Nos. 18-16349 & 18-16460

IN THE

United States Court of Appeals for the Ninth Circuit

IN RE: BARD IVC FILTERS PRODUCT LIABILITY LITIGATION

SHERR-UNA BOOKER,

Plaintiffs/Appellee/Cross-Appellant,

V.

C.R. BARD, INC., ET AL.,

Defendants/Appellants/Cross-Appellees.

On Appeal from the United States District Court for the District of Arizona
Case Nos. 2:15-md-02641 & 2:16-cv-0474
The Honorable David G. Campbell, United States District Judge

BRIEF OF THE AMERICAN ASSOCIATION FOR JUSTICE AS AMICUS CURIAE IN SUPPORT OF PLAINTIFF/APPELLEE/CROSS-APPELLANT AND AFFIRMANCE

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, amicus curiae the American Association for Justice certifies that it is a non-profit voluntary national bar association. There is no parent corporation or publicly owned corporation that owns 10% or more of this entity's stock.

Respectfully submitted this 17th day of May, 2019.

/s/ Robert S. Peck

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AMICUS CURIAE'S IDENTITY, INTEREST, AND AUTHORITY TO FILE

The American Association for Justice ("AAJ") is a national, voluntary bar association established in 1946 to strengthen the civil justice system, preserve the right to trial by jury, and protect access to the courts for those who have been wrongfully injured. With members in the United States, Canada, and abroad, AAJ is the world's largest trial bar. AAJ's members primarily represent plaintiffs in personal injury actions, employment rights cases, consumer cases, and other civil actions, including medical device cases. Throughout its more than 70-year history, AAJ has served as a leading advocate of the right of all Americans to seek legal recourse for wrongful injury.[1]

This case is of acute interest to AAJ and its members. AAJ works to protect the ability of plaintiffs to vindicate their rights under state tort laws. Since the trilogy of decisions affecting drug and medical device preemption under the Food, Drug, and Cosmetic Act, manufacturers of drug and medical devices have sought to curtail plaintiffs' state-law rights by seeking an expansive view of preemption that would displace lawsuits seeking compensation for injuries received from the

[1] All parties have consented to the filing of this brief. No party or party's counsel authored this brief in whole or in part. No person, other than amicus curiae, its members, and its counsel, contributed money that was intended to fund the preparation or submission of this brief.

manufacturers' products. In this case, the defendant-manufacturer has explicitly proposed the courts enlarge the preemptive scope of federal law.

Based on its members' experience with pharmaceutical and medical-device tort litigation—and its organizational concern for the development of the law in this area—AAJ is well positioned to explain why such an expansion of federal preemption doctrine is both ill-conceived and contrary to the statutory scheme and precedent.

STATEMENT OF ISSUE PRESENTED

Does 21 U.S.C. § 360k(a) of the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetics Act ("FDCA") expressly preempt Plaintiff's state law tort claims?

SUMMARY OF ARGUMENT

The disposition of the preemption issue in this appeal is controlled by the Supreme Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), and by the FDA's own regulations and actions, which are consistent with *Lohr*. Applying that precedent and FDA regulations faithfully, the district court correctly held that the underlying action in this matter was not expressly or impliedly preempted.

It is little wonder then that Appellant-Defendant C.R. Bard, Inc. ("Bard") asks this court to treat *Lohr* as antiquated and irrelevant to the current regulatory scheme, because as long as *Lohr* is good law, it cannot prevail. Bard's request, however, fails

for one fundamental reason: *Lohr* remains good law. It is unimpaired by subsequent decisions or subsequent statutory or regulatory language.

Under Bard's specious argument, a device manufacturer relying on 510(k) substantial equivalence status but who engaged in a self-anointed process that has elements different from what the FDA imposes as requirements would receive preemption treatment on a par with those whose devices actually follow FDA requirements. Yet, pretend requirements are not the stuff that animates preemption. Under Bard's theory, the manufacturer, not the FDA or federal law, determines the preemptive status of the regulatory scheme. Yet, preemption is a function of the Supremacy Clause and the exercise of federal power; it is not a license for a manufacturer to impose its own basis for preemption – or excuse itself from liability. Bard's compliance with generally applicable processes, which is all it really claims, does not provide a basis for preemption.

At bottom, the district court engaged in the correct analysis of Bard's preemption defense and should be affirmed.

ARGUMENT

I. *MEDTRONIC, INC. v. LOHR* CONTROLS DISPOSITION OF THE PREEMPTION ISSUES.

As the district court correctly held, *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), controls the disposition of the preemption issues in this case. In *Lohr*, the Supreme Court held that only federal requirements specific to a particular device

preempt state law, consistent with the Food and Drug Administration's ("FDA") regulations. 518 U.S. at 500-03. Bard's suggestion that this was a plurality view is wrong.

