

IN THE SUPREME COURT OF TEXAS

=====
No. 96-0675
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TEMPIE FORTSON WORTHY, PETITIONER

v.

COLLAGEN CORPORATION, RESPONDENT

=====
ON APPLICATION FOR WRIT OF ERROR TO THE
COURT OF APPEALS FOR THE FIFTH DISTRICT OF TEXAS
=====

Argued on December 17, 1996

JUSTICE HECHT delivered the opinion of the Court.

The principal issue before us is whether the Medical Device Amendments of 1976 to the federal Food, Drug and Cosmetic Act preempt this action against a manufacturer brought under the Texas Deceptive Trade Practices—Consumer Protection Act for damages resulting from the injection of a collagen implant material that is a class III medical device under the Act and that has received premarketing approval from the federal Food and Drug Administration. To resolve the issue we must construe and apply the United States Supreme Court’s recent opinions in *Medtronic, Inc. v. Lohr*, ___ U.S. ___, 116 S. Ct. 2240 (1996). We agree with the lower courts, 921 S.W.2d 711, that this action is preempted.

I

Tempie Fortson Worthy sued Collagen Corporation and Dr. James Gilmore, alleging that she was injured when Dr. Gilmore injected her with Zyderm[®] and Zyplast[®] (“Zyderm”), products manufactured by Collagen for cosmetic use. Zyderm is made from a purified form of bovine dermal collagen, a natural protein that provides structural support for skin, muscles, tendons, and bones. The collagen is processed so that it will be accepted by the human body, and the product is injected into connective tissue to repair soft tissue deformities such as scars, pockmarks, and wrinkles, caused

by disease, trauma, surgery, or aging. Worthy alleges that these injections caused her to suffer autoimmune disease and physical deformities.

The federal Food and Drug Administration has determined that Zyderm is a Class III medical device as defined by the Medical Device Amendments of 1976 to the Food, Drug and Cosmetic Act (“the MDA”, “the FDCA”, or “the Act”) — that is, a device that either is for “use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or []presents a potential unreasonable risk of illness or injury”. 21 U.S.C. § 360c(a)(1)(C)(ii). With certain exceptions, a Class III device may not be marketed without FDA approval. *Id.* §§ 331(a), 351(f); *Medtronic*, ___ U.S. at ___, 116 S. Ct. at 2246-2247. To obtain approval, a person must provide the FDA with “reasonable assurance” that the device is both safe and effective. 21 U.S.C. § 360e(d)(2); *Medtronic*, ___ U.S. at ___, 116 S. Ct. at 2246. “[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.” 21 U.S.C. § 360c(a)(2). “[T]he process of establishing this ‘reasonable assurance,’ which is known as the ‘premarket approval,’ or ‘PMA’ process, is a rigorous one. Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission.” *Medtronic*, ___ U.S. at ___, 116 S. Ct. at 2246-2247; *see* 21 U.S.C. § 360e(c); 21 C.F.R. 814.1-.126 (1997).

Specifically, a PMA application must contain:

(A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;

(B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device;

(D) . . . adequate information to show that [any aspect of the device subject to certain performance standards] fully meets such performance standard or adequate information to justify any deviation from such standard;

(E) such samples of such device and of components thereof as [the FDA] may reasonably require . . . ;

(F) specimens of the labeling proposed to be used for such device; and

(G) such other information relevant to the subject matter of the application as [the FDA] may require.

21 U.S.C. § 360e(c)(1). The PMA application must also include: “[a] general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended”, 21 C.F.R. § 814.20(b)(3)(i); “[a]n explanation of how the device functions, the basic scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device”, *id.* § 814.20(b)(3)(ii); “[a] description of existing alternative practices or procedures for diagnosing, treating, preventing, curing, or mitigating the disease or condition for which the device is intended”, *id.* § 814.20(b)(3)(iii); “[a] discussion demonstrating that the data and information in the application constitute valid scientific evidence . . . and provide reasonable assurance that the device is safe and effective for its intended use”, *id.* § 814.20(b)(3)(vi); and a discussion of the “benefit and risk considerations related to the device including a discussion of any adverse effects of the device on health and any proposed additional studies or surveillance the applicant intends to conduct following approval of the PMA”, *id.* These are but a few of the requirements for a PMA application. *See* 21 C.F.R. § 814.20.

A PMA application is ordinarily referred to a panel of experts for study. 21 U.S.C. §§ 360e(c)(2), 360c(b). When the study is completed, the panel gives the FDA “a report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation.” *Id.* §360e(c). The FDA grants premarketing approval only if it finds reasonable assurance that the device is safe and effective with respect to the conditions of use prescribed, recommended, or suggested in the labeling, that the manufacturing and

processing methods and facilities are satisfactory, and that the proposed labeling is not false or misleading in any manner. 21 U.S.C. § 360e(d)(2); *see also* 21 C.F.R. § 814.44. A device approved for marketing cannot be “manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device.” 21 C.F.R. § 814.80.

