No. 15-1102

UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

DONNA CISSON AND DAN CISSON.
Plaintiffs-Appellees,

v.

C.R. BARD, INC.,
Defendant-Appellant.

On Appeal from the United States District Court for the Southern District of West Virginia (Charleston) – No. 2:11-cv-00195 (Hon. Joseph R. Goodwin)

BRIEF OF *AMICUS CURIAE* COOK INCORPORATED, COOK MEDICAL LLC AND COOK BIOTECH INCORPORATED IN SUPPORT OF APPELLANT C.R. BARD, INC. AND URGING REVERSAL

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1 and Local Rule 26.1, the undersigned certifies that the Cook Incorporated, Cook Medical LLC and Cook Biotech Incorporated (collectively "Cook") makes the following disclosure:

1. Is party/amicus a publicly held corporation or other publicly held entity? No.

2. Does party/amicus have any parent corporations? Yes. Cook Group Incorporated is the parent of Cook Incorporated, Cook Medical LLC and Cook Biotech Incorporated.

3. Is 10% or more of the stock of a party/amicus owned by a publicly held corporation or other publicly held entity? No.

4. Is there any other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation (Local Rule 26.1(b))? No.

5. Is party a trade association? (amici curiae do not complete this question) n/a.

6. Does this case arise out of a bankruptcy proceeding? No.

Dated: April 20, 2015

/s/ Douglas B. King
Douglas B. King

BRIEF OF AMICUS CURIAE COOK INCORPORATED, COOK MEDICAL LLC AND COOK BIOTECH INCORPORATED IN SUPPORT OF APPELLANT C.R. BARD, INC. AND URGING REVERSAL

I. INTEREST OF THE *AMICUS CURIAE*[1]

Cook Incorporated, Cook Medical LLC and Cook Biotech Incorporated (collectively, "Cook"), as *amicus curiae*, respectfully submit this brief in support of Defendant/Appellant C.R. Bard, Inc. ("Bard"). Cook urges this Court to reverse the United States District Court for the Southern District of West Virginia (the "District Court") and hold that evidence of a medical device manufacturer's compliance with FDA regulations, including the steps it took to obtain clearance to market the medical device at issue under Section 510(k) of the Food, Drug and Cosmetic Act (the "510(k) program") is relevant and admissible. While the 510(k) program as it existed at the time of the Supreme Court's decision in *Medtronic v. Lohr*, 518 U.S. 470 (1996), may not have included a determination by FDA that a device cleared for marketing was safe and effective, the 510(k) program as it **now** exists does include a determination by FDA that the medical device is safe and effective. Accordingly, proof that a medical device manufacturer complied with FDA's 510(k) program is relevant evidence that the device is not defective.

Cook, an active participant in medical device litigation, is uniquely situated to alert this Court to two practical issues of significance to its decision. First, FDA's 510(k) program now does include that agency's determination that the device thereby cleared for marketing is safe and effective because FDA has determined in the 510(k) program that the device is substantially equivalent to a device already on the market and thus with a proven track record in the real world of safety and effectiveness. Second, as Cook is unfortunately all too familiar with the harmful

[1] No counsel for a party authored this brief in whole or part, and no counsel or party made a monetary contribution to fund the preparation or submission of this brief. No person other than the *amicus curiae*, its members, and its counsel made any monetary contribution to its preparation and submission. The parties have consented to this filing.

effects of mass tort litigation on the medical device industry, Cook knows that preclusion of such evidence will have a prejudicial effect on the medical device industry, by inhibiting innovation in medical devices, decreasing the availability of potentially beneficial medical treatments, and increasing the cost of medical devices.

Cook was founded in 1963 by Bill and Gayle Cook in Bloomington, Indiana. Since then, Cook has expanded into various fields of medicine. Today, Cook is the largest privately held manufacturer of medical devices in the world, continuing the philosophy of Bill Cook in working closely with physicians to develop new ways to improve minimally invasive medicine. Cook makes 16,000 medical products that serve 13 hospital lines. Cook provides products to 135 countries. Cook, and similarly situated medical device manufacturers, will be unnecessarily stripped of a viable defense, which is compelled by and consistent with how FDA regulates the medical device industry, if device manufacturers cannot present evidence that they complied with FDA's regulations in products liability litigation.

