences the convinced the courts in *Cisson* and *Huskey* that juries should not hear about the 510(k) regulatory process.

The application of FRE 403 is inevitably subjective. Even though the judge is supposed to somehow balance factors on both sides of the equation, there is no way to quantify them. About the best a judge can do is to make some rough determination, such as low, medium, or high.[77] That is why appellate courts routinely say that district courts will only be reversed for an abuse of discretion in making these types of decisions.[78]

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[73] FED. R. EVID. 401, Notes of Advisory Comm. on Proposed Rules.

[74] *See infra* §V. Jury Issues in a Product Defect Case.

[75] *See also* Fang Bu, *Searching for a Better Constitutional Guarantor for FRE 413-415: The Conflict among Circuits Applying the FRE 403 Balancing Test and a New Solution*, 2016 U. ILL. L. REV. 1905, 1919-20 (2016) (citing *United States v. LeMay*, 260 F.3d 1018, 1022, 1027-28 (9th Cir. 2001) (quoting *Rudy-Glanzer v. Glazer*, 232 F.3d 1258, 1268 (9th Cir. 2000) (analyzing considerations for the court when determining probative value including "the necessity of the evidence beyond testimonies already offered at trial").

[76] *See also* Fed. R. Evid. 403, Notes of Advisory Committee on Proposed Rules (suggesting courts should grant a continuance rather than exclude evidence).

[77] *See* Bu, *supra* note 75, at 1930-31.

[78] *Huskey v. Ethicon, Inc.,* 848 F.3d 151, 160-61 (4th Cir. 2017) (maintaining the standard for overruling exclusion or admission of evidence lies in the abuse of discretion from the judge); *Hrymoc v. Ethicon, Inc.*, 249 A.3d 191, 211 (N.J.Super.A.D. 2021) (understanding that judges have discretion to make 403 determinations, but acknowledging that those determinations sometimes go too far).

A judge is not a passive actor in this balancing process. While she cannot increase the probative value one way or the other, she can limit the weight of the countervailing considerations. For example, if the countervailing consideration is that the evidence, though probative, is so complicated that the jury will be confused because it can't make sense of the evidence, the judge can guide the jury through instructions to mitigate the confusion and it can direct the parties to present the evidence in a way that is less confusing and more helpful. That was the approach taken in the *Ethicon* case discussed above.[79]

V. JURY ISSUES IN A PRODUCT DEFECT CASE

Just as FDA safety regulation is complex, the questions juries are asked to decide in a product defect case are complex, too. In a "simple" criminal case, juries are usually asked to decide one key fact – did the defendant shoot the victim or rob the bank? Affirmative defenses, such as self-defense, insanity, or the particular mens rea of the defendant, can complicate the analysis, but the entire case can turn on a single fact – did the defendant pull the trigger or take the money?

The factual issues in a product defect case, particularly for complex products such as medical devices, are much more complicated. The first set of issues has to do with whether the product is defective or unreasonably dangerous. In states that use a "risk/utility" standard, jurors are asked to become mini-regulators, balancing costs and benefits of a particular design.[80] Even in states that do not use such a test expressly, jurors typically have to take into account, not just the product itself, but all the circumstances, including possible alternatives, the risks and benefits of a particular design, and the state of knowledge in the industry.[81]

A second set of considerations deals with whether punitive damages are appropriate. Jurors are asked to consider, for example, the defendant's awareness of the risk and how quickly the defendant reacted to new information about the problems with the product. Below are examples of various instructions that attempt to capture the state's statutory and judicial interpretations of the state's design defect standard and standard for punitive damages.[82]

Instructions Regarding Risk From Using the Product [83]

> Example 1: In considering whether the design is unreasonably dangerous, you may take into account alternative forms of design that were available at the time of the design of this product, and among other things, the knowledge common to

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[79] *Hymroc*, 249 A.3d 191, 210 n. 15 (looking to other courts that have also used a limiting instruction to guide their holding). "Some unpublished district court opinions, which we will not cite here in accordance with Rule 1:36-3, have reached a result similar to Booker. At least one of those unpublished opinions suggested, like Booker, the use of a limiting instruction to guide the jurors."

[80] *See infra* Instructions Regarding Risk From Using the Product, Example 2.

[81] *See infra* Instructions Regarding Risk From Using the Product, Example 1.

[82] *See infra* Instructions Regarding Risk From Using the Product.

[83] *See* Phil Goldberg, *It's Time to Stop Blindfolding Juries in Medical Device Cases*, WASH. LEGAL FOUND. (Dec. 3, 2021) (https://www.wlf.org/2021/12/03/publishing/its-time-to-stop-blindfolding-juries-in- medical-device-cases/) (acknowledging that courts find evidence confusing and limiting instructions are a helpful tool).

those in the industry, the defendant's expertise, the dangers involved and the knowledge that was available to the defendant.

Example 2: As used in these instructions, a product is in "a defective condition and unreasonably dangerous" if it creates such a risk of injuring its user that an ordinarily prudent manufacturer of [identify type of product], being fully aware of the risk, would not have put the product on the market.

Example 3: I instruct you that a product is defectively designed if the plaintiff proves that (1) it failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, or (2) the product's design proximately caused injury and the defendant fails to prove, in light of the relevant factors, that on balance the benefits of the challenged design outweigh the risk of danger inherent in such design. [84]

Example 4: It is for you, as the triers of fact, to determine, based on knowledge available at the time of its manufacture, the likelihood that this product would cause harm, whether the seriousness of any such harm outweighed the manufacturer's duty to design a product that would have prevented such harms, and as well the adverse effect that an alternative design would have on the usefulness of the product.