A device manufacturer must promptly report to the FDA any malfunctions of a device or any deaths or serious injuries caused by it. 21 C.F.R. § 803.1 (1997). The FDA is authorized to notify the public of risks presented by medical devices, 21 U.S.C. § 360h(a); to require manufacturers to repair or replace defective devices, *id.* § 360h(b); to institute recall campaigns, *id.* § 360h(e); to require that records and reports be made of adverse reactions, serious injuries, and death associated with devices, *id.* § 360i; to require postmarketing surveillance of devices, *id.* § 360l; and to withdraw marketing approval if it finds that an approved device is not safe and effective, *id.* § 360e(e).

There are three exceptions to the PMA requirement. One is for devices marketed prior to May 28, 1976. They can continue to be marketed pending the FDA’s completion of the PMA process. 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1) (1997). A second is for devices “substantially equivalent” to devices marketed before May 28, 1976. 21 U.S.C. § 360e(b)(1)(b). They also can be marketed pending completion of the PMA process, but they are subject to a premarket notification process, referred to as a “§ 510(k) process” (after the relevant provision of the statute before codification). 21 U.S.C. §§ 360e(b)(2), 360(k); 21 C.F.R. § 814.1(c)(1) (1997); *Medtronic*, ___ U.S. at ___, 116 S. Ct. at 2247. A third exception is for devices being investigated for human use. They cannot be used without FDA approval obtained through a process different from the PMA process but involving comparably rigorous review. 21 U.S.C. 360j(g); 21 C.F.R. 812.1-.150 (1997)

None of these exceptions applied to Zyderm. Collagen applied for premarketing approval of its product in May 1980. The initial application consisted of eight volumes containing safety and effectiveness data, in vitro data, animal data, clinical data from tests with more than five thousand

patients, a statement of ingredients, a reference to performance standards, labeling, a bibliography, significant articles, manufacturing methods, product samples, and patient report forms. While the application was pending, Collagen amended it to correct deficiencies noted by the FDA. In July 1981 the FDA approved Zyderm subject to several conditions. The FDA restricted Zyderm to prescription use and required that it be distributed with FDA-approved labeling and with a patient manual. The FDA also required that “[n]o advertisement for this device shall recommend or imply that the device may be used for any use that is not mentioned in the approved labeling for the device. All written promotional material shall state the indications, contraindications, warnings, precautions and adverse effects of the device.” The FDA required that patient studies continue under specified guidelines and that patients be monitored for adverse reactions to the product. Finally, the FDA required Collagen to submit a supplemental PMA before making any changes “that may affect the safety or effectiveness” of Zyderm, including changes in use; labeling; manufacturing facilities, methods, or quality control procedures; subcontractors, suppliers, or distributors; sterilization procedures; packaging; and performance or design specifications, components, or ingredients. Changes to enhance safety could be made after notice to the FDA and before approval, such as the addition of warnings, contraindications, or side effects; deletion of misleading, false, or unsupported indications; and changes in the manufacturing process or quality controls to provide additional assurance of purity, identity, strength, or reliability. The FDA published notice of its premarketing approval order in the Federal Register. 46 Fed. Reg. 46394 (1981).

In 1989, Collagen filed a supplemental PMA application requesting the FDA’s approval of certain labeling changes. The FDA granted Collagen’s application but again imposed strict limitations on the labeling of the product and any further changes. Additionally, the FDA required Collagen to add warnings to its product that soft tissues may not return to their original shape and texture after collagen implantation, and that patients should not receive such implants if they desire only temporary effects. These additional requirements were precipitated by media stories concerning collagen implants.

Inf the Oversight and Investigations Subcommittee of the House of Representatives Committee on Energy and Commerce, wrote the FDA of his concerns regarding the frequency and severity of adverse reactions to Zyderm, both local and systemic immune-related. Congressman Dingle asserted that many such reactions were not being reported to the FDA as required by the conditions of Collagen's PMA approval, and that Stanford University and Collagen had committed numerous serious violations of good clinical practices and failed to report to the FDA significant adverse immunologic events which occurred during the Zyderm clinical trials. Congressman Dingle asked the FDA to reevaluate the validity and reliability of the clinical trials supporting Collagen's PMA application. The FDA complied, completing the process in February 1992. While the FDA found shortcomings in the review of Collagen's PMA application and the decision to grant approval, it nevertheless concluded that approval was appropriate. After making numerous specific and detailed findings, the Director of the FDA's Office of Device Evaluation concluded that no issues had been raised regarding the safety and effectiveness of Zyderm to warrant withdrawing of marketing approval.

