No. _____

In The
Supreme Court of the United States

BRITTANY BILLETS, et al.,

Petitioners,

v.

MENTOR WORLDWIDE LLC,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

The question presented is whether preemption under the Medical Device Amendments to the Food, Drug, and Cosmetic Act supports Rule 12(b)(6) dismissal of state common law claims alleging failure to warn by virtue of inaccurate post-approval, post-sale public reporting of adverse events, and claims alleging defective manufacture of medical devices.

PARTIES TO THE PROCEEDING

Petitioners here include appellants in four appeals in the court below, pursuant to this Court's Rule 12.4. The court below issued identical orders on the same date in all four appeals, and Petitioners' allegations and positions here are materially identical. Not all appellants in the proceedings below are parties to this Petition. The Petitioners before this Court include:

Brittany Billetts, et al. v. Mentor Worldwide LLC, et al., 9th Circuit, 19-56398; Dist. of Cent. California 19-cv-01026 (including petitioners Brittany Billetts, Vivian Aguiar, Cornelia Ditto, and Leah Johnson);

Nicole Vieira, et al. v. Mentor Worldwide LLC, et al., 9th Circuit 19-56394; Dist. of Cent. California 19-cv-04939 (including petitioners Nicole Vieira and Emilia Barozzi);

Kate Nunn, et al. v. Mentor Worldwide LLC, et al., 9th Circuit 19-56391, Dist. of Cent. California 19-cv-01484 (including petitioners Kathryn Nunn, Aluvia Solano, and April Zimmerman);

Mary Sewell, et al. v. Mentor Worldwide LLC, et al., 9th Circuit 19-56393; Dist. of Cent. California 19-cv-01126 (including petitioners Mary Sewell, Yulia Rose, Aurora Victoria Corona Cattuzzo, Michael Anthony Cattuzzo, Barbara Johncke, Anders Johncke, Marianne Curry, Joseph Zacharzuk Jr., Deborah Michelle Destasio,

PARTIES TO THE PROCEEDING – Continued

Joseph Destasio, Stacey Holden, Mark Clark Holden, Kristina Ruiz, and Steven Ruiz)

Each of the four appeals included multiple appellees, but only one is implicated by this Petition, Respondent Mentor Worldwide LLC.

STATEMENT OF RELATED CASES

The following proceedings are directly related to this petition:

- United States District Court for the Central District of California Judgments:
  - *Billetts v. Mentor Worldwide LLC*, ED CV 19-01026-AB (PLAx). Judgment entered October 29, 2019.
  - *Vieira v. Mentor Worldwide LLC*, CV 19-04939-AB (PLAx). Judgment entered October 29, 2019.
  - *Jacob v. Mentor Worldwide LLC*, CV-19-01484-AB (PLAx). Judgment entered October 29, 2019.
  - *Sewell v. Mentor Worldwide LLC*, SA CV 19-01126-AB (PLAx). Judgment entered October 29, 2019.

STATEMENT OF RELATED CASES – Continued

- United States Court of Appeals for the Ninth Circuit Judgments:
    - *Billetts v. Mentor Worldwide LLC*, 19-56398. Judgment entered February 5, 2021.
    - *Vieira v. Mentor Worldwide LLC*, 19-56394. Judgment entered February 5, 2021.
    - *Nunn v. Mentor Worldwide LLC*, 19-56391. Judgment entered February 5, 2021.
    - *Sewell v. Mentor Worldwide LLC*, 19-56393. Judgment entered February 5, 2021.
- A substantially similar Petition for Writ of Certiorari was filed before this Court on June 25, 2021 in *Brooks v. Mentor Worldwide LLC*, 985 F.3d 1272 (10th Cir. 2021).

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PETITION FOR A WRIT OF CERTIORARI

Petitioners respectfully petition for a writ of certiorari to review the judgments of the United States Court of Appeals for the Ninth Circuit.

OPINIONS BELOW

The opinions of the Ninth Circuit Court of Appeals are reported at:

Billetts v. Mentor Worldwide LLC, 847 F. App'x 377 (9th Cir. Feb. 5, 2021), App. 1.

Vieira v. Mentor Worldwide LLC, 845 F. App'x 503 (9th Cir. Feb. 5, 2021), App. 92.

Nunn v. Mentor Worldwide LLC, 847 F. App'x 373 (9th Cir. Feb. 5, 2021), App. 29.

Sewell v. Mentor Worldwide LLC, 847 F. App'x 380 (9th Cir. Feb. 5, 2021), App. 60.

The Orders of the United States District Court for the Central District of California are officially reported or otherwise available at:

Billetts v. Mentor Worldwide LLC, 2019 WL 4038218 (C.D. Cal. Aug. 27, 2019), App. 6.

Vieira v. Mentor Worldwide LLC, 392 F. Supp. 3d 1117 (C.D. Cal. Aug. 1, 2019), App. 97.

Jacob v. Mentor Worldwide LLC, 393 F. Supp. 3d 912 (C.D. Cal. Aug. 1, 2019), App. 34 (On appeal, "*Nunn v. Mentor*").

Sewell v. Mentor Worldwide LLC, 2019 WL 4038219 (C.D. Cal. Aug. 27, 2019), App. 65.

JURISDICTION

The four judgments of the Ninth Circuit Court of Appeals were entered on February 5, 2021. The jurisdiction of this Court is invoked pursuant to 28 U.S.C. § 1254(1).

This Petition is timely under this Court's Order of March 19, 2020, regarding filing deadlines in the COVID-19 pandemic, extending the time for filing the Petition to 150 days from the date of the judgment below.

STATUTORY PROVISIONS

21 U.S.C. § 360k

§ 360k. State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b), 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 –

(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.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if –

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement –

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

STATEMENT

1. Introduction

Through its rulings in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) and *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), this Court established that state law claims arising from requirements that are "parallel" under state and federal law are neither expressly nor impliedly preempted.

The court below misapplied *Buckman* and *Riegel* in finding that claims alleging failure to warn through inaccurate public reporting of adverse events are preempted. The Ninth Circuit's misapplication of this Court's precedent reflects a conflict between circuits and an acknowledged state of confusion across the federal judiciary.

The court below further misapplied *Buckman* and *Riegel* in declaring defective manufacture claims to be preempted, and by granting, without leave to amend, a 12(b)(6) motion based upon preemption, an affirmative defense. The Tenth Circuit's ruling manifests a nationwide wave of federal court rulings extending *Buckman* and *Riegel* far beyond the Court's intention, establishing what now appears to be overbroad immunity from suit for medical device manufacturers who defectively manufacture their products, an immunity never intended by Congress.

2. Factual Background

a. FDA Approval of Silicone Gel-Filled Breast Implants

Silicone gel-filled breast implants first entered the American market in 1963. For more than a decade, the devices were largely subject to regulation by the states.

In 1976, Congress passed the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA"). The MDA divides medical devices into three classes, based upon patient risk and need for regulatory scrutiny. Class I devices require the least, and most general, oversight. 21 U.S.C. § 360c(a)(1)(A). Class II devices are reviewed according to more stringent "special controls," such as performance standards. 21 U.S.C. § 360c(a)(1)(B). Finally, Class III devices receive the most oversight and require rigorous premarket review and approval. 21 U.S.C. § 360c(a)(1)(C)(ii).

