No. _____

In The

Supreme Court of the United States

AMBER BROOKS AND JAMIE GALE,

Petitioners,

v.

MENTOR WORLDWIDE LLC,

Respondent.

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

PETITION FOR WRIT OF CERTIORARI

ANDY DOGALI
DOGALI LAW GROUP, P.A.
19321 US Hwy. 19 North, Suite 307
Clearwater, FL 33764
adogali@dogalilaw.com
(813) 289-0700

Counsel for Petitioners

COCKLE LEGAL BRIEFS (800) 225-6964
WWW.COCKLELEGALBRIEFS.COM

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 public reporting of adverse events, and claims alleging defective manufacture of medical devices.

PARTIES TO THE PROCEEDING

The parties in the court below, petitioners here, are Jamie Gale and Amber Brooks, on behalf of themselves. The respondent here is Mentor Worldwide LLC, on behalf of itself.

STATEMENT OF RELATED CASES

The following proceedings are directly related to this petition:

- *Brooks v. Mentor Worldwide LLC*, 19-cv-02088, United States District Court for the District of Kansas. Judgment entered September 24, 2019.
- *Brooks v. Mentor Worldwide LLC*, 19-3240, United States Court of Appeals for the Tenth Circuit. Judgment entered January 26, 2021.

TABLE OF CONTENTS

TABLE OF CONTENTS – Continued

TABLE OF CONTENTS – Continued

TABLE OF AUTHORITIES

Page

CASES

TABLE OF AUTHORITIES – Continued

Page

TABLE OF AUTHORITIES – Continued

TABLE OF AUTHORITIES – Continued

TABLE OF AUTHORITIES – Continued

TABLE OF AUTHORITIES – Continued

STATUTES

TABLE OF AUTHORITIES – Continued

TABLE OF AUTHORITIES – Continued

Page

TABLE OF AUTHORITIES – Continued

Page

PETITION FOR A WRIT OF CERTIORARI

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

OPINION BELOW

The decision of the Tenth Circuit Court of Appeals affirming the District Court of Kansas ruling is reported at 985 F.3d 1272 (10th Cir. 2021), App. 1. The memorandum and order of the United States District Court of Kansas is not officially reported but is otherwise available at 2019 WL 4628264 (D. Kan. 2019), App. 19.

JURISDICTION

The judgment of the Court of Appeals was entered on January 26, 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, issued in relation to 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 Committee*, 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 Tenth 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. *Id*. § 360c(a)(1)(B). Finally, Class III devices receive the most oversight and require rigorous premarket review and approval. *Id.* § 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

---

[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.").

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 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,

---

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

and weight fluctuation.[3] These ten symptoms are only a few of 89 systemic symptoms that the FDA 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

---

[3] *See id.*, Food and Drug Administration, 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).

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

[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

of whether the recipient's implants remained intact or ruptured.[7] Some patients who present common symptomatic BII frequently experience significant 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

---

(July 2020) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7294749/pdf/spa-85-s82.pdf (last visited June 19, 2021).

[7] *See id.* 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).

[8] *See id*. 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).

six times more likely than smooth implants to lead to BIA-ALCL. The FDA's most recent update confirms 733 total unique cases and 36 deaths associated with BIA-ALCL.[10]

d. Facts Specific to Amber Brooks and Jamie Gale

Amber Brooks underwent surgery and received Mentor MemoryGel Silicone Breast Implants in March 2016. Though Ms. Brooks is a resident of Missouri, she chose a surgeon a short distance away across the river in Kansas. After the surgery was completed, she was released from the hospital and returned home. Soon thereafter, Ms. Brooks developed an array of ailments and painful symptoms that are consistent with breast implant illness. Less than one year after the devices were implanted, they were surgically explanted, and it was discovered that silicone was present in Ms. Brooks' system. After removal of the implants, some of Ms. Brooks' symptoms and conditions improved or disappeared. Some of the conditions remain and may be permanent. The remaining pertinent events occurred in Missouri.

