**NO.**

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# IN THE
# SUPREME COURT OF THE UNITED STATES

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**REBECA LAWRENCE,**

*Petitioner*

v.

**MEDTRONIC, a foreign corporation**,

*Respondent*

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**On Petition For Writ Of Certiorari To the 9th District Court of Appeal For Central District Of California**

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# PETITION FOR WRIT OF CERTIORARI

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## Questions Presented for Review

This case involves implantable opioids-infusion pumps produced by Medtronic Inc. ("Respondent"). The pumps have Pre-Market Approval ("PMA") granted by the Federal Drug Administration ("FDA") for newly-developed technology. PMA is conditioned on strict adherence to numerous FDA conditions, including requirements to analyze and report adverse events to the FDA. Petitioner, 65 years old, had 3 pumps fail and therefore explanted from her body. According to PMA requirements, the explanted pumps should have been acknowledged and analyzed by Respondent. However, Respondent claims that it has no records of any pumps ever being returned for analysis. Petitioner alleges Respondent violated PMA mandates and committed fraud by hiding the failed devices and not reporting adverse events to the FDA.

The Ninth Circuit Court of Appeal affirmed the district court's ruling granting respondent's Motion to Dismiss ("MDT12(b)") as to both Petitioner's original complaint and Petitioner's First Amended Complaint ("FAC"), thus dismissing Petitioner's causes of action for fraud and deceit. The Ninth Circuit found that: (1) to have a claim, the Petitioner must identify the specific nature of the pumps' defects and (2) PMA requires Respondent only to report, but not to analyze adverse events to the FDA. In sum, the Appellate Court held that the issue of whether Respondent committed fraud by hiding "adverse events" was moot because Petitioner was unable to establish the exact physical defect experienced by the pumps. Petitioner's argument that the trial court dismissed

Petitioner's allegations of fraud prematurely without affording Petitioner a chance for discovery was also rejected as moot by the Ninth Circuit.

**Four questions presented:**

**1**. What is the scope of the FDA's requirements of reporting of adverse events and whether Title 21 §803.50; Title 21 §803.56; and Title 21 §814.84 explicitly and implicitly require a company to not only report, but also analyze each adverse event and the company's remedial actions for fixing and improving future product design and reliability?

**2**. What are the proper criteria for a product liability cause of action where the product at-issue has PMA? According to the Appellate court, Petitioner must know the specific nature of the pump's physical defect and allege specific violations of a procedural nature, i.e. Petitioner's allegations of failure to report and analyze the adverse events was not sufficient to state a claim.

**3**. What is the proper stage at which allegations of fraud can be dismissed? Whether dismissing allegations of fraud at the pleading stage is unjust and prejudicial as it denies Petitioner of an opportunity to conduct reasonable discovery concerning the alleged fraud, which is often discreet, secret and difficult to uncover?

**4**. What is the standard for failure-to warn claims and causes of action based on detrimental reliance? Both standards are extremely subjective and represent a matter of fact, which should be left for the jury to decide. Additionally, in the instant matter, Petitioner relied on the advice of her doctor, who was also misled

by Respondent. The issue of what is reasonable (especially when a doctor is involved) is measured by the "reasonable man" standard and should be left to the trier of fact to determine.

## LIST OF PARTIES

1. All parties below are listed in the caption.

2. United States District Court for the Central District of California

## RELATED CASES

- United States District Court for the Central District of California
  R. Lawrence v Medtronic CV 16-7289 DSF (ASx)
  1) Granting Motion to Dismiss Original Complaint 02/27/2017
  2) Granting Motion to Dismiss FAC Complaint 05/30/2017
  3) Motion for Summary Judgment 05/27/2018

- United States Court of Appeal for the NINTH CIRCUIT
  R. Lawrence v Medtronic No. 18-55621 Decided on January 28, 2020

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**In The**
**Supreme Court of the United States**

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**PETITION FOR WRIT OF CERTIORARI**

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Petitioner Rebeca Lawrence ("Petitioner") respectfully prays that a writ of certiorari issue to review the judgment below.

## OPINIONS BELOW

1. The opinion of the United States Court of Appeal for the NINTH CIRCUIT Before: BOGGS,** WARDLAW, and BEA, Circuit Judges. UNPUBLISHED. The court's Memorandum appears at Appendix A to this petition.
Decided on January 28, 2020; Jurisdiction under 28 U.S.C. § 1291.

2. The opinion of the United States District Court for the Central District of California Dale S. Fischer, District Judge, Presiding. The court's Ruling on MTD under 12(b)(a) Original Complaint appear at Appendix B.

Ruling on MTD FAC 12(b)(a) appear at Appendix C. UNPUBLISHED.

## JURISDICTION

The United States Court of Appeal for the NINTH CIRCUIT decided this case on January 28, 2020. It appears at appendix A to this petition. The jurisdiction of this Court is invoked under original Jurisdiction 28 U. S. C. § 1254(1).

## CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

### 21 CFR § 803.30 – MEDICAL DEVICE REPORTING

(2) *Reports of serious injury*. You must submit a report to the manufacturer of the device no later than 10 work days after the day that you become aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of your facility. If the manufacturer is not known, you must submit the report to us. You must report information required by 803.32. Reports sent to the Agency must be submitted in accordance with the requirements of 803.12 (b).

**21 CFR § 803.50(a)** - FDA's requirement to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred;
(a) If you are a manufacturer, you must report to us the information required by 803.52 in accordance with the requirements of 803.12(a), no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market:

(1) May have caused or contributed to a death or serious injury or

(2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

(b) What information does FDA consider "reasonably known" to me?

(1) You must submit all information required in this subpart E that is reasonably known to you. We consider the following information to be reasonably known to you:

(i) Any information that you can obtain by contacting a user facility, importer, or other initial reporter;

(ii) Any information in your possession; or

(iii) Any information that you can obtain by analysis, testing, or other evaluation of the device.

(2) You are responsible for obtaining and submitting to us information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters.

(3) You are also responsible for conducting an investigation of each event and evaluating the cause of the event. If you cannot submit complete information on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the information. If you later obtain

any required information that was not available at the time you filed your initial report, you must submit this information in a supplemental report under 803.56 in accordance with the requirements of 803.12(a).

**21 CFR § 814.84 -Reports of Continuous Reports of Device Safety;**

Requirement to inform the FDA of "new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know; (i) Unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant.

**California General Duty of Care Laws under Sections 11590 & 111595** adopted pursuant FDCPA (21 U.S.C. 352, 355(i), 360) and

**Cal. Health & Safety Code Sec. 24176 & 24174** that are identical and not "*in addition to*" the requirements under the CGMP.

## STATEMENT OF THE CASE

### I. What is the scope of the FDA's Title 21 requirements of reporting of adverse events? Do §803.50, §803.56, and §814.84 explicitly and implicitly require Respondent to not only report, but also analyze the reason for the failure for each pump and report actions related to fixing and improving future product design and reliability?