Worthy received her injections in February 1991 and filed this suit in October 1992. In her original petition Worthy alleged: that Collagen was negligent and grossly negligent in designing, manufacturing, and distributing Zyderm, in failing to warn adequately of the risks of its use, in failing to report adverse reactions to the FDA, in failing to test and monitor product use, and in mislabeling the product; that Collagen breached express and implied warranties relating to Zyderm; that Collagen was strictly liable for Zyderm because its defective design, manufacture, and marketing made it unreasonably dangerous; and that Collagen had fraudulently misrepresented information to and concealed information from the FDA and the public. The district court granted summary judgment for Collagen on the ground that all these claims were preempted by the FDCA. Because Dr. Gilmore, Worthy's physician, remained a defendant in the case, the summary judgment for Collagen was interlocutory. Worthy then cause of action against Collagen and nonsuited Gilmore. The court again granted summary judgment for Collagen on preemption grounds, and Worthy

appealed. The court of appeals held that Worthy's DTPA action was preempted and that she had failed to preserve for appeal any complaint concerning her other claims because she had not included in the appellate record the pleading in which those claims were asserted. 921 S.W.2d 711.

Worthy applied to this Court for writ of error, contending that none of her claims are preempted by the FDCA and that she has preserved that complaint for all her claims. Because the preemption issue is a difficult and recurring one, we granted Worthy's application.

II

Before turning to the preemption issue, we must first address Worthy's preservation argument. Worthy failed to include in the clerk's record on appeal her original pleading in which she asserted the causes of action dismissed by the first summary judgment. When she discovered the omission, she moved the court of appeals for leave to supplement the record. The court granted her motion, but Worthy did not file the supplemental record due, according to her, to "miscommunication". When the court issued its opinion holding that Worthy had failed to preserve her complaint concerning dismissal of the claims in her original pleading, she again moved to supplement the record. This time the court denied her motion, explaining in an opinion on rehearing: "Worthy has made no showing of any unusual circumstances that would justify allowing her to supplement the record at this late date. Indeed, Worthy does not even attempt to explain her failure to include her original petition in the appellate record prior to submission of the case." 921 S.W.2d at 723.

Worthy argues that the court of appeals abused its discretion in denying her leave to supplement the record. Former Rule 55(b) of the Texas Rules of Appellate Procedure required an appellate court to grant a party leave to supplement the record prior to submission unless it would unreasonably delay disposition of the appeal. After submission, however, and after judgment especially, the court has more discretion to deny supplementation. In *Silk v. Terrill*, 898 S.W.2d 764 (Tex. 1995) (per curiam), we held that the court of appeals abused its discretion in denying leave to supplement the record when the omitted item was attached to the party's brief and the party

requested supplementation following oral argument and prior to the court's decision. We stated: "Judicial economy is not served when a case, ripe for decision, is decided on a procedural technicality of this nature. In the interests of justiciaries of this nature can be easily corrected." *Id.* at 766. While we adhere to this view, supplementation of the record *after* a case is decided is a different matter. It certainly does not serve judicial economy for the appellate court to allow a supplementation of the record that would require it to reconsider its decision on the merits when a party has had ample opportunity to correct the omission prior to decision. The court of appeals decided this case not on a procedural technicality but on a record Worthy failed to supplement even after requesting and being granted leave to do so. The court of appeals did not abuse its discretion in denying leave to supplement the record after its opinion issued.

Worthy also argues that some claims asserted in her original pleading were carried forward in her second amended pleading, so that it is not necessary that her original pleading be in the record. Specifically, she contends that allegations that Zyderm was unsafe and that Collagen breached warranties and withheld information raise claims not only for DTPA violations but for products liability, breach of warranty, misrepresentation, and fraud. Worthy's reading of her second amended petition is not completely unreasonable, but we reject it for other reasons. In her response to Collagen's second motion for summary judgment, Worthy told the district court that her second amended petition asserted only DTPA claims and that Collagen's motion "presents a simply, straightforward legal issue" of whether the FDCA preempts a DTPA cause of action. Furthermore, Worthy told the court of appeals in oral argument that her second amended petition did not allege any of the causes of action alleged in her original petition. 921 S.W.2d at 722. Having told both lower courts that her second amended petition contained only DTPA claims, Worthy cannot be permitted to argue now for a broader reading of her pleadings.

Finally, Worthy argues that the claims in her orfirst motion for summary judgment to preserve her complaint that they should not have been dismissed. Assuming that grounds for summary judgment could ever be challenged on appeal without the pertinent pleadings in the record,

the court of appeals correctly held that Worthy's claims cannot be sufficiently discerned from Collagen's motion for summary judgment to permit a determination whether they are preempted by the FDCA. That determination requires "a careful comparison" between the claims asserted and the alleged federal requirements. *Medtronic*, ___ U.S. at ___, 116 S. Ct. at 2257-2258. Worthy's claims cannot be adequately ascertained from Collagen's pleadings.

The court of appeals did not err in limiting its consideration to Worthy's DTPA claims. We limit our own consideration as well.