Initially, breast implants were categorized as Class II devices, reviewed only through the premarket notification process. In 1988, due to growing safety concerns, the FDA re-classified breast implants as Class III devices.

Class III devices support or sustain human life, are of substantial importance in preventing impairment of human health, or present a potential, unreasonable risk of illness or injury. Because the FDA deems general and special controls alone to be insufficient to assure the safety and effectiveness of Class III

devices, the FDA subjects breast implants to the more rigorous premarket approval ("PMA") process. Through the PMA process, the FDA conducts a scientific and regulatory evaluation of the safety and effectiveness of Class III medical devices. When a manufacturer submits a PMA application, the application is to be denied where the manufacturer fails to give "reasonable assurance" of the products' safety and effectiveness. 21 U.S.C. § 360e(d)(2).

In 1991, the FDA finalized its regulations implementing the PMA process for silicone gel-filled breast implants. Later that year, the FDA determined that the PMA application data submitted by manufacturers, including Mentor Worldwide LLC ("Mentor") for its MemoryGel Silicone Gel Breast Implants, was insufficient to support approval.

In January 1992, the FDA announced a voluntary moratorium on silicone gel-filled breast implants, requesting that manufacturers stop supplying them and surgeons stop implanting them, while the FDA reviewed new safety and effectiveness information that had been submitted.

On April 16, 1992, the FDA made the moratorium mandatory, when it announced it would allow implantation of silicone gel-filled breast implants only after mastectomy or correction of congenital deformities (reconstruction), or replacement of ruptured silicone gel-filled implants due to medical or surgical reasons (revision). Even for these applications, the FDA would consider silicone gel-filled implants to be

investigational devices, requiring women who received them to be monitored through adjunct clinical studies.

After the April 1992 moratorium, silicone gel-filled breast implants, including Mentor's MemoryGel Silicone Gel products, were no longer openly marketed in the United States.

In December 2003, Mentor submitted a PMA for its MemoryGel Silicone Gel Breast Implants. In 2006, the FDA approved Mentor's PMA, ending the 14-year moratorium against marketing silicone gel-filled breast implants for augmentation. Mentor's approval was conditioned on the performance by Mentor of six specific post-approval studies.

b. Adverse Event Reporting

Separate from the requirements of the Mentor-specific post-approval studies that were imposed upon Mentor by the FDA, Mentor was required to meet the reporting requirements imposed upon all manufacturers by 21 C.F.R. § 812.150(b), including the duty to report unanticipated adverse device effects (with evaluation) to the FDA, all Institutional Review Boards, and investigators within 10 working days after notification by the investigator.

Mentor is further required to maintain and submit information required by 21 U.S.C. § 360i, including adverse reaction reports, 21 C.F.R. § 803.50, and to establish internal procedures for reviewing complaints and event reports, 21 C.F.R. § 820.198(a). 21 C.F.R. § 803.50

requires a manufacturer to report information no later than 30 days after it is received, from any source, if that information suggests that the device may have contributed to a serious injury or has malfunctioned in a manner likely to contribute to a serious injury if it were to recur.

In addition to requiring manufacturers to submit adverse event reports, the FDA also encourages patients and physicians to submit them, as part of "MedWatch, the FDA's medical product safety reporting program for health professionals, patients and consumers."[1]

Information and reports submitted to the FDA have long been made available to the public through a searchable internet database called MAUDE (Manufacturer and User Facility Device Experience), which is updated monthly. The general public, including physicians and patients, is encouraged to access information available through the MAUDE database to obtain safety data on medical devices.

On August 20, 2020, the FDA released its own study across its history of adverse event reports. The FDA tabulated the adverse event reports it had

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[1] FDA, *MedWatch: The FDA Safety Information and Adverse Event Reporting Program*, https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program (last visited June 19, 2021); *See also* FDA, *Breast Implants*, https://www.fda.gov/medical-devices/implants-and-prosthetics/breast-implants (last visited June 19, 2021) (through which FDA "Encourage[s] patients to report adverse events associated with breast implants through the FDA's Medwatch.").

received that contained reference to BII symptoms. The agency reported that it received only 1,080 such reports during the 11 years encompassed by the period of January 2008 to October 2018. The FDA received more than twice as many such reports, a total of 2,497 reports, during the next 11 ***months***.[2] The inference is inescapable: manufacturers were systematically under-reporting breast implant illness symptoms, for more than a decade.

c. Breast Implant Illness

Breast implant illness ("BII") is a term generally applied to a collection of systemic signs and symptoms which patients often report after receiving breast implants. The FDA identifies the most common symptoms reported by patients with breast implants as fatigue, "brain fog," joint pain, anxiety, hair loss, depression, rash, autoimmune diseases, inflammation, and weight fluctuation.[3] These ten symptoms are only a few of 89 systemic symptoms that the FDA

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[2] *See* FDA Press Release, *FDA Updates Analysis of Medical Device Reports of Breast Implant Illness and Breast Implant-Associated Lymphoma* (Aug. 20, 2020), https://www.fda.gov/news-events/press-announcements/fda-updates-analysis-medical-device-reports-breast-implant-illness-and-breast-implant-associated (last visited June 22, 2021).

[3] *See* FDA Press Release, *supra* note 2; *See also* FDA, *Medical Device Reports for Systemic Symptoms in Women with Breast Implants* (Aug. 20, 2020) ("Medical Device Reports for Systemic Symptoms"), https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-systemic-symptoms-women-breast-implants (last visited June 19, 2021) (identifying most common systemic signs and symptoms from MDR database review).

recognizes as included in BII.[4] Many medical providers classify the indicators as connective tissue or autoimmune symptoms, but women are often not diagnosed with a specific disorder.

Commonly diagnosed conditions that arise after implant rupture include fibromyalgia, Hashimoto's thyroiditis, mixed connective tissue disease, and pulmonary fibrosis, among others.[5]

Recent research suggests that BII is an autoimmune or inflammatory response to silicone. Histological analysis of tissue surrounding implants reveals infiltration of inflammatory cells into tissue surrounding the implants.[6] Silicone reactions occur irrespective of whether the recipient's implants remained intact or ruptured.[7] Some patients who present common symptomatic BII frequently experience significant

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[4] *See* Medical Device Reports of Systemic Symptoms, *supra* note 3.

[5] *See* Diana Zuckerman, Ph.D., *Breast Implant Illnesses: What's the Evidence?* National Center for Health Research, p. 10, 12, https://www.center4research.org/wp-content/uploads/2020/09/Breast-Implant-Illnesses-Whats-the-Evidence.pdf (last visited June 19, 2021).

[6] *See* Corinne E. Wee, M.D., et al., *Understanding Breast Implant Illness, Before and After Explantation*, *A Patient-Reported Outcomes Study*, 85 Annals of Plastic Surgery, Sup. 1, S82, S84 (July 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7294749/pdf/spa-85-s82.pdf (last visited June 19, 2021).