Petitioner argues that Respondent perpetrated fraud on the FDA by hiding the adverse events and by not reporting to the FDA instances of failures and the results of the analysis of the failures, as required under PMA. The Appellate Court did not address this. Instead, in its decision, the Appellate Court implied that the issue of the missing failed pumps was moot because there "is no federal regulation mandating any analysis of removed medical devices." The Ninth Circuit stated:

> Lawrence identifies no federal authority that requires medical-device manufacturers to send removed medical devices anywhere for evaluation. **Indeed, there is no federal regulation mandating any analysis of removed medical devices,** and thus a tort claim premised on such a course of conduct would impose a requirement that is "different from" and "in addition to" what is required under federal law.
>
> See Appendix A p1. §1

The Ninth Circuit is incorrect and its ruling contradicts the holdings of sister Federal Courts and Federal Statutes. The Appellate Court accepted the notion that the Federal Statutes require Respondent to *report adverse events*, but they do not require Respondent to *analyze the failed pumps* in order to determine

the nature of the defects. That is grossly incorrect and clearly not what the FDA wanted in granting PMA. The Appellate Court's ruling directly contradicts numerous provisions of Title 21 Food and Drug Administration. First, Respondent failed to even report the three separate pumps failure. Second, the Appellate court ignored clear language of applicable FDA's statutes cited by Petitioner in the pleadings, and reiterated and emphasized again during oral argument. In reading applicable FDA statutes, it is difficult to understand how the court could disregard the requirement of an investigation and/or analyses in addition to reporting. Relevant Federal Statutes from Title 21 are attached as Appendixes F,G,& H.

Shorts excerpts below clearly illustrate the point:

**Title 21 Food and Drug Administration. §803.50 Reports**.

(iii) Any information that you can obtain **by analysis, testing, or other evaluation** of the device.

3) You are also responsible for **conducting an investigation of each event and evaluating the cause of the event.** If you cannot submit complete information on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the information. If you later obtain any required information that was not available at the time you filed your initial report, you must submit this information in a supplemental report under 803.56 in accordance with the requirements of 803.12(a).

Appendix G: §803.50:

i) Unpublished reports of data from **any clinical investigations** or nonclinical laboratory studies involving the device or related devices **and known to or that** reasonably should be known to the applicant.

Appendix H: §814.84

It is unambiguous that Federal Mandate requires manufacturers to report adverse incidents, diligently analyze and investigate the reasons for the adverse

events, and then to notify the FDA of what happened with the devices and what was done to fix and improve the devices. It is only commonsensical: the entire idea of PMA is to protect the company from any legal liability because the FDA understands the importance to promote a fragile new technology. The FDA's intention is to protect companies from lawsuits and thus, facilitate improvements of the new devices to improve their future effectiveness and reliability. The FDA understands that new devices will inevitably fail; however, the future benefits from these improved devices outweigh the risks of injury or even death to the present patients. PMA protection exists to allow companies to analyze and improve devices. Thus, PMA's federal requirements are not "split" into "reporting" on one hand and "analysis" on the other—it is obvious why these two must go hand-in-hand: there is nothing to report unless the company conducts an analysis and determines the nature of the defect.

## II. Respondent Violated the Strict Language of the FDA Conditional Letter of PMA Approval Mandating Analysis as Well As Reporting

Based on the existing Federal Mandate expressly stated in a **Conditional Letter of Approval** (Appendix E) issued on September 19, 2003, the FDA permitted the sale of the Pumps. That Letter also explicitly states conditions of Post-Market Approval, including the mandate to provide not only reporting, but also analysis of the failed pumps in order to improve Respondent's pump design. The Conditional Letter of Approval mandates to reporting:

**POSTAPPROVAL REPORTS.** Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of **1** year from the date of approval of the original PMA.

1. Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

2. Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

3. unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

**ADVERSE REACTION AND DEVICE DEFECT REPORTING.** As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

1. A mix-up of the device or its labeling with another article.

2. **Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and:**
   a. has not been addressed by the device's labeling; or
   b. has been addressed by the device's labeling but is occurring with unexpected severity or frequency.

Contrary to the Appellate Court's holding, the reporting must include an analysis of what is wrong with the device i.e. "Any adverse reaction, side effect, injury, toxicity….." *Id.*

The Post-Approval Requirements unequivocally demands reporting of all failures, all analysis, and all modifications to the pumps. However, Respondent has no records of any failed pumps existing and Respondent failed to provide any reports to the FDA, in violation of federal statute.

**III. What are the proper criteria for Petitioner to sustain her case for product liability? According to the Appellate court, the Petitioner must know the specific nature of the physical defect and make allegations of specific violations of procedural nature, i.e. requirements to report and analyze the adverse events is not enough. The Appellate and District Courts Erred in Finding that Plaintiff's Complaint Failed to Allege Specific Violations of the FDA'S PMA Requirements.**

The Appellate Court opined that:

> Lawrence's First Amended Complaint contains only conclusory allegations, which *fail to identify any specific federal requirement that was violated or the specific nature of the Pump's purported defects.*"
>
> Appendix A p.3 §3

Contrary to the Ninth Circuit's finding, in her FAC, Petitioner stated her allegations of violations of federal requirements with specificity, and identified in her claim each Federal Statues that was violated. Petitioner also identified with detail and particularity, the dates and numbers of all removed pumps. However, despite such specificity, the District Court granted Respondent's Motion to Dismiss the First Amended Complaint (Appendix C):

> The **complaint once again does not allege** that Defendant failed to comply with the **FDA's PMA-imposed requirements**. In fact, Plaintiff admits that she has no idea what the source of the purported defect might be and has little prospect of figuring it out. See FAC ¶ 28. She appears to want to proceed in a *res ipsa loquitur* manner – because the system failed for her multiple times, it must be defective. *This does not allow her claims* to *survive* because, as stated previously, failure of a Class III device that has passed the PMA process can only lead to *liability if the device manufacturer failed to follow the requirements set out by the FDA in granting the PMA*.
>
> District Court's Ruling on MTD FAC App. C

Judge Fischer continues:

> "…while somewhat vague, the adverse events reporting claim appears to be based on a failure to report the **failures of Plaintiff's own pumps**…"
>
> Court's ruling on MTD FAC *Id*

In FAC Complaint, Plaintiff alleges violations of:

- 21CFR §803.30 - Medical User Facility Reporting Requirements
- 21CFR §803.50 - Manufacture Reporting Requirements - FDA's requirement to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred;
- 21 CFR § 814.84 – Post-approval reporting;
- 21 CFR § 814.84(a)(9) -Reports of Continuous Reports of Device Safety;

Petitioner also alleges that Respondent violated California General Duty of Care Laws under Sections 11590 & 111595 adopted pursuant FDCPA (21 U.S.C. 352, 355(i), 360) and Cal. Health & Safety Code Sec. 24176 & 24174 that are identical and not "*in addition to*" the requirements under the CGMP. Petitioner properly alleged that Respondent failed to analyze and report the adverse events of Petitioner's pump failures to the FDA.