III

A

Our role in determining the extent to which the FDCA preempts state causes of action is a limited one. We are, of course, bound to give effect to the will of Congress. "[T]he 'ultimate touchstone' in every pre-emption case" is the intent and purpose of Congress as discerned primarily from the language of the statutory provision and the context of its enactment, and then through "the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law." *Medtronic*, ___ U.S. at ___, 116 S. Ct. at 2250-2251. We are also bound to follow the decisions of the United States Supreme Court, the final authority on federal preemption issues. With these two masters to guide, the path should perhaps be clearer than it is. The MDA's preemption provision is, in the Supreme Court's words in *Medtronic*, "highly ambiguous". *Medtronic*, ___ U.S. at ___, 116 S. Ct. at 2260 (Breyer, J., concurring). Unfortunately, it may fairly be said that the Court's three opinions in *Medtronic* do not dispel all confusion. As the United States Court of Appeals for the Seventh Circuit recently observed, "although we have an obligation to be absolutely faithful to the holdings of the Supreme Court of the United States, the holding in *Medtronic* contains several ambiguities that impair our ability to perceive with absolute clarity the path that the Court has chosen for us to follow." *Mitchell v. Collagen Corp.*, 126 F.3d 902, 910 (7th Cir. 1997). Still, we must attempt to decide what the Supreme Court thinks Congress intended when it enacted the preemption provision

in the MDA.

That provision states: “[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement — (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.” 21 U.S.C. § 360k(a). In other words:

- (1) A federal requirement made applicable to a device by the MDA preempts
- (2) a state law requirement with respect to the device that both
- (3) differs from or adds to the federal requirement and
- (4) relates to the device’s safety or effectiveness or to any other matter included in the federal requirement.

Clearly, the provision prohibits a state from passing a law that directly conflicts with an FDA regulation or order regarding how a device is to be made. Less clear are what other state laws are “requirements” “with respect to” devices, what pronouncements by a federal authority are “requirements” “applicable to” devices, and what state “requirements” are “different from, or in addition to” federal “requirements”.

In *Medtronic*, the Supreme Court held that the FDA’s determination that a device is substantially similar to devices marketed before 1976 and thus may be marketed without premarketing approval — the § 510(k) process — does not preempt a lawsuit involving state common law negligence and products liability claims that the device was defectively designed, manufactured, and labeled, and that the device violated FDA regulations. Since *Medtronic*, courts have held that a “substantially similar” determination by the FDA under the § 510(k) process does not preempt a suit based on state law for personal injuries caused by a device. *See, e.g., Oja v. Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997); *Reeves v. AcroMed Corp.*, 103 F.3d 442 (5th Cir. 1997); *Duvall v. Bristol-Myers-Squibb Co.*, 103 F.3d 324 (4th Cir. 1996); *Shea v. Oscor Medical Corp.*, 950 F. Supp. 246 (N.D. Ill. 1996). But *Medtronic* does not directly address what preemptive effect should be given premarketing approval or the comparably rigorous determination that a device

qualifies for investigational use. To resolve this issue we must look beyond the holding of *Medtronic* to its rationale.

This task is complicated by the fact that the Supreme Court issued three opinions in *Medtronic*. JUSTICE STEVENS wrote an opinion in parts for a five-member majority but in other parts for a four-member plurality. JUSTICE BREYER wrote an opinion concurring in parts of JUSTICE STEVENS' opinion, and JUSTICE O'CONNOR wrote a concurring and dissenting opinion joined by three other Justices. So many courts have summarized the *Medtronic* opinions that we think it useless to repeat the task. Instead, we assume a familiarity with those opinions themselves and attempt straightway to distill from them precepts pertinent to this case that find support in the views of a majority of the Supreme Court. Some of these precepts have the stature of the Court's holding under the rule that "[w]hen the Supreme Court issues a plurality decision, and 'no rationale explaining the result enjoys the assent of five Justices, 'the holding of the Court may be viewed as that position taken by those Members who concurred in the judgments on the narrowest grounds'" *Milkiewicz v. Baxter Healthcare Corp.*, 963 F. Supp. 1150, 1155 (M.D. Fla. 1996) (quoting *Marks v. United States*, 430 U.S. 188, 193 (1977), quoting *Gregg v. Georgia*, 428 U.S. 153, 169 n.15 (1976)). This rule focuses our attention particularly on JUSTICE BREYER's opinion because his grounds for concurring in the judgment are narrower than those stated by the plurality. His views consistent with the judgment must be treated as the Court's holding. But JUSTICE BREYER also joins in parts of JUSTICE O'CONNOR's opinion, and while the Justices on that opinion do not concur fully in the judgment, we believe we should treat as authoritative the matters on which JUSTICE BREYER and JUSTICE O'CONNOR agree. Altogether, then, these precepts are as follows.

B

First: The MDA preempts only state requirements that directly conflict with federal requirements or thwart the purpose of the Act. As JUSTICE BREYER explained, so-called "field" preemption exists when "the scheme of federal regulation is 'so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it'". *Medtronic*, ___ U.S. at ___,

116 S. Ct. at 2261 (Breyer, J., concurring) (citations omitted). At least a majority of the Supreme Court, and perhaps the entire Court, reads the MDA as not preempting all state regulation. Rather, under the MDA a federal requirement preempts a state requirement if “the state requirement actually conflicts with the federal requirement — either because compliance with both is impossible, or because the state requirement ‘stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’” *Id.* (citations omitted).