II. SUMMARY OF THE ARGUMENT

FDA's 510(k) program includes a determination that the medical device thus cleared for marketing is safe and effective. FDA's 510(k) program requires manufacturers to submit information showing the device's safety and effectiveness. FDA itself has said that,"[t]he 510(k) program, as it currently exists, is intended to support FDA's public health mission by meeting two important goals; making available to consumers devices that are safe and effective, and fostering innovation in the medical device industry." [2] Preventing device manufacturers from presenting evidence of their compliance with the FDA's 510(k) program frustrates both

[2] FDA, CDRH, Preliminary Internal Evaluations – Volume 1, 510(k) Working Group Preliminary Report and Recommendations (Aug. 2010) ("The Current 510(k) Program"), Executive Summary, at 3.

important FDA goals. Consequently, numerous jurisdictions have held the evidence of a defendant manufacturer's compliance with FDA's 510(k) program is relevant and admissible.

III. ARGUMENT

A. The Overwhelming Weight of Authority Admits Evidence of a Defendant's Compliance with Product Safety Regulations in a Product Liability Case

Concerning compliance with product safety statutes or regulations, the Restatement (Third) of Torts states,

> [i]n connection with liability for defective design or inadequate instructions or warnings: . . . (b) a product's compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation, but such compliance does not preclude as a matter of law a finding of product defect.

Restat. 3d of Torts: Products Liability, § 4(b) (1998). "The overwhelming majority of jurisdictions hold that compliance with product safety regulation is relevant and admissible on the question of defectiveness, but is not necessarily controlling." *Id.*, Reporter's notes to comment e (1998). In support of the quoted statement, the Reporter cites six cases, four of which deal specifically with FDA compliance. *See O'Gilvie v. International Playtex, Inc.*, 821 F.2d 1438 (10th Cir.1987) (proper under Kansas law to give instruction that fact that tampon package warning was in conformity with FDA regulations was not a complete defense in strict liability action if reasonable manufacturer would have taken additional precautions); *Foyle v. Lederle Labs.*, 674 F.Supp. 530, 533 (E.D.N.C.1987) ("[i]n summary, compliance with FDA regulations is evidence of due care but it is not controlling"); *Carlin v. Superior Court*, 920 P.2d 1347 (Cal.1996) (compliance with FDA regulations is relevant in a common-law action for failure to warn); *Washington State Physicians Ins. Exch. & Assoc. v. Fisons Corp.*, 858 P.2d 1054, 1069 (Wash.1993) (evidence of compliance with FDA regulations does not necessarily

relieve a drug manufacturer of liability for failure to warn, but is evidence that warning was proper, because the FDA regulations merely set minimum requirements).

The District Court carved out an exception to this general rule of admissibility on the grounds that Bard's device at issue was cleared for marketing under FDA's 510(k) program. The Court did so because the Restatement and applicable Georgia law use the words "*safety* statute," and the Supreme Court held in *Medtronic v. Lohr* that the 510(k) program does not include an assessment of whether the medical device product is safe and effective, and, therefore, evidence of compliance with FDA's 510(k) program was not relevant. While that may have been true of the FDA's 510(k) program at issue in *Medtronic v. Lohr*, it is no longer true. The District Court's determination that FDA's 510(k) program does not relate to safety is, therefore, erroneous.

B. FDA's 510(k) Current Program Includes a Determination that the Device is Safe and Effective

In its Order on C.R. Bard, Inc.'s Motion for Clarification and Reconsideration, the District Court relied upon *Medtronic, Inc. v. Lohr* and *Riegel v. Medtronic, Inc*., 552 U.S. 312, (2008), for the proposition that, when FDA clears a device for marketing under its 510(k) program, FDA is not thereby deciding that the medical device is safe and effective. In doing so, the District Court ignored the persuasive analysis of the Supreme Court in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). In *Buckman*, the Court stated both FDA's Premarket Approval ("PMA") program **and** its 510(k) program are intended "to ensure . . . that medical devices are reasonably safe and effective." *Id*., at 349-50. Though typically not as rigorous as the PMA process, the 510(k) process is also a "comprehensive scheme" that "imposes upon applications a variety of requirements" and necessitates submission of a variety of information. *Id*. at 348-50.