[7] *See* Corinne E. Wee, *supra* note 6, at S85 (explaining than an analysis of intact implants illustrates mild cell reactions with minimal chronic inflammatory infiltrate, while tissue surrounding ruptured implants will exhibit a more severe reaction, i.e., foreign body giant cell reaction, in response to free silicone).

immediate and sustained improvement on explant surgery.[8] Unfortunately, not all patients enjoy substantial relief.

After years of denial by manufacturers, the FDA has acknowledged that breast implants increase the risk of an especially serious autoimmune disease known as breast implant-associated anaplastic large cell lymphoma ("BIA-ALCL") – BIA-ALCL is a cancer of the immune system with symptoms that include fluid collection, capsular mass, skin rash, and lymphadenopathy.[9]

The FDA currently does not limit the risk of developing BIA-ALCL to any particular product model or manufacturer, though textured breast implants are six times more likely than smooth implants to lead to BIA-ALCL. A recent FDA update confirms 733 total unique cases and 36 deaths associated with BIA-ALCL.[10]

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[8] *See* Corinne E. Wee, *supra* note 6, at S83, S85.

[9] *See* FDA, *The FDA Requests Allergan Voluntarily Recall Natrelle BIOCELL Textured Breast Implants and Tissue Expanders from the Market to Protect Patients: FDA Safety Communication* (June 1, 2020), https://www.fda.gov/medical-devices/safety-communications/fda-requests-allergan-voluntarily-recall-natrelle-biocell-textured-breast-implants-and-tissue (last visited June 22, 2021); Mark W. Clements, M.D., et al., *How to Diagnose and Treat Breast Implant-Associated Anaplastic Large Cell Lymphoma*, Plast. Reconst. Surgery Journal 141(4), 568e (2018).

[10] *See* Press Release, FDA, *FDA Updates Analysis of Medical Device Reports of Breast Implant Illness and Breast Implant-Associated Lymphoma* (Aug. 20, 2020), https://www.fda.gov/news-events/press-announcements/fda-updates-analysis-medical-device-

d. Facts Specific to Petitioners

The Petitioners include seventeen implant recipients and six spouses. Though each of their stories is unique, their experiences with MemoryGel breast implants are alarmingly similar. Of the 17 implant recipients, 16 have had one or both breast implants explanted;[11] 14 women suffered at least one implant rupture;[12] 13 experienced gel bleed;[13] and 15 post-explant investigations revealed manufacturing defects, including impaired durability in shell materials, internal ruptures, capsular tears, shell elastomer failures, and gel anomalies.[14]

Petitioners suffer from a litany of symptoms which first appeared after the implant of their Mentor devices in their breasts. The symptoms are recognized in relation to BII, and many are common across Petitioners. Of the 17 implant recipients, five or more of them suffer from fatigue (13), joint pain (11), memory loss (11), vision problems (10), skin rashes (10), hair loss (9), numbness (9), muscle pain (9), cognitive dysfunction (8), chest pain (8), swelling (8), dizziness (8), nausea (8), dry eyes (7), shortness of breath (7), night sweats (7), migraine (6), and metallic taste (5). Other

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reports-breast-implant-illness-and-breast-implant-associated (last visited June 22, 2021).

[11] *Billetts* Complaint ¶¶ 26, 34, 38. The *Billetts* case is cited as exemplary; each of the other Complaints or records contains corresponding allegations.

[12] *Billetts* Complaint ¶¶ 23, 26, 34, 38.

[13] *Billetts* Complaint ¶¶ 26, 34, 38.

[14] *Billetts* Complaint ¶¶ 27, 35, 39.

ailments and disorders are common across smaller segments of the Petitioners.

Had the women been aware of or known of the risk that silicone would be injurious to their bodies, they would not have elected to receive Mentor Memory-Gel Breast Implants. *Billetts* Complaint ¶¶ 137, 199.

Petitioners bring claims under the common law of nine states, spread across the Fifth, Eighth, Ninth, Tenth, and Eleventh Circuits.

e. Facts and Allegations Specific to Mentor

Petitioners' Complaints contain considerable allegations relating to Mentor's checkered manufacturing past. The allegations include testimony from Mentor's management-level employees in the late 1990s about deliberately false reporting of rupture rates, systemic inadequacies in Mentor's manufacturing processes, concealment of data relating to rupture rates and defective manufacturing, omitted finished device testing, and omitted materials sterilization testing. *Billetts* Complaint ¶¶ 61-63.

The Complaints further allege that additional witnesses reported that Mentor was still fraudulently reporting its test results and device failure rates and was destroying and is concealing evidence relating to such witnesses. *Billetts* Complaint ¶¶ 64-65. The record on dismissal in the trial and appellate courts included specific evidence of Mentor "whistle blower"

reports, including a letter published by a non-profit consumer rights advocacy group, precisely detailing Mentor's false reporting practices and false test result data. *Billetts* D.11-5, 11-6, 11-7.

Petitioners allege that detailed information relating to a manufacturer's experiences rests solely with the manufacturer. *Billetts* Complaint ¶ 100. The record before the trial court upon dismissal established same. "Only Mentor, however, is responsible for the manufacturing process and reporting adverse events to the FDA." Mentor Not. of Removal, *Vieira* App. Rec. 20 D. ¶ 24. That is, in the absence of accurate reporting, no plaintiff can possess, at the time she files her complaint, detailed information about inadequacies in a manufacturer's reporting, or about its inaccurate manufacturing processes and experiences. Only Mentor can accurately report its own knowledge relating to rates of rupture, causes of ruptures, and linkage between any claimed symptoms or injuries and its breast implant products. *Billetts* Complaint ¶ 100. Similarly, only Mentor can maintain accurate records of its own processes, records that, absent court permitted discovery, will never be available to patients who fear or discover that dangerous devices have been surgically implanted into their breasts. *Billetts* Complaint ¶¶ 138, 153, 218.

Petitioners specifically allege in their Complaints that Mentor failed to accurately "report newly acquired information [and] true information about: instances of silicone toxicity; instances of adverse events; instances

of adverse events requiring removal; instances of constellations of adverse symptoms; instances of chronic/persistent autoimmune-like complaints and inflammatory issues; rupture rates; and more." *Billetts* Complaint ¶¶ 120, 130, 136, 164-65, 170, 173-74, 209. They allege that if Mentor had accurately reported its experience and knowledge relating to ruptures, the Petitioners would have been on notice of a rupture rate for Mentor MemoryGel Breast Implants that is significantly higher than the rates publicly disclosed by Mentor and touted in Mentor's product insert. *Billetts* Complaint ¶ 101.

Petitioners further specifically allege that if Mentor had accurately reported its experience and knowledge of patient symptoms, they would have been on notice of risks attendant to Mentor's MemoryGel Breast Implants that are significantly greater than the risks publicly reported by Mentor and touted in Mentor's product insert. *Billetts* Complaint ¶ 102.

The 23 Petitioners allege that if Mentor had accurately reported adverse events known to it, "additional information would have been available to the public, including Plaintiffs' treating physicians, [and] [i]f Plaintiffs had been adequately warned of the serious risks and adverse events by Defendant Mentor, they would not have agreed to implantation of Mentor MemoryGel Silicone Gel Breast Implants." *Billetts* Complaint ¶¶ 136-37. Likewise, if post-implant adverse events had been accurately reported, risk data and patient experiences would have been available to

the medical community at a significantly earlier date than was otherwise the case, and "Plaintiffs would have been able to undergo the explantation surgery at an earlier date and would have been less severely damaged and injured." *Billetts* Complaint ¶¶ 205-06.

