No. 19-1276

IN THE
SUPREME COURT OF THE UNITED STATES

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MICHAEL WHITE
ESTATE OF DARLA K. WHITE, DEC.
PETITIONER

v

MEDTRONIC, INC.
MEDTRONIC SOFAMOR DANEK USA, INC.
MEDTRONIC SOFAMOR DANEK, INC.
RESPONDENTS

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# PETITION FOR WRIT OF CERTIORAIRI

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PETITIONER PRO SE:

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## CORPORATE DISCLOSURE STATEMENT

Pursuant to U.S. Supreme Court Rule 29.6, Michael White is an individual, the Estate of Darla K. White, deceased is a probate estate formed in Saginaw County Probate Court, Michigan.

## QUESTIONS PRESENTED

The 6th Circuit Court of Appeals incorrectly affirmed the U.S. District Court's grant of summary disposition due to an incorrect application of federal medical device preemption law, 21 USC 360. The decision is a perversion of Riegel and Buckman and in direct conflict with the 7th (Bausch) and 9th (Stengel) circuits, and the 6th Circuit's earlier decision in Howard v Sulzer Orthopedics, Inc., 382 Fed App'x436, 440 (6th Circuit 2010). The prohibition against adulteration has been on the books since 1938. The proper application of law requires Defendants' motion to dismiss be denied, and the case remanded to state court. The 6th Circuit determined all of Petitioners claims expressly or impliedly preempted, or not properly plead per federal standards, without opportunity to amend. Per this 6th Circuit decision medical device manufacturers may violate of MDA law with immunity, literally leaving pain, suffering, and death across the nation. This Supreme Court has visited many of the issues when it reviewed and denied Medtronic's petition for writ of certiorari in *Stengel v Medtronic*, 704 F3d 1224 (9th Circuit 2013), cert. denied U.S., case 12-1351 (2015), including the amicus brief of the United States. Under

MDA, preemption solely relates to medical devices, by MDA definition misbranded, adulterated, and illegally promoted products are not a medical device. 21 USC 351(f)(1)(B) a device shall be deemed adulterated if it is a Class III device intended by the manufacturer to be used for an unapproved or off-label use.

1. Adulterated products are not a medical device, no preemption for FDA violations.
2. A doctor could not develop well-informed off-label use opinion based on false information created and disseminated by Medtronic.
3. Petitioner has private causes of action.
4. State court is the proper jurisdiction.
5. Michigan requirements are the proper pleading standard.
6. Summary disposition and failure to remand were improper.

## PARTIES TO THE PRCEEDINGS

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## ORDER BELOW

On January 29, 2020, the 6th Circuit Court of Appeals issued two unpublished orders for case #19-1370, an original and an amended order, see Appendix, App 1 and 2.

## JURISDICTION

U.S. Supreme Court has jurisdiction under 18 USC 1254(1) and 11 USC 2101(c). The 6th Circuit Court of Appeals had jurisdiction per 28 USC 1291. Being a state matter, Petitioner asserts the U.S. District Court, did not have jurisdiction under 28 USC 1441 or 28 USC 1332.

## STATUTORY PROVISION INVOLVED

21 USC 351(f)(1)(B) a device shall be **deemed adulterated** if it is a Class III device **intended** by the manufacturer to be used for an **unapproved or off-label use**. 21 USC 360k, no preemption for a non-medical device. Generally, FDCA; MDA. 21 USC 360k general medical device preemption. 21 USC 321(h) definition of medical device; what is not a medical device, generally, §321(n); 331; 343; 351; 352; and 360. 28 USC 1332 diversity of citizenship and amount in controversy. 28 USC 1446 removal to federal court. General pleading standards. 21 USC 337 in the name of the United States; 21 USC 396 legal off-label use based on a doctor's well-informed opinion formed on firm scientific rationale and sound medical evidence. U.S. Supreme Court Rule 28.8, except by leave. Table of Authorities in 6th Circuit filing, attached as Appendix 3.