## IV. The Ninth Circuit's Ruling On the PMA Protection Conflicts with Other Courts' Rulings

The courts are deeply divided on the issue of pre-emption, especially where allegations of fraud and concealment of adverse data have been made. Appellate Courts are divided over the extent to which state common-law claims are pre-empted by the PMA.

In *Littlebear,* plaintiff was implanted with a Class III PMA device manufactured by the defendant. After receiving PMA, defendant contracted with a new supplier for assembly of the device, but failed to notify the FDA and plaintiff of the change. Plaintiff was subsequently injured by the device and sued for fraud, violation of the Oklahoma Consumer Protection Act, strict liability, and negligence *per se*. *Littlebear v. Advanced Bionics, LLC,* 896 F. Supp. 2d 1085, 1089, 2012 U.S. Dist. LEXIS 179388, *6, (N.D. Okla. 2012). The *Littlebear* Court found that devices not satisfying the Current Good Manufacturing Practices ("CGMP") requirements are considered "adulterated" under 21 U.S.C. §351(f),(h). Thus, claims predicated on the failure to comply with specific CGMPs in the manufacturing of the devices <u>are not preempted</u>, and claims predicated on the failure to test under actual or simulated use conditions <u>are not preempted</u>. Thus, state law claims that parallel federal regulatory requirements fit in the "narrow gap" between express and implied preemption. *Howard v. Sulzer Orthopedics, Inc.*, 796 F. Supp. 2d 1305, 1310 (N.D. Okla. 2011) ("suing for <u>conduct that *violates*</u> the FDCA, <u>*but [not] suing because the conduct*</u> violates the FDCA").

Other courts permit a variety of claims to proceed. *Purcel v. Advanced Bionics Corp.,* Case No. 07-cv-1777, 2008 WL 3874713 (N.D.Tex. Aug. 13, 2008) ("*Purcel I*") (finding no pre-emption of Texas strict liability or implied warranty of merchantability claims); *Purcel v. Advanced Bionics Corp.,* Case No. 07-cv-1777, 2010 WL 2679988 (N.D.Tex. June 30, 2010) ("*Purcel II*") (finding no pre-emption of Texas products liability, breach of implied warranty of merchantability, breach of express warranty, fraud and some negligence claims;); *Hearn v. Advanced Bionics Corp.,* 06-cv-1114 (S.D.Miss. Nov. 5, 2007) (finding only some claims preempted) ("*Hearn I*"); *Lannon v. Advanced Bionics Corp.,* Case No. 09-cv-1192 (W.D.Wash. Jan. 29, 2010) (denying 12(b)(6) motion based on pre-emption ("*Lannon* Order"); *Purchase v. Advanced Bionics, LLC,* 896 F.Supp.2d 694, 08-cv-2442, 2011 WL 9688280 (W.D.Tenn. Aug. 4, 2011) ("*Purchase* Order") (finding claims based on deviation from production/design requirements in the PMA and failure-to-perform testing under actual use conditions are not pre-empted).

Each court must evaluate each case on an individual basis and rule based on its understanding of the merits of the claims asserted. Furthermore, in *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495, 116 S. Ct. 2240, 2255 (U.S. 1996), the Court found that Lohrs' allegations may include claims that Medtronic has violated FDA regulations and that these claims can be maintained without being pre-empted by § 360k.

> Nothing in §360k denies [the State] the right to provide a traditional damages remedy for violations of common-law duties . . . additional elements of the state-law cause of action would make the state

> requirements narrower, not broader, than the federal requirement. While such a narrower requirement might be "different from" the federal rules in a literal sense, such a difference would surely provide a strange reason for finding pre-emption of a state rule insofar as it duplicates the federal rule. The presence of a damages remedy does not amount to the additional or different "requirement" that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing "requirements" under federal law. *Id.*

The Court found that, at such an early stage in the litigation, there was no reason to preclude Lohrs' manufacturing and labeling claims to the extent that they rest on claims that Medtronic negligently failed to comply with duties "equal to, or substantially identical to, requirements imposed" under federal law. *Id.* at 497.

The courts are deeply and for different reasons split as to pre-emption, though many find that state claims should be allowed, especially early in the litigation, as the legislative history confirms that "§360(k) simply was not intended to pre-empt most, let alone all, general common-law duties enforced by damages actions." *Id.* Thus, "Medtronic's argument [suggesting otherwise] is not only unpersuasive, it is implausible." *Id.* at 487.

Here, in the case at bar, Petitioner's claims of fraud and failure to report were dismissed at the pleading stage, on a MTD 12(b), before discovery could be done. While the precise contour of purported "parallel claims" is uncertain, no court has excluded claims that seek to impose liability where non-compliance with the applicable FDCA is apparent. In the instant matter, Petitioner asserts parallel claim against Respondent, seeking to impose liability based on

Respondent's failure to comply with the FDCA requirements, which Petitioner clearly identified.

Plaintiffs may bring claims directly against device manufacturers if their state law claims parallel federal law, i.e., do not impose requirements that are *different from, or in addition to*, those already imposed on the manufacturers by federal law. District courts in numerous cases opined that a well-pleaded parallel claim must at least (1) identify the federal requirement applicable to the device with which it allegedly failed to comply and (2) explain how that violation of a federal requirement caused the plaintiff's injury. *See Smith v. St. Jude Med. Cardiac Rhythm Mgmt. Div.; Ali v. Allergan USA, Inc.*; *Viserta v. St. Jude Med., Inc.*; *Bishoff v. Medtronic Inc.*; *Covert v. Stryker Corp.*

Some courts accept the sufficiency of pleading parallel claims based on violations of FDA's requirements. See *Hofts v. Howmedica; Purcel v. Advanced Bionics, Rollins v. St. Jude Medical.*

In *Riegel*, 552 U.S. 312, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008), the Court similarly went on to hold that the PMA preemption provision does not bar a state from imposing damages for a claim premised on the violation of FDA regulations, as long as the state duties "parallel," rather than add to, federal requirements. *Riegel, supra*, 128 S.Ct. at 1011. Thus, Petitioner may bring claims against Respondent if her state law claims parallel federal law, i.e., do not impose requirements that are <u>different from, or in addition</u> to, those already imposed by federal law. *See In re Medtronic, Inc. Sprint Fidelis Leads, supra,* 623 F.3d at

1204. In this case, however, the Appellate Court seems to suggest that requirements of honest and truthful reporting would be still an "additional" requirement under *Riegel*, and thus, would have warranted dismissal:

> "to the extent that they [impose requirements that] are 'different from, or in addition to' the requirements imposed by federal law."
> *Riegel v. Medtronic, Inc.*, App. A p.1 §1

In other words, the Appellate court states that even if the instances of fraud are proven, the case must be dismissed anyway because there is no explicit wording in the Federal Statutes stating that the company (grantee of the PMA) should not commit fraud, should not deceive, should not lie, etc. It is a ridiculous position requiring an explicit language in statues in *order not to commit* a crime.