All of these instructions relating to the basic issue of the defectiveness of the product try to capture the degree of risk posed by the device. Sometimes the state's law, and the resulting instruction, is explicit in asking jurors to engage in balancing the risks of a device with the alternatives. Sometimes the instruction is not quite so explicit, but in all the cases, the jury is supposed to assess the degree of risk and whether it is reasonable. Both parties in a product defect case will call experts who opine on the degree of risk, one side saying it is low and the other side saying it is high. In this context, it is hard to see how a review by the FDA, which is performed by the nation's premier experts on drug safety and it relatively unbiased, would not help the jury make this complex determination.

Instructions Regarding Punitive Damages[85]

Example 1: In determining whether to award punitive damages against this defendant and, if you do so determine, the amount of such award, you should give consideration to any of the following factors which have been presented in the evidence: the seriousness or otherwise of the danger to the public posed by the marketing or other misconduct; its profitability to the defendant; the defendant's attitude on discovery of the misconduct; the degree of awareness of the hazard

[84] With respect to products like drugs and medical devices, most states recognize a "learned intermediary" doctrine under which the obligation of the manufacturer is to warn the prescriber of the product. *See Hrymoc*, 249 A.2d at 217 ((citing *Perez v. Wyeth Labs. Inc.*, 161 N.J. 1 (1999) (quoting *Niemiera v. Schneider*, 114 N.J. 550 (1989))); *see also Ackermann v. Wyeth Pharm.*, 526 F.3d 203 (5th Cir. 2008).

[85] *See generally, White v. Ford Motor Co.*, 312 F.3d 988, 1012 (9th Cir. 2002) (discussing jury instructions for punitive damages "must fairly and adequately cover the issues presented, must correctly state the law, and must not be misleading.").

presented due to defendant's misconduct; the number and level of employees involved in causing or in covering up the misconduct; the duration of the misconduct and of its cover-up; the amount it would have cost to reduce the danger to an acceptable level; and the deterrent effect your award is likely to have on other manufacturers or suppliers in the same line of production.

Example 2: If you find the evidence you have heard to be clear and convincing that the defendant's actions in connection with the supply of this product were [reckless, intentional, in bad faith, etc.], then you may consider awarding, in addition to that sum required to compensate the plaintiff for his/her injuries, such a sum as you consider appropriate to punish, deter, and make an example of the defendant.[86]

Example 3: Punitive damages may be awarded, in addition to compensatory damages, if you find that the defendant acted maliciously toward the plaintiff or with an intentional disregard of the rights of the plaintiff. A person's acts are malicious when they are the result of hatred, ill will, desire for revenge, or inflicted under circumstances where insult or injury is intended. A person acts in an intentional disregard of the rights of the plaintiff if the person acts with the purpose to disregard the plaintiff's rights, or is aware that his or her acts are substantially certain to result in the plaintiff's rights being disregarded. Before you can find an intentional disregard of the rights of the plaintiff, you must be satisfied that the defendant's act or course of conduct was: (1) deliberate; (2) an actual disregard of the plaintiff's right to safety, health, or life, a property right, or some other right; and (3) sufficiently aggravated to warrant punishment by punitive damages.

Punitive damage instructions tend to allow juries to consider a host of factors as shown in the examples above. The defendant's efforts in going through the 510(k) process would obviously have some relevance to these determinations, one way or the other. For example, if the defendant lied to the FDA and told the agency that it had no information about adverse events, that would count toward punitive damages. On the other hand, if it made good faith, reasonable efforts to learn about adverse events in order to comply with the 510(k) process and found none, that should count in the other direction. Moreover, these considerations about human behavior are something that juries are very familiar with. Compared to the incredibly technical issues that juries are called upon to evaluate, they are easy to understand and evaluate.

VII. CONCLUSION

A review of all these considerations suggests the following. First, courts are going to have to be educated about what actually happened as the product went through the FDA's 510(k) clearance process. In particular, they need to understand if the review was limited to the

[86] The mental state or "mens rea" of the defendant required for punitive damages varies from state to state. *Compare Resol. Tr. Corp. v. S & K Chevrolet*, 868 F.Supp. 1047, 1062 (C. D. Ill. 1994) (requiring mens rea to impose punitive damages) *with Dammon v. W.L. Folse*, 846 F.Supp. 36, 38 (E.D. La. 1994) (arguing a lack of mens rea does not "preclude the imposition of punitive damages").

truncated review process that was envisioned by Congress as transitional or the later more extensive review process. If the process truly involved no review of safety at all, there is a good argument that 510(k) clearance is irrelevant on the key issue of risk. On the other hand, if there was some safety review, preventing the jury from hearing that the premier experts in the country found that the product did not create an unreasonable risk is counter to the principles of the Federal Rules of Evidence. Second, because of the complexity of the FDA process and its relationship to what the jury is being asked to find, courts should control the presentation of the evidence in this area in order to ensure that it is useful to the jury and fair to both parties. Finally, it seems obvious that the 510(k) process is relevant to punitive damages regardless of the probative value on the issue of product safety.

If the court feels that introducing the 510(k) process unduly complicates the basic liability finding, it could conceivably bifurcate the proceeding so that the jury doesn't have to hear about 510(k) until there is a finding on liability. In most cases, however, the jury should be able to deal with the evidence on liability and punitive damages at the same time. The point of the proceeding is to fairly compensate a person when there really has been a breach of duty under state law, but the proceeding must be fair, too. Preventing the jury from hearing about the 510(k) process, which is, after all, how the nation's policymakers decided to make sure products are safe and effective, is not only unfair, it increases the chances that a product defect case results in unfairly penalizing the manufacturer. That in turn, can have the practical effect of keeping products off the market that benefit thousands of Americans.