## STATEMENT OF THE CASE

Summary of Infuse component (rh-BMP-2) activity:

Medtronic's illegal and unethical behavior resulted in the U.S. Senate Finance Committee Baucus-Grassley Medtronic Investigation Report, www.finance.senate.gov/imo/media/doc/Medtronic_Report3.pdf and Yale Open Data Access (YODA) report www.ncbi.nlm.nih.gov/pmc/articles/PMC4596165/ which Petitioner incorporates by reference, in their entirety. Medtronic's Infuse activities have resulted in many medical and scientific articles. The above was explained in the complaint and lower court briefs. The U.S. Senate report is approximately 2,000 pages, containing all the necessary who, what, when, where, why, and how much money. The senate report incorporates data from Medtronic's own documents. Defendants have not disavowed the accuracy of the reports.

Darla's implant was November 2009. YODA study began about 2011. The Senate investigation started approximately June 2011, completed October 2012.

Under normal and legal circumstances Medtronic's Infuse rh-BMP-2 with LT-cage is a Class III medical device. For Darla and about 6,000 other people, Class III status was lost shortly after receiving FDA approval because Medtronic began a highly orchestrated program to violate FDA regulation (21 USC 351(f)(1)(B)), adulteration rendered Infuse components to non-medical device status. In order to receive FDA approval, Medtronic agreed to warned doctors to never use the rh-BMP-2, which is placed in a carrier sponge, without the containment cage. After FDA PMA approval, Medtronic engaged in a promotion campaign creating false

studies and selectively editing real studies regarding the safety and effectiveness of using rh-BMP-2 without the cage, and in body locations never evaluated by the FDA. Medtronic paid millions to create a body of manipulated literature to fool doctors into believing off-label use offered enormous patient benefits. Eventually the truth was discovered, the promoted off-label uses were unsafe.

During the general time period of Darla's operation, sales of Medtronic's illegally promoted, misbranded, and adulterated materials dwarfed sales of its legitimate Class III Infuse medical device. Medtronic received several billion in off-label revenues for a material more dangerous than available standard methods of growing bone to fuse vertebra.

Relevant to this case, the FDA limited Infuse approval by requiring product labeling to warn the containment cage must always be used to avoid exuberate bone growth, causing nerve impingement. To limit the amount of rh-BMP-2 in the body, it was only approved for use in one disc. Vertebra disc space openings are wider in the front than the back, nerves leave the spine from the back, and at L4 there is an important blood vessel, for these reasons the FDA limited implanting the approved device to abdominal entry.

For sake of argument, Petitioner concedes, in part, because the material implanted into Darla did not use the containment cage it was a smaller implant likely making back entry less significant.

For the years bracketing 2018 era, Medtronic's SEC Annual 10-K Reports state about 6,000 people claimed harm from rh-BMP-2 due to off-label use, Darla K. White was one of them. She died January 1, 2015, age 52.

The rh-BMD-2 implant:

In September 2007, Darla developed lower back problems related to degenerative disc disease. The family doctor recommended a Saginaw, Michigan surgeon, who recommended Dr. Frank LaMarca at the University of Michigan.

On or about November 24, 2009, Darla had triple off-label surgery, Infuse components, but not the cage, were implanted into L4-L5 and L5-S1 disc spaces. Implant was from the back; the approved method is from the abdomen. Material was implanted in two spaces, rather than one as approved by the FDA.

Prior to the surgery, Whites were under the impression the first surgery would be by back entry using Darla's hip bone and a second surgery would be by abdominal entry. There was no second surgery, both discs were fused in one surgery. Darla had great pain that never went away, and got worse, she often begged for just five minutes of relief.

