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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC **ORDER**

This multidistrict litigation ("MDL") involves more than 3,000 personal injury cases brought against Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard manufactures and markets medical devices, including inferior vena cava ("IVC") filters. Each Plaintiff received a Bard IVC filter implant and claims that the filter is defective and has caused Plaintiff to suffer serious injury or death. Plaintiffs assert various state law claims and seek both compensatory and punitive damages.

In this motion, Bard seeks summary judgment on the ground that Plaintiffs' state claims are expressly preempted by the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360 et seq., and impliedly preempted by the MDA under the Supreme Court's conflict preemption principles. Doc. 5396. The motion is fully briefed, and the Court heard oral arguments on November 17, 2017. The Court will deny Bard's motion.

I. Background.

The Court will begin by describing IVC filters and their uses, the history of the MDA, the relevant regulatory process, and the claims asserted by Plaintiffs.

A. IVC Filters.

The IVC is a large vein that carries de-oxygenated blood from the lower body to the heart. IVC filters are small metal devices implanted in the upper portion of the IVC to stop blood clots from travelling to the heart and lungs. Blood clots often develop in the legs from a condition called deep vein thrombosis or "DVT." Once blood clots reach the lungs, they are deemed pulmonary emboli or "PE." Pulmonary emboli and other thromboembolic events, such as strokes, can cause serious injury or death.

People at risk for DVT and PE may be prescribed blood thinners such as Heparin or Warfarin to help prevent blood clots. But these medications do not prevent blood clotting for certain people at high risk for DVT or PE, and blood thinners may not be an option for bariatric and trauma patients who could experience thromboembolic events during surgery. In those situations, physicians may recommend implanting an IVC filter to catch any blood clots before they reach a vital organ.

IVC filters originally were designed to be implanted permanently. Because some patients need only temporary filters, however, medical device manufacturers such as Bard developed retrievable filters. Bard first obtained Food and Drug Administration ("FDA") clearance to market a retrievable IVC filter in 2003. Seven different versions of Bard filters are at issue in this MDL – the Recovery, G2, G2 Express, G2X, Eclipse, Meridian, and Denali. They are spider-shaped devices with multiple struts fanning out from a cone-shaped head. The struts consist of legs with hooks that attach to the IVC wall, and shorter curved arms that serve to catch or break up blood clots. Each of these filters is a variation of its predecessor. The last-generation Denali filter received FDA clearance in May 2013. The filters are designed to be retrievable using Bard's Recovery Cone Removal System.

B. History of the MDA.

Throughout our history, states have exercised police powers to protect the health and safety of their residents. The federal government first entered this field more than a century ago with passage of the Food and Drug Act of 1906, 34 Stat. 768, which

prohibited the manufacture of adulterated or misbranded food and drugs. Congress broadened the coverage of the statute to include misbranded or adulterated cosmetics and medical devices in the Food, Drug, and Cosmetic Act of 1938 ("FDCA"), 52 Stat. 1040, as amended, 21 U.S.C. § 301 et seq.

The FDCA required premarket approval for new drugs, but not new medical devices. As technology advanced and reliance on medical devices grew, policymakers and the public became concerned about the increasing number of injuries resulting from device failures. Notable in this regard were injuries women suffered from the Dalkon Shield contraceptive device in the 1960s and early 1970s. Other devices, including catheters, artificial heart valves, and pacemakers, also created possible health risks. Several states responded with regulatory measures, such as California's 1970 law requiring premarket approval of medical devices. 1970 Cal. Stats. ch. 1573, §§ 26670-26693.

In 1976, Congress passed the MDA "to provide for the safety and effectiveness of medical device[s] intended for human use[.]" Pub. L. No. 94-295, 90 Stat. 539 (1976). The MDA extends coverage of the FDCA to medical devices through federal oversight measures implemented by the FDA. It also curtails state regulation of medical devices through a provision that preempts state requirements that differ from or add to federal requirements. 21 U.S.C. § 360k.

C. FDA Regulatory Process.

The MDA gives the FDA broad powers to classify and regulate medical devices. The FDA assigns medical devices to Class I, Class II, or Class III based on their risk levels. Class I devices, which include products such as bandages and tongue depressors, are low-risk and subject to oversight only through "general controls" such as labeling requirements. 21 U.S.C. § 360c(a)(1)(A). Class II devices pose moderate health risks. The original MDA definition of a Class II device identified performance standards as the means by which the FDA could reasonably ensure safety and effectiveness. The Safe Medical Devices Act of 1990 ("SMDA"), Pub. L. 101-629, added various "special

controls" for this purpose. The special controls may include FDA guidance documents, premarket data requirements, performance standards, postmarket surveillance measures, and patient registries. 21 U.S.C. § 360c(a)(1)(B). Class III includes devices used to support human life, such as pacemakers and hearts valves, and devices that pose a high risk of injury. 21 U.S.C. § 360c(a)(1)(C). They receive the highest level of regulatory control.[1] IVC filters originally were designated as Class III devices, but were moved to Class II, along with many other pre-MDA devices, in 2000. *See* 65 Fed. Reg. 17138, 17144 (Mar. 31, 2000); 21 C.F.R. § 870.3375.

The FDA applies different levels of scrutiny to medical devices before approving or clearing them for market, and the level of scrutiny can affect whether state laws are preempted. The most rigorous level of scrutiny is known as "premarket approval," often referred to as the "PMA process." 21 U.S.C. § 360e(a). To comply, a manufacturer must file an application that provides a wide range of detailed information to the FDA in order to demonstrate that the device is safe and effective. *See* 21 U.S.C. § 360e(c). If the FDA finds the device safe and effective, it approves the device for marketing.[2]

Others medical devices can be cleared for market through a less rigorous process known as section "510(k)" review after the original statutory provision describing the review. A manufacture can satisfy this level of review, and be exempt from the PMA process, by providing premarket notice to the FDA that its device is "substantially equivalent" to a predicate device already on the market.[3] § 360c(f)(1)(A). This 510(k)

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[1] *See generally FDA Medical Devices, Regulatory Controls* (last updated June 26, 2014), *available at* https://www.fda.gov/ MedicalDevices/DeviceRegulationandGuidance /Overview/GeneralandSpecialControls/default.htm (last visited Nov. 17, 2017).