The Complaints allege that under applicable state law, once a manufacturer is called upon to report information relating to the safety of its products, it must do so accurately. *Billetts* Complaint ¶¶ 120, 122, 134, 184, 186, 206. This duty, to accurately report safety experience, is parallel with, and no broader or stricter than, the same duty that is imposed upon Mentor by the FDCA. Mentor expected that patients and their physicians, in deciding whether to incorporate Mentor's devices into the patients' bodies, would rely upon the accuracy of Mentor's adverse event reports. Mentor knew the FDA routinely publishes such information on its public websites for precisely such reliance by physicians and patients. *Billetts* Complaint ¶¶ 123, 125, 129, 190, 192.

The Complaints also allege that Mentor defectively manufactured the implants by failing to follow the product specifications approved by the FDA, using unapproved materials and components, using materials and components that were not commercially reasonable, failing to follow standard manufacturing processes, failing to follow FDA-approved manufacturing processes, failing to use reasonable care in inspecting and testing, and in quality control and quality assurance. *Billetts* Complaint ¶¶ 142, 145. The devices' "rupture, leakage, and bleeding of silicone . . . , due to

porous or weak containment in the Implant shell, is inconsistent with [FDA regulations]." *Billetts* Complaint ¶ 220. As with failure to warn, the Plaintiffs expressly alleged that the duties and standards imposed by California law upon Mentor in its manufacturing processes, and its reporting of same, are no different than, and are thus parallel with, the duties imposed upon Mentor by federal law. *Billetts* Complaint ¶¶ 141, 143, 154.

f. This Court's Pronouncements Regarding MDA Preemption

On three prior occasions, this Court has considered preemption under Section 360k of the MDA. In 1996, the Court ruled that the MDA does not expressly preempt state law requirements that parallel federal requirements. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 494-497 (1996). *Lohr* established that the MDA preemption analysis is appropriate when a duty imposed under state law relates to a particular device that is also the subject of a duty imposed under federal law. In that event, a common law claim arising from breach of a duty imposed by state law which parallels a duty imposed by federal law is not preempted by the MDA. *Id*. at 492-494, 499-501. Because Congress intended to preempt state law only where it creates a broader duty that is specific to a particular device, the FDA's labeling and manufacturing regulations, which apply generally on an industry-wide basis, do not trigger preemption as they do not include device-specific requirements. *Id*. at 501.

In 2001, the Court decided *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). In *Buckman*, the Court held that the MDA preempts claims that effectively allege "fraud on the FDA." That is, where a manufacturer lies to the FDA, inducing the FDA to approve the public sale of a device, a plaintiff cannot contort the claim into a common law tort. The so called "fraud on the FDA" is impliedly preempted. The Court explained that this unusual fraud-based claim stems from the breach of a duty that exists solely under federal law – a duty to be truthful in making statements to the FDA which are intended to induce FDA reliance during the product approval process. *See Buckman*, 531 U.S. at 352-353. Because manufacturers might lie to the FDA to induce the FDA to approve a product for public sale, "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration." *Id*. at 348.

In 2008, the Court issued its decision in *Riegel v. Medtronic, Inc*., 552 U.S. 312 (2008). In *Riegel*, the Court held that the PMA through which some medical devices secure marketing permission from the FDA establishes device-specific requirements that, under § 360k(a), expressly preempt different or additional state-law requirements, but not, the Court reiterated, state-law claims that parallel federal requirements. In section 360k(a), the Court stated, it "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations." *Riegel*, 552 U.S. at 330. The Court also restated *Lohr*'s conclusion that federal labeling requirements that apply

"across the board to almost all medical devices" generally do not preempt state requirements. *Id*. at 322.

3. Proceedings Below

In 2018 and 2019, a total of 33 Petitioners filed their complaints in the four underlying cases in three different California counties. Each case was removed to the United States District Court for the Central District of California,[15] after which Mentor moved for dismissal of each case on preemption grounds. The District Court granted Mentor's motions and dismissed the complaints in two cases on August 1, 2019, and in the other two cases on August 27, 2019. The Plaintiffs filed motions for reconsideration, which the District Court denied on October 29, 2019. The Plaintiffs filed notices of appeal, and the United States Circuit Court of Appeals for the Ninth Circuit issued its judgments on the appeals on February 5, 2021.[16]

[15] The complaint in each of the four cases originally included, in addition to Mentor, non-diverse defendants. After removal, the plaintiffs in each of the four cases sought remand, which Mentor opposed based upon allegedly fraudulent joinder. The District Court denied remand in all four cases, rulings that are not at issue in connection with this Petition.

[16] Petitioners include four of five *Billets* Plaintiffs, both *Vieira* Plaintiffs, three of five *Nunn* Plaintiffs, and 14 of 21 *Sewell* Plaintiffs.

REASONS FOR GRANTING THE PETITION

1. Lower Courts Widely Acknowledge Difficulty in Applying the *Buckman* and *Riegel* "Parallel Claim" Analysis, Leading to Inconsistent Rulings Among the Circuits; the Courts are Erroneously Applying an Ever-Narrowing "Narrow Gap"

The court below begins its preemption analysis by noting a phrase first adopted at the appellate level by the Eighth Circuit and since cited and repeated by the federal judiciary nearly 200 times:

> *Riegel* and *Buckman* create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption. The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*).

In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig., 623 F.3d 1200, 1204 (8th Cir. 2010), *quoting Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009), *quoted in part in Billetts v. Mentor Worldwide LLC*, 847 F. App'x at 379, App. 1, *quoting Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013).

The basis for finding a "narrow gap" to exist is unclear, as this Court has not used the term. More importantly, no "narrow gap" should exist between *Buckman* and other decisions, as *Buckman* itself is a

narrow ruling. By its language, *Buckman* applies where a claim is alleged to arise out of a "fraud on the FDA"; that is, out of a representation made to the FDA to induce the FDA's reliance in approving a product.

The Eighth Circuit's oft-cited "narrow gap" has created widespread ambiguity and inconsistency among the circuits as they attempt to decide the parameters of this narrow gap. The Tenth Circuit recently noted this confused state of the law in *Brooks v. Mentor Worldwide LLC*, 985 F.3d 1272 (10th Cir. 2021).[17] In *Brooks*, the court observed that the concept of federal preemption of state law claims in relation to medical devices first appeared when Congress enacted the MDA in 1976. That introduction of federal law "has left, by both express and implied preemption, only a narrow gap within which a plaintiff can plead a tort claim arising from the failure of a medical device. Successful pleading requires navigating a legal quagmire that has consumed unwary legal professionals for more than forty years." *Brooks*, 985 F.3d at 1276.

"Lower courts have struggled ever since [*Lohr*] when it comes to trying to decide whether particular state claims do or don't 'parallel' putative federal counterparts." *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1338 (10th Cir. 2015). Applying Congress's and the Court's "competing instructions [is] 'no easy task.'" *Id.* at 1340, *quoting Martin v. Medtronic, Inc.*, 254 F.3d 573,

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[17] A Petition for Writ of Certiorari, substantially similar to the instant Petition, was filed with this Court on June 25, 2021 in *Brooks*.