Litigation history:

*Thomas Carroll etal v Medtronic, Inc. etal*, case 1422-CC09065,

22nd Circuit Court City of St. Louis, Missouri:

On January 23, 2013, Whites retained Cutter Law (Sacramento, California) to represent them in a mass tort against Medtronic, Inc. and Medtronic Sofamor Danek, USA, Inc., filed in Missouri, containing approximately 96 plaintiffs, many

from out-of-state, Whites are from Michigan. Darla died on January 1, 2015. Medtronic offered settlement to all plaintiffs, nearly all accepted, including the St. Louis, Missouri "anchor" plaintiff, Thomas Carroll. Plaintiff attorneys were granted permission to withdraw. The Estate of Darla K. White, dec. and Michael White did not accept the settlement and were dismissed without prejudice. Per internet sources after expenses each plaintiff received approximately $2,500.

White, Darla: Saginaw County (Michigan) Probate Estate:

Michael White was appointed personal representative to the Estate of Darla K. White, dec., Saginaw County (Michigan) Probate Court, case 16-134506-DE. Michael was the husband of Darla, sole heir, and the estate had no creditors. See *Bass v Leatherwood*, 788 F3d 228 (6th Circuit 2015).

*White v Medtronic*, Genesee County (Michigan) Seventh Circuit Court, case 18-110783-N:

The case was filed pro se on/about April 17, 2018. Medtronic, Inc.; Medtronic Sofamor Danek USA, Inc.; and Medtronic Sofamor Danek, Inc. removed the case to federal court. Medtronic Sofamor Danek, Inc. is not registered in Michigan, White states Michigan court rules for service were properly followed, this entity did not join in removal, having made no filings whatsoever despite having a "shared service agreement" with Medtronic, Inc. were service on one is service on all. Medtronic Sofamor Danek, Inc. is a wholly-owned subsidiary of Medtronic, Inc. Removing defendants did not serve notice of removal on Medtronic Sofamor Danek, Inc.

White v Medtronic, case 18-11590, E.D. Mich Port Huron, case 18-11590:

The District Court deemed service on Medtronic Sofamor Danek, Inc. improper. White filed a motion to remand for Medtronic Sofamor Danek, Inc. failing to join the removal, Medtronic's valuation being under the controversy threshold, non-diversity of citizenship. The motion to remand was denied. On March 25, 2019, the U.S. District Court granted Medtronic's Motion to Dismiss, Docket 33.

White v Medtronic, case 19-1370 (6th Cir. Jan. 29, 2020):

White appealed to the 6th Circuit Court of Appeals simultaneously motioning the 6th Circuit solicit amicus brief from the U. S. Department of Health and Human Services regarding key issues. The 6th Circuit denied the motion. Amended order dated January 29, 2020 affirmed the District Court, leading to this Petition For Writ of Certiorari.

## REASONS FOR GRANTING THE WRIT

There are excellent reasons for the U.S. Supreme Court to accept this petition. Tens of thousands of innocent people have been harmed by incorrect court interpretation of 21 USC 360k preemption.

Incredibly, in nearly every federal circuit, Medtronic has actually convinced a federal court that once they scheme their way through FDA pre-market approval, they can fake scientific reports and use any portion of their product, by any method, even though that use has not been evaluated. They further demand the right to use

their product off-label even though they possess information knowing the use will cause pain, suffering, and death. And, they demand complete immunity.

An adulterated product is not a medical device. Petitioner has reviewed dozens of medical device preemption cases, not a single court has taken the logical first step, does the case involve a medical device?

All courts automatically assume anything that has received any FDA pre-market approval is a medical device, but 21 USC 321(h) lists what is not a medical device. By definition products that are misbranded, §321(n); adulterated, §331(i); or deficiently labeled, §343(f) are not a medical device. FDA regulation §351(f)(1)(B) makes it abundantly clear, the Medtronic product implanted into Darla was not a medical device, "a device shall be **deemed adulterated** if it is a Class III device **intended** by the manufacturer to be used for an **unapproved or off-label use.**

When (former) medical devices, or their components, violate federal regulation they are standard state tort claims, with no federal question (Bausch). The law has been on the books, but overlooked, since 1976. This interpretation does not harm manufacturers, as long as they follow FDA regulation.