Determining whether compliance with both a federal requirement and a state requirement is impossible is a relatively easy matter. But determining whether a state requirement “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress” is difficult because those purposes and objectives are not adequately defined in either the MDA or the *Medtronic* opinions. A majority of the Supreme Court briefly explained the history and motivation of the MDA:

As technologies advanced and medicine relied to an increasing degree on a vast array of medical equipment “[f]rom bedpans to brainscans,” including kidney dialysis units, artificial heart valves, and heart pacemakers, policymakers and the public became concerned about the increasingly severe injuries that resulted from the failure of such devices.

In 1970, for example, the Dalkon Shield, an intrauterine contraceptive device, was introduced to the American public and throughout the world. Touted as a safe and effective contraceptive, the Dalkon Shield resulted in a disturbingly high percentage of inadvertent pregnancies, serious infections, and even, in a few cases, death. In the early 1970’s, several other devices, including catheters, artificial heart valves, defibrillators, and pacemakers (including pacemakers manufactured by petitioner Medtronic), attracted the attention of consumers, the FDA, and Congress as possible health risks.

In response to the mounting consumer and regulatory concern, Congress enacted the [MDA].

Id. at 2246 (Stevens, J., majority) (citations omitted). The preamble of the MDA states that the statute is “to provide for the safety and effectiveness of medical devices intended for human use”. 90 Stat. 539 (1976). Quoting a House Committee report, the FDA has recently observed: “Congress sought ‘to assure that the public is protected from unsafe and ineffective medical devices, that health professionals have more confidence in the devices they use or prescribe, and that innovations in

medical device technology are not stifled by unnecessary restrictions.” 62 Fed. Reg. 65384, 65385 (Dec. 12, 1997) (proposed amendment to 21 CFR § 808.1) (quoting H.R. Rep. No. 853, 94th Cong., 2d Sess. 8 (1976)). A plurality of the Supreme Court read the last clause as not limiting personal injury lawsuits in any way, but this was clearly not the view of a majority. *Medtronic*, ___ U.S. at ___, 116 S. Ct. at 2253 (Stevens, J., plurality) ; *id.* at 2261-2262 (Breyer, J., concurring).

While it seems clear both from the statute and the *Medtronic* opinions that Congress did not intend FDA approval of a device to insulate the manufacturer from all liability for injuries resulting from its use, it seems equally clear that Congress did not intend FDA approval as merely a precondition for marketing the device. For one thing, by approving a device the FDA not only allows it to be marketed but prohibits it from being marketed in any way other than as approved. 21 C.F.R. § 814.80 (1997). FDA approval is more of a substantive regulation and not merely a license to sell. For another, FDA review is substantive and regulatory. To obtain premarketing approval, the design, manufacture, distribution, and use of a device are all subject to thorough scrutiny by a panel of experts. The FDA requires adherence to specified standards. Furthermore, if Congress intended only that FDA approval be a prerequisite to marketing of a device and nothing more, there would be little if any need for any preemption provision at all. If FDA approval meant nothing more than that a manufacturer could market a device subject to any and all liability claims that might be made, then JUSTICE STEVENS was correct: preemption of such claims would be “rare indeed”. *Medtronic*, ___ U.S. at ___, 116 S. Ct. at 2259 (Stevens, J., plurality). A majority of the Supreme Court expressly rejected this view. *Id.* at 2262 (Breyer, J., concurring); *id.* (O’Connor, J., concurring and dissenting).

In the expansive area between conclusive approval of a device and mere licensure, however, we are unable to find a clear indication of how Congress intended state and federal regulation of medical devices to be balanced to ensure safety and instill confidence but not stifle innovation. Neither the statute nor the *Medtronic* opinions suggest a general unified theory of medical device regulation to guide preemption analysis. Short of that, there do appear to be two or three basic rules.

C

Second: The more specific a federal requirement under the MDA is, the more likely that that requirement will be deemed preemptive. The FDA’s regulation construing the MDA’s preemption provision states: “State or local requirements are preempted only when the Food and Drug Administration has established *specific* counterpart regulations or there are other *specific* requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the *specific* Food and Drug Administration requirements.” 21 C.F.R. § 808.1(d) (emphasis added). JUSTICE STEVENS’ and JUSTICE BREYER’S opinions both endorse this construction of the statute, *Medtronic*, ___ U.S. at ___, 116 S. Ct. at 2257 (Stevens, J.) & 2260-2261 (Breyer, J., concurring), although neither opinion rules out giving a general federal requirement preemptive effect. JUSTICE STEVENS states: “Although we do not believe that this statutory and regulatory language necessarily precludes ‘general’ federal requirements from ever pre-empting state requirements, or ‘general’ state requirements from ever being pre-empted, it is impossible to ignore its overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest.” *Id.* at 2257 (Stevens, J., majority).