As in this case, *Lohr* involved a medical device cleared for use through the 510(k) process, rather than through the more rigorous premarket approval ("PMA") process. As the district court and the parties' briefs explain in detail, the 510(k) process involves a determination that device is "substantially equivalent" to one that has previously been approved for marketing. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008). The *Lohr* Court found it significant, for purposes of preemption analysis, that the 510(k) process did not involve the same type of device-specific regulation that accompanies the much more comprehensive premarket approval regime, which takes considerably longer to complete than the 510(k) process.

Subsequently, in *Riegel*, the Court adhered to the same sharp line drawn in *Lohr* between devices that underwent PMA approval and those that received 510(k) approval. This Court has relied on the same distinction, finding no reason to find issue with what it recognized was plainly a majority holding in *Lohr*. *Papike v. Tambrands Inc.*, 107 F.3d 737, 742 (9th Cir. 1997) ("'the scope of preemption is limited to instances where there are specific FDA requirements applicable to a particular device.'") (citation omitted).

Bard's suggestion that *Lohr* represents outmoded thinking on preemption contradicts a fair reading of the caselaw.

A. *Lohr* Remains Mandatory Precedent.

Bard suggests that *Lohr* should receive a somewhat lesser status than is normally accorded a decision of the Supreme Court of the United States. Bard does so because it contends the district court erroneously relied upon *Lohr*. Bard First Brief on Cross-Appeal ("Bard Br.") 39. Bard insinuates that the *Lohr* decision is due less respect because the "deciding vote making up the plurality" resulted in a "fractured preemption analysis." Bard Br. 30. Relatedly, Bard claims that *Lohr* was undercut by subsequent decisions in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), and *Puerto Rico v. Franklin Cal. Tax-Free Tr.*, 136 S. Ct. 1938, 1946 (2016). Bard Br. 32. Bard's arguments are built on false premises.

1. Lohr is a majority decision and binding on this Court.

Justice Stevens wrote the opinion *for the Court* in *Lohr* with respect to Parts I, II, III, V, and VII of the decision. 518 U.S. at 474; *see also id.* at 508 (Breyer, J., concurring in part and concurring in the judgment) ("I also join the Court's opinion, but for Parts IV and VI."). These statements establish that a clear majority of the Court supported the essential holdings in *Lohr*. In Part V of the opinion, *the Court* determined that the "company's defense exaggerates the importance of the § 510(k) process and the FDA letter to the company regarding the pacemaker's substantial

equivalence to a grandfathered device." *Id.* at 492-93. It agreed with the lower court and held that the 510(k) process was concerned with "'*equivalence*, not safety.'" *Id.* at 493 (citation omitted). That evaluation, the Court said, was quite different from a device that is "formally reviewed under the MDA for safety or efficacy." *Id.*

Of significance, the Court stated that

> even though the FDA may well examine § 510(k) applications for Class III devices (as it examines the entire medical device industry) with a concern for the safety and effectiveness of the device, . . . it did not "require" Medtronics' pacemaker to take any particular form for any particular reason; the agency simply allowed the pacemaker, as a device substantially equivalent to one that existed before 1976, to be marketed without running the gauntlet of the PMA process.

Id. at 493-94. *Lohr* further held that § 360k does not preempt state law claims on devices cleared through the 510(k) process because review for substantial equivalency places no federal requirements on a device. *Id.* at 492-94.

This finding is not a plurality view, but a majority holding. It remains unimpaired, controlling precedent that was properly relied upon by the district court here. With that analysis, the *Lohr* Court *held* the "'substantial equivalence' provision did not pre-empt the Lohrs' design claims." *Id.* at 494. Similarly, within this section of the Court's opinion, *Lohr* denied preemption of "manufacturing and labeling claims to the extent that they rest on claims that Medtronic negligently failed to comply with duties 'equal to, or substantially identical to, requirements imposed'

under federal law," permitting all of the Lohrs' manufacturing and labeling claims to go forward. *Id.* at 497, 502.