578-579 (5th Cir. 2001) (noting difficulty in "extracting the final meaning" of the Supreme Court's preemption decisions). "The Supreme Court has issued a number of opinions that embody 'divergent views' about the proper role of the MDA's preemption provision, a fact that has yielded considerable 'uncertainty' among the lower courts seeking to apply the statute to cases like this one." *Id.* at 1337.

The Sixth Circuit has likewise noted that "[s]ince *Riegel*, courts have struggled to determine which claims fit into the 'narrow exception' to MDA preemption left open by *Riegel* and *Lohr*." *White v. Medtronic, Inc.*, 808 F. App'x 290, 294 (6th Cir. 2020), *cert. denied*, 141 S. Ct. 239, 208 (2020), *quoting Weber v. Allergan, Inc.*, 940 F.3d 1106, 1114 (9th Cir. 2019), *cert. denied*, 140 S. Ct. 2555 (2020).

The Ninth Circuit, in *Weber*, *supra*, noted the existence of an "intercircuit disagreement" regarding the breadth of the "parallel claim" exception to preemption. *Weber*, 940 F.3d at 1114, *cert. denied*, 140 S. Ct. 2555 (2020); *see generally, Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 700 (S.D. Tex. 2014) ("Courts have struggled with applying the Supreme Court's preemption rulings to cases involving the Infuse device."); *Carrelo v. Advanced Neuromodulation Sys., Inc.*, 777 F. Supp. 2d 303, 310 (D. P.R. 2011) (noting "the present struggle . . . to determine whether state-law claims are preempted by the MDA"); M. Helveston, *Preemption Without Borders: The Modern Conflation of Tort and Contract Liabilities*, 48 Ga. L. Rev. 1085, 1124 (2014); M. Herrmann, D. Alden, B. Harrison, *The Meaning of*

the Parallel Requirements Exception Under Lohr *and* Riegel, 65 N.Y.U. Ann. Surv. Am. L. 545, 546 (2010) ("This parallel requirements exception is far from clear."). D. Chang, Note, *Internalizing the External Costs of Medical Device Preemption*, 65 Hastings L.J. 283, 295 (2013) (the Court's decisions have not "provide[d] much guidance as to what constitutes a parallel claim").

Petitioners' claims perfectly manifest the difficulty created by division among the Circuits, as Petitioners reside in five different Circuits, several of which take different approaches when applying this Court's preemption decisions.

2. *Buckman* Does Not Apply to Manufacturers' Post-Sale Submissions of False or Inaccurate Adverse Event Reports

Difficulty applying this Court's prior decisions is evidenced by the present case. The Ninth Circuit cited *Buckman* in support of a preemption bar against Petitioners' claims that Mentor engages in a practice of inaccurately reporting adverse events. The subject adverse events are not reported to the FDA for the purpose of inducing FDA reliance; instead, they are submitted to the FDA for the purpose of inducing reliance by others, including doctors and patients. The duty to submit such reports is not unique to Mentor or its products, and continues indefinitely into the future, regardless of the date of product approval.

The Court's decision in *Buckman* has no bearing upon any analysis of claims arising from submission of

information to the FDA that is intended not for FDA pre-approval reliance but instead for patient and physician post-approval reliance.

a. *Buckman* Does Not Apply to Reports Submitted to the FDA for Reliance by Others

Petitioners allege that Mentor submitted false adverse event data to the FDA. In this context, "to the FDA" relates to reports submitted with the express expectation that the FDA will make the reports available for public review and analysis, through public websites that are specifically intended for physician and patient reliance. 21 U.S.C. § 360i, 21 C.F.R. §§ 803.1(a), 803.9(a). The database through which adverse event reports are made available to the public could easily be maintained by any federal agency, or by an outside contractor – it does not contain work product that is uniquely attributable to the FDA. Rather, the FDA uses its websites simply to make the reported information publicly available. Consequently, the FDA does not confirm the accuracy of MAUDE-published data but simply "assumes that reports received are truthful." *Billetts* D.1-4 p.158. The FDA's MAUDE and MedWatch programs are more akin to a public library than public regulation.

In relation to post-sale adverse event reports, Petitioners do not claim that any "fraud on the FDA" occurred, as no reliance by the FDA is directly at issue. Reliance has long been an element of any fraud-based claim. *See*, *e.g.*, *Pence v. United States*, 316 U.S. 332,

338 (1942); *McGonigle v. Combs*, 968 F.2d 810, 817 (9th Cir. 1992). Reliance by the FDA is at the core of *Buckman*, as the Court focused on manufacturers' untruthful statements to induce the agency's reliance in approving a product for public sale. *Buckman*, 531 U.S. at 348-351.

The court below properly noted, as it had previously ruled, that California law recognizes that a "manufacturer's failure to report adverse events to the FDA can form the basis of a parallel claim that survives preemption." *Billetts*, 847 F. App'x at 379, App. 1, *citing Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013). Then the Ninth Circuit then oversimplified the analysis by separating those toward which a false representation might be made into three wholly distinct categories of persons – FDA, patients, and physicians. The Ninth Circuit ruled that "to the extent Plaintiffs argue that Mentor failed to warn them or their doctors directly, such claims are preempted because there are no such federal requirements." *Billetts*, at 380, App. 1.

The Ninth Circuit appears not to have considered the potential that Mentor can disseminate false information indirectly, *through* the FDA, to the medical and patient community, even though the same court had held so previously. In *Stengel*, the court found that a common law duty to accurately report adverse events and data "through" the FDA will support a parallel claim, because, "[u]nder Arizona law, a warning to a third party satisfies a manufacturer's duty if, given the nature of the warning and the relationship of the third

party, there is "reasonable assurance that the information will reach those whose safety depends on their having it"), *quoting Anguiano v. E.I. DuPont de Nemours & Co.*, 808 F. Supp. 719, 723 (D. Ariz. 1992), *affirmed*, 44 F.3d 806 (9th Cir. 1995).

Mentor's adverse event reports were submitted to the FDA not for reliance by the FDA, but for reliance by others. As noted in *Stengel*, the FDA is a "third party" to the communication. *Id.* In light of this sound reasoning, one cannot determine why the Ninth Circuit limited its own prior analysis so narrowly to the FDA, physicians, and patients as non-overlapping separate groups with which a manufacturer might "directly" communicate. *Billetts*, at 380, App. 1.

Mentor's duty to submit adverse event reports for public reliance is distinguishable from Mentor's duty to submit test results for FDA reliance in approving Mentor's PMA application. Such results are submitted principally for consumption by the FDA and are provided to the FDA in response to a requirement that is "particular" to Mentor's breast implant device.

b. *Buckman* Does Not Apply to Manufacturers' Post-Sale Conduct

Just as *Buckman*'s preemption of "fraud on the FDA" claims cannot apply to data or reports that are submitted to or through the FDA for reliance by others, it cannot apply to data or reports that are submitted to or through the FDA *after* approval of the product, or after the implantation of the product into a

woman's breasts. The Ninth Circuit erred in applying the Court's preemption decisions to post-sale conduct. Mentor cannot conceivably posit that its post-sale adverse event reports, which are required continually and in the ordinary course for many products, are submitted to create retroactive reliance by the FDA to induce approval of a product that has already been approved. This is particularly true given the FDA's own pronouncements; the purpose of the databases in which adverse event report data is stored and through which such data is shared is public access to information, and public reliance. *See supra*, n.1.