At the same time, the court stated that "To avoid preemption, a Petitioner bringing a state tort claim must *allege that the state-law duty* at issue parallels a federal requirement." *Id.*

In this case, Petitioner is doing exactly that – alleging specific violations of the PMA i.e. hiding instances of adverse events in order to deceive the FDA, public, government, etc. The adverse events are clearly identified: dates, pumps' serial numbers, identity of participants, etc.). Obviously, the fraud was never part of any "granted" protections under the PMA. The requirement of honesty and truthfulness in dealing with FDA, public, and in general cannot be considered as "additional" requirements to the Federal Mandate and thus pre-empted. Fraud was never a "foreseeable" part of the PMA and is not subject to its protection. Therefore, the Appellate court's argument under *Riegel,* is off-point and inapplicable. Although it is true that Petitioner cannot identify the specific

defects with the devices, it is unnecessary for her to do so. The actual defect does not go to the merits of this case. Rather, the continuous disappearance of the devices makes this case about fraud—Respondent engaged in a strategy employed to hide adverse events and circumvent federal regulations.

**V. What Is The Proper Early Stage Of The Case At Which The Allegations Of Fraud Can Be Dismissed On Motion To Dismiss 12(B)(6) And Whether Dismissing Allegations Of Fraud Too Early In The Case Is Unjust And Prejudicial As It Denies The Petitioner Of Opportunity To Conduct Reasonable Discovery Of Alleged Fraud?**

**Petitioner Had Sufficient Evidence to Establish *PRIMA FASCIA* for Fraud and Misrepresentation and thus, the Discovery Shall be Allowed.**

This case is also distinguishable from other cases because it involves the the disappearance of multiple experimental devices – the devices that should have been secured and protected because they represented valuable data for future research, which is at the center of the PMA's purpose. The unexplained missing pumps and their corresponding reporting to the FDA is the basis of Petitioner's allegations of violations of PMA requirements—this case is not about the devices' specific defects. Although this is not the only case raising the issue of Respondent's non-reporting of adverse events to the FDA, this is the first and only case where the allegations involve more than a single pump failure; in fact, this case concerns three pumps that had to be explanted within a short period of time. Because the disappearance of three (3) pumps cannot be a mere coincident, the disappearances raise an inference of intentional acts, a scheme possibly employed by Respondent for personal benefits. Respondent refused to provide any answer as

to what happened to the explanted pumps. The only information Respondent provided was a declaration from its Director of Customer Quality, Lisa M. Woodward Clarke, signed under penalty of perjury, stating that Respondent did not have any records of the failed pumps:

> "…Consistent with paragraph 3 above, **Medtronic's business records do not reflect** that any of Plaintiffs SynchroMed® II pumps (bearing serial numbers NGP326345H, NGP407855H, NGP409465H, and NGP416551H**) were ever returned to Medtronic following explant**… Appendix E **¶3**

As of today, the main question of "what happened to the pumps" has yet to be answered. That question is crucial in determining whether any violation of Federal Mandate was committed. Petitioner was denied the right to investigate the pumps' whereabouts because her case was improperly dismissed by the lower courts for inability to provide a specific defect in the pumps. To identify a specific defect in the pump, as the trial court demanded, Petitioner would need to have possession of the pumps to analyze then. These are medically extracted pumps that require properly handling—they are not toys Petitioner could take home with her post-operation. The Appellate Court and the Trial Court however applied a "specific defect" criteria. At the same time, they also precluded Petitioner from gaining discovery. The district court dismissed allegations of fraud on defendants' Motions to Dismiss at a very early stage without providing Petitioner opportunity to conduct any discovery on the issue of pumps disappearance. Then, the Court dismissed the case in its entirety. That is simply unjust.

**VI. The District Court's Erred in Dismissal Fraud Charges on Motion to Dismiss 12(b) Thus Limiting Petitioner's Ability to Engage in Meaningful Discovery**.

In her FAC, Petitioner established a P*rima Facie* case of fraud. If she had been allowed discovery, she would have found additional information concerning Respondent's fraud and misrepresentation. Petitioner's allegations were credible and should have been allowed to proceed. However, the district court dismissed all fraud counts, thus preventing Petitioner from vital discovery.

**VII. What is the standard for Failure-to-Warn Claims and Detrimental Reliance? Both standards are extremely subjective and represent a matter of fact, thus they should be left for the jury to decide. Additionally, the Petitioner was relying on the advice of her doctor, who was also misled by the company. The issue what is reasonable (especially when a doctor is involved) is measured by the standards of a "reasonable man" i.e. a jury, and should not be left to the court to decide. By doing that we are substituting the wisdom of the jury on opinion of the judge. Petitioner's Failure-to-Warn Claims are Well Plead and Shall be Allowed.**

The controlling opinion in California that reinstated state-law failure-to-warn claims is ***Stengel***. In *Stengel v. Medtronic Inc.,* 704 F.3d 1224, 1226, 2013 U.S. App. LEXIS 621, *1 (9th Cir. Ariz. 2013*),* Plaintiff contended that Medtronic was negligent under Arizona law because it failed to provide the FDA with information about adverse events involving its medical device. The Ninth Circuit held that *Stengel*'s state law claim <u>was not impliedly or expressly preempted</u> by the PMA], and that the general duty of care under Arizona common law incorporated a requirement to furnish adverse-event information to the FDA.

Here, Petitioner claims that if Respondent had not hid the pumps and had timely notified the FDA of the failures, the FDA would have required Respondent

to perform mandated analysis and improve future designs. However, the trial court found that Petitioner would have agreed to install the replacement pumps regardless of whether improvements had been made to the pumps:

> Defendant claims that this allegation is false, but, in any event, there is no way that Plaintiff could have detrimentally relied on Defendant's failure to inform the FDA of the failures of her own pumps – facts that Plaintiff clearly already knew.
>
> District Court Ruling on FAC App. C

It is extremely speculative for the court to decide that the Petitioner could not possibly rely on anything when making her decision to implant another pump; especially in light of the fact that there were three (3) pumps, with the first installed on 2009. The decision whether it was "reasonable" or "unreasonable" for Petitioner to rely on something is very subjective and should be left for the trier-of-fact to decide. What is reasonable for one is not for another. Different people may decide differently under the facts of the case, where Petitioner relied not only on the reporting by Respondent, but also on statements of the Respondent's agent and Petitioner's own doctor, who was persuade by Respondent's agent as well.

Petitioner's First Amended Complaint was well-pled and specified with particularities the substance of Respondent's failure-to-warn claims.