Significantly, and in contrast to Bard's argument, *Riegel* subsequently recognized and endorsed the clear line *Lohr* drew between substantially equivalent devices and those that underwent the PMA process. *Riegel*, 552 U.S. at 322. The Court noted that there was agreement among all nine justices in *Lohr* that § 510(k) approval involved a "qualification for an exemption rather than a requirement." *Id.* (citing *Lohr*, 518 U.S. at 493-94; *id.*, at 513 (O'Connor, J., concurring in part and dissenting in part)). The *Riegel* Court went on to state that, unlike a substantial equivalency determination, "[p]remarket approval, in contrast, imposes 'requirements.'" *Id.*

Bard's argument that *Lohr* has diminished gravitational pull focuses on Section IV of the opinion, which only commanded the votes of four justices. Yet, the section does not announce a holding in the case and does not implicate the basis of the decision below. Section IV consists of an analysis of the legislative history of the MDA's preemption provision. That legislative history and its implications have no bearing on the express preemption argument that Bard has appealed. That Justice Breyer's partial concurrence did not join this section does not change the relevant holding in *Lohr* or its status as mandatory precedent. Justice Breyer simply held out a greater possibility than the plurality did that a state tort action, and not just state

statutory law, could be preempted. *Riegel*, 552 U.S. at 504-05. Still, nothing in the district court's decision in this case implicates the disagreement that Justice Breyer expressed with the plurality portion of the opinion in *Lohr*.

Moreover, because five justices disagreed with the plurality on that issue, *Lohr* did not hold that tort claims are outside the preemptive scope of the MDA and thus, no rationale undergirding *Lohr* could be impaired by subsequent decisions, as Bard asserts it does. After all, when five justices assent to a "single rationale explaining the result," it constitutes the holding of the Court. *See Marks v. United States*, 430 U.S. 188, 193 (1977); *see also Riegel*, 552 U.S. at 323. *Lohr's* actual rationale, a straightforward construction of the preemptive language of the MDA, fortified by FDA regulations, remains unquestioned. *See Papike*, 107 F.3d at 742 (examining the interplay of Justice Breyer's concurrence and the rest of *Lohr*, and rejecting the same argument Bard puts forth here).

Contrary to Bard's portrayal, Justice Breyer subscribed to the critical preemption analysis and the fundamental holdings in *Lohr*, rendering those aspects of the decision to be holdings of the Court. Bard's suggestion that *Lohr* is little more than a fractured opinion that lacks a consistent rationale amounts to nothing more than a red herring.

B. *Lohr's* Holding is Neither Impaired Nor Open to Question in the Lower Courts.

Bard's claim that *Lohr* was undercut by subsequent decisions is without merit.

1. Riegel *Follows and Does Not Impair* Lohr.

Bard fancifully claims that *Riegel* undercuts *Lohr*. Yet, *Riegel* echoed *Lohr's* holdings that only federal requirements preempt state law, that 510(k) review does not impose such requirements but merely qualifies a device for the market, and that the MDA's preemption provision still allowed a State to "provid[e] a damages remedy for claims premised on a violation of FDA regulations." *Riegel*, 552 U.S. at 322, 330. The holding that a damages remedy remains available when the federal requirement at issue is duplicative of a state common-law duty endorsed the need for a specific requirement to invoke preemption and the *Lohr* plurality's "understanding that § 360(k) [the express preemption provision] simply was not intended to pre-empt most, let alone all, general common-law duties enforced by damages actions." *Lohr*, 518 U.S. at 491 (plurality op.). *Riegel's* consistency with *Lohr* destroys Bard's claim that the newer decision undercuts the previous decision.

Riegel reaffirmed the key distinctions between PMA and 510(k) approval that warrant different preemption approaches for devices. As in *Lohr*, the *Riegel* Court acknowledged that only the PMA process "imposes 'requirements'" under the MDA that are "specific to individual devices" and, through those requirements, "provides a reasonable assurance of safety and effectiveness." 552 U.S. at 322-23.

Bard rests its contention that *Lohr* was impaired by *Riegel* on the canard that *Riegel* rejected Justice Stevens' view for the plurality of the Court that § 360k(a)'s

preemptive effect did not seek to reach state tort cases. Bard Br. 32. Yet, as already explained, a clear majority in *Lohr* indicated that state tort cases were subject to preemption under the right circumstances, and that the rationale about state tort cases was not an element of the majority's view on the preemption analysis that must take place here. Contrary to Bard's presentation of the issue as a reversal of *Lohr* on the status of state tort claims, *Riegel* "adhere[s] to th[e] view" expressed by five justices in *Lohr*. *Riegel*, 552 U.S. at 324 (citing *Lohr*, 518 U.S. at 512 (opinion of O'Connor, J., joined by Rehnquist, C. J., and Scalia and Thomas, JJ.), 503-05 (Breyer, J., concurring in part and concurring in judgment)). In other words, there was no reversal. Still, the issue of state tort claims has no relevance to the Court's consistent reading of differences between the 510(k) and PMA processes and is immaterial to the analysis undertaken by the district court in this case.