[2] *See generally FDA Medical Devices, Device Advice: Comprehensive Regulatory Assistance* (last updated Sept. 29, 2017), *available at* https://www.fda.gov/Medical Devices/DeviceRegulationandGuidance/ (last visited Nov. 17, 2017).

[3] A "predicate device" is one that (1) was legally marketed before passage of the MDA and no PMA process was required, (2) has been reclassified from Class III to Class II or I, or (3) has been found to be a substantially equivalent device through 510(k) review. 21 C.F.R § 807.92(a)(3). A device is "substantially equivalent" to a predicate device where it has the same intended use and (1) has "the same technological characteristics as the predicate device," or (2) any technological differences "do not raise different questions of safety and effectiveness than the predicate device."

review is more streamlined than the PMA process and focuses primarily on equivalence rather than safety and effectiveness. If a 510(k) notice results in an FDA finding of substantial equivalence, the device is cleared for marketing.

The FDA maintains a bright line between devices "approved" through the PMA process and devices "cleared" through 510(k) review. PMA approval results in a finding of safety and effectiveness, while 510(k) clearance results only in a finding of substantial equivalence. FDA regulations require manufacturers to maintain this distinction:

> Submission of a [510(k) notice] in accordance with this subpart, and a subsequent determination by the Commissioner that the device intended for introduction into commercial distribution is substantially equivalent to a device in commercial distribution . . . does not in any way denote official approval of the device. Any representation that creates an impression of official approval of a device because of complying with [510(k) notification] is misleading and constitutes misbranding.

21 C.F.R § 807.97.

The Bard IVC filters at issue in this case, like most medical devices on the market today, received FDA clearance through 510(k) review. Each Bard filter was deemed to be substantially equivalent to a predicate filter already on the market. No Bard filter has received FDA approval through the PMA process.

D. Plaintiffs' Claims.

Plaintiffs allege that Bard IVC filters are defective. Plaintiffs contend that the filters tilt, perforate the IVC, and fracture and migrate to neighboring organs such as the heart and lungs. Plaintiffs claim that Bard filters are more dangerous than other kinds of IVC filters, and that Bard concealed adverse information and otherwise failed to warn the medical community and the public about the risks posed by its filters. Bard vigorously disputes Plaintiffs' allegations of high risk levels, contending that overall complication rates associated with Bard filters are low and comparable to those of other IVC filters.

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§ 360c(i)(1)(A); *see* 21 C.F.R. § 807.100(b) (describing criteria the FDA uses in its substantial equivalence review).

Plaintiffs' master complaint asserts 17 causes of action under various state laws: strict product liability claims for manufacturing, information, and design defects (Counts I-III); negligence claims for design, manufacturing, failure to recall or retrofit, failure to warn, misrepresentation, and per se negligence (Counts IV-IX); breach of warranties (Counts X-XI); fraudulent misrepresentation and concealment (Counts XII-XIII); consumer fraud and unfair trade practices (Count XIV); loss of consortium (Count XV); wrongful death (Count XVI); and survival claims (Count XVII). Doc. 303-1.[4]

Bard seeks summary judgment on each cause of action, arguing that the MDA preempts them all. Doc. 5396 at 14-34.[5] For reasons explained below, the Court finds that Bard has not met its burden of establishing preemption and therefore will deny summary judgment.

II. Summary Judgment Standard.

A party seeking summary judgment "bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Summary judgment is appropriate if the moving party shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). Only disputes over facts that might affect the outcome of the suit will preclude summary judgment, and the disputed evidence must be "such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The evidence of the nonmoving party is to be believed, and all reasonable inferences are to be

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[4] The master complaint is the operative pleading for most of the cases in this MDL. It was created for the sake of convenience and serves as a long-form complaint giving notice, pursuant to Rule 8, of the allegations that Plaintiffs assert in this case. Plaintiff -specific allegations are contained in individual short-form complaints or certain complaints served on Bard before the filing of the master complaint. *See* Doc. 249. Plaintiffs also provide Bard with fact sheets that describe their individual conditions and claims. *See* Doc. 365.

[5] Page citations are to numbers placed at the top of each page by the Court's electronic filing system rather than the document's original page numbers.

drawn in that party's favor, because the weighing of evidence and drawing of inferences are jury functions. *Id.* at 255.

III. Basic Preemption Principles.

"When a transferee court receives a case from the MDL Panel, the transferee court applies the law of the circuit in which it is located to issues of federal law." *In re Gen. Am. Life Ins. Co. Sales Practices Litig.*, 391 F.3d 907, 911 (8th Cir. 2004). In this case, that would be the law of the Ninth Circuit. Thus, in performing its federal preemption analysis, the Court will look primarily to Supreme Court and Ninth Circuit cases.

"The Supremacy Clause provides a clear rule that federal law 'shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, anything in the Constitution or Laws of any State to the Contrary notwithstanding.'" *Arizona v. United States*, 567 U.S. 387, 399 (2012) (quoting U.S. Const. art. VI, cl. 2). Under this clause, "Congress has the power to preempt state law." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372, (2000).

"'[T]he purpose of Congress is the ultimate touchstone'" in determining whether Congress has preempted a state law. *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (quoting *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978)). Federal preemption may be either express or implied. *Attay v. Cty. of Maui*, 842 F.3d 688, 699 (9th Cir. 2016). Where there is no express congressional command, a state law is impliedly preempted if "it actually conflicts with federal law[.]" *Id.* (citing *Cipollone*, 505 U.S. at 516). Conflict preemption occurs "where compliance with both federal and state regulations is a physical impossibility[.]" *Arizona*, 567 U.S. at 399 (internal citations and quotation marks omitted).