One court recently considered this question and reached precisely this conclusion, that claims asserting a breach of duty arising after FDA approval simply do not trigger a federal preemption analysis. In *Mories v. Boston Scientific Corp.*, 494 F. Supp. 3d 461, 473 (S.D. Ohio 2020), the court properly extended inferences in favor of the plaintiff's pleading, as is appropriate in connection with a Rule 12(b)(6) motion. Upon doing so, the court noted a distinction between pre-approval, *Buckman*-barred activity, and post-approval activity, observing that "[t]he difference between the preempted and non-preempted failure-to-warn claim is temporal – i.e., before or after the FDA approved the warnings and literature associated with the [product]." *Mories*, 494 F. Supp. 3d at 473. Logically, based upon this temporal distinction, the court denied the motion to dismiss the plaintiff's failure to warn claim to the extent the complaint alleged "a breach of Defendant's duty under state law to warn of potential defects, based

on information Defendant obtained *after* the FDA's approval of the medical device. In other words, if Plaintiff is alleging that Defendant failed-to-warn of design or manufacture defects after the FDA approved of the warnings and literature, then she is not asking for a court to disagree with any federal determination." *Mories* at 473 (emphasis in original), *citing Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000).

The federal courts are inconsistently applying the Court's *Buckman* "fraud on the FDA" reasoning. The district court in *Babayev v. Medtronic, Inc.*, 228 F. Supp. 3d 192, 212 (E.D.N.Y. 2017), in the absence of Second Circuit authority, surveyed the "parallel claim" decisions and found in 2017 that "[a]t least six Circuit Courts of Appeals have attempted to clarify this issue, but have promulgated standards which are at least somewhat – and sometimes very – different from one another." *Babayev*, 228 F. Supp. 3d at 212. The *Babayev* court's survey found preemption to be more broadly applied in the Sixth and Eighth Circuits, based upon "an expansive view of *Buckman*." *Id.* at 213, *citing In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) and *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 586 (6th Cir. 2013).

In contrast, the Fifth, Seventh, and Eleventh Circuits have more narrowly limited preemption under *Buckman* to fraud-on-the-FDA claims. *Babayev*, 228 F. Supp. 3d at 213, *citing Funk v. Stryker Corp.*, 631 F.3d 777, 779 (5th Cir. 2011), *Bausch v. Stryker Corp.*, 630 F.3d 546, 552 (7th Cir. 2010), *Kallal v. CIBA Vision Corp.*, 779 F.3d 443, 447 (7th Cir. 2015) and *Hughes v.*

Boston Scientific Corp., 631 F.3d 762, 774-776 (5th Cir. 2011).

In *Brooks v. Mentor Worldwide LLC*, 985 F.3d 1272 (10th Cir. 2021), the Tenth Circuit Court considered a complaint very similar to Petitioners' Complaints. The court affirmed the preemption of those plaintiffs' claims that Mentor breached its duty to warn by indirectly providing false and inaccurate adverse event reports through the FDA. The Tenth Circuit recently joined the Sixth and Eighth Circuits with an unfortunately broad and "expansive" application of *Buckman*. *Id.*

The present cases and *Brooks* cannot be reconciled with the Fifth Circuit's decision in *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011). In *Hughes*, the court held that a failure to warn claim is not expressly preempted to the extent it is based on the manufacturer's violation of FDA regulations requiring accurate reporting of serious injuries; such a claim is "parallel" because it does not arise from duties greater or different from those required under the federal regulations. *Id.* at 771.

3. Lower Courts, Including the Court Below, are Inappropriately Dismissing Claims of Defective Manufacture on Preemption Grounds, Because Preemption is an Affirmative Defense; a Split Among the Circuits Exists

The Court should grant the Petition because dismissal of Petitioners' Complaints was premature, and

the premature dismissal is indicative of an unfortunate nationwide trend.

The District Court dismissed Plaintiffs' first Complaints, without leave to amend. The Ninth Circuit affirmed, without opinion, *Billetts*, 847 F. App'x at 380, App. 1, thus leaving in place the District Court's resolution of the issue. In finding that Plaintiffs' Complaint inadequately alleged defective manufacture, the District Court ruled that "a plaintiff must identify [the] specific regulatory violation at issue." *Billetts*, 2019 WL 4038218, *7, App. 6.

The rulings of the courts below demonstrate that Petitioners are unfortunate victims of the pleading "quagmire" noted by the Tenth Circuit in *Brooks v. Mentor Worldwide LLC*, 985 F.3d at 1276. In ruling on Mentor's Rule 12(b)(6) motion to dismiss, the Central District of California properly looked for guidance to this Court's decisions in *Ashcroft v. Iqbal*, 556 U.S. 662 (2009) and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007). Apparently, the district court determined that *Iqbal* and *Twombly* require a plaintiff to have precisely identified and alleged a specific flaw in Mentor's manufactured product. The decisions of the courts below, like the Tenth Circuit's in *Brooks*, fail to recognize that in order for a plaintiff to possess the information deemed necessary to survive Rule 12 dismissal, a plaintiff must possess, during the drafting stage, information that ordinarily cannot be obtained until the discovery stage. Where the ground for dismissal is an affirmative defense like preemption, these decisions require a plaintiff to be clairvoyant.

The Seventh Circuit has noted that, even in a jurisdiction in which "federal law does not preempt parallel claims under state law based on a medical device manufacturer's violation of federal law," it is "difficult . . . to plead such a claim sufficiently to survive a motion to dismiss" under Rule 12(b)(6). *Bausch*, 630 F.3d at 558. The court held that district courts applying the *Iqbal/Twombly* plausibility standard "must keep in mind that much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law. Formal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim." *Bausch*, at 558. Upon such a ruling, the *Bausch* court reversed a district court's order dismissing, without leave to amend, a complaint alleging defective manufacture of a medical device. *Id*.; *accord Marion v. Smith & Nephew, Inc.*, 2015 WL 7756063, *2 (D. Utah 2015) ("Given the disparate outcomes and uncertainty among the federal courts on this issue, the court understands the Marions' initial uncertainty with respect to the required pleading standard. While 'the difficulty of crafting a complaint sufficient to satisfy all [the] demands' of § 360k(a) is not a proper legal basis for allowing a plaintiff to proceed to discovery, the court does find it sufficient to warrant leave to amend.").

The Seventh Circuit's decision in *Bausch* soundly acknowledges a practical reality that exists for plaintiffs who suffer from having had injurious devices implanted into their bodies. But the decision and line of

reasoning are not simply sound as a practical matter. *Bausch* is sound as a matter of law because the federal courts should not be routinely dismissing, on preemption grounds, complaints that allege defective manufacture, or claims alleging other "parallel claims" for that matter, because a Rule 12(b)(6) motion is an inappropriate vehicle for addressing claims of preemption.