Medtronic v. Lohr is distinguishable because, unlike the earlier version of the 510(k) program there before the Supreme Court, the current 510(k) program **does** involve a determination by FDA that the device is safe and effective because, among other things, manufacturers must submit an "adequate summary of any information respecting safety and effectiveness." 21 U.S.C. 360c(i)(3)(A). In *Lohr,* the device at issue was cleared for marketing in 1982. Since that time, there have been "significant and material statutory and regulatory changes in the 510(k) system" under which, now, "FDA makes a safety and effectiveness determination [.]" R. Hall and M. Mercer, Food and Drug Law Institute, at 24 (2012) ("Hall and Mercer"), for the Court's convenience, a copy of that law review article is included in this Brief as Exhibit "A").

Specifically, in 1990, Congress passed the Safe Medical Device Act ("SMDA"). "The SMDA materially changed medical device regulation and specifically increased the robustness of the 510(k) process, creating more safety and effectiveness requirements on 510(k) medical devices." *Id.* In particular, "the SMDA created the 'special controls' system, defined 'substantial equivalence' and required 510(k) devices to have both the same intended use and same technological characteristics as the predicate device or undergo a new safety and effectiveness review to ensure that the new product did not present new safety or effectiveness issues." *Id.* (internal citations omitted). Accordingly, after passage of the SMDA, FDA has "substantially more robust authority" to ensure safety and effectiveness of 510(k) medical devices and such authority did not exist in 1982 when FDA cleared Medtronic's lead that was at issue in *Lohr*. *Id.* In order to establish the safety and effectiveness of a 510(k) device, the system compares the device under review to a device that has been cleared and for which a "reasonable assurance of safety and effectiveness" already exists. Hall and Mercer, at 25. "While the comparative

assessment methodology may be different form the PMA system, which looks at each device in isolation, the objective to provide a reasonable assurance of safety and effectiveness is identical." *Id*.

Not only does the current medical device regulatory system establish FDA's authority to conduct a safety and effectiveness assessment for 510(k) devices, but FDA in fact currently assesses safety and effectiveness as part of its 510(k) program. FDA states that the statutory changes to its 510(k) program now require FDA to consider safety and effectiveness:

> [T]he 510(k) program has changed significantly since its inception. The MDA established the premarket notification process as a simple check to assure proper device classification. Through various statutory and regulatory modifications over time, it has become a multifaceted premarket review process that is expected to assure that cleared devices, subject to general and applicable special controls, provide reasonable assurance of safety and effectiveness, and to facilitate innovation in the medical device industry.

The Current 510(k) Program, *supra*, at 34.

FDA recently explained how its 510(k) Program includes a determination that a device cleared to be marketed under that program is safe and effective in its 2014 Guidance for Industry and Staff: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] (hereinafter "FDA's 2014 Guidance"). Though the PMA process and the 510(k) process have differences, FDA explained the 501(k) program in its 2014 Guidance as follows:

> The 510(k) review standard (substantial equivalence of a new device to a legally marketed (predicate) device) differs from the PMA review standard (reasonable assurance of safety and effectiveness). The 510(k) review standard is comparative, whereas the PMA standard relies on an independent demonstration of safety and effectiveness. **Nonetheless, the principles of safety and effectiveness underlie the substantial equivalence determination in every 510(k) review….**
>
> **Safety and effectiveness factor into both parts of the FDA's review.** First, FDA must find that the intended use of the device

> and its predicate are "the same."…[D]ifferences in the indications for use, such as the population for which a device is intended or the disease a device is intended to treat do not necessarily result in a new intended use. Such differences result in a new intended use when they affect (or may affect) the safety and/or effectiveness of the new device as compared to the predicate device and the differences cannot be adequately evaluated under the comparative standard of substantial equivalence….
>
> Second, when comparing a new device to a predicate device, FDA must find that the two devices have "the same technological characteristics," or that a "significant change in the materials, design, energy source or other features of the device" does not raise different questions of safety and effectiveness and that the device is as safe and effective as a legally marketed device….
>
> Although the 510(k) process involves a comparison of a new device to a predicate device rather than an independent demonstration of a new device's safety and effectiveness, as is required for approval of a PMA, **in both cases FDA's review decision reflects a determination of the level of control necessary to provide a "reasonable assurance of safety and effectiveness."**

Id., at 6-7 (emphasis added; footnote omitted).

FDA thus makes clear that its 510(k) program includes a determination that the subject medical device is safe and effective. FDA has been charged by Congress with implementing the Food, Drug & Cosmetics Act. FDA's explanation of how it implements its 510(k) program is, therefore, entitled to substantial weight.