"Where the intent of a statutory provision that speaks expressly to the question of preemption is at issue, '[courts] do not invoke any presumption against pre-emption but instead focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.'" *Attay*, 842 F.3d at 699 (quoting *Puerto Rico v. Franklin Cal. Tax-Free Trust*, ––– U.S. –––, 136 S. Ct. 1938, 1946 (2016)). Where

there is no express preemption and a federal statute regulates in an area "traditionally occupied by states, such as health, safety, and land use, a 'presumption against preemption' adheres." *Gobeille v. Liberty Mut. Ins. Co.*, — U.S. —–, 136 S. Ct 936, 946 (2016) (quoting *Wyeth v. Levine*, 555 U.S. 555, 565 n.3 (2009)).

The Court first will discuss express preemption under § 360k of the MDA, and then turn to implied preemption.

IV. Express Preemption.

Section 360k of the MDA includes this express preemption clause:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
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> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The Supreme Court has held that this clause applies when (1) the federal government has established "requirements" applicable to the device in question, and (2) state law claims are based on state requirements that are different from, or in addition to, the federal requirements, and that relate to safety and effectiveness. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321-22 (2008). Consistent with this guidance, the Court first will determine whether the FDA's 510(k) review established federal "requirements" for the Bard IVC filters, and then whether Plaintiffs' state law claims would impose "requirements" different from, or in addition to, any federal requirements.

A. Federal Requirements.

1. Supreme Court Precedent.

The Supreme Court has interpreted § 360k in two cases, *Riegel* and *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).[6] *Lohr* involved a pacemaker that was cleared by the

[6] The Supreme Court addressed implied preemption under the MDA in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), but declined to express a view on whether the state claims were expressly preempted under § 360k. *Id.* at 348 n.2.

FDA in 1982 through 510(k) review. The plaintiff, who suffered injuries when her pacemaker failed, brought state common law claims for negligence and strict liability against the manufacturer, Medtronic. The majority opinion in *Lohr* held that § 360k does not preempt state law claims directed at medical devices cleared through the 510(k) process because the substantial equivalence review of that process places no federal requirements on a device. 518 U.S. at 492-94; *see Riegel*, 552 U.S. at 322-23.

Central to the holding in *Lohr* was the Supreme Court's finding that "[t]he § 510(k) notification process is by no means comparable to the PMA process[.]" 518 U.S. at 478-79. *Lohr* noted that the PMA process is a "rigorous" examination of the product in question that takes an average of 1,200 hours to complete, while "the 510(k) review is completed in an average of only 20 hours." *Id.* at 477-79. *Lohr* noted that the "510(k) process is focused on *equivalence*, not safety[.]" *Id.* at 493 (emphasis in original; citation and quotation marks omitted). *Lohr* concluded that the FDA's 510(k) review "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.

Riegel involved a cardiovascular catheter approved by the FDA through the PMA process. *Riegel* did not disagree with *Lohr*'s conclusion that 510(k) review imposes no federal requirements on manufacturers, but held that the more rigorous PMA process does impose such requirements. 552 U.S. at 322. *Riegel* disagreed with *Lohr*'s view of state law claims and held that such claims can impose requirements within the meaning of § 360k. *Id.* at 322-24. Because the common law tort claims asserted in *Riegel* would impose requirements different from federal requirements established through the PMA process, *Riegel* found the plaintiffs' state law tort claims preempted by § 360k. *Id.* at 323-25.

Riegel was decided nearly 20 years after passage of the SMDA and the start of FDA's use of "special controls" during 510(k) review, and yet the Supreme Court still

found that 510(k) review was not close to the PMA process. *Riegel* described the PMA process in detail and held that it imposes federal "requirements" within the meaning of § 360k. In doing so, *Riegel* distinguished 510(k) review:

> Premarket approval, in contrast [to 510(k) clearance], imposes "requirements" under the MDA as we interpreted it in *Lohr*. Unlike general labeling duties, premarket approval is specific to individual devices. And it is in no sense an exemption from federal safety review—it *is* federal safety review. Thus, the attributes that *Lohr* found lacking in 510(k) review are present here.

552 U.S. at 322-23 (emphasis in original).

Riegel explicitly addressed, and did not disagree with, *Lohr*'s finding that 510(k) review imposes no device-specific requirements on manufacturers:

> Even though substantial-equivalence review under 510(k) is device specific, *Lohr* also rejected the manufacturer's contention that 510(k) approval imposed device-specific "requirements." We regarded the fact that products entering the market through 510(k) may be marketed only so long as they remain substantial equivalents of the relevant 1976 devices as a qualification for an exemption rather than a requirement.

552 U.S. at 322.

The Ninth Circuit likewise has recognized significant differences between 510(k) review and the PMA process. In *Perez v. Nidek Co.*, 711 F.3d 1109 (9th Cir. 2013), the circuit court found a state law fraud claim preempted by the MDA because the device at issue, "[l]ike the device in *Riegel*, . . . was subject to device-specific requirements under the PMA [process]." *Id.* at 1118. *Perez* contrasted the 510(k) review in *Lohr*, which imposes no "requirements," with the more rigorous PMA process:

> None of the federal laws or regulations at issue [in *Lohr*] imposed device-specific requirements. In contrast, the Court in *Riegel* held that § 360k preempted common-law claims challenging the safety and effectiveness of a medical device that had received premarket approval from the FDA. Unlike the federal laws and regulations at issue in *Lohr*, premarket approval imposes device-specific requirements.

711 F.3d at 1118; *see also Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1230 (9th Cir. 2013) (en banc) (noting that the Court in *Riegel* "was careful to state that . . . *Lohr* remained good law").