## VIII. District Court Failed to Recognize the "Narrow Gap" Exemption to the PMA Preemption.

Sections 360k(a) and 337 preempt most state-tort PMA-device claims against medical device manufacturers. However, a "narrow gap" exists allowing to proceed only state-law claims that precisely parallel a federal law. *See Perez*

*v. Nidek Co.*, 711 F.3d. 1109, 1120 *see Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1228 (9th Cir. 2013). To fall within that "narrow gap" of non-preempted claims, "[t]he plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *Perez*, 711 F.3d at 1120 (quoting *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*,623 F.3d 1200, 1204 (8th Cir. 2010)).

This case satisfies this requirement and thus falls within the "narrow gap." Petitioner's Complaint is not based on specific pump defects, but rather on Respondent's conduct that *violates* the Federal Mandate of Post-Approval Reporting:

**21 U.S.C. § 360i** –requirement to inform the FDA of "new_clinical investigations or scientific studies concerning the device," which the applicant knows of or reasonably should know of;

**21 CFR § 814.84(b)(2) -** report incidents in which the devices may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred,

**21 CFR § 803.50; 803.30** – report Any information that you can obtain by analysis, testing, or other evaluation of the device.

## REASONS FOR GRANTING THE WRIT

### A. This Issue is Vitally Important.

This is as straightforward a certiorari candidate as any PMA disputed case can be. It is manifestly important: what are the PMA requirements and how far PMA protections extend. Different courts interpret the issue of a "parallel" case differently, causing a split between circuits.

It is clear that FDA can enforce fraud, but in order to be able to do that, the FDA must be aware of fraud perpetrated by companies. Under the Ninth Circuit's ruling, a company that commits fraud by preventing the FDA from discovering instances of failed devices can never be identified, as any claims against it based on fraudulently concealed pumps would be preempted and dismissed. Thus, the perpetrator would be protected from any liability under the PMA. That is the circle that the Supreme Court shall break.

The most important for the FDA is the percentage of reliability, i.e. what percentage of the devices will fail. This reliability reading's importance is understandable, because each instance of failure can bring sever injury or death. All implantable devices, such as Opioid-Infusing Pumps produced by Respondent can be fatal if they fail. Respondent prides itself on its 99.9% reliability record. This data is very sensitive. Even a few "adverse events" can shift total percentage to an "unacceptable" level and force the FDA to reevaluate or even recall the device's PMA. The consequences to Respondent of reporting failures could be devastating, including the loss of market share, lower stock price, etc. In other words, there is an

incredibly large incentive to hide failed pumps. Petitioner makes allegations related to widespread practice by Respondent to conceal failed devices in order to not report those incidents to the FDA. Petitioner's Complaint alleged that Respondent adopted a "policy" to defraud the FDA and public. As in *Stengel*, the Petitioner alleges widespread *suppression of adverse event reports*, 704 F.3d at 1226-27.

**B. This Case Is An Ideal Vehicle.**

It is not often when an implanted device fails. It is extremely rare when two devices fail within weeks from each other. All other cases involving Respondent's alleged violations of the Federal Mandate involved only a singular device, thus to draw any conclusion of any fraudulent scheme was impossible. Non-reporting of a failure of only one device cannot be used as an indication as of anything more than negligence. There were no prior cases and the courts never dealt with the facts as in this case – devices with 99.9% reliability failing within weeks of one another and then disappearing into thin air. There were no prior cases with the facts similar to this case and the courts had never really dealt with the issue: what to do with allegations of blatant fraud adopted as a company policy for years? Respondent argues that under PMA everything is protected. Petitioner disagrees and that is the substance of the instant dispute.

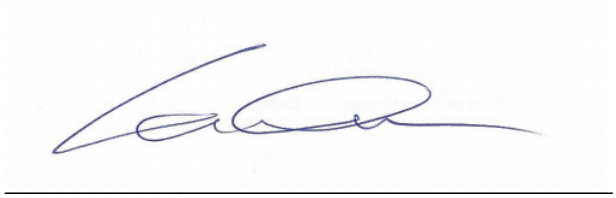
PMA should never be a protection against fraud – it is not the legislative intent to create fraudulent schemes to milk the taxpayers of billions of dollars. The consequences of this case are enormous. Respondent (and probably other manufacturers) continues to perpetrate this fraud. This is because attempts to

investigate into suspicious practices have been prematurely prohibited. The role of the courts should not be to impede those who are trying to discover the truth, but rather to reasonably assist and encourage plaintiffs' discovery and then, and only then, consider the full spectrum of evidence before rendering an opinion. Such opinion shall not be premature and in haste, but based on the totality of admissible evidence and made at a later stage of the case. In this case, Petitioner's allegations were dismissed at the very early stage on MTD12(b), based on disputed evidence, and without providing a reasonable opportunity for discovery.

**CONCLUSION**

This Court should grant certiorari.

Dated: April 23, 2020



Respectfully submitted, Leon Ozeran
*Counsel of Record for Petitioner*
OZERAN LAW OFFICES
8400 Wilshire Blvd.
Suite 400
Beverly Hills, CA 90211
(310) 461-3730
*ozeranlaw@gmail.com*

# APPENDIX

Case: 18-55621, 01/28/2020, ID: 11576304, DktEntry: 46-1, Page 1 of 5

**NOT FOR PUBLICATION**

FILED

JAN 28 2020

MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

| | |
|---|---|
| REBECA LAWRENCE,<br><br>Plaintiff-Appellant,<br><br>v.<br><br>MEDTRONIC, a foreign corporation,<br><br>Defendant-Appellee. | No. 18-55621<br><br>D.C. No.<br>2:16-cv-07289-DSF-AS<br><br>MEMORANDUM* |

Appeal from the United States District Court
for the Central District of California
Dale S. Fischer, District Judge, Presiding

Argued and Submitted December 12, 2019
Pasadena, California

Before: BOGGS,** WARDLAW, and BEA, Circuit Judges.

Rebeca Lawrence sued Medtronic, alleging a variety of state-law tort claims stemming from her use of Medtronic's SynchroMed II drug-infusion pump ("the Pump"), which is a Class III medical device subject to the Food and Drug Administration's ("FDA") pre-market approval process ("PMA"). She appeals the

* This disposition is not appropriate for publication and is not precedent except as provided by Ninth Circuit Rule 36-3.

** The Honorable Danny J. Boggs, United States Circuit Judge for the U.S. Court of Appeals for the Sixth Circuit, sitting by designation.

district court's dismissal of her product-defect and failure-to-warn claims for failure to state a claim and its dismissal of her misrepresentation claims at summary judgment. We have jurisdiction under 28 U.S.C. § 1291, and we affirm.