Jamie Gale was implanted with Mentor MemoryGel Silicone Gel Breast Implants in September 2009.

---

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

Thereafter, she suffered for many years from a variety of symptoms consistent with breast implant illness. In 2017, an MRI showed extracapsular silicone around both implants. Soon thereafter, the implants were removed. After the surgery, it was observed that silicone had escaped from both implants and their capsules. Immediately after removal, many of Ms. Gale's symptoms greatly improved or disappeared. Some of the conditions remain and may be permanent. Jamie Gale is a resident of the state of Kansas, where all pertinent events occurred.

e. Facts and Allegations Specific to Mentor

Amber Brooks and Jamie Gale's Complaint contains 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 manufacture, omitted finished device testing, and omitted materials sterilization testing. Comp. [D.1] ¶¶ 48-50.

The Complaint further alleges that in 2005 and 2006, additional witnesses reported that Mentor was still fraudulently reporting its test results and device failure rates and that Mentor has destroyed or is concealing evidence relating to such witnesses. *Id.* ¶¶ 51,

90. These witnesses include multiple Mentor 'whistle blowers,' one of whose comments was published by a non-profit consumer rights advocacy group.

Ms. Brooks and Ms. Gale allege that detailed information relating to a manufacturer's experiences rests solely with the manufacturer. *Id.* ¶ 87. 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. *Id.* 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. *Id.* ¶¶ 116, 131, 194.

Petitioners specifically alleged in their Complaint 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." *Id.* ¶ 108. They allege that if Mentor had accurately reported its experience and knowledge relating to ruptures, Ms. Brooks

and Ms. Gale 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. *Id.* ¶ 88.

Petitioners further specifically allege that if Mentor had accurately reported its experience and knowledge of patient symptoms, Ms. Brooks and Ms. Gale 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. *Id.* ¶ 89.

Both Petitioners allege that if Mentor had accurately reported adverse events that were 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." *Id.* ¶¶ 114-115. 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." *Id.* ¶¶ 182-183.

The Complaint alleged 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. *Id.* ¶¶ 98-100, 112, 161-163; 183. 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 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. *Id.* ¶¶ 101-103, 107, 167-169.

The Complaint also alleged 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. *Id.* ¶¶ 120, 123. The devices' "rupture, leakage, and bleeding of silicone . . . , due to porous or weak containment in the Implant shell, is inconsistent with [FDA regulations]." *Id.* ¶¶ 196. As with failure to warn, the Plaintiffs expressly alleged that the duties and standards imposed by Kansas 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. *Id.* ¶¶ 119, 121, 132.

As further evidence of defective manufacture, Amber Brooks' Complaint specifically alleged that one of her devices ruptured less than one year after it was implanted into her breast. *Id.* ¶¶ 14-15.

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 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 v. Plaintiffs' Legal Committee*, 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. Section 360k(a), the Court stated, "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

Amber Brooks and Jamie Gale filed their Complaint in the United States District Court for the District of Kansas on February 14, 2019. The Complaint alleged claims under Kansas law, including actions sounding in negligence, in relation to Mentor's failure to warn (Count 1, part A) and defective manufacture of the devices (Count 1, part B), and strict products liability, in relation to Mentor's failure to warn (Count 2) and defective manufacture (Count 3). [D.1].

On April 15, 2019, Mentor moved to dismiss the Complaint, on preemption grounds. [D.11].

On September 23, 2019, the District of Kansas issued its order granting Mentor's motion. [D.40]. The court separately addressed the Plaintiffs' failure to warn claims and defective manufacture claims, each of which was pleaded under theories of negligence, strict products liability, and negligence per se.[11]

On the failure to warn claims, the district court considered the claims as asserting a duty to warn three distinct bodies: patients, physicians and the FDA. The court determined that:

- State law will not support a claim against a manufacturer for failing to warn a *patient*;

---

[11] This Petition does not challenge the district court's dismissal of the claims predicated upon a theory of negligence per se.