As yet another example of FDA's focus on safety and effectiveness as an integral part of 510(k) process, Exhibit "B" hereto is a copy of Appendix A to FDA's 2014 Guidance, which shows how, at crucial steps in the 510(k) decision-making process, questions of safety and effectiveness must be answered. FDA's assessment of safety and effectiveness are clearly an integral part of its 510(k) program. As the expert in medical devices charged by Congress with oversight of the medical device industry, FDA's determination that a medical device is safe and effective clearly has probative value on the issue of whether that device is defective.

A medical device manufacturer's 510(k) submission itself is evidence that its device is safe and effective. A device manufacturer generally must submit an "adequate summary of any information respecting safety and effectiveness." 21 U.S.C. 360c(i)(3)(A). FDA has the authority to require additional safety-related information. FDA "has access to 'all available safety and effectiveness' information' on the 510(k) device." Hall and Mercer, at 25. "Thus, the requisite basis and additional scientific information submitted with every 510(k) submission or available to the FDA substantiates FDA's safety and effectiveness determination because the basis of clearance requires evidence demonstrating that the device operates similarly to its predicate, and that the device is safe and effective for its intended purpose." *Id*.

As explained in Hall and Mercer, one of "the best tests for whether the 510(k) system in fact assesses safety and effectiveness is to look at how the system is actually implemented." *Id*. In Hall and Mercer, the authors looked at examples of recent 510(k) summaries for 510(k) medical devices which demonstrated that the FDA "does indeed make a safety and effectiveness assessment as part of a 510(k) review." *Id*. For example:

> Via Biomedical, Inc.'s Stent Graft Balloon Catheter was determined substantially equivalent and cleared for market distribution in 2009. Included in the 510(k) summary was the flowing: "The Stent Graft Balloon Catheter underwent mechanical, performance, and biocompatibility testing to verify that the device functions in a safe and effective manner. The results of the tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its indications for use."
>
> In accepting Via Biomedical's 510(k) summary and clearing the catheter for market, FDA acknowledged and confirmed the devices substantial equivalence for the indications determined safe and effective in the proceeding summary.

Hall and Mercer, *supra*, at 25. As evidenced by actual 510(k) applications, it is clear Congress created and FDA implements a system that specifically includes a safety and effectiveness

determination. Accordingly, based on *Buckman*, the **current** 510(k) program, and FDA's own statements and actions, FDA's decision to clear a medical device for marketing under its 510(k) program includes a determination that the device is safe and effective. The District Court's conclusion to the contrary is erroneous.

C. Evidence of Compliance with FDA's 510(k) Program is Relevant and Admissible

Evidence is relevant if "it has a tendency to make a fact more or less probable than it would be without the evidence" and "the fact is of consequence in determining the action." Fed. R. Evid. 401. Irrelevant evidence is not admissible. Fed. R. Evid. 402. Relevant evidence may be excluded if "its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence. Fed. R. Evid. 403. Based on Fed. R. Evid. 402 and 403, the District Court excluded Bard's proffered evidence that it had completed with FDA's 510(k) program because it determined that evidence was irrelevant and its introduction would waste time, unduly prejudice the plaintiff and mislead the jury. *Cisson*, Dkt. No. 309, pp. 3-4, Dkt No. 302, pp. 3-4.

Because FDA's 510(k) program includes an assessment by the experts at FDA that the device is safe and effective, the District Court's reasoning is erroneous, and evidence that a device manufacturer complied with FDA's 510(k) program is evidence of compliance with a product safety regulation that is, therefore, relevant to whether the device is defective. Restat. 3d of Torts: Products Liability, § 4(b), Reporter's notes to comment e (1998). Numerous courts across the country have adopted such a position. *See Musgrave v. Breg, Inc.*, 2011 U.S. Dist. LEXIS 113661 (S.D. Ohio Oct. 3, 2011) (rejecting the proposition that a 510(k) FDA clearance was irrelevant and holding it had probative value and such value was not substantially

outweighed by the danger of confusion of the issues or misleading the jury); *Block v. Woo Young Med. Co.*, 937 F. Supp. 2d 1028 (D. Minn. 2013) (finding testimony admissible as to "the general nature of the FDA's approval and regulatory process and "the FDA's general expectations" regarding a §510(k)-cleared product); *Placencia v. I-Flow Corp.*, 2012 U.S. Dist. LEXIS 165618 (D. Ariz. Nov. 20, 2012) (finding evidence of FDA compliance relevant to "determin[e] the appropriate standard of care"); *Pritchett v. I-Flow Corp.*, 2012 U.S. Dist. LEXIS 54179 (D. Colo. Apr. 18, 2012) ("whether Defendant complied with federal regulations is relevant"); *Corrigan v. Methodist Hosp.*, 874 F. Supp. 657, 658 (E.D. Pa. 1995) (FDA approval status of 510(k) medical device is relevant and probative and denying exclusion based on Fed. R. Evid. 403).[3]