2. Puerto Rico v. Franklin Is Consistent with Lohr.

Bard rests its argument on an even thinner reed when it invokes *Puerto Rico v. Franklin Cal. Tax-Free Tr.*, 136 S. Ct. 1938 (2016) to suggest that *Lohr's* rationale was undermined so that the district court should not have relied upon it. *Puerto Rico* involved a preemption question under the Bankruptcy Act, not the MDA. Because express preemption analysis is statute-specific, reflecting congressional intent in that specific law, the distinction is significant.

In *Puerto Rico*, the Court held that the presumption against preemption does not apply to express preemption because the proper "focus [is] on the plain wording of the [preemption] clause, which necessarily contains the best evidence of Congress' pre-emptive intent." 136 S. Ct. at 1946 (citations omitted). The decision does not comment upon or cite *Lohr* in any respect. As a result, it does not affect *Lohr's* vitality. If the Supreme Court seeks to overrule a prior precedent, it "does not normally overturn, or so dramatically limit, earlier authority *sub silentio*." *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 18 (2000).

The Third Circuit recently disagreed with an argument similar to the one made by Bard that "[a]ny presumption against express preemption no longer exists." *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 771 n.9 (3d Cir. 2018). It held that *Puerto Rico* "did not address preemption of claims invoking 'historic . . . state regulation of matters of health and safety,' such as the products liability claims at issue here," and pledged to "continue to apply the presumption against preemption to claims, like those in this case, that invoke 'the historic police powers of the State.'" *Id.* (quoting *Lohr*, 518 U.S. at 485). Thus, the Third Circuit rejected Bard's argument about both *Puerto Rico* and *Lohr* in one fell swoop.

The presumption against preemption has been declared dead before only to be revived. *See Air Evac EMS, Inc. v. Cheatham*, 910 F.3d 751, 762 n.1 (4th Cir. 2018) (expressing confusion over conflicting Supreme Court precedent); Robert S. Peck,

A Separation-of-Powers Defense of the "Presumption Against Preemption," 84 Tul. L. Rev. 1185, 1185-86 (2010) (describing the "ping-pong nature of the Court's treatment of the antipreemption presumption"). Still, presumption continues to play a significant role in preemption analyses post-*Puerto Rico*, both in this Circuit and in sister circuits. *See, e.g.*, *Knox v. Brnovich*, 907 F.3d 1167, 1174 (9th Cir. 2018) ("presumption against preemption applies when a state regulates in an area of historic state power even if the law 'touche[s] on' an area of significant federal presence.") (citation omitted); *Durnford v. MusclePharm Corp*., 907 F.3d 595, 601 (9th Cir. 2018) ("a presumption against preemption applies to the extent the FDCA is used to displace state law in an area of traditional state police power."); *Int'l Ass'n of Machinists Dist. Ten & Local Lodge 873 v. Allen*, 904 F.3d 490, 515 (7th Cir. 2018), *cert. dismissed*, 2019 WL 1746784 (U.S. Apr. 19, 2019) ("Importantly, preemption analysis 'begins with a presumption *against* preemption and focuses first on the text of the statute.'" (citation omitted)); *Bedoya v. Am. Eagle Express Inc*., 914 F.3d 812, 818 (3d Cir. 2019) (because issue involves exercise of state's police power, "the presumption against preemption by federal law applies.").

Regardless of the presumption's status, *Lohr*, like *Puerto Rico*, stated that the "'ultimate touchstone' in every pre-emption case," namely, congressional intent, is primarily "discerned from the language of the pre-emption statute and the 'statutory framework' surrounding it." 518 U.S. at 485-86.

In making its determination in this case, the district court only utilized the presumption against preemption after holding that there was no express preemption and engaging Bard's alternative argument about implied preemption. (*See* Doc. 8872, at 25 ("Bard has also failed to overcome the presumption against preemption that applies to its implied preemption argument.")). There is nothing in the district court's use of the presumption against preemption in that manner that conflicts with *Puerto Rico*.

3. The Supreme Court has reserved to itself the privilege of overruling its precedent.

Bard's argument essentially asks this Court to either treat *Lohr* as bad law or overlook it. Yet, the Supreme Court has rejected the notion that lower courts "should conclude our more recent cases have, by implication, overruled an earlier precedent." *Agostini v. Felton*, 521 U.S. 203, 237 (1997). Similarly, this Court has observed that "binding authority is very powerful medicine," and a "decision of the Supreme Court will control that corner of the law unless and until the Supreme Court itself overrules or modifies it." *Hart v. Massanari*, 266 F.3d 1155, 1171 (9th Cir. 2001).