Additionally, it may be audacious for a pro per to suggest the U.S. Supreme Court got it wrong, but the plain language of §360k limits preemption to non-federal government requirements to the medical device, having zero effect on the patient's

right to recover damages. The purpose of §360k preemption is simple, to prevent the potential hazard of having one medical device having to be designed to the specific requirements of 50 different states.

This is consistent with Silkwood, and MDA congressional concern. Before enactment of the Medical Device Amendments Act in 1976, states, local and other non-federal governments established medical device design requirements because the federal government had done nothing. Recognizing the wild west frontier, the federal government decided to occupy the field and did so in a big way, including very specific evaluation of the individual nuance of each proposed medical device.

§360k preemption solely exists within MDA, it is limited to device requirements, having absolutely no applicability to damage remedies. This is made clear when §360k is read in its entirety, not a single word references, or even implies, any damage remedy is preempted. Subsection (a)(1) and (2) use the word "and." The requirements of both (1) and (2) must be applicable before there is any preemption. Before any non-federal device requirement can be preempted that requirement must relate to safety, effectiveness, or other device requirement AND be different from, or in addition to, the federal requirement AND be in Chapter 9 Food, Drug, Cosmetic Act. Chapter 9 does not address damage remedies whatsoever. This is consistent with Silkwood which allows (legitimate) state damages when in compliance with federal law, however, Silkwood diverges from White v Medtronic because when Medtronic adulterated their product, they violated both state and federal law, removing any hint of medical device preemption.

Medtronic's argument is: once they receive any form of pre-market approval under MDA they can do anything they desire even though the individual components or the new use were never evaluated, their position has been affirmed by numerous federal courts but this is inconsistent with (Bausch, Stengel, and Howard) and the law as written. It is impossible to contemplate Congress would deny an injured person any redress, such concept would be worse than before the Medical Device Amendments were enacted.

The complete unregulated, unstudied, off-label use Medtronic espouses should never be confused with legitimate use of a PMA-approved medical device.

When (former) medical devices, or their components, violate federal regulation they revert back to standard state tort claims, with no federal question. This interpretation will not harm manufacturers, as long as they follow FDA regulation, they have preemption.

Petitioner believes this is something the United States missed in its amicus brief in Stengel, in the end the United States made the correct determination, "A federal misbranding claim...is not expressly preempted...," *Stengel* U.S. amicus br. p. 14.

Another reason this Court should accept this petition is because when Medtronic lost the Stengel case, Medtronic said, "The Ninth Circuit's decision in this case [Stengel] deepens two direct and acknowledged circuit splits concerning the preemptive effect of the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA")." Medtronic Petition For Certiorari, page 1, May 10, 2013; Stengel

v Medtronic, 704 F3d 1224 (9th Circuit 2013), cert. denied U.S., case 12-1351 (2015). Seemingly, Medtronic has no objection to the U.S. Supreme Court accepting this case.

Petitioner argues there is no concrete evidence to support the rumored contention Congress intended the MDA to preempt, eliminate, and deny an injured patient's right to recover damages in order to encourage medical device innovation. When a medical device is stringently evaluated before it enters the marketplace its safety and effectiveness increases, patient injuries decrease, the manufacturer's cost of doing business decrease because lawsuit costs go down.

To suggest safety and effectiveness increases by eliminating injured parties the right to recoup damages is absurd, defeating the plain language of MDA regarding misbranding, labeling, adulteration, and preventing the promotion of unapproved uses. No plain language can be construed to give any damage immunity to those manufacturers who violate FDA regulation, *Bausch v Stryker Corp.*, 630 F3d 546, 563 (7th Circuit 2010).

As stated above, 21 USC 321(h) lists what is not a medical device and by definition products that are misbranded, §321(n); adulterated, §331(i); or deficiently labeled, §343(f) are not a medical device.