- Any state law claim based upon a "duty to report negative test results to the *FDA*" is impliedly preempted; and
- Any state law claim that a manufacturer breaches a duty to warn *physicians* by failing to report information to the FDA is impliedly preempted.

In dismissing the Complaint, the district court denied leave for Plaintiffs to amend, finding the Plaintiffs had failed to comply with a local rule relating to amendments.[12]

On October 23, 2019, Petitioners filed their Notice of Appeal to the United States Court of Appeals for the Tenth Circuit. [D.42]. After briefing and oral argument, the Tenth Circuit issued its opinion on January 26, 2021. *See Brooks v. Mentor Worldwide LLC*, 985 F.3d 1272 (10th Cir. 2021), App. 1. The Tenth Circuit affirmed the district court, finding the failure to warn claims to be preempted. *Id.* at 1280-1281. The appellate court followed the district court's approach to analyzing the failure to warn claims, dividing them into

[12] A District of Kansas Local Rule requires a plaintiff to file, along with its opposition to a motion to dismiss, a motion expressly seeking leave to amend and attaching a draft of the amended complaint that would be filed if the existing complaint is dismissed. Separate from the fact that the local rule requires clairvoyance, in so far as it requires a plaintiff to predict the nature and scope of a future order of dismissal, Petitioners argued that the rule should not apply in the context of a motion to dismiss that is based upon an *affirmative defense*, like preemption, since the defense bears the burden of presenting prima facie support for an affirmative defense in the first instance.

three distinct categories based upon whether the recipient of the "warning" was to be patients, physicians, or the FDA, and issuing similar rulings as to each. *Id.* at 1280.

The Tenth Circuit took a different approach toward the defective manufacture claims, affirming the district court's result, but for a different reason: The Tenth Circuit ruled that Ms. Brooks and Ms. Gale's Complaint failed to meet the *Iqbal/Twombly* specificity standard for stating a plausible claim. The court otherwise left the district court's preemption ruling in place. *Id.* at 1281-1282.

REASONS FOR GRANTING THE PETITION

1. Lower Courts, including the Court Below, Uniformly Acknowledge Difficulty in Applying the *Buckman* and *Riegel* "Parallel Claim" Analysis, Leading to Inconsistent Rulings Among the Circuits

The opinion of the court below begins with the court's observation 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. Today we again wade into that quagmire." *Brooks v. Mentor Worldwide LLC*, 985 F.3d 1272, 1276 (10th Cir. 2021), App. 1.

"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' and the Court's "competing instructions [is] 'no easy task.'" *Id.* at 1340, *quoting Martin v. Medtronic, Inc.*, 254 F.3d 573, 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 conflict among circuits is precisely manifested by the present case. To the extent the Tenth Circuit barred Petitioners from bringing a claim for failing to report adverse events occurring after approval of the product or its implantation into Petitioners' breasts, the decision cannot be reconciled with the Ninth Circuit's decision in *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013).

The conflict is most apparent in relation to adverse events that are reported inaccurately, versus reports that are not submitted at all. Stengel found that Arizona law imposes upon manufacturers a parallel

duty to warn of adverse post-sale events, and such duty can apply where the manufacturer's disclosures are submitted to or through a third party. *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) ("Under 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). Even in the absence of Kansas decisions addressing this precise issue, there is no reason to believe Kansas law does not recognize the same duty, especially in relation to the submission of adverse event reports that are inaccurate, in contrast to those a manufacturer simply fails to submit. The common law consistently recognizes, across the states, that even where no duty to report is created by law or contract, once a party undertakes to make a disclosure, it must do so accurately, and inaccurate or dishonest disclosures are actionable at common law. *See*, *for example*, *Caiola v. Citibank, N.A.*, 295 F.3d 312, 331 (2d Cir. 2002); *Lau v. Opera Limited*, 2021 WL 964642, *6 (S.D.N.Y. 2021); *Trahan v. Interactive Intel. Grp., Inc.*, 308 F. Supp. 3d 977, 991 (S.D. Ind. 2018), *citing Stransky v. Cummins Engine Co., Inc.*, 51 F.3d 1329, 1331 (7th Cir. 1995); *Thimjon Farms P'ship v. First Int'l Bank & Tr.*, 837 N.W.2d 327, 339 (N.D. 2013); *New Milford Sav. Bank v. Zandy*, 2001 WL 79830, *2 (Conn. Super. Ct. 2001); *United States v. Singh*, 2020 WL 5500232, *6 (S.D. Cal. 2020); *Chester Cty. Employees' Ret. Fund v. KCG Holdings, Inc.*, 2019