Bard's suggestion that *Lohr* be ignored is also inconsistent with the doctrine of *stare decisis*. Following precedent is "a foundation stone of the rule of law, necessary to ensure that legal rules develop 'in a principled and intelligible fashion.'" *Michigan v. Bay Mills Indian Cmty.*, 572 U.S. 782, 798 (2014) (quoting

Vasquez v. Hillery, 474 U.S. 254, 265 (1986)). It constitutes the "preferred course because it promotes the evenhanded, predictable, and consistent development of legal principles, fosters reliance on judicial decisions, and contributes to the actual and perceived integrity of the judicial process." *Payne v. Tennessee*, 501 U.S. 808, 827 (1991). It also "reduces incentives for challenging settled precedents, saving parties and courts the expense of endless relitigation." *Kimble v. Marvel Entm't, LLC*, 135 S. Ct. 2401, 2409 (2015).

It is also important to note that *Lohr* construed the requirements of an express preemption provision. Doing so is a matter of statutory interpretation, which is why the text of a preemption clause matters. Cases interpreting statutes are accorded heightened status and "special force" under *stare decisis*, because, "unlike in the context of constitutional interpretation, the legislative power is implicated, and Congress remains free to alter what we have done." *Hohn v. United States*, 524 U.S. 236, 251 (1998) (citation omitted) (internal quotation marks omitted).

Even when precedent "appears to rest on reasons rejected in some other line of decisions, the Court of Appeals should follow the case which directly controls, leaving to this [Supreme] Court the prerogative of overruling its own decisions." *Rodriguez de Quijas v. Shearson/Am. Exp., Inc.*, 490 U.S. 477, 484 (1989). *See also Retail Digital Network, LLC v. Prieto*, 861 F.3d 839, 849 (9th Cir. 2017) (same).

The district court did not err in relying on *Lohr*.

II. THE SAFE MEDICAL DEVICES ACT DOES NOT CHANGE THE ANALYSIS FOR "SUBSTANTIALLY EQUIVALENT" DEVICES.

Alternatively, Bard asserts that because the device in *Lohr* went through the 510(k) process before enactment of the Safe Medical Devices Act of 1990 ("SMDA"), P.L. No. 101-629, 104 Stat. 4511 (1990), the *Lohr* analysis has no relevance here. Bard Br. 29 n.6, 40. Bard's argument essentially asserts that the SMDA changed the substantial equivalency test so that it imposes requirements, making the proper analysis the same one used for PMA devices. The district court correctly spurned this novel argument.

A. The SMDA Was Enacted to Increase After-Market Monitoring of Device Safety.

Enactment of the SMDA, which still predates the relevant Supreme Court jurisprudence relied upon by the district court, does not change the preemption calculus. The SMDA came into being because Congress was alarmed that even after passage of the MDA, devices continued to fail at an alarming rate. In enacting the SMDA, Congress was concerned that existing "postmarket surveillance, product classification, product approval, and enforcement requirements for devices" still failed to translate into sufficient safety. Charles J. Raubicheck, *The FDA's Implementation of the Safe Medical Devices Act of 1990*, 46 Food Drug Cosm. L.J. 885, 885 (1991). *Lohr*, rather than ignore its enactment, acknowledged the SMDA's existence as amending the MDA, explaining that the SMDA was "designed to reduce

the FDA's reliance on the § 510(k) process while continuing to ensure that particularly risky devices received full PMA review." *Lohr*, 518 U.S. at 480 n.4. As the district court here observed, it makes little sense that the Court would adopt an approach to preemption of 510(k)-approved devices that did not account for the SMDA, even if the device before it was approved under a pre-SMDA process. (Doc. 8872, at 13).

Even in Bard's telling, the SMDA was enacted to streamline the FDA review process for 510(k) clearance because of an accumulating backlog of applications. Bard Br. 7. *See also* S. Rep. 513, 101st Cong., at 15 (1990); SMDA § 4(b)(1), 104 Stat. 4515-16 (codified as amended at 21 U.S.C. § 360e(i)) (to address that backlog, the SMDA imposed deadlines for the FDA to reclassify or commence the premarket-approval process for grandfathered Class III devices and their substantial equivalents.).

Speeding the process, however, undermines, rather than qualifies, 510(k) review as a PMA equivalent. The PMA process involves an average FDA expenditure of 1,200 hours reviewing manufacturer submissions of detailed information regarding the safety and efficacy of their devices, making the process a "rigorous one." *Lohr*, 518 U.S. at 477. Instead, the speeded-up process lessens the rigor imposed and further disqualifies devices so approved for treatment, akin to that accorded those that underwent the PMA process.