1. The district court did not err in dismissing Lawrence's claims that were based on Medtronic's failure to ship her old Pumps back to company headquarters for further analysis because such claims are preempted. State-law claims for devices that have undergone PMA are preempted "to the extent that they [impose requirements that] are 'different from, or in addition to' the requirements imposed by federal law." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (quoting 21 U.S.C. § 360k(a)(1)). To avoid preemption, a plaintiff bringing a state tort claim must allege that the state-law duty at issue parallels a federal requirement. *Id.* Lawrence identifies no federal authority that requires medical-device manufacturers to send removed medical devices anywhere for evaluation. Indeed, there is no federal regulation mandating any analysis of removed medical devices, and thus a tort claim premised on such a course of conduct would impose a requirement that is "different from" and "in addition to" what is required under federal law. *See id.*

2. The district court did not err in dismissing Lawrence's claims to the extent they were based on Medtronic's alleged failure to report adverse events to the FDA because they failed to state plausible claims for relief. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). To prevail, Lawrence must plausibly allege that had

Medtronic "properly reported the adverse events to the FDA as required under federal law, that information would have reached [her] doctors in time to prevent [her] injuries." *See Stengel v. Medtronic*, 704 F. 3d 1224, 1234 (9th Cir. 2013) (en banc) (Watford, J., concurring). Lawrence cannot plausibly allege that the purported absence of adverse-event reports regarding her own pumps caused her any injury. Moreover, contrary to Lawrence's assertions, the record indicates that Medtronic did in fact file the reports at issue. Medtronic included the reports, which were the proper subjects of judicial notice, in several attached exhibits to its motion to dismiss. *See* Fed. R. Evid. 201. Accordingly, Lawrence's allegations are facially implausible and are not enough for us to "draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678.

3. The district court did not err in dismissing Lawrence's claims that were based on product-defect theories of recovery. Although such theories are not preempted if the claim is that Medtronic failed to comply with a federal requirement, Lawrence's First Amended Complaint contains only conclusory allegations, which fail to identify any specific federal requirement that was violated or the specific nature of the Pump's purported defects. Several of our sister circuits have not permitted such product-defect theories to proceed if the plaintiff cannot plausibly allege either the violation of a specific requirement or the specific nature of the defect. *See Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011) (affirming

dismissal when the complaint failed to "specify a causal connection between the failure of the specific manufacturing process and the specific defect in the process that caused the personal injury"); *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1206 (8th Cir. 2010) (affirming dismissal when the "[p]laintiffs failed to identify any specific federal requirement in the PMA approval . . . for an unpreempted parallel claim"). Lawrence does neither and thus the district court properly dismissed the claims associated with these theories.

4. The district court did not err in dismissing Lawrence's claims for negligent and intentional misrepresentation at summary judgment because Lawrence failed to demonstrate a genuine dispute of material fact over whether she justifiably relied on any statement made by Medtronic. *Weber v. Allergan*, 940 F.3d 1106, 1110 (9th Cir. 2019) (standard of review). Under California law, a plaintiff claiming either intentional or negligent misrepresentation must prove justifiable reliance to prevail. *Small v. Fritz Cos., Inc.*, 30 Cal. 4th 167, 173–74 (2003). During Lawrence's deposition, she admitted that she did not rely on Medtronic's statements when she decided to continue using the Pumps. She further admitted that she agreed to get each pump without knowing whether her doctor had received any analysis of the explanted pumps, and before it would have been possible for any analysis of the previous pump to be completed. Notwithstanding this lack of information, Lawrence was most concerned about the "potential benefits" of the Pumps and

continued using the Pumps without the analysis from Medtronic. The district court's grant of summary judgment was thus proper.

**AFFIRMED**.

**APPENDIX A** – Opinion of The United States Court of Appeal for the NINTH CIRCUIT Dated & Decided on January 28, 2020

**APPENDIX B** ---- Order Of The United States District Court For the Central District Of California Granting Motion To Dismiss 12(b) Original Complaint

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

**MEMORANDUM**

| | | | |
|---|---|---|---|
| Case No. | CV 16-7289 DSF (ASx) | Date | 2/27/17 |
| Title | Rebeca Lawrence v. Medtronic | | |

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|---|---|
| Present: The Honorable | DALE S. FISCHER, United States District Judge |

| | |
|---|---|
| Debra Plato | Not Present |
| Deputy Clerk | Court Reporter |
| Attorneys Present for Plaintiffs: | Attorneys Present for Defendants: |
| Not Present | Not Present |

**Proceedings:** (In Chambers) Order GRANTING Motion to Dismiss (Dkt. No. 17)

Plaintiff Rebeca Lawrence received multiple implants of allegedly defective Synchromed II Programmable Drug Infusion Systems designed and manufactured by Defendant Medtronic, Inc. She now sues under various state law theories for recovery of harm suffered due to the defective devices. Defendant moves to dismiss. The Court deems this matter appropriate for decision without oral argument. See Fed. R. Civ. P. 78; Local Rule 7-15. The hearing set for March 6, 2017 is removed from the Court's calendar.

The Synchromed system, a Class III prescription medical device, is subject to extensive review by the FDA under the Premarket Approval (PMA) process. See 21 U.S.C. § 360e; Riegel v. Medtronic, Inc., 552 U.S. 312, 316-20 (2008). Specific regulation of a particular device by the FDA through the PMA process results in express preemption of any state law requirements that are "different from, or in addition to" the FDA's requirements.[1] Id. at 322-30. A plaintiff, however, can bring a state law claim if the state law in question only provides a remedy for violation of a federal requirement. Id. at 330. The complaint does not allege that Defendant failed to comply with the

[1] Plaintiff suggests that Defendant's approval under the PMA was somehow automatically revoked by alleged violations of the terms of the PMA. Plaintiff provides no support for this, and, in fact, revocation of a PMA requires express action by the FDA. See 21 U.S.C. § 360e(e).

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

**MEMORANDUM**

FDA's PMA-imposed requirements. This means that Plaintiff's state law claims based on design and manufacturing defects are preempted to the degree that they are not based on a violation of the FDA's particularized standards for the Synchromed product. While Plaintiff provides conclusory allegations that Defendant violated FDA requirements, there is no suggestion of what the actual defect is purported to be or how Defendant's design or manufacturing violated an FDA mandate.[2] Plaintiff's intentional infliction of emotional distress and breach of implied warranty claims are similarly expressly preempted because they are premised on alleged product defects that are not necessarily co-extensive with the FDA's requirements. Plaintiff's fraud claims based on a failure to disclose information to people or entities other than the FDA are also expressly preempted if they impose requirements in addition to those imposed by the FDA. Perez v. Nidek Co., Ltd., 711 F.3d 1109, 1118-19 (9th Cir. 2013). Plaintiff's claim that Defendant failed to make required adverse event reports to the FDA is not preempted, see Stengel v. Medtronic, Inc., 704 F.3d 1224, 1233 (9th Cir. 2013), but Plaintiff fails to allege that any such failure caused her harm. Specifically, Plaintiff fails to allege that the defective devices would not have been implanted if Defendant had made the required disclosures. See id. at 1234-35 (Watford, J., concurring).