21 USC 321(n) states, "If an article is **alleged** to be **misbranded** because the labeling or **advertising is misleading**, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only **representations made or suggested** by statement, word, design, device, or any combination thereof, but also the extent to which

the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual."

21 USC 331(i) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise prohibited acts include, 21 USC 331(a) the introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded. 21 USC 331(b) the adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce. 21 USC 331(c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise. 21 USC 331(g) the manufacture within any Territory of any food , drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

21 USC 352(f) adequate label warnings against use in those pathological conditions...where its use may be dangerous to health, or against unsafe dosage.

21 USC 360c(a)(2), "[T]he safety and effectiveness of a device are to be determined— (A) with respect to the persons for whose use the device is represented or intended; (B) with respect to the conditions of use prescribed,

recommended, or suggested in the labeling of the device; and (C) **weighing** any **probable benefit** to health from the use of the device **against any probable risk** of injury or illness from such use."

§360c(a)(1)(C) Medtronic's Infuse is a Class III medical device, when legally used. §360c(a)(2)(B) conditions labeling on the recommend use. §360e(d)(1) The FDA approves the marketing of devices under the "conditions of use included in the proposed labeling" submitted with the PMA application. §360e(d)(1)(A) safe and effective under the conditions of use included in the proposed labeling. §360e(d)(2) Pre-Market Approval (PMA) **approval authorizes the manufacturer to market the device only for that use.** §360e(d)(2)(B) the FDA is required to deny approval if a device is not safe and effective for the uses recommended or suggested on the label. §360i(a)(1) and (3) **manufacturers are required to report adverse events** caused by the device, and 21 CFR 803.50(a) requires a manufacturer reporting of malfunction causing or contributing to death or serious injury. **To market a substantially equivalent device for a new use** requires the manufacturer first obtain Pre-Market Approval, 21 CFR 807.92(a)(5).

Preemption generally:

Federalism concerns caution against rushing to preempt state law, The Federalist No. 33, at 206-08, by Alexander Hamilton, 1788.

In *Florida Lime &* Avocado Growers, *Inc. v. Paul*, 373 U.S. 132 (1963), the U.S. Supreme Court denied preemption, stating the proper test "is whether both

regulations can be enforced without impairing the federal superintendence of the field, not whether they are aimed at similar or different objectives," preemption should be found only when there are "persuasive reasons—either that the nature of the regulated subject matter permits no other conclusion or that the Congress has unmistakably so ordained."

Petitioner argues if "Congress has **unmistakably** so ordained" MDA preemption of injury recovery there would be no continuing question forty-fours years after the enactment of 21 USC 360k.

In *Silkwood v. Kerr-McGee Corp.,* 464 U.S. 238 at 251 (1984), Defendant Kerr-McGee was in full compliance with federal regulation but still caused injury to Silkwood. The U.S. Supreme Court determined there was no preemption, plaintiff had the right to sue under state law. *Silkwood,* at 251, "It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct. See *Construction Workers* v. *Laburnum Corp.,* 347 U.S. 656, 663-664 (1954)." "Congress assumed that persons injured by nuclear accidents were free to utilize existing state tort law remedies," *Silkwood* at 252. "The belief that the NRC's exclusive authority to set safety standards did not foreclose the use of state tort remedies was reaffirmed when the Price-Anderson Act was amended in 1966. The 1966 amendment was designed to respond to concerns about the adequacy of state-law remedies," *Silkwood* at 253. "...pre-emption should not be judged on the basis that the Federal Government has so completely occupied the field of safety that state remedies are foreclosed," *Silkwood* at 256. "Paying both

federal fines and state-imposed punitive damages for the same incident would not appear to be physically impossible. Nor does exposure to punitive damages frustrate any purpose of the federal remedial scheme," *Silkwood* at 257.