This principle was recognized in the Seventh Circuit's recent application of *Bausch*. In *Benson v. Fannie May Confections Brands, Inc.*, 944 F.3d 639 (7th Cir. 2019), the court reversed a district court's dismissal on preemption grounds, noting that preemption is "an affirmative defense upon which the defendants bear the burden of proof," and "[a]ffirmative defenses do not justify dismissal under Rule 12(b)(6)." *Id.* at 645, *quoting Fifth Third Bank ex rel. Tr. Officer v. CSX Corp.*, 415 F.3d 741, 745 (7th Cir. 2005), *Doe v. GTE Corp.*, 347 F.3d 655, 657 (7th Cir. 2003).

Unable to ignore the important distinctions between Rule 12(b)(6) motions and other types of motion practice, the Seventh Circuit concluded that "[t]he district court thus erred by penalizing Benson for failing to anticipate an affirmative defense in her complaint and dismissing the action based on FDCA preemption." *Id.* at 645. The Ninth Circuit decisions that are the subject of this Petition, and the Tenth Circuit's decision in *Brooks* that is also the subject of a petition before this Court, cannot be reconciled with *Bausch* and *Benson*.

Undoubtedly, "preemption is an affirmative defense." *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 251 n.2 (2011) (Sotomayor, J., dissenting), *citing Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 255 (1984); *Brown v. Earthboard Sports USA, Inc.*, 481 F.3d 901, 912 (6th Cir. 2007) ("federal preemption is an affirmative defense upon which the defendants bear the burden of proof"), *quoting Fifth Third Bank*, 415 F.3d at 745; *accord Flo & Eddie, Inc. v. Pandora Media, LLC*, 789 F. App'x 569, 572 (9th Cir. 2019); *Muhammad v. Norfolk S. Ry. Co.*, 925 F.3d 192, 196 (4th Cir. 2019); *Bedoya v. Am. Eagle Express Inc.*, 914 F.3d 812, 817 (3d Cir. 2019), *cert. denied*, 140 S. Ct. 102 (2019); *Sickle v. Torres Advanced Enter. Sols., LLC*, 884 F.3d 338, 345 (D.C. Cir. 2018); *Fisher v. Halliburton*, 667 F.3d 602, 609 (5th Cir. 2012).

A plaintiff is not required to anticipate and negate an affirmative defense in his complaint. *See Gomez v. Toledo*, 446 U.S. 635, 640 (1980); *ABB Turbo Sys. AG v. Turbousa, Inc.*, 774 F.3d 979, 985 (Fed. Cir. 2014); *Flying Food Grp., Inc. v. N.L.R.B.*, 471 F.3d 178, 183 (D.C. Cir. 2006); *Oakes v. United States*, 400 F.3d 92, 98 (1st Cir. 2005); *La Grasta v. First Union Sec., Inc.*, 358 F.3d 840, 845 (11th Cir. 2004); *Tregenza v. Great Am. Commc'ns Co.*, 12 F.3d 717, 718 (7th Cir. 1993). For this reason, it is generally inappropriate to grant a Rule 12(b)(6) motion to dismiss based upon an affirmative defense. Fed. R. Civ. P. 12(b)(6); *see Deswal v. U.S. Nat. Ass'n*, 603 F. App'x 22, 23-24 (2d Cir. 2015); *Omar ex rel. Cannon v. Lindsey*, 334 F.3d 1246, 1252 (11th Cir.

2003); *Scott v. Kuhlmann*, 746 F.2d 1377, 1378 (9th Cir. 1984).

This general rule is subject to an exception where it is unequivocally established from the face of the pleading that the claim is barred as a matter of law. *See ABB Turbo Sys. AG*, 774 F.3d at 985 (dismissal based upon an affirmative defense "ordinarily is improper unless it is 'apparent from the face of the complaint that the claim is time-barred' "), *quoting La Grasta*, 358 F.3d at 845-846, *quoting Tregenza*, 12 F.3d at 718.

Dismissal based upon an affirmative defense is proper "only when the complaint itself admits all the elements of the affirmative defense by alleging the factual basis for those elements," as when the "plaintiff pleads itself out of court [b]y admit[ting] all [of] the ingredients of an impenetrable defense." *Fernandez v. Clean House, LLC*, 883 F.3d 1296, 1299 (10th Cir. 2018), *quoting Xechem, Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899, 901 (7th Cir. 2004)

In application, "[a]lthough a motion to dismiss based upon an affirmative defense may be granted if 'it is apparent from the face of the complaint' that dismissal is warranted, a motion to dismiss should not be granted 'where resolution depends either on facts not yet in evidence or on construing factual ambiguities in the complaint in defendants' favor.' " *N. Am. Elite Ins. Co. v. SW Transp. Servs., Ltd.*, 2014 WL 12452456, *4 (S.D. Fla. 2014), *quoting Lesti v. Wells Fargo Bank,*

N.A., 960 F. Supp. 2d 1311, 1317 (M.D. Fla. 2013), *citing Omar*, 334 F.3d at 1252.

With these principles firmly established, the courts should be loath, and not eager, to grant Rule 12 motions based upon preemption. *See Garcia v. Does*, 779 F.3d 84, 96-97 (2d Cir. 2015) ("It is certainly true that motions to dismiss a plaintiff's complaint under Rule 12(b)(6) on the basis of an affirmative defense will generally face a difficult road."). Even so, such dismissals are becoming *routine*. *See, for example, Williams v. Mentor Worldwide LLC*, 2019 WL 4750843, *4, and n.4 (N.D. Ohio 2019) ("the Fifth Circuit and Louisiana federal courts *routinely* apply Section 360k(a) to dismiss cases against PMA-approved Class III medical devices based on preemption"; "Similarly, courts within the Sixth Circuit *consistently* dismiss state law claims against PMA-approved Class III medical devices based on preemption.") (emphases added).

Under Rule 12(b)(6), it should *never* be "routine" to dismiss a complaint, particularly without leave to amend, based upon the *affirmative defense* of preemption.

Since the burden of proof is on the defendant in relation to preemption, it is indeed penalizing, as the Seventh Circuit has noted, to dismiss a complaint for a lack of detailed factual allegations relating to issues that cannot be known to a plaintiff in the absence of discovery. The punitive nature of the ruling is compounded when the complaint is the initial filing, as is the case here, and is dismissed without leave to amend.

The court below should not have dismissed, particularly without leave to amend, Petitioners' defective manufacture claim. Petitioners cannot possess, without discovery, the kind of information that the Ninth Circuit apparently deemed necessary under *Iqbal* and *Twombly*. Even with no discovery, the dismissed complaints included extensive allegations regarding Mentor's historically horrid manufacturing processes, along with anticipated witness and whistleblower testimony.

Instead of dismissing the complaints due to plaintiffs' ignorance of information that is impossible for them to know, the court below should have taken the approach espoused in *Mories v. Boston Scientific Corp.*, 494 F. Supp. 3d 461 (S.D. Ohio 2020). The *Mories* court recognized the inappropriateness of granting a Rule 12(b)(6) motion based upon preemption, ruling that "[i]f, following the completion of discovery, Plaintiff cannot sustain a claim under state requirements that parallel federal requirements, Defendant would be free to file a motion for summary judgment." *Mories*, 494 F. Supp. 3d at 471.