To the extent that the District Court found Bard's crucial evidence of compliance with the FDA's 510(k) program to be unfairly prejudicial, misleading and a waste of time and, therefore, inadmissible under Fed. R. Evid. 403, that decision was an abuse of discretion. For example, in *Musgrave* and *Corrigan*, the Courts specifically denied exclusion of evidence of compliance with FDA's 510(k) program based on Fed. R. Evid. 403.

Although not specific to FDA's 510(k) program, numerous courts have found evidence of compliance federal regulations relevant and admissible regardless of potential issues under Fed. R. Evid. 403 concerning regulatory morass distracting the jury from other aspects of the case. *See* Restat. 3d of Torts: Products Liability §4, reporter's notes to comment e (1998) (stating

[3] Numerous courts have found that compliance with FDA regulations, in general, is relevant and admissible evidence. *See, e.g., Tobin v. Astra Pharmaceutical Products, Inc.*, 993 F. 2d 528, 538 (6th Cir. 1993); *Salmon v. Parke Davis & Co.*, 520 F.2d 1359, 1362 (4th Cir. 1975); *Rader v. Teva Parental Medicines, Inc.*, 795 F. Supp. 2d 1143, 1149 (D. Nev. 2011); *Torkie-Tork v. Wyeth*, 739 F. Supp. 2d 895, 900 (E.D. Va. 2010); *Erickson v. Baxter Healthcare, Inc.*, 151 F. Supp.2d 952, 966 (N.D. Ill. 2011); *Hegna v. E.I. du Pont de Nemours & Co.*, 806 F. Supp. 822, 830 (D. Minn. 1992); *Mazur v. Merk Co.*, 742 F. Supp. 239, 247 (E.D. Pa. 1990); *Martinkovic v. Wyeth Laboratories, Inc.*, 669 F. Supp. 212, 217 (N.D. Ill. 1987); *Graham v. Wyeth Laboratories*, 666 F. Supp. 1483, 1493 (D. Kan. 1987); *Brick v. Barnes-Hines Pharmaceutical Co.*, 428 F. Supp. 496, 498 (D.D.C. 1977).

"[t]he overwhelming majority of jurisdictions hold that compliance with product safety regulation is relevant and admissible on the question of defectiveness, but is not necessarily controlling); *see also S. L. M. v. Dorel Juvenile Group, Inc.*, 514 Fed. Appx. 389, 391 (4th Cir. Va. 2013) (stating "a product's compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation"); *Talley v. Danek Med., Inc.*, 7 F. Supp. 2d 725, 731 (E.D. Va. 1998) (observing that, in evaluating design defect, "a court should consider whether the product fails to satisfy . . . applicable government standards"); *In re Methyl Tertiary Butyl Ether("MTBE") Prods. Liab. Litig.*, 438 F. Supp. 2d 291, 301 (S.D.N.Y. 2006) (stating "while Congressional regulation is relevant to tort liability, it is not dispositive"); and *Covell v. Bell Sports, Inc.*, 651 F.3d 357, 365 (3d Cir. Pa. 2011) (stating "most jurisdictions applying the Restatement (Third) of Torts to products liability cases hold that evidence of compliance with product regulations is admissible to prove whether or not a product is defective").

The District Court could have eliminated any Fed. R. Evid. 403 concerns by simply instructing the jury on the proper weight to be given such regulations. *Bartlett v. Mutual Pharmaceutical Co.*, 760 F. Supp.2d 220, 249 (D.N.H. 2011) (instructing jury that compliance with FDA requirement relevant but "not necessarily conclusive or controlling") (reversed on other grounds). Thus, this Court should reverse the District Court's decision to exclude evidence of compliance with government regulations.

D. Excluding Evidence of Compliance with FDA Regulations will have a Detrimental Effect on the Medical Device Industry

Evidence concerning compliance with federal regulations is highly relevant and probative in medical device product liability litigation. Preclusion of such evidence will put medical

device manufacturers at risk of even more litigation across the country. Several harmful effects will result.