*Medtronic v Lohr*, 518 U.S. 470 at 495 (1996):

*Lohr* involved a "grandfathered" pacemaker medical device in the market before the enactment of the MDA. The U.S. Supreme Court denied the manufacturer's contention it had complete immunity for design defect liability because the legislative history of the Act in no way supported the argument. In this case, "complete immunity" is the effective result of the 6th Circuit's decision.

State damage remedies are not preempted because states have traditionally exercised their police powers to protect the health of their citizens, when Congress is preempting a law in a field traditionally governed by the states, the Supreme Court assumes that the powers of the state are not to be preempted unless that was the clear purpose of Congress. The *Lohr* claims were not preempted because they were general state common-law requirements that every manufacturer must use due care to avoid foreseeable dangers in its products and inform users of potentially dangerous risks involved in their use. These general requirements in no way reflect the concerns Congress expressed regarding regulation of specific devices in the Act.

(Although a non-medical device is not regulated by MDA,) *Lohr, Riegel*, and *Buckman* are not applicable because adulteration, misbranding, and intentional

manufacture for new and off-label uses are general requirements applicable to all medical devices and not preempted by *Lohr*.

*Riegel v Medtronic*, 552 U.S. 312 (2008):

Regardless of conflicting plaintiff-defendant opinions, all sides agree *Riegel* does not create an across the board prohibition against the right of an injury person to recover damages. The right to collect damages for harm caused is not a safety or effectiveness issue. What caused the damages is the safety or effectiveness issue. The Court did a two-part analysis of a three-part question: 1) safety/effectiveness, 2) different from/in addition to, and 3) the "requirement" must be in Chapter 9. Chapter 9 does not prohibit collection of damages, but Chapter 9 does replace a more onerous state requirement with the federal standard, §360k.

Everyone agrees the number of atmospheres of pressure a balloon catheter can withstand is a safety and effectiveness issue. No one disputes that when the federal government approved 8 atmospheres of pressure, and if New York would have, in the hypothetical, required ten, the standard is 8 atmospheres. If the catheter functions as designed, tested, and approved at 8 atmospheres, there is no cause of action. If, for sake of argument, it fails at 5 atmospheres causing injury, there is a cause of action and damages are recoverable.

Riegel admitted no federal design, manufacture, labeling or other requirement had been violated, thus no cause of action.

For the Court to do a straight forward statute analysis concluding "other requirement" means you do have not right to collect under a cause of action, is unsupported by Chapter 9. Recovery of state damages is not preempted, what is preempted is a state standard of safety and effectiveness which is more onerous than the federal standard, but once federal law is violated there is a cause of action, if the violation caused harm. *Bausch v Stryker.*

For example, the federal standard is clear, 21 USC 351(f)(1)(B) a device shall be **deemed adulterated** if it is a Class III device **intended** by the manufacturer to be used for an **unapproved or off-label use.** This is the standard, Michigan cannot enforce a more onerous standard, Michigan does not attempt to, but when the federal standard is violated, a Michigan resident has the right to seek damages for harm the violation caused, and to do so under Michigan law, Michigan recovery laws pre-date MDA. Several courts have concluded state fraud claims against Medtronic are not preempted, these court have concluded the pleading standard is state law, not federal pleading standards.

In *Riegel*, Justice Ginsburg dissented the majority's opinion, stating, "[It is] difficult to believe that Congress would, without comment, remove all means of judicial recourse [for consumers injured by FDA-approved devices.]" She is correct, damage preemption is not addressed in Chapter 9. While possible her argument could have been more refined, "other requirement" does not restrict the right to collect damages, but it does relate to whether there is a cause of action which gives rise to the right to collect damages. If a state "other requirement" is more

burdensome than the federal requirement it is reduced to the federal requirement, after reduction, if a violation caused harm, the state resident can collect damages related to that harm.