Troublingly, and deserving of this Court's attention in deciding whether to grant this Petition, the federal courts are now reading this Court's decisions as support for preemption-based dismissals of defective manufacture claims on a widespread basis. This trend creates a patent unfairness, in so far as manufacturing claims are among those that most clearly call for some level of discovery prior to preemption-based dismissal.

Decisions involving other plaintiffs who unfortunately fell into the impossible pleading "quagmire" of having to know and plead information that cannot be known or pleaded, and thus suffering dismissal on preemption grounds of their defective manufacture claims, include *Brooks v. Mentor Worldwide LLC*, 985 F.3d 1272 (10th Cir. 2021); *Ebrahimi v. Mentor Worldwide LLC*, 804 F. App'x 871, 2020 WL 2510760 (9th Cir. May. 15, 2020); *Jankowski v. Zydus Pharm. USA, Inc.*, 2021 WL 2190913 (D.N.J. 2021); *D'Addario v. Johnson & Johnson*, 2021 WL 1214896 (D.N.J. 2021); *Ignacuinos v. Boehringer Ingelheim Pharm. Inc.*, 2020 WL 5659071 (D. Conn. 2020); *Webb v. Mentor Worldwide LLC*, 453 F. Supp. 3d 550 (N.D.N.Y. 2020); *Allo v. Allergan USA, Inc.*, 2020 WL 814855 (E.D. La. 2020); *L. Jacob v. Mentor Worldwide LLC*, 2019 WL 6766574 (M.D. Fla. 2019); *Williams v. Mentor Worldwide LLC*, 2019 WL 4750843 (N.D. Ohio 2019); *Shelp v. Allergan, Inc*., 2018 WL 6694287 (W.D. Wash. 2018).

The expansion of dismissal based upon the *affirmative defense* of preemption necessarily creates a chilling effect for patients who are physically hurting from having had injurious devices implanted into them, since they cannot find counsel to represent them. Due to the need to "navigat[e] a legal quagmire that has consumed unwary legal professionals for more than forty years," *Brooks*, 985 F.3d at 1276, such patients cannot find counsel, at least in most circuits. Sadly, given the difficulty that faces practitioners who attempt to navigate the quagmire, it is difficult to imagine an unrepresented plaintiff ever being able

to do so. Cases resulting in prejudicial dismissal, on preemption grounds, of complaints filed by *pro se* plaintiff breast implant victims include: *Jacob v. Mentor Worldwide, LLC*, 2019 WL 6766574 (M.D. Fla. 2019); *Williams v. Mentor Worldwide LLC*, 2019 WL 4750843, *4, and n.4 (N.D. Ohio 2019); *Stampley v. Allergan USA, Inc.*, 2019 WL 1604201 (W.D. La. 2019), *rep. and rec. adopted*, 2019 WL 1601613 (W.D. La. 2019); *Shelp v. Allergan, Inc.*, 2018 WL 5734664 (W.D. Wash. Nov. 2, 2018) (Allergan motion); *Shelp v. Allergan, Inc.*, 2018 WL 6694287 (W.D. Wash. 2018) (Mentor motion). *See also Laux v. Mentor Worldwide LLC*, 786 F. App'x 84 (9th Cir. 2019), *cert. denied*, 141 S. Ct. 455 (2020), *reh'g denied*, 141 S. Ct. 888 (2020) (affirming summary judgment against *pro se* breast implant victim on preemption grounds, denying leave to amend complaint).

This Court can remedy the "quagmire" that now exists for practitioners and *pro se* victims by eliminating "routine" preemption-based dismissal of claims alleging defective manufacture. "Routine" dismissals are improper in relation to affirmative defenses.

4. The Case Presents an Issue of National Importance

The unfettered defense of preemption is an issue of national importance for the health and safety of the community. Between 2007 and 2020, American plastic surgeons placed more than 4,000,000 breast implant

devices inside Americans' bodies.[18] About 60% of the total, or at least 2.4 million implants, were filled with silicone gel.[19] Meanwhile, the FDA has given heightened focus to the nationwide growth of the adverse effects of silicone implants, noting the need to further investigate the widespread common symptoms of BII. The FDA has only recently recognized a connection between breast implants and a rare cancer known as BIA-ALCL, an illness which has killed dozens of persons to date.

Perhaps due to the negative impression of legacy cases, the federal judiciary is struggling to consistently analyze MDA preemption cases, routinely issuing irreconcilable rulings. In addition, the federal courts seem to be routinely dismissing state law claims, particularly claims alleging negligent manufacture claims, on Rule 12 motions, even though preemption is an affirmative defense, one about which manufacturers possess all relevant evaluative data, which the claimants cannot access without some level of discovery.

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[18] *See 2020 National Plastic Surgery Statistics Report*, *Cosmetic Surgical Procedures*, American Society of Plastic Surgeons, https://www.plasticsurgery.org/documents/News/Statistics/2020/plastic-surgery-statistics-report-2020.pdf (last visited June 19, 2021), and corresponding annual reports for each prior year, 2007-2010, 2012-2018 (each last visited June 19, 2021).

[19] *See 2020 National Plastic Surgery Statistics Report, Cosmetic Surgical Procedures*, *supra* note 18 (2011, 2019 data not available).

By taking steps to curtail this trend, the Court can realign the judiciary with the need to provide relief to thousands of Americans who are living in pain and fear due to the presence of the dangerous products that have been implanted in their bodies. Broad preemption, particularly of claims based upon defective manufacture and inaccurate post-sale reports and warnings, is deterring individuals from pursuing relief from the effects of the foreign objects which now reside inside them.

During more than a decade from 2008 to late 2018, FDA focused little on BII. During that time, manufacturers rarely reported adverse events relating to BII symptoms. As soon as the FDA began to give due attention to widespread complaints of BII, the frequency of manufacturers' reports of adverse events relating to BII symptoms increased 2700%.[20] Thousands of patients whose claims accrued during the period of under-reporting appear now to have little recourse. With each year of continued deterrence, thousands of potential claims are barred by the various state product liability statutes of limitation. The judicial process will give these women a chance to investigate their own claims and discovery, in parallel with the FDA, the information the manufacturers have known all along.

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[20] *See* FDA Press Release, supra note 2. (From 2008 to October 2018 manufacturers submitted, on average, 8 adverse event reports per month in relation to reported BII symptoms and experiences. Beginning in November 2018, the average jumped to 227 per month).

Judicial divisions on the basic questions of the MDA's preemptive scope produce widespread uncertainty and unfairness. Potential claimants should not feel frozen out of relief, nor should medical device manufacturers feel the comfort of overbroad immunity against liability, based purely upon geography. Such legal uncertainty would be undesirable in relation to any particular body of federal law but is especially untenable in relation to MDA preemption. The purpose of the MDA was to render consistent conflicting regulations and requirements, thereby promoting the availability of safe and effective medical devices. Instead of the intended consistency, Americans have confusion. Only this Court can render order from the present chaos.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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