Nonetheless, Bard contends that that the process adopted "is intended to provide reasonable assurances of safety and effectiveness" for devices "substantially equivalent" to those that received more rigorous premarket approval. Bard Br. 7-9. Bard's argument is at odds with principles of statutory construction, the applicable regulatory scheme, and precedent. In fact, it is remarkable that Bard advances this novel argument nearly 30 years after the SMDA was passed, yet no court has adopted its assertion that the SMDA has undermined the vitality of *Lohr*.

The purpose of the SMDA was "to modify the underlying law in ways that will result in greater protection of the public health." H.R. Rep. No. 808, 101th Cong., at 13 (1990) (reprinted in 1990 U.S.C.C.A.N. 6305, 6306). To do so, Congress did not change the classification scheme for medical devices so that a Class II device, like the Bard IVC Filter at issue here, had to undergo the same rigorous review that a brand-new Class III device receives.

As this Court knows, the MDA set up three classes of medical devices, from Class I to Class III, in ascending order of risk. 21 U.S.C. § 360c. Class III devices "presen[t] a potential unreasonable risk of illness or injury," or are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." *Id*. at § 360c(a)(1)(C). Class I and II devices do not present the same unreasonable risks and thus are not subjected to the same level of scrutiny. Still, even Class III devices,

despite the searching examination that they can receive, generate state tort claims that are not preempted. *See, e.g.*, *Stengel v. Medtronic Inc.*, 704 F.3d 1224 (9th Cir. 2013) (en banc), *cert. denied*, 573 U.S. 930 (2014) (failure to warn claim involving Class III implanted medical pain pump not preempted); *Bass v. Stryker Corp*., 669 F.3d 501 (5th Cir. 2012) (strict liability claim based on a manufacturing defect, negligent manufacturing claim, and claim for breach of an implied warranty involving Class III hip prosthesis not preempted); *Bausch v. Stryker Corp*., 630 F.3d 546 (7th Cir. 2010), *cert. denied*, 565 U.S. 976 (2011) (negligence and strict liability claims for defective Class III hip replacement system not preempted).

Bard IVC Filters are now designated as Class II devices, for which "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." 21 U.S.C. § 360c(a)(1)(B). Its evaluation at the FDA is not focused on safety and effectiveness, but substantial equivalence. *Id.* at § 360c(f)(1)(A)(ii). Only when the new device "has different technological characteristics" than the device it seeks to duplicate will the FDA engage in a limited safety and effectiveness review designed solely to assure that the changes maintain the comparative safety and effectiveness as the device upon which it is based. *Id.* at § 360c(i)(1)(A)(ii). Thus, the 510(k) process remains one of "equivalence, not safety." *Riegel*, 552 U.S. at 323. *Cf.* Inst. of Medicine, Medical

Devices and the Public's Health 118, at 91 (2011), *available at* https://www.nap.edu/read/13150/chapter/1 ("The 510(k) process determines only the substantial equivalence of a new device to a previously cleared device, not the new device's safety and effectiveness or whether it is innovative.").

Riegel maintained *Lohr's* distinction between 510(k) and PMA devices, even though the SMDA was indisputably fully incorporated into the MDA at that point. It stated that "[w]hile § 510(k) is focused on equivalence, not safety, premarket approval is focused on safety, not equivalence." *Riegel*, 552 U.S. at 323 (citation and internal quotation marks omitted). It further recognized that

> while the FDA does not require that a device allowed to enter the market as a substantial equivalent take any particular form for any particular reason, the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness.

Id. (citation and internal quotation marks omitted).

Congress was motivated to enact the SMDA in part because the Government Accounting Office had "documented a significant weakness in FDA's information gathering ability and its follow-up mechanisms, once information is in hand." S. Rep. 513, 101st Cong., at 15 (1990). The SMDA provided an additional means of monitoring injuries after devices were approved under the 510k process by enlisting hospitals and health care facilities to report device problems to the FDA in the form

of "user reports," supplementing what was received directly but often inadequately from manufacturers. 21 U.S.C. § 360i(b)(1)(A). The SMDA also codified the FDA's treatment of "substantial equivalence" for 510(k) devices. *See* S. Rep. 513, 101st Cong., at 28; H.R. Rep. 101-808, at 25 (1990).