Many cases interpret *Riegel* and *Lohr* to mean that PMA approval preempts different or additional requirements imposed by state tort law, while 510(k) clearance does not. *See, e.g.*, *Hovey v. Cook Inc.*, 97 F. Supp. 3d 836, 844-46 (S.D. W. Va. Apr. 1, 2015) (rejecting the manufacturer's preemption argument under § 360k and finding that 510(k) clearance of the medical device did not preempt state law tort claims in light of *Lohr* and *Riegel*); *Horrillo v. Cook Inc.*, No. 08-60931-CIV, 2014 WL 8186704, at *3 (S.D. Fla. June 6, 2014) ("[U]nder *Lohr* and *Riegel*, because the stent received FDA approval under the § 510(k) process, Defendant is precluded, as a matter of law, from arguing that Plaintiff's claims are preempted under the express preemption provision set forth in § 360k(a)."); *Cisson v. C. R. Bard, Inc.*, No. 2:11-cv-00195, 2013 WL 5700513, at *12 (S.D. W. Va. Oct. 18, 2013) ("[T]he 510(k) process does not address product safety and efficacy and therefore is not relevant to Bard's obligations under Georgia state tort law") (citing *Lohr* and *Riegel*); *James v. Diva Int'l, Inc.*, 803 F. Supp. 2d 945, 951 (Mar. 18, 2011) ("The device at issue before the Court was approved by the 'substantially equivalent' process. Defendant argues that this is of no consequence. However, it is worth noting that the Supreme Court has held that this process implements only generally applicable standards and does are not constitute sufficient 'requirements' to trigger preemption under Section 360k(a).") (citing *Lohr*, 518 U.S. at 492-93).[7]

Bard argues that *Lohr* is outdated and does not control this case. Bard notes that *Lohr* concerned a pacemaker cleared by the FDA in 1982, and argues that the 510(k) clearance process was dramatically altered when Congress passed the SMDA in 1990. Doc. 5396 at 19-20. Bard emphasizes that § 12 of the SMDA authorizes the FDA to find

[7] This Court reached a similar conclusion in another case, finding that 510(k) review for a pain pump device did not preempt Arizona negligence and strict liability claims. *Placencia v. I-Flow Corp.*, No. CV10-2520 PHX DGC, 2012 WL 5877624, at *5 (D. Ariz. Nov. 20, 2012).

a device "substantially equivalent" under 510(k) review if it is "as safe and effective as a legally marketed device" and "does not raise different questions of safety and efficacy than the predicate device." PL 101-629 § 12. Bard argues that this consideration of safety and effectiveness was not present in *Lohr*, and, when combined with FDA discretion to require clinical data and testing information, can result in 510(k) clearance procedures that are closer to PMA approval and have preemptive effect. Bard argues that its IVC filters went through a rigorous 510(k) review focused on safety and effectiveness.

The Court does not agree that *Lohr* is outdated. The SMDA did introduce safety and effectiveness considerations into 510(k) review, but only comparatively. Under § 12, the FDA does not make a determination that the device being cleared is safe and effective; it concludes that the device is substantially equivalent to the predicate device. *Id.* True, the FDA may do this by finding that the device "is as safe and effective" as the predicate device, but that is still a comparative exercise. The assumption is that the predicate device is safe and effective enough to be on the market, and that the proposed device, if sufficiently similar, must be so as well. The FDA's 510(k) review "continues to primarily focus on equivalence as opposed to safety." *Hovey*, 97 F. Supp. 3d at 845; *see Riegel*, 552 U.S. at 323.

A 510(k) notice must include information regarding the device, its intended use, and its planned labelling and advertising; whether it is similar to or different from comparable products in commercial distribution; an assurance that the information submitted is truthful and accurate; and any additional information regarding the device requested by the FDA that is necessary to make a finding as to whether or not the device is substantially equivalent to a predicate device. 21C.F.R § 807.87. FDA regulations provide that a 510(k) notice can result in one of several possible outcomes. The FDA can (1) declare the device substantially equivalent to a predicate device, (2) declare the device not substantially equivalent to any predicate device, (3) request additional information, (4) withhold the decision, or (5) advise the applicant that 510(k) clearance is not required. 21 C.F.R. § 807.100(a). Determining that the device is safe and effective is not one of

the available FDA options. Indeed, because the FDA makes no determination regarding the device's safety and effectiveness comparable to PMA approval, FDA regulations specifically prohibit a manufacturer from "misbranding" a 510(k)-cleared device by claiming that it has been "approved" by the FDA. 21 C.F.R. § 807.97.

The PMA process, by contrast, requires a manufacturer to show that its product is sufficiently safe and effective for the U.S. market. *See Buckman*, 531 U.S. at 344-45. If successful, the process results in an FDA finding of safety and effectiveness. Indeed, after PMA approval, the manufacturer cannot change the design, manufacturing process, labeling, or any other attribute of the product that could affect its safety or effectiveness without FDA permission. § 360e(d)(6)(A)(i). The manufacturer must also report to the FDA any information concerning the safety of the device that it learns after receiving approval. § 360i. "[P]remarket approval is focused on safety, not equivalence." *Riegel*, 552 U.S. at 323. It remains fundamentally different from 510(k) review.