A determination by the FDA that one device is substantially similar to another is too general to have preemptive effect. On this the Supreme Court was unanimous. In JUSTICE O’CONNOR’S words, “the § 510(k) process seeks merely to establish whether a pre-1976 device and a post-1976 device are equivalent, and places no ‘requirements’ on a device”. *Medtronic*, ___ U.S. at ___, 116 S. Ct. at 2264 (O’Connor, J., concurring and dissenting). A majority of the Supreme Court also rejected the argument that the FDA’s Good Manufacturing Practice regulations, 21 C.F.R. §§ 820.20-.198 (1997), and labeling requirements, *id.* § 801.109, are specific enough to have preemptive effect. *Medtronic*, ___ U.S. at ___, 116 S. Ct. at 2256-2257 (Stevens, J., majority). A majority of the Court does not suggest whether premarketing approval might have preemptive effect but does contrast the PMA and § 510(k) processes:

[T]he “premarket approval,” or “PMA” process, is a rigorous one. Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission.

* * *

The § 510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours. As one commentator noted, “[t]he attraction of substantial equivalence to manufacturers is clear. [Section] 510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly.”

Medtronic, ___ U.S. at ___, 116 S. Ct. at 2247 (Stevens, J., majority) (citations omitted). Three times on one page the majority calls the PMA process “rigorous”. *Id.*

D

Third: Causes of action for damages based on state law impose requirements within the meaning of the MDA. In JUSTICE O’CONNOR’S words, “state common-law damages actions do impose ‘requirements’ and are therefore pre-empted where such requirements would differ from those imposed by the FDCA.” *Medtronic*, ___ U.S. at ___, 116 S. Ct. at 2262 (O’Connor, J., concurring and dissenting). Citing the holding in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521-522 (1992) (plurality opinion), *id.* at 548-549 (Scalia, J., concurring and dissenting), JUSTICE O’CONNOR added:

Whether relating to the labeling of cigarettes or the manufacture of medical devices, state common-law damages actions operate to require manufacturers to comply with common-law duties. As *Cipollone* declared, in answer to the same argument raised here that common-law actions do not impose requirements, “such an analysis is at odds both with the plain words” of the statute and “with the general understanding of common-law damages actions.” If § 360k’s language is given its ordinary meaning, it clearly pre-empts any state common-law action that would impose a requirement different from, or in addition to, that applicable under the FDCA — just as it would pre-empt a state statute or regulation that had that effect.

Medtronic, ___ U.S. at ___, 116 S. Ct. at 2262-2263 (O’Connor, J., concurring and dissenting) (citation omitted). JUSTICE BREYER stated, “I basically agree with Justice O’CONNOR’S discussion of this point and with her conclusion”, *id.* at 2259 (Breyer, J., concurring), and added: “I believe that ordinarily, insofar as the MDA pre-empts a state requirement embodied in a state statute, rule,

regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action”, *id.* at 2260. JUSTICE O’CONNOR acknowledged JUSTICE BREYER’s agreement, *id.* at 2263 (O’Connor, J., concurring and dissenting), thus confirming that the view she expressed was that of a majority of the Supreme Court. JUSTICE STEVENS’ contrary view that “[i]t will be rare indeed for a court hearing a common-law cause of action to issue a decree that has ‘the effect of establishing a substantive requirement for a specific device’”, *id.* at 2259 (citation omitted), was expressly rejected by a majority of the Supreme Court. *Id.* at 2262 (Breyer, J., concurring); *id.* (O’Connor, J., concurring and dissenting).

However, the portions of JUSTICE STEVENS’ opinion joined by JUSTICE BREYER include the following passage:

[T]he general state common-law requirements in this case were not specifically developed “with respect to” medical devices. Accordingly, they are not the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements. The legal duty that is the predicate for the Lohrs’ negligent manufacturing claim is the general duty of every manufacturer to use due care to avoid foreseeable dangers in its products. Similarly, the predicate for the failure to warn claim is the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use. These general obligations are no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a workforce. These state requirements therefore escape pre-emption, not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be “with respect to” specific devices such as pacemakers.

Id. at 2258 (Stevens, J., majority). There is some tension between this view and that expressed by JUSTICE BREYER in his own opinion, as well as with the view expressed by JUSTICE O’CONNOR and with which JUSTICE BREYER expressly agreed. To reconcile these views, we take JUSTICE BREYER’s position to be that while a federal requirement would ordinarily not preempt general state common law requirements such as a duty of care or a duty to warn in the abstract, a federal requirement would preempt a particularized application of such duties that imposed a specific “standard of care or behavior” different or in addition to the federal requirement. *Id.* at 2260 (Breyer, J., concurring). We think this is reflected in the example JUSTICE BREYER chose to illustrate his position:

Imagine that, in respect to a particular hearing aid component, a federal MDA regulation requires a 2-inch wire, but a state agency regulation requires a 1-inch wire. If the federal law, embodied in the “2-inch” MDA regulation, pre-empts the state “1-inch” agency regulation, why would it not similarly pre-empt a state law tort action that premises liability upon the defendant manufacturer's failure to use a 1-inch wire (say, an award by a jury persuaded by expert testimony that use of a more than 1-inch wire is negligent)? The effects of the state agency regulation and the state tort suit are identical. To distinguish between them for pre-emption purposes would grant greater power (to set state standards “different from, or in addition to” federal standards) to a single state jury than to state officials acting through state administrative or legislative lawmaking processes. Where Congress likely did not focus specifically upon the matter, I would not take it to have intended this anomalous result.