Defendant's motion to dismiss is GRANTED. The complaint is dismissed with leave to amend consistent with this order. An amended complaint must be filed and served no later than March 27, 2017. Failure to file by that date will waive the right to do so. The Court does not grant leave to add new defendants or new claims. Leave to add defendants or new claims must be sought by a separate, properly noticed motion. Defendant's response will be due April 24, 2017.

IT IS SO ORDERED.

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[2] The Court is not convinced at this time that a claim could never be made for violation of any of the FDA's Current Good Manufacturing Practices (CGMP) regulations, 21 C.F.R. Part 820. Defendant fails to provide meaningful analysis on this point, instead referring the Court to a string of citations and quotations from other district courts. The Court declines to review the entirety of the CGMP regulations to see if any are specific enough to theoretically form the basis of a claim. The Court recognizes, however, that the more specific manufacturing requirements of a product's PMA would control if there were a conflict between the PMA and the CGMP.

**APPENDIX C** —— Order Of The United States District Court For the Central District Of California Granting MTD FAC 12(b)

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

**MEMORANDUM**

| | | | |
|---|---|---|---|
| Case No. | CV 16-7289 DSF (ASx) | Date | 5/30/17 |
| Title | Rebeca Lawrence v. Medtronic | | |

| | |
|---|---|
| Present: The Honorable | DALE S. FISCHER, United States District Judge |

| | |
|---|---|
| Debra Plato | Not Present |
| Deputy Clerk | Court Reporter |
| Attorneys Present for Plaintiffs: | Attorneys Present for Defendants: |
| Not Present | Not Present |

**Proceedings:** (In Chambers) Order GRANTING Motion to Dismiss (Dkt. No. 26)

Plaintiff Rebeca Lawrence received multiple implants of allegedly defective Synchromed II Programmable Drug Infusion Systems designed and manufactured by Defendant Medtronic, Inc. She now sues under various state law theories for recovery of harm suffered due to the defective devices. The Court previously granted a motion to dismiss and Plaintiff amended her complaint. Defendant now moves again to dismiss. The Court deems this matter appropriate for decision without oral argument. See Fed. R. Civ. P. 78; Local Rule 7-15. The hearing set for June 5, 2017 is removed from the Court's calendar.

The Court previously held that because the Synchromed system is a Class III prescription medical device subject to extensive review by the FDA under the Premarket Approval (PMA) process, state law requirements that are "different from, or in addition to" the FDA's requirements are expressly preempted. A plaintiff, however, can bring a state law claim if the state law in question only provides a remedy for violation of a federal requirement.

The complaint once again does not allege that Defendant failed to comply with the FDA's PMA-imposed requirements. In fact, Plaintiff admits that she has no idea what the source of the purported defect might be and has little prospect of figuring it out. See FAC ¶ 28. She appears to want to proceed in a *res ipsa loquitur* manner – because the system failed for her multiple times, it must be defective. This does not allow her claims

to survive because, as stated previously, failure of a Class III device that has passed the PMA process can only lead to liability if the device manufacturer failed to follow the requirements set out by the FDA in granting the PMA. This analysis eliminates all of Plaintiff's non-misrepresentation claims because they are all premised on the allegedly defective nature of the device.

The Court previously found Plaintiff's failure to warn claims preempted other than those that alleged a failure to report adverse events to the FDA. The FAC continues to allege a failure to report adverse events as well as fraud based on explicitly false statements by an employee of Defendant to Plaintiff. While somewhat vague, the adverse events reporting claim appears to be based on a failure to report the failures of Plaintiff's own pumps. See FAC ¶¶ 29-32. Defendant claims that this allegation is false, but, in any event, there is no way that Plaintiff could have detrimentally relied on Defendant's failure to inform the FDA of the failures of her own pumps – facts that Plaintiff clearly already knew.

Defendant has failed to establish that the learned intermediary doctrine bars Plaintiff's direct intentional misrepresentation claim. In California, the duty to warn regarding implantable medical devices runs to the physician, not the patient. Bigler-Engler v. Breg, Inc., 7 Cal. App. 5th 276, 319 (2017). Plaintiff claims that an employee of Defendant made direct and express representations to her after the first pump failure(s) that Defendant was taking, and had taken, steps to rectify the situation. These representations are alleged to have induced Plaintiff into having a pump implanted again, only to have it fail again. This is not a failure to warn claim, nor is it akin to one. It is an allegation of a direct misrepresentation intended to induce Plaintiff into using Defendant's product. None of the cases cited by Plaintiff are remotely similar to these facts.

Defendant's motion to dismiss is GRANTED IN PART and DENIED IN PART consistent with this order. Leave to amend the dismissed claims is not granted because it is clear that Plaintiff has no ability to plead a claim that will not be preempted given her inability to allege a violation of the PMA requirements.

IT IS SO ORDERED.

**APPENDIX D** ---- Conditional Letter of Approval

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 2003

RECEIVED
SEP 19 2003

Mr. Kenneth Jensen
Principal Regulatory Affairs Specialist
Medtronic Neurological, Medtronic Incorporated
710 Medtronic Parkway
Minneapolis, Minnesota 55432

Re: P860004 / S56
Medtronic® SynchroMed® II Programmable Drug Infusion System
Filed: April 7, 2003
Amended: April 28, August 25, and September 11, 2003

Dear Mr. Jensen:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its evaluation of your premarket approval application (PMA) supplement, which requested approval for: Medtronic® SynchroMed® II Programmable Drug Infusion System which includes Model 8637 SynchroMed II Programmable Pump, SynchroMed II Application Software on the Model 8870 Application Card, Model 8551 Refill Kit, Model 8540 Catheter Access Port Kit, and Model 8590-1 Pouch Kit.

Based upon the information submitted, the PMA supplement is approved. You may begin commercial distribution of the device as modified by your PMA supplement in accordance with the conditions described below and in the "Conditions of Approval" (enclosed).

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

In addition to the post approval requirements outlined in the enclosure, you have agreed to conduct a post approval study and submit reports as described in your amendments received August 25, and September 11, 2003. The reports must be submitted every 3 months for the first 12 months of the study and every 6 months and until the study is complete. The post approval study should be conducted until at least 61 evaluable patients have been enrolled.

CDRH does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws.

Failure to comply with the conditions of approval as attached invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that as soon as possible and before commercial distribution of your device you must submit an amendment to this PMA with copies of all approved labeling in final form. The labeling will not routinely be reviewed by FDA staff when PMA supplement applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have questions concerning this approval order, please contact Pandu Soprey Ph.D. at (301) 594-1287 x 178.

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Last Modified: 1-31-02

# CONDITIONS OF APPROVAL

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e) or (f). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations that require a PMA supplement cannot be briefly summarized; therefore, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report (see below). FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

Alternate submissions permitted under 21 CFR 814.39(f) for manufacturing process changes include the use of a 30-day Notice. The manufacturer may distribute the device 30 days after the date on which the FDA receives the 30-day Notice, unless the FDA notifies the applicant within 30 days from receipt of the notice that the notice is not adequate.