The Court cannot conclude that the *Lohr* majority was ignorant of current FDA practices or the 1990 changes made by the SDMA. *Lohr* was decided six years after passage of the SMDA, and any changes to 510(k) review were available to the Court in interpreting Congress's intent. 518 U.S. at 480 n. 4. And yet the Court still concluded that "[t]here is no suggestion in either the statutory scheme or the legislative history that the § 510(k) exemption process was intended to do anything other than maintain the status quo with respect to the marketing of existing medical devices and their substantial equivalents." *Id.* at 494. That status quo, *Lohr* noted, "included the possibility that the manufacturer of the device would have to defend itself against state-law claims of negligent design." *Id.*

In short, *Lohr* remains good law, and clearance of a product under 510(k) usually does not preempt state common law claims. But this does not mean that 510(k) clearance can never result in preemption. As Bard notes, the fifth and concurring justice in the *Lohr* majority, Justice Breyer, acknowledged that preemption could occur if specific federal requirements were imposed on a device by the FDA. *Id.* at 503-04. And the

Ninth Circuit has held that state law failure-to-warn claims were preempted for a 510(k) device on which the FDA imposed specific product and disease warning requirements. *See Papike v. Tambrands Inc.*, 107 F.3d 737, 740 (9th Cir. 1997).

How, then, does one identify 510(k) cases where state law claims are preempted? The preemption provision itself provides some helpful guidance. Section 360(k) gives preemptive power only to requirements "applicable to the device." 21 U.S.C. § 360(k). The requirements must be device-specific. In *Lohr*, the Supreme Court also looked to a regulation promulgated by the FDA – 21 C.F.R. § 808.1(d) – for help on the preemptive scope of § 360(k). 518 U.S. at 498-501; *see also id.* at 506-07 (Breyer, J., concurring). That regulation confirms that any preemptive requirement must specifically apply to the device in question:

> State or local requirements are preempted only when the Food and Drug Administration 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) (emphasis added).

Thus, preemption can occur under the 510(k) process only when the FDA has imposed requirements specific to the device in question. More general FDA requirements – what *Riegel* calls "federal manufacturing and labeling requirements applicable across the board to almost all medical devices" – do not preempt state law claims. 552 U.S. at 322. The FDA requirements must do more than reflect "entirely generic concerns about device regulation generally." *Id.* (citations to *Lohr* omitted).

2. Has the FDA Imposed Specific Requirements on Bard Filters?

Bard argues that the FDA has imposed three categories of specific requirements on its filters: (1) special controls, primarily in the form of FDA guidance documents; (2) clinical studies, and testing and design information; and (3) labelling and other information requirements. Doc. 5396 at 24-30. The Court will review each category.

a. Special Controls (Guidance Documents).

Bard relies heavily on the special controls issued by the FDA in connection with 510(k) review of IVC filters generally. One of the special controls is a guidance document issued in November 1999 and titled "Guidance for Cardiovascular Intravascular Filter 510(k) Submissions." 21 C.F.R. § 870.3375(b)(2)(ii); *see* Doc. 5398 ¶ 29, Ex. F. Bard contends that this guidance document is a "specific and detailed directive the FDA issued" for IVC filters. Doc. 5396 at 24. The Court does not agree.

The 1999 guidance document is not a "directive" as Bard claims. It contains this disclaimer: "This document is intended to provide guidance. It represents the [FDA's] current thinking . . . . It does not create or confer any rights for or on any person and does not operate to bind the FDA or the public." Doc. 5398 ¶ 29, Ex. F at 1 n.1.

The document describes itself as a "draft," and makes clear that it does not mandate any particular course of action. IVC filter manufacturers can obtain 510(k) clearance by following "either the specific recommendations of this guidance or some alternate control that provides equivalent assurances of safety and effectiveness." *Id.* at 1. Thus, manufacturers can choose between following the "recommendations" in the guidance document or alternative approaches.

Bard emphasized at oral argument that the guidance document contains a section on "Filter Performance," but this section simply includes "an outline of the general issues that need to be addressed when seeking premarket clearance for a filter" under 510(k). *Id.* at 3. The section leaves it to the manufacturer to determine what tests or data should be submitted: "Test protocols and acceptance criteria for these tests are the responsibility of the submitter. FDA recognizes that there are many different testing methods that may be used to satisfy the objective." *Id.* The document also includes a suggested general format for filter labels, but no specific regulatory mandate. Manufacturers are free to include other language "specific to [their] particular device design." *Id.* at 9-10. In short, the document leaves much to the discretion of filter manufacturers and provides guidance instead of imposing specific requirements. *See Thompson v. DePuy Orthopaedics, Inc.*,

No. 1:13-CV-00602, 2015 WL 7888387, at *10 (S.D. Ohio Dec. 4, 2015) (noting that the guidance document at issue was "directed mostly to what needs to be submitted to the FDA to facilitate review of the 510(k) application" and contained no "language that mandates anything from the manufacturers").[8]

The two other documents identified by the FDA as special controls for IVC filters are (1) "Use of International Standards Organization's ISO 10993 'Biological Evaluation of Medical Devices Part I: Evaluation and Testing,'" and (2) "510(k) Sterility Review Guidance and Revision of 2/12/90 (K90-1)" 21 U.S.C. § 870.3375(b)(1), (b)(2)(i); *see* Doc. 5398 ¶ 28. These documents impose only generic requirements for all implantable medical devices and offer nothing specific to IVC filter design, manufacturing, performance, or labeling. Doc. 7369 at 24 n.17. As *Riegel* noted, "federal manufacturing and labeling requirements applicable across the board to almost all medical devices" do not preempt state common law claims. 552 U.S. at 322. Bard does not contend otherwise.[9]

b. Clinical Studies and Testing and Design Information.

Bard places much emphasis on the fact that clinical studies were required by FDA for 510(k) clearance of the Recovery, G2, and Denali filters. Doc. 5396 at 26-28. But the FDA regulations state that clinical studies can be requested for the purpose of deciding whether a device is substantially equivalent to a predicate device:

> FDA will determine that a device is substantially equivalent to a predicate device using the following criteria: . . .

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[8] *Whitson v. Safeskin*, 313 F. Supp. 2d 473 (M.D. Pa. 2004), is distinguishable because the FDA had established clear and specific requirements for the product in a manual titled "Regulatory Requirements for Medical Gloves." *Id.* at 477.