In this case, none of Petitioner's claims challenge the safety or effectiveness of the federal standard. Petitioner does not argue the carrier sponge should have been larger or smaller, or rh-BMD-2 should have contained different materials. Petitioner merely wishes to enforce the federal standard in light of his Michigan right to do so. The product implanted into Darla was manufactured with the intent to use it in a manner not evaluated by the FDA, being no containment cage and double the dosage, therefore the material was adulterated.

When Medtronic volunteered to register and do business in Michigan, it consented to Michigan law. If they did not wish to be exposed to Michigan liability, they had the option to comply with the law or not do business in Michigan.

Since the *Riegel* decision and its "parallel claim" theory several courts have upheld the right to collect state damages caused by medical device harm, the following are for example only: *Canary v Medtronic*, #16-11742, 2017 WL 1382298 (E.D. Mich. April 18, 2017) state standard for fraud allowed to proceed, other claims were not necessarily preempted but were inadequately plead. *Estate of Katlyn Jones*, case A17-1124, Minnesota Court of Appeals (2018) no implied preemption when rooted in traditional state tort that would entitle plaintiff to recovery in the absence of FDCA. *Stengel v Medtronic*, 704 F3d 1224 (9th Circuit 2013), cert. denied U.S., case 12-1351 (2015) state claims for failure to warn survives preemption.

*Wright v Medtronic*, Inc. etal, case 13-716, (W.D. Mich. S. D., Jan. 23, 2015, Michigan fraud claim survives preemption.

*Thorn v Medtronic* etal, 81 FSupp3d 619, case 13-00239, (W.D. Mich. S.D. 2015); *Thorn v Bergman*, 624 Fed App'x 433 (6th Circuit 2015); *Thorn v Bergman*, case 2017-022284-NM, Montcalm Cty Cir Court (2016); *Thorn v Bergman*, case 338384 (MiCOA, March 1, 2018) this case took a circuitous route, the Michigan Court of Appeals determined had Thorn's attorney not committed malpractice the state fraud claim would have survived preemption.

In this case, the 6th Circuit decision is contrary to *Riegel*, and inconsistent with other federal cases, including cases filed in Michigan on the same topic.

*Buckman v Plaintiffs' Legal Committee*, 531 U.S. 341 (2001):

"Indeed, an overly expansive reading of *Buckman* would extinguish the very parallel claims that Section 360k(a) preserves," *Stengel*, U.S. amicus br. p. 22, filed May 20, 2014), available at www.justice.gov/sites/default/files/osg/briefs/2013/01/01/2012-1351.pet.ami.inv.pdf

Not only have most federal courts failed to understand the simplicity of *Riegel*, they have overstated the significance of *Buckman*. *Buckman* is premised on 21 USC 337, proceedings in the name of the United States. Many courts falsely believe only the FDA can sue the device manufacturer, but as stated above that would incorrectly nullify §360k. In *Buckman*, plaintiffs had brought various causes of action, all claims regarded the exact same product, including fraud on plaintiffs, the

Court allowed those claims to proceed because it relied solely on traditional state tort law predating the FDCA, and would exist in the absence of the Act (See *Katlyn Jones*, above). These claims were then settled out-of-court. The only claim not settled was the claim of fraud on the FDA.

*Buckman* proves fraud can be upon more than one entity, it can, simultaneously, be on the FDA, on one patient, thousands of patients, and hundreds of medical professionals. In a claim of fraud on the FDA, the party in interest is the FDA, not the citizens of the United States, however, that does not exclude citizens from bringing a fraud claim under state law when the medical device manufacturer committed fraud on them, or fraud on their doctor which then caused harm to the patient. *Buckman* cannot be read so broadly that it impinges on patient rights preserved in 21 USC 360k, in other words, *Buckman* cannot go beyond the law.