It is true that the SMDA added various "special controls" to the general controls utilized for Class I devices. Those special controls can include FDA guidance documents, premarket data requirements, performance standards, postmarket surveillance measures, and patient registries. 21 U.S.C. § 360c(a)(1)(B). Still, a manufacturer satisfies 510(k) review, and avoids the PMA process, by notifying the FDA that its device is "substantially equivalent" to a predicate device already on the market. 21 U.S.C. § 360c(f)(1)(A). Moreover, the substantial equivalency requirement does not impose device-specific requirements, only comparability.

The concern with after-market reporting of device problems does not suggest that the SMDA was aimed at raising the review process for substantially equivalent devices to the level of a PMA and thus impose federal requirements from which a device could not deviate. It therefore did not change the preemption regime applicable to 510(k)-approved devices.

B. No Court Has Accepted Bard's Novel SMDA Theory.

In nearly three decades since the SMDA was enacted, no court has adopted Bard's novel SMDA preemption theory. The fact that it was only recently "discovered" suggests that it is not lodged in congressional intent and is not meritorious.

Counsel has found but one federal case (and no state cases) that considered the argument prior to the decision in the court below. In *Horrillo v. Cook, Inc*., No. 08-60931-Civ., 2014 WL 8186704 (S.D. Fla. Jun. 6, 2014), the defendant also argued that its medical device "was approved under a revised, more rigorous version of the § 510(k) process which did, in fact, make a safety and effectiveness determination," that *Lohr* was "outdated," and that "the revised § 510(k) process—which arose out of Congress' passage of the Safe Medical Device Act in 1990—is more akin to the premarket approval process." *Id.* at *3. The *Horrillo* court rejected the argument, noting that no legal authority outside a law review article supported it and that the court was still obliged to follow *Lohr* and *Riegel*. *Id.*

In this case, the district court carefully considered and also rejected Bard's argument that the SMDA changed the 510(k) process sufficiently that the preemption analysis must also change. It correctly noted that the 510(k) process remains one about comparisons. (Doc. 8872, at 12). Under 21 C.F.R. § 807.100(a), it recognized that the only favorable outcome an FDA evaluation can make is to

"declare the device substantially equivalent to a predicate device," not to make an assessment of safety and effectiveness. (*Id.*). It further noted that the FDA "specifically prohibit[s] a manufacturer from 'misbranding' a 510(k)-cleared device by claiming that it has been 'approved' by the FDA." (*Id*. at 13 (citing 21 C.F.R. § 807.97)).

The district court correctly rejected Bard's argument that the SMDA changed the preemption calculus from the approach taken in *Lohr*.

III. BARD'S ARGUMENT MERELY REPRISES THE ARGUMENT THAT FAILED IN *LOHR*.

In the end, Bard's preemption argument merely reprises the argument that failed in *Lohr*. It contends that the 510(k) process is sufficiently intense that it imposes requirements. That is exactly the argument that Medtronic made in *Lohr* and that the Court found unavailing. As the majority found in *Lohr* about Medtronic, Bard's "defense exaggerates the importance of the § 510(k) process and the FDA letter to the company regarding the [device]'s substantial equivalence to a grandfathered device." *Lohr*, 518 U.S. at 492-93. Instead, the FDA "did not 'require' Medtronics' pacemaker [or Bard's IVC Filter] to take any particular form for any particular reason; the agency simply allowed the pacemaker, as a device substantially equivalent to one that existed [previously], to be marketed without running the gauntlet of the PMA process." *Id.* at 493-94.

The district court faithfully followed that analysis. It began by noting that Section 360(k) gives preemptive effect "only to requirements 'applicable to the device,'" or requirements that are "device-specific." (Doc. 8872, at 14, quoting 21 U.S.C. § 360(k)). Bard argued, there as here, that there were three types of specific requirements imposed upon it: special controls, clinical studies, and labelling requirements. (*Id.*). The district court found none of these qualified as device specific-requirements.

The special controls consisted of largely of a guidance document that generally told manufacturers what was required for "Cardiovascular Intravascular Filter 510(k) Submissions." 21 C.F.R. § 870.3375(b)(2)(ii). Rather than constitute a specific requirement, it merely provided draft and non-binding guidance without creating or conferring rights. (Doc. 8872, at 15). While manufacturers were free to follow it, they were also free to develop alternatives capable of providing equivalent assurances of safety and effectiveness as the predicate device does. (*Id.*)

Other documents offered by Bard as special control requirements only stated "generic requirements for all implantable medical devices and offer nothing specific to IVC filter design, manufacturing, performance, or labeling." (*Id.* at 16).

The court below also correctly found that the clinical studies conducted and the information provided in response to FDA requests were normal parts of the

510(k) process and did not impose requirements that the Bard had to follow as it designed, manufactured, or labeled its IVC filters. (*Id.* at 18).