[9] In its reply brief, Bard discusses internal FDA documents relating to the decision to reclassify IVC filters from Class III to Class II devices. Doc. 7828 at 8-9. Bard notes that the FDA had determined that special controls would provide reasonable assurance of the safety and effectiveness of IVC filters. *Id.* at 9. But this is true for all Class II devices subject to special controls, or at least those reclassified along with IVC filters in 2000. *See* 65 Fed. Reg. 17138-01 (Mar. 31, 200). Bard cites no legal authority for the proposition that mere reclassification, or assignment of special controls to a device cleared through 510(k) review, imposes "requirements" for purposes of § 360k.

> (B) The data submitted establishes that the device is substantially equivalent to the predicate device and contains information, *including clinical data if deemed necessary by the Commissioner*, that demonstrates that the device is as safe and as effective as a legally marketed device[.]

21 C.F.R. § 807.100(b)(2)(ii)(B) (emphasis added). Two points are relevant. First, requesting such clinical studies is a recognized part of 510(k) review. Second, analysis of the clinical data remains comparative – deciding whether the device is substantially equivalent to the predicate. Bard cites no authority for the proposition that clinical studies required during 510(k) review constitute preemptive requirements for purposes of § 360k. Nor does Bard identify the specific clinical study "requirements" that the Court could compare to the various state law duties to determine whether those duties are preempted.

Bard also notes that the FDA sought information about the testing and design of its IVC filters. *Id.* at 29-30. But the FDA may request additional information, including information concerning safety and effectiveness, to determine "whether or not the device is substantially equivalent to a [predicate] device[.]" 21 C.F.R § 807.87(l); *see James*, 803 F. Supp. 2d at 947-48. Bard has not shown that the FDA's request for testing and design information was outside the scope of a normal 510(k) review or sufficient to make it as rigorous as the PMA process.

Bard suggests that its EVEREST and Denali clinical studies were similar to the rigorous FDA review in *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004). Doc. 5396 at 27-28. But *Horn* involved the PMA process, not 510(k) review, a distinction the Third Circuit found critical: "The primary element distinguishing *Lohr* from the instant case is the fact that the [device] received FDA approval through the rigorous § 360e(c) PMA process, not through the § 510(k) 'substantial equivalence' process." *Id.* at 169. After *Riegel*, there is nothing remarkable about the conclusion in *Horn* that "the PMA process imposed requirements that were specifically applicable to the [device], and that triggered preemption under § 360k(a)." *Id.* at 170; *see also Kemp v. Medtronic, Inc.*, 231

F.3d 216, 227-28 (6th Cir. 2000) (finding FDA approval of a PMA supplement to be a "specific federal requirement applicable to the device").

What is more, the heart pump at issue in *Horn* took nearly twenty years to receive FDA approval. 376 F.3d at 169-70. The device underwent ten years of live animal and human cadaver studies before it was granted an investigational device exemption ("IDE") by the FDA in order to permit human clinical trials. *Id.* at 169. The manufacturer then conducted seven years of clinical studies at hospitals, during which it submitted 90 supplements to the FDA. *Id.* The FDA approved the PMA application only after extensive review that spanned three years and included a substantial number of amendments and responses to FDA questions. *Id.* at 170. This process was clearly more rigorous than the 510(k) review of the Bard IVC filters.

Bard cites *Kemp*, 231 F.3d at 227, for the proposition that the IDE clinical trials for the G2 and Denali filters are device-specific and therefore preemptive. Doc. 5396 at 25-26; *see also Martin v. Telectronics Pacing Sys., Inc.*, 105 F.3d 1090, 1097 (6th Cir. 1997) (regulations governing investigational devices are device-specific); *Parks v. Howmedica Osteonics Corp.*, No. 8:15-cv-0075-MSS-MAP, 2016 WL 7220707, at *7 (M.D. Fla. Mar. 11, 2016) (IDE approval process is device-specific). But as Plaintiffs correctly note, the G2 and Denali filters were given 510(k) clearance before completion of their respective IDE clinical studies. Doc. 7369 at 28. Moreover, Bard fails to explain how IDE clinical studies conducted as part of the 510(k) substantial equivalence review impose requirements for purposes of § 360k. In other words, even if the FDA required IDE clinical studies, Bard does not describe any resulting § 360k "requirements" that would preempt Plaintiffs' state law claims. *See Oja v. Howmedica, Inc.*, 111 F.3d 782, 787-89 (10th Cir. 1997) (rejecting hip implant manufacturer's arguments that discussions with the FDA to obtain 510(k) clearance including IDE clinical study of cement-less use constituted a specific requirement under *Lohr*).[10]

[10] Bard notes in its reply that clinical trials are required as part of the PMA process. Doc. 7828 at 12 (citing *Scovil v. Medtronic, Inc.*, 995 F. Supp. 2d 1082, 1093 (D. Ariz. 2014)). True, but the rigorous PMA process requires more than clinical trials,

c. Labelling and Other Requirements.

Bard argues that, pursuant 21 U.S.C. § 807.87(e), the FDA required proposed labeling for each Bard IVC filter. Doc. 5396 at 28. But proposed labeling is required for *every* 501(k) submission. Section 807.87 simply describes the information that "[e]ach premarket notification shall contain[.]" These are "federal . . . labeling requirements applicable across the board to almost all medical devices" – requirements which do not preempt state common law claims. *Riegel*, 552 U.S. at 322. They are not like the device- and disease-specific labelling regulation at issue in *Papike*. 107 F.3d at 739-40.

Bard contends that the FDA reviewed and made specific changes to its labels, including adding language regarding bariatric patients and off-label use for the G2 filter and language regarding potential nickel leaching for the Meridian and Denali filters. Doc. 5396 at 28-29. But these changes did not preclude Bard from strengthening its warnings about the risks posed by filter migration, fractures, and perforation. The FDA allows – and in fact encourages – medical device manufactures to "monitor device usage and promptly revise the warning and precautions section [of a label] based on use experience." Doc. 5398 ¶ 38, Ex. G at 11.