21 USC 396:

21 U.S.C. § 396 states, "Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any **legally marketed device** to a patient for any condition or disease within a legitimate health care practitioner-patient relationship. This section shall not limit any existing authority of the Secretary to establish and enforce restrictions on the *sale or distribution*, or in the labeling, of a device that are part of a determination of substantial equivalence, established as a condition of approval, or promulgated

through regulations. **Further, this section shall not change any existing prohibition on the *promotion* of unapproved uses of legally marketed devices."** The FDA does not regulate doctors, it does regulate device manufacturers.

Pleading standard:

In this case, the 6th Circuit determined Petitioner did not meet federal pleading standards, including fraud, denying all rights to amend. Petitioner avers the correct standard is Michigan. The federal courts are being inconsistent with one another.

Diversity of citizenship:

28 USC 1332(a)(1), the question of diversity of citizenship has been addressed by Congress and U.S. Supreme Court, yet remains a confused area of law. It appears the U.S. Supreme Court has issued at least ten decisions on the topic. Originally, access to federal courts was permitted to address perceived bias against an out-of-state entity. At that time there were few, if any, registration requirements for out-of-state corporations conducting business in another state. Per law, corporations are persons. As this Supreme Court has addressed before, unlike natural persons, corporations can be in several places at once, leading to the logic of the "nerve center" test in *Hertz v Friend,* 559 U.S. 77 (2010). The Supreme Court states, "while imperfect, is superior to other possibilities."

28 USC 1332(c)(1), per *Hertz*, "The statute's word "place" is singular, not plural. Its word "principal" requires that the main, prominent, or most important place be chosen." With all due respect, the *Hertz* logic ignores the statute's preceding words

"a corporation shall be deemed to be a citizen of every State." In law, there is often is more than one "final judgment" though written in the singular. "Every state" is clearly written in plural, there can be more than one "principal place of business." Nothing compels a corporation to do business in Michigan, it is something they do voluntarily. As part of that registration they must select a principal place of business in Michigan, and for purposes of §1332 are citizens of Michigan. When an out-of-state corporation such as Medtronic, Inc. and Medtronic Sofamor Danek USA, Inc. voluntarily register with the Michigan corporation division to do significant business in Michigan, they also volunteer to the jurisdiction of Michigan law, otherwise registering with Michigan LARA corporation division would be meaningless.

As stated earlier, Petitioner asserts Medtronic Sofamor Danek, Inc. was served in accordance with Michigan law, it did not join in the removal action, as such removal was improper, remand is necessay. Medtronic, Inc. and Medtronic Sofamor Danek, USA, Inc. admit they were properly served in Michigan, at their registered principal place of business. For sake of argument, if Medtronic Sofamor Danek, Inc. was not properly served, under the "every state" language of §1332 all remaining entities are Michigan citizens, with no diversity.

Pro se pleading standards:

Pleading are intended to serve as a means of arriving at fair and just settlement of controversies between litigants. Pleadings should not raise barriers which prevent the achievement of that end. Proper pleading is important, but its

importance consists in its effectiveness as a means to accomplish the end of the just judgment," *Maty v Grasselli Chemical Co.*, 303 U.S. 197 (1938).

Pro se litigants who are entitled "to a less stringent standards than formal pleadings drafted by lawyers," *Haines v Kerner*, 404 U.S. 519, 520 (1972). A pro se complaint requires a less stringent reading than one drafted by a lawyer, *Puckett v Cox*, 456 F2d 233 (6th Circuit 1972).

## OTHER

Petitioner does not waive any cause of action contained in the complaint but for attempted brevity has not discussed each here. For clarity, Michigan has a drug preemption law, but not a medical device preemption law.

## CONCLUSION

The petition for a writ of certiorari should be granted. Petitioner does not oppose oral argument.

## RELIEF REQUESTED

Petitioner respectfully requests the decision of the 6th Circuit Court of Appeals be overturned and remanded for further proceeding, including, as this Court may decide, remand to state court. Or, in the Court's discretion, decide the primary issues of jurisdiction for adulterated products and matters related to 21 USC 360k preemption with full briefing and oral argument.

April 24, 2020 X _____

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