**POSTAPPROVAL REPORTS.** Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

1. Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

2. Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

   a. unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

   b. reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

**ADVERSE REACTION AND DEVICE DEFECT REPORTING.** As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

1. A mix-up of the device or its labeling with another article.

2. Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and:

   a. has not been addressed by the device's labeling; or

   b. has been addressed by the device's labeling but is occurring with unexpected severity or frequency.

3. Any significant chemical, physical or other change or deterioration in the device, or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

**REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION.**
The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984. This regulation was replaced by the reporting requirements of the Safe Medical Devices Act of 1990 which became effective July 31, 1996 and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for a PMA, the manufacturer shall submit the appropriate reports required by the MDR Regulation within the time frames as identified in 21 CFR 803.10(c) using FDA Form 3500A, i.e., 30 days after becoming aware of a reportable death, serious injury, or malfunction as described in 21 CFR 803.50 and 21 CFR 803.52 and 5 days after becoming aware that a reportable MDR event requires remedial action to prevent an unreasonable risk of substantial harm to the public health. The manufacturer is responsible for submitting a baseline report on FDA Form 3417 for a device when the device model is first reported under 21 CFR 803.50. This baseline report is to include the PMA reference number. Any written report and its envelope is to be specifically identified, e.g., "Manufacturer Report," "5-Day Report," "Baseline Report," etc.

Any written report is to be submitted to:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
PO Box 3002
Rockville, Maryland 20847-3002

Copies of the MDR Regulation (FOD # 336&1336)and FDA publications entitled "An Overview of the Medical Device Reporting Regulation" (FOD # 509) and "Medical Device Reporting for Manufacturers" (FOD #987) are available on the CDRH WWW Home Page. They are also available through CDRH's Fact-On-Demand (F-O-D) at 800-899-0381. Written requests for information can be made by sending a facsimile to CDRH's Division of Small Manufacturers International and Consumer Assistance (DSMICA) at 301-443-8818.

**APPENDIX E** ---- Declaration of Lisa M. Woodward Clark

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE CENTRAL DISTRICT OF CALIFORNIA,**
**EASTERN DIVISION**

| | |
|---|---|
| REBECA LAWRENCE, individual,<br><br>Plaintiff,<br><br>v.<br><br>MEDTRONIC, a Foreign Corporation, Does 1-20 inclusive,<br><br>Defendants. | Case No. 2:16-cv-07289-DSF-AS<br><br>**DECLARATION OF Lisa M Woodward Clark** |

I, Lisa M Woodward Clark, declare and state as follows:

1. I have been employed by Medtronic, Inc. ("Medtronic") since 2013. My current position is Director, Customer Quality. I have personal knowledge of the matters set forth herein and am competent to testify thereto if called upon as a witness to do so.

2. Attached as Exhibits A – D are true and correct copies of publicly-available records of Medical Device Reports ("MDRs") that Medtronic's Customer Quality Department submitted to the U.S. Food and Drug Administration ("FDA") in connection with Plaintiff. These documents were obtained by accessing FDA's online MAUDE database.[1] FDA has discretion to publish MDRs submitted by medical device manufacturers. *See* 21 C.F.R. 803.9(a).

3. Each of the MDRs states that Plaintiff's medical devices were not available to Medtronic for evaluation. Specifically, in each MDR, in response to the question "Was Device Available For Evaluation?", Medtronic stated "No." (*See* Exs. A – D.)

4. Consistent with paragraph 3 above, Medtronic's business records do not reflect that any of Plaintiff's SynchroMed® II pumps (bearing serial numbers NGP326345H, NGP407855H,

[1] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.

NGP409465H, and NGP416551H) were ever returned to Medtronic following explant.

I certify under penalty of perjury under the laws of the State of California and the United States of America that the foregoing is true and correct.

Dated: 12 DECEMBER, 2017

Lisa M Woodward Clark

Lisa M Woodward Clark

# STATUTES INVOLVED:

**APPENDIX F** ------ Title 21 §803

# TITLE 21--FOOD AND DRUGS
# CHAPTER I--FOOD AND DRUG ADMINISTRATION
# DEPARTMENT OF HEALTH AND HUMAN SERVICES
# SUBCHAPTER H--MEDICAL DEVICES

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=803.50

PART 803 -- MEDICAL DEVICE REPORTING

Subpart E--Manufacturer Reporting Requirements

Sec. 803.50 If I am a manufacturer, what reporting requirements apply to me?

(a) If you are a manufacturer, you must report to us the information required by 803.52 in accordance with the requirements of 803.12(a), no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market:

(1) May have caused or contributed to a death or serious injury or

(2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

(b) What information does FDA consider "reasonably known" to me?

(1) You must submit all information required in this subpart E that is reasonably known to you. We consider the following information to be reasonably known to you:

(i) Any information that you can obtain by contacting a user facility, importer, or other initial reporter;

(ii) Any information in your possession; or

(iii) Any information that you can obtain by analysis, testing, or other evaluation of the device.

(2) You are responsible for obtaining and submitting to us information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters.

(3) You are also responsible for conducting an investigation of each event and evaluating the cause of the event. If you cannot submit complete information on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the information. If you later obtain any required information that was not available at the time you filed your initial report, you must submit this information in a supplemental report under 803.56 in accordance with the requirements of 803.12(a).

**APPENDIX G** ---- Title 21 §814.84

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2019]
[CITE: 21CFR814.84]

See Related Information

# TITLE 21--FOOD AND DRUGS
# CHAPTER I--FOOD AND DRUG ADMINISTRATION
# DEPARTMENT OF HEALTH AND HUMAN SERVICES
# SUBCHAPTER H--MEDICAL DEVICES

PART 814 -- PREMARKET APPROVAL OF MEDICAL DEVICES

Subpart E--Postapproval Requirements

Sec. 814.84 Reports.

(a) The holder of an approved PMA shall comply with the requirements of part 803 and with any other requirements applicable to the device by other regulations in this subchapter or by order approving the device.

(b) Unless FDA specifies otherwise, any periodic report shall:

(1) Identify changes described in 814.39(a) and changes required to be reported to FDA under 814.39(b).

(2) Contain a summary and bibliography of the following information not previously submitted as part of the PMA:

(i) Unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant.

(ii) Reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant. If, after reviewing the summary and bibliography, FDA concludes that the agency needs a copy of the unpublished or published reports, FDA will notify the applicant that copies of such reports shall be submitted.

(3) Identify changes made pursuant to an exception or alternative granted under 801.128 or 809.11 of this chapter.

(4) Identify each device identifier currently in use for the device, and each device identifier for the device that has been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013.

[51 FR 26364, July 22, 1986, as amended at 51 FR 43344, Dec. 2, 1986; 67 FR 9587, Mar. 4, 2002; 72 FR 73602, Dec. 28, 2007; 78 FR 58822, Sept. 24, 2013]