Bards notes that the FDA has issued post-SMDA design controls and "good manufacturing" rules, and that these procedures were applied to Bard filters. Doc. 5396 at 22 (citing 21 C.F.R. §820.30; *Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation*, 61 Fed. Reg. 52615 (FDA Oct. 7, 1996)). But Bard fails to explain how these generally applicable rules constitute filter-specific requirements that would preempt Plaintiffs' state law claims.[11]

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see Scovil, 995 F. Supp. 2d at 1088-89, and Bard has not shown that the two IDE clinical trials in this case reflect the rigor that makes FDA premarket approval preemptive.

[11] Bard notes that the FDA has itself indicated that special controls are "regulatory requirements for class II devices." Doc. 5396 at 20 n.16 (citing *FDA Medical Devices, Regulatory Controls*, https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm (last updated June 26, 2014). Yet Bard cites no legal authority showing that this statement by the agency is controlling for purposes of preemption. *See Wyeth*, 555 U.S. at 556 (giving no deference to the FDA's mere assertion that state law is preempted where it had enacted no regulation to this effect).

Finally, Bard has submitted more than 800 factual paragraphs to illustrate its extensive communications with the FDA concerning the seven generations of filters at issue in this case. Doc. 5398. But the Court agrees with Plaintiffs' suggestion that these communications merely reflect the back-and-forth of 510(k) review. *See* Doc. 7369 at 25-29. The FDA invoked its regulatory power to require additional information from Bard as a condition for clearance. *See* 21 U.S.C. § 807.87(l). The mere volume of these communications does not show that the FDA's review imposed specific requirements on Bard filters or departed from the 510(k) substantial equivalence standard.[12]

d. *Papike* and *Degelmann* Are Distinguishable.

Bard cites other cases in support of their argument, but the Court finds them distinguishable. *Papike* involved various claims under California law based on injuries the plaintiff sustained when she contracted Toxic Shock Syndrome ("TSS") while using Tampax tampons. 107 F.3d at 738. The Ninth Circuit found the state failure-to-warn claim preempted under § 360k, but not the state claims for negligence, design defect, and breach of warranties. *Id.* at 738, 742-44. Although tampons are Class II devices subject to special controls, *see id.* at 739, this was not the reason for preemption. Rather, *Papike* found that the FDA had promulgated a device-specific regulation "mandating the specific substantive content of the TSS warnings on tampon boxes[.]" *Id.* at 740. The regulation was "not only device-specific (tampons), but also disease-specific (TSS)." *Id.* "This fact distinguishe[d] Papike's case from prior relevant MDA preemption cases, including [*Lohr*]." *Id.*; *see also Rasheed v. Church & Dwight Co.*, No. 5:11CV80, 2012 WL 262619, at *7-8 (E.D. Tex. Jan. 12, 2012) (finding failure-to-warn claim preempted

[12] Bard asserts that its more than 800 paragraphs of facts are both material and undisputed, and that "there is no genuine issue to be tried." Doc. 5398 at 1. But as Plaintiffs correctly note, Bard's statement includes many documents and communications that are not central to the issues in this case – whether the 510(k) review imposed device-specific requirements. And the sheer volume of the submission proves nothing. "Lawyers are tasked with bringing clarity out of chaos, and voluminous filings rarely do that." *State Compensation Ins. Fund v. Drobot*, No. CV 13-0956 AG, 2016 WL 6661338, at *1 (C.D. Cal. Aug. 10, 2016).

where the FDA had issued a specific regulation governing labels for condoms under the same rule subpart as tampons). Bard cites no similar regulation in this case.

Bard's reliance on *Degelmann v. Advanced Medical Optics Inc.*, 659 F.3d 835 (9th Cir. 2011), fares no better. *Degelmann* has been vacated by the Ninth Circuit. *See Placencia*, 2012 WL 5877624, at *5 n.3. Moreover, even if *Degelmann* was still good law, it would not control here. Doc. 5396 at 13, 19. *Degelmann* concerned contact lens solution approved through 510(k) review and the plaintiffs' state-law claims that the solution was mislabeled as "disinfecting." 659 F.3d at 840-42. The FDA had issued a guidance document containing special controls that "mandate" specific stand-alone performance criteria with which manufacturers "must comply" in order to label their contact lens products as a "disinfecting solution." *Id.* at 341-42. The Ninth Circuit found the guidance document to be a specific requirement that the manufacturer undisputedly had met, and held that the state consumer protection and false advertising claims were preempted because they would impose a state requirement in addition to the federal requirements. *Id.* at 842; *see also Tuttle v. CIBA Vision Corp.*, No. 2:05-CV-340 TS, 2007 WL 677134, at *2 (D. Utah Mar. 1, 2007) (finding same guidance document to be a requirement because it is comprehensive and "governs the form, content, and requirements for labels on hydrogen peroxide-based solutions").

e. Federal Requirements Conclusion.

The various FDA reviews of Bard filters do appear to have been more extensive than the 510(k) review at issue in *Lohr*. But Bard has not shown that the reviews imposed device-specific requirements as needed for preemption under § 360(k). The "requirements" identified by Bard are either general, non-preemptive regulations or normal parts of the 510(k) substantial equivalence inquiry.

B. State Requirements.

Lohr instructs courts to undertake a "careful comparison" between the federal requirements at issue and the allegedly preempted state requirements to determine whether they fall within the preemptive scope of § 360k. 518 U.S. at 500. The state law

must be compared to the federal requirements to determine whether the state law establishes requirements "different from, or in addition to," the federal requirements. 21 U.S.C. § 360k(a)(1)(1). But such a comparison is impossible where, as here, no device-specific federal requirements can be ascertained.