Finally, Bard asserted that the FDA imposed labeling requirements, however, the district court correctly understood that "proposed labeling is required for every 501(k) submission," and that, as held in *Riegel*, "'federal . . . labeling requirements applicable across the board to almost all medical devices are not device-specific requirements' and 'do not preempt state common law claims.'" (*Id.* at 19, quoting *Riegel*, 552 U.S. at 322).

Preemption is an affirmative defense, in which the party asserting it bears the burden of establishing it. *Dilts v. Penske Logistics, LLC*, 769 F.3d 637, 649 (9th Cir. 2014). With no asserted basis for claiming that there is a device-specific requirement that plaintiffs' case theory would add to or conflict with, there cannot be any preemption.

IV. BOTH CONGRESS AND THE FDA UNDERSTAND THAT STATE TORT LAWSUITS PROVIDE AN ADDITIONAL LAYER OF PROTECTION FOR CONSUMERS OF MEDICAL DEVICES, AND THE MDA AND ITS REGULATIONS REFLECT THAT.

It remains true, as it was more than three decades ago, that without changing the preemptive language of the MDA, it is "difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984). Congress, through the MDA, sought to maximize the protection of consumers from

"increasingly complex devices which pose serious risk if inadequately tested or improperly designed or used." S. Rep. No. 33, 94th Cong., 2d Sess., at 5 (1976) (reprinted in 1976 U.S.C.C.A.N. 1070, 1075). Indeed, in adding the MDA to an existing statutory scheme that had served the nation since 1906 and was understood to "supplement[] the protection for consumers already provided by state regulation and common-law liability," *Wyeth v. Levine*, 555 U.S. 555, 566 (2009), Congress understood that the MDA would coexist with state common-law liability because the rest of the statute did under existing precedent.

To be sure, subsequent amendments to the original act have changed the responsibilities of the FDA and manufacturers. Still, the essential dual protection that state tort law and federal regulations provided has remained a common feature of drug and medical device safety. Thus, for example, when the Food and Drug Act became the Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040, as amended, 21 U.S.C. § 301 *et seq*., the innovation of premarket approval still permitted lawsuits for compensation under state tort law. *See Wyeth*, 555 U.S. at 566.

This approach to construing the preemptive scope of a statute through congressional purpose is consistent with the Supreme Court's instructions that a court should examine the "'statutory framework' surrounding" the preemption provision, as well as the "'structure and purpose of the statute as a whole.'" *Lohr*,

518 U.S. at 486 (citations omitted). It is also a standard canon of statutory construction. *See Jackson v. Birmingham Bd. of Educ.*, 544 U.S. 167, 176 (2005) (finding it "not only appropriate but also realistic to presume that Congress was thoroughly familiar with [earlier relevant precedent] and . . . expected its enactment . . . to be interpreted in conformity with it.") (internal quotation marks and alterations omitted); *Lorillard v. Pons*, 434 U.S. 575, 580 (1978) (noting that "Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change").

It is not just Congress that understood that state tort actions would continue except where it conflicts with or adds to federal requirements. The FDA understands that as well. It has promulgated regulations that emphasize that 510(k) approval does not amount to "official approval of a device" and claiming that compliance with that process is regarded as "misleading and constitutes misbranding." 21 C.F.R § 807.97.

Repeatedly, the FDA has insisted that preemption applies only when the agency "has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements." 21 C.F.R. § 808.1(d).

Congress and the FDA have drawn careful lines to assure sufficient uniformity in medical device requirements while permitting lawsuits to compensate individuals injured by those devices when those requirements are not followed or when no requirements displace state law. The district court understood that and its ruling that no preemption applies here is amply supported by the text, the supporting regulatory framework, controlling precedent, and the record below.

CONCLUSION

For the foregoing reasons, the decision of the district court denying Bard's affirmative defense of preemption should be affirmed.

Date: May 17, 2019

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I HEREBY CERTIFY that this brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(a)(5) because this brief contains 6,215 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f). I further certify that this brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point Times New Roman type style.

Date: May 17, 2019

/s/ Robert S. Peck
ROBERT S. PECK

CERTIFICATE OF SERVICE

I, Robert S. Peck, counsel for amicus curiae and a member of the Bar of this Court, certify that on May 17, 2019, I electronically filed the foregoing document with the Clerk of Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system. I also certify that the foregoing document is being served on this day on all counsel of record via transmission of the Notice of Electronic Filing generated by CM/ECF. All participants in this case are registered CM/ECF users.

/s/ Robert S. Peck
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