Id. at 2259-2260 (citation omitted). Inasmuch as it appears that the dissenting Justices would not disagree with this example, we take it to be the view of a majority of the Supreme Court that a federal requirement concerning a device can preempt a suit in which the claim is that the device should have been made or marketed differently provided, as we have already observed, the federal requirement is sufficiently specific.

E

Fourth: FDA regulations guide construction of the MDA's preemption provision but are not controlling. In expressing her disagreement, JUSTICE O'CONNOR summarized the other opinions as follows:

To reach its particularized reading of the statute, the Court imports the interpretation put forth by the FDA's regulations. Justice BREYER similarly relies on the FDA regulations to arrive at an understanding of § 360k. *Ante*, at 2260-61. Apparently recognizing that *Chevron* deference is unwarranted here, the Court does not admit to deferring to these regulations, but merely permits them to “infor[m]” the Court's interpretation. *Ante*, at 2255. It is not certain that an agency regulation determining the pre-emptive effect of *any* federal statute is entitled to deference, cf. *Smiley v. Citibank (South Dakota), N.A.*, 517 U.S., at ---, 116 S. Ct., at 1734, but one pertaining to the clear statute at issue here is surely not. “If the statute contains an express pre-emption clause, the task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.” *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664, 113 S. Ct. 1732, 1737, 123 L.Ed.2d 387 (1993). Where the language of the statute is clear, resort to the agency's interpretation is improper. See *Chevron U.S.A. Inc., v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-843, 104 S. Ct. 2778, 2781-2782, 81 L.Ed.2d 694 (1984). Title 21 U.S.C. § 360k(a)(1) directs the pre-emption of “any [state] requirement” “which is different from, or in addition to, any requirement applicable under [the FDCA] to the device.” As explained above, and as Justice BREYER agrees, *ante*, at 2259-60, the term “requirement” encompasses state common-law causes of action. The Court errs when it employs an

agency's narrowing construction of a statute where no such deference is warranted. The statute makes no mention of a requirement of specificity, and there is no sound basis for determining that such a restriction on "any requirement" exists.

Medtronic, ___ U.S. at ___, 116 S. Ct. at 2263 (O'Connor, J., concurring and dissenting) (emphasis in original). As JUSTICE O'CONNOR notes, although JUSTICE STEVENS stated that "Congress has given the FDA a unique role in determining the scope of § 360k's pre-emptive effect", and that "the agency is uniquely qualified to determine whether a particular form of state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,' and, therefore, whether it should be pre-empted", *id.* at 2255 (Stevens, J., majority) (citation omitted), he stopped short of giving the FDA's regulations controlling authority. Rather, he stated: "The ambiguity in the statute — and the congressional grant of authority to the agency on the matter contained within it — provide a 'sound basis' for giving substantial weight to the agency's view of the statute." *Id.* at 2256 (citation omitted). In JUSTICE BREYER'S words, the FDA should be given "a degree of leeway to determine which rules, regulations, or other administrative actions will have pre-emptive effect." *Id.* at 2260 (Breyer, J., concurring).

Both opinions accept the FDA regulation's limitation of preemption to "specific" requirements. Whether a majority of the Supreme Court would accept further limitations by the FDA is unclear. Presumably, JUSTICE BREYER would hold that a "2-inch" requirement on a hearing aid wire would preempt a different state requirement, even if the FDA thought it should not. After all, the scope of preemption has been set by Congress, and the agency has no discretion to prescribe either or more or less preemptive effect to its actions. The agency can only provide guidance in assessing the regulatory scheme as a factor in discerning Congressional intent in the statute.

III

With these precepts we now attempt to determine whether the present action is preempted. We look first to the FDA's actions with respect to Zyderm, then to Worthy's claims.