WL 2564093, *11 (Del. Ch. 2019); *Owens v. Nationwide Prop. & Cas. Ins. Co.*, 2014 WL 4258084, *6 (N.D. Ala. 2014) (where insurer had no duty to disclose, "once it undertook to speak, it was required to make a full and fair disclosure"), *quoting Dominick v. Dixie Nat. Life Ins. Co.*, 809 F.2d 1559, 1570 (11th Cir. 1987). Here, Petitioners allege not only that Mentor failed to submit required post-approval reports and data, but that it also submitted false and inaccurate post-approval and post-sale reports and data.

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 Products Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) (the "contours of the parallel claim exception" are "as-yet ill defined") 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*, *e.g.*, *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) (a state tort claim is "parallel" if it is a "remedy for claims premised on a violation of FDA regulations") and *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 774-776 (5th Cir. 2011) (claims for failure to warn, premised on violation of FDA regulations, are not preempted).

Citing *Caplinger*, the Tenth Circuit was said to have "adopted an entirely different approach." *Babayev*, 228 F. Supp. 3d at 214. Presumably, with its decision issued in the instant case, the Tenth Circuit has joined the Sixth and Eighth Circuits in adopting an analysis which adds to the "quagmire" for practitioners attempting to draft a pleading that might survive Rule 12 scrutiny.

Most recently, the Sixth Circuit noted while addressing this question 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).

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 also*, *gen., 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").

The Court should bring clarity to this area of the law.

2. Lower Courts, Including the Court Below, are Inappropriately Dismissing Negligent Manufacture Claims on Preemption Grounds, Because Preemption is an Affirmative Defense

The Court should grant the Petition because dismissal of Petitioners' complaint by the court below was premature, and the premature dismissal is indicative of an unfortunate nationwide trend.

As noted *supra*, the court below observed that the present uncertainty regarding the state of preemption

law not only creates a "struggle" for the courts; it also creates a "quagmire" for plaintiffs attempting to draft a complaint that states a viable action. *See Brooks*, 985 F.3d at 1276, App. 1. As it turns out, the ruling of the court below leave Ms. Brooks and Ms. Gale as unfortunate victims of this "quagmire." The Tenth Circuit dismissed the Plaintiffs' negligent manufacture claims due to the Plaintiffs' failure to plead specific facts that, in the Tenth Circuit's view, were required to meet the "plausibility" pleading standard established by this Court's decisions in *Ashcroft v. Iqbal*, 556 U.S. 662 (2009) and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007).

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 with defectively manufactured 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, while many contrary decisions, including the ruling of the court below, are unsound as a matter of law, because the federal courts should not be routinely dismissing 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 court 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.

It is quite clear that "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) ("Federal preemption is an affirmative defense that a defendant must plead and prove.").

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).

The 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*, 400 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").

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.[13]

---

[13] In the court below, this argument was most clearly expressed during oral argument. *See* https://www.ca10.uscourts.gov/oralarguments/19/19-3240.mp3 at 35:00.