The claims asserted by Plaintiffs involve the laws of 50 states – laws the Court must apply in this MDL. *See Am. Life Ins.*, 391 F.3d at 911. Plaintiffs assert multiple causes of action, including claims for strict liability, negligence, breach of warranty, misrepresentation, concealment, and consumer fraud. Doc. 303-1. And yet Bard does not discuss the specific law of any particular state. Bard instead summarizes general state law duties and asserts that those duties impose requirements that are preempted by the requirements imposed on its products through the 510(k) reviews. Doc. 5396 at 30. Such conclusory assertions are insufficient to meet the "careful comparison" required by *Lohr*. For this reason as well, Bard has failed to show that any state law claim is expressly preempted by federal requirements.

V. Implied Preemption.

Because the health and safety of citizens are "'primarily, and historically, matters of local concern,' the 'States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." *Lohr*, 518 U.S. at 475 (internal citations omitted). Thus, this case presents a classic example of Congress legislating in a field – public health and safety – historically occupied by state police powers. For purposes of implied preemption, therefore, the Court begins with a presumption that state laws are not superseded by the federal statute, a presumption that can be overcome only if preemption "'was the clear and manifest purpose of Congress.'" *Id.* (citation omitted).

Bard contends that Plaintiffs' state law claims are impliedly preempted because it is impossible for Bard to do under federal law what the state laws require. Doc. 5396 at 32-34. The Court does not agree.

Bard relies on two Supreme Court cases that involved the FDCA's labeling requirements for generic prescription drugs, *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), and *Mutual Pharmaceutical Co. v. Bartlett*, —— U.S. ——, 133 S.Ct. 2466 (2013). Under the FDCA, a manufacturer can obtain FDA approval to market a drug only by submitting a new-drug application ("NDA") that is similar to the comprehensive PMA application. 21 U.S.C. § 355(a)-(b); *see Bartlett*, 133 S. Ct. at 2471 (noting that the "process of submitting an NDA is both onerous and lengthy"). The FDA's approval of an NDA includes the approval of the exact text of the proposed label. 21 U.S.C. § 355(d). Generally speaking, a manufacturer may change a drug label only after the FDA approves a supplemental NDA. *See Wyeth*, 555 U.S. at 568. Manufacturers essentially are prohibited from making any change to a generic drug label because the label must at all times be the same as the label of the corresponding brand-name drug. 21 U.S.C. § 314.150(b).

In *Mensing* and *Bartlett*, the Supreme Court found state law failure-to-warn claims preempted by the FDCA because it was impossible under federal law for the manufacturers to do what state law required. *Mensing*, 564 U.S. at 618; *Bartlett*, 133 S. Ct. at 2476-78. As the Court explained: "it was impossible for the [m]anufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same." *Mensing*, 564 U.S. at 618. "Federal law require[d] a very specific label for [the drug], and state law [forbade] the use of that label." *Bartlett*, 133 S. Ct. at 2479.

Bard has identified no similar conflict in this case. Bard asserts that it is prohibited from making changes to their filters without FDA approval, but changing a product is quite different from changing a label. FDA regulations understandably provide that FDA clearance is required when a manufacturer's product "is about to be significantly changed or modified in design, components, method of manufacture, or intended use." 21 C.F.R. § 807.81(a)(3). The Court does not find such a change comparable to the label changes at issue in *Mensing* and *Bartlett*.

Bard also asserts that the FDA prohibits it from making unilateral labeling changes that significantly impact safety and effectiveness without first submitting a new 510(k) notification. Doc. 5396 at 33. In support, Bard cites to an FDA guidance document on when 510(k) submissions are required. *Id.*; Doc. 5398, ¶ 38. The most relevant part of this guidance document for purposes of Plaintiffs' failure-to-warn claims would seem to be the section on changes in warnings or precautions. That section reads as follows:

> In order to facilitate a continuous upgrading in device labelling, manufacturers should monitor device usage and promptly revise the warning and precautions section based on use experience. Events that precipitate changes of this type are routinely reported under the medical device reporting regulation. 510(k)s for such labelling changes are generally unnecessary however, manufacturer's [sic] are encouraged to discuss these situations with [the FDA's Center for Devices and Radiological Health].

Doc. 5398, Ex. G at 11. This guidance clearly does not prohibit Bard from making warning changes without FDA approval.[13]

"Impossibility pre-emption is a demanding defense." *Wyeth*, 555 U.S. at 573. Bard has failed to show that it is impossible to make any labeling changes that may be required by state law. Indeed, Bard acknowledges that the FDA previously has cleared labeling changes to Bard IVC filters and in one instance found that no 510(k) was needed. Doc. 5396 at 33. Bard's impossibility preemption defense is without merit. *See Wyeth*, 555 at 571 ("[A]bsent clear evidence that the FDA would not have approved a change to [the drug's] label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements."); *Mullins v. Ethicon, Inc.*, 147 F. Supp. 3d 478, 480-85 (S.D. W. Va. 2015) (rejecting impossibility preemption given "Congress' purpose in enacting the 510(k) provision and the absence of any actual conflict between

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[13] The guidance document recently has been superseded. *See* FDA, *Deciding When to Submit a 510(k) for a Change to an Existing Device*, *Guidance for Industry and FDA Staff* (Oct. 25, 2017), *available at* https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm514771.pdf (last visited Nov. 16, 2017). The new guidance document also allows for changes in warnings without a 510(k) submission. *See id.* at 22. Moreover, both documents make clear that they are meant to provide guidance only and do not bind the FDA or the regulated industry.

state and federal law"). Bard has also failed to overcome the presumption against preemption that applies to its implied preemption argument.

IT IS ORDERED that Defendants' motion for summary judgment regarding preemption (Doc. 5396) is **denied**.

Dated this 22nd day of November, 2017.

David G. Campbell
United States District Judge