As FDA has said, its current 510(k) program is intended not only to ensure that medical devices made available to consumers are safe and effective, but also to foster innovation in the medical industry. The Current 510(k) Program, *supra*, at 3. That second goal will be frustrated if evidence of a medical device manufacturer's compliance with FDA's 510(k) program is excluded.

Precluding evidence supportive of such a viable and probative defense will stifle the innovation of important and life-changing medical devices. In its 2004 report entitled Innovation or Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products, FDA noted that there is a "growing crisis in moving basic discoveries to the market where they can be made available to patients." As FDA observed, "there is growing concern that many of the new basic science discoveries made in recent years may not quickly yield more effective, more affordable, and safe medical products for patients. This is because the current medical product development path is becoming increasingly challenging, inefficient, and costly." *Id.*

The American Medical Association has stated that, "[i]nnovative new products are not being developed or are being withheld from the market because of liability concerns or inability to obtain adequate insurance." *See Riegel v. Medtronic, Inc.*, 2007 U.S. S. Ct. Briefs LEXIS 1290, *Amicus Brief* at *38 (citing Am. Med. Ass'n Bd. Of Trs., *Impact of Product Liability on the Development of New Medical Technologies* 1 (1988)). It is difficult in this litigious climate to effectively insure against tort risks. *Id.* (David Dial et al., *Tort Excess 2005: The Necessity for Reform from a Policy, Legal and Risk Management Prespective*, 9-10 (2005) ("[t]he unpredictable and catastrophic nature of U.S. tort exposures . . . has made insuring large-scale

liability risks substantially more challenging"); Scott E. Harrington, *Tort Liability, Insurance Rates, and the Insurance Cyclce, Brookings-Wharton Papers on Financial Services* (2004) ("An expanding tort liability system that entails substantial uncertainty about the cost of future claims will inevitably lead to increasingly expensive [insurance] coverage")).

"[M]edical equipment companies are increasingly reluctant to innovate because of concern about suits with larger numbers of claimants and extraordinary awards." *Id*. at *39 (Lawrence Tancredi & Dorothy Nelkin, *Medical Malpractice and Its Effects on Innovation*, 251, 260, in the Liabilty Maze (P.W. Huber & R.E. Litan eds., 1991)). "The threat of . . . enormous awards has detrimental effect on the research and development of new products. Some manufacturers of prescription drugs, for example, have decided that it is better to avoid uncertain liability than to introduce a new pill or vaccine into the market." *Id*. (quoting *Browning Ferris Indus. Of Vt., Inc. v. Kelco Disposal, Inc.*, 492 U.S. 257, 282 (1989) (O'Connor, J., concurring in part and dissenting in part)).

Professor Michael E. Porter of the Harvard Business School has explained that "product liability is so extreme and uncertain as to **retard innovation**" because "the legal and regulatory climate places firms in constant jeopardy of costly and, as importantly, lengthy product liability suits" and "goes beyond any reasonable need to protect consumers." *Id*. at *39-40 (quoting Michael E. Porter, *The Competitive Advantage of Nations*, 649 (1990) (emphasis added)).

Another harmful result of the added uncertainty to the litigation process is the increased cost of medical devices. For example, between 1980 and 1989, "the wholesale price of most vaccines doubled or tripled; in contrast, the price of two vaccines with a high perceived liability potential increased by factors of 40 and seven in the same time period." *Riegel v. Medtronic, Inc.*, 2007 U.S. S. Ct. Briefs LEXIS 1290, Amicus Brief at *48 (citing Richard L. Manning,

Changing Rules in Tort Law and the Market for Childhood Vaccines, 37 J. L. &Econ., 247, 254-57, 273 (1994)). "In setting the price of medical therapies, not only must a manufacturer recoup its research, development, and production costs through devices sales . . . but it also must insure against litigation risks." *Id*. Having inconsistent standards concerning the admissibility of such probative and relevant evidence would add additional risk to bringing devices to market, and that risk will be reflected in the cost of the medical devices.

Therefore, exclusion of evidence of compliance with FDA's 510(k) program will stifle medical device innovation, deprive patients of safe and effective medical treatments, and increase the cost of medical devices.

IV. CONCLUSION

Based on the foregoing, the decision of the District Court excluding Bard's evidence that it obtained clearance to market the medical device from FDA under its 510(k) program should be reversed.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 20, 2015, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Douglas B. King
Douglas B. King, IN Bar # 5199-49