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 Tenth Circuit apparently deemed necessary under *Iqbal* and *Twombly*. Even with no discovery, the dismissed complaint included extensive allegations regarding Mentor's historically horrid manufacturing processes, along with anticipated witness and whistleblower testimony. 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, is the fact that the federal courts are now reading this Court's decisions as support for preemption-based dismissals of manufacturing 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. Even so, it appears only this Court can advise whether immunity against liability for defective manufacturing is the intended scope of the Court's rulings. *See Billetts v. Mentor Worldwide*

LLC, 847 F. App'x 377 (9th Cir. 2021) (affirming dismissal of manufacturing defect claim on basis of preemption); *Vieira v. Mentor Worldwide LLC*, 845 Fed. Appx 503 (9th Cir. Feb. 5, 2021) (affirming dismissal of manufacturing defect claim on basis of preemption); *Sewell v. Mentor Worldwide LLC*, 847 F. App'x 380 (9th Cir. Feb. 5, 2021) (affirming dismissal of manufacturing defect claim on basis of preemption); *Nunn v. Mentor Worldwide LLC*, 847 F. App'x 373 (9th Cir. Feb. 5, 2021) (affirming dismissal of manufacturing defect claim on basis of preemption); *Ebrahimi v. Mentor Worldwide LLC*, 804 F. App'x. 871, 2020 WL 2510760 (9th Cir. May. 15, 2020) (affirming dismissal of manufacturing defect claim on basis of preemption); *Jankowski v. Zydus Pharm. USA, Inc.*, 2021 WL 2190913 (D.N.J. 2021) (dismissal based on preemption of manufacturing defect claim); *D'Addario v. Johnson & Johnson*, 2021 WL 1214896 (D.N.J. 2021) (dismissing manufacturing defect claim on basis of preemption); *Ignacuinos v. Boehringer Ingelheim Pharm. Inc.*, 2020 WL 5659071 (D. Conn. 2020) (dismissing design and manufacturing defect claims as preempted); *Webb v. Mentor Worldwide LLC*, 453 F. Supp. 3d 550 (N.D.N.Y. 2020) (dismissing defective manufacture claim on basis of preemption); *Allo v. Allergan USA, Inc.*, 2020 WL 814855 (E.D. La. 2020) (dismissing product defect claim on basis of preemption); *L. Jacob v. Mentor Worldwide LLC*, 2019 WL 6766574 (M.D. Fla. 2019) (dismissing product defect claims on basis of preemption); *Williams v. Mentor Worldwide LLC*, 2019 WL 4750843 (N.D. Ohio 2019) (dismissing design defect, product defect and manufacturing defect claims);

Shelp v. Allergan, Inc., 2018 WL 6694287 (W.D. Wash. Dec. 20, 2018) (dismissing design defect claims).

3. *Buckman* Does Not Apply to a Manufacturer's Post-Sale Submissions of False or Inaccurate Adverse Event Reports; the Order Below Manifests a Split Among the Circuits

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

In this case, Petitioners claim that Mentor submitted false adverse event data to the FDA. In this context, "to the FDA" relates to reports that are 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. The FDA's MAUDE and MedWatch programs are more akin to a public library than public regulation.

Petitioners do not claim that any "fraud on the FDA" occurred here, as no reliance by 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); *Osterhaus v. Toth*, 249 P.3d 888, 896 (Kan. 2011); *Hale v. Emporia State Univ.*, 2018 WL 1609552, *3 (D. Kan. 2018) (noting that elements of Kansas common law fraud claim are the same as those listed in *Pence v. United States*, 316 U.S. at 338). Reliance by FDA is at the core of *Buckman*, as the Court stressed that its analysis was limited to untruthful statements made by a manufacturer to induce the agency's reliance in approving the product for public sale. *See Buckman*, 531 U.S. at 348. *Buckman* emphasizes its application to statements made to induce FDA reliance in the approval process. *See id.* at 348-351. Buckman simply does not apply to post-sale conduct. *Cf. In re Volkswagen "Clean Diesel" Marketing, Sales Practices, and Prods. Liability Lit.*, 959 F.3d 1201, 1225-1226 (9th Cir. 2020) (reversing dismissal upon finding no basis for Clean Water Act preemption of claims arising from *post-sale* conduct). Nor does *Buckman* apply to submission of information to FDA that is intended not for FDA pre-approval reliance but instead for patient and physician post-approval reliance.

Petitioners are not the first medical device patients to argue for allowance of their claims arising from post-sale or post-implantation conduct. One court recently 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. Based upon this logical 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 at *Mories* at 473 (emphasis in original), *citing Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000).

The Tenth Circuit, like the District of Kansas, over-simplified the analysis by separating the parties into separate categories of persons – FDA, patients, physicians – toward which a false representation might be made. However, the Tenth Circuit gave no credence to the potential that Mentor can disseminate false information indirectly, *through* the FDA, to the medical and patient community.

As outlined *supra*, even if state law does not expressly impose a duty to accurately report information to or through the FDA, the court below ignored the fact that even where no duty to report is created by law or

contract, once a party undertakes to make a disclosure, it assumes a duty to do so accurately, and inaccurate or dishonest disclosures are actionable at common law. *See Caiola v. Citibank, N.A.*, 295 F.3d 312, 331 (2d Cir. 2002); *Lau v. Opera Limited*, 2021 WL 964642, *6 (S.D.N.Y. 2021); *Trahan v. Interactive Intel. Grp., Inc.*, 308 F. Supp. 3d 977, 991 (S.D. Ind. 2018), *citing Stransky v. Cummins Engine Co., Inc.*, 51 F.3d 1329, 1331 (7th Cir. 1995); *Thimjon Farms P'ship v. First Int'l Bank & Tr.*, 837 N.W.2d 327, 339 (N.D. 2013); *New Milford Sav. Bank v. Zandy*, 2001 WL 79830, *2 (Conn. Super. Ct. 2001); *United States v. Singh*, 2020 WL 5500232, *6 (S.D. Cal. 2020); *Chester Cty. Employees' Ret. Fund v. KCG Holdings, Inc.*, 2019 WL 2564093, *11 (Del. Ch. 2019); *Owens v. Nationwide Prop. & Cas. Ins. Co.*, 2014 WL 4258084, *6 (N.D. Ala. 2014) (where insurer had no duty to disclose, "once it undertook to speak, it was required to make a full and fair disclosure"), *quoting Dominick v. Dixie Nat. Life Ins. Co.*, 809 F.2d 1559, 1570 (11th Cir. 1987).

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

As recognized in *Stengel v. Medtronic Inc.*, 704 F.3d 1224 (9th Cir. 2013), a common law duty to accurately report adverse events and data "through" the FDA will support a parallel claim. *Stengel*, 704 F.3d at 1233 (state common law claim to accurately report events and data to a third party is not preempted, where manufacturer is reasonably assured the information will

reach physicians and patients). Just as Petitioners alleged in the instant case, Mentor's reports were submitted to the FDA not for reliance by the FDA, but for the reliance of others. For exactly this reason, the court in *Stengel* recognized that where post-approval submissions to the FDA are intended to be relied upon by others, the FDA is a "third party" to the communication. *Id.*

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 calculated 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. Consequently, Petitioners' claim is not similar to *Cupek v. Medtronic, Inc.*, 405 F.3d 421 (6th Cir. 2005), in which the Sixth Circuit preempted claims that a device manufacturer was negligent per se and negligent in failing to provide post-sale test data and thus in "failing to comply with the FDA's conditions of [premarket] approval." 405 F.3d at 423. Petitioners here do not rely upon Mentor's failure to comply with the FDA's conditions of approval, abject as such failure may have been.

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.[14] About 60% of the total, or at least 2.4 million implants, were filled with silicone gel.[15] 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.

By taking steps to curtail this trend, the Court can realign the judiciary with the need to provide relief to

---

[14] *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).

[15] *Id.* (2011, 2019 data not available).

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%. 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.[16] 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.

---

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

ANDY DOGALI
DOGALI LAW GROUP, P.A.
19321 US Hwy. 19 North, Suite 307
Clearwater, FL 33764
adogali@dogalilaw.com
(813) 289-0700
Counsel for Petitioners