A

1

Since *Medtronic*, several courts have considered whether the PMA process results in requirements specific enough to be given preemptive effect. Most have answered yes. *Mitchell v. Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997); *Easterling v. Cardiac Pacemakers, Inc.*, ___ F. Supp. ___, ___ (E.D. La. 1997) (“[T]he FDA’s affirmative approval of the device and its subsequent modifications [in the PMA process] constitute device-specific requirements.”); *Milkiewicz v. Baxter Healthcare Corp.*, 963 F. Supp. 1150, 1156 (M.D. Fla. 1996) (“[A]s a result of the PMA process, the FDA regulates the particular device undergoing review by ensuring that it meets specific requirements, then provides approval for those devices ‘that have been shown to be safe and effective and that otherwise meet the statutory criteria for approval.’ 21 C.F.R. § 814.2(a).”); *Steele v. Collagen Corp.*, 63 Cal. Rptr. 2d 879, 882 (Cal. Ct. App. 1997) (“Most courts that have dealt with the issue of MDA preemption with respect to Class III devices that have passed through the PMA process, including cases involving Zyderm, have concluded that some or all state common law claims are preempted.”); *Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763, 771 (Cal. Ct. App. 1996) (“[I]n approving [the product] through the PMA process, the FDA imposed federal requirements specific to that product which govern virtually every aspect of its production and sale.”); *Kernats v. Smith Indus. Medical Sys. Inc.*, 669 N.E.2d 1300, 1308 (Ill. App. Ct.), app. denied 675 N.E.2d. 634 (1996), *cert. denied*, ___ U.S. ___, 118 S.Ct. 684 (1998)(“We conclude, as have the majority of courts, that the PMA process is a specific federal requirement.”); *Mears v. Marshall*, 944 P.2d 984, 993 (Or. Ct. App. 1997) (“Without question, [the PMA process completed by Zyderm] established requirements that governed nearly every aspect of Zyderm’s commercial existence.”); *Green v. Dolsky*, 685 A.2d 110, 117 (Pa. 1996), *cert. denied*, ___ U.S. ___, 117 S. Ct. 1695 (1997); *Fry v. Allergan Medical Optics*, 695 A.2d 511, 516 (R.I. 1997), *cert. denied*, ___ U.S. ___, 118 S. Ct. 374 (1997) (“We conclude that the premarket approval process constitutes a specific federal interest as contemplated in *Medtronic* and that, therefore, the FDA approval served to impose strict FDA requirements upon the defendant.”); *Wutzke v. Schwaegler*, 940 P.2d 1386, 1391 (Wash. Ct. App. 1997) (“The general consensus is that the rigorous process of the PMA results in approval

of a device's design that rises to the level of specific federal requirements.”). *See also Michael v. Shiley, Inc.*, 46 F.3d 1316, 1324 (3d Cir.), *cert. denied*, ___ U.S. ___, 116 S. Ct. 67 (1995); *Martello v. Ciba Vision Corp.*, 42 F.3d 1167, 1169 (8th Cir. 1994), *cert. denied*, ___ U.S. ___, 115 S. Ct. 2614 (1995); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1422-1423 & n.3, 1424 n.8 (5th Cir. 1993); *King v. Collagen Corp.*, 983 F.2d 1130, 1134 (1st Cir.), *cert. denied*, 510 U.S. 824 (1993) (all pre-*Medtronic* cases). As the Seventh Circuit has observed in connection with *Zyderm*:

During the PMA process, the federal government, it can truly be said, has “‘weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.’”

Mitchell, 126 F.3d at 911 (quoting *Papike v. Tambrands, Inc.*, 107 F.3d 737, 741 (9th Cir. 1997), *cert. denied*, ___ U.S. ___, 118 S. Ct. 166 (1997), in turn quoting *Medtronic*, ___ U.S. at ___, 116 S. Ct. at 2258 (Stevens, J., majority)).

A relatively small but insistent minority of courts have held that the PMA process does not in itself result in preemptive federal requirements. *Lakie v. SmithKline Beecham*, 965 F. Supp. 49, 54 (D.D.C. 1997) (“The fact that the PMA process requires certain information and mandates certain procedures from manufacturers does not transform the PMA process *itself* into a specific federal requirement which triggers preemption and protects a manufacturer from suit.”); *Comeau v. Heller*, 945 F. Supp. 7, 12 (D. Mass. 1996) (“The Supreme Court was well aware of the distinction between a PMA-approved device and a § 510(k)-approved device, yet it failed to limit the *Medtronic* holding to the latter.”); *Walker v. Johnson & Johnson Vision Prods., Inc.*, 552 N.W.2d 679, 684 (Mich. Ct. App. 1996) (“While most federal and state courts that have considered similar arguments have concluded that the premarket approval process satisfies the FDA’s preemption rule and preempts state common-law claims, we agree with the court in [*Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1458-1459 (9th Cir. 1995), *cert. denied*, ___ U.S. ___, 116 S. Ct. 2579 (1996)] that these courts have failed to consider whether Class III medical devices as a group can constitute a ‘particular device’ within the FDA’s understanding of that term.”); *Sowell v. Bausch & Lomb, Inc.*, 656 N.Y.S.2d 16,

20 (N.Y. App. Div. 1997) (“[W]hile a PMA review is considerably more rigorous and detailed than the premarket notification process at issue in *Medtronic*, it is, in fact, no more ‘specific’ a requirement.”). See also *Kennedy*, 67 F.3d at 1458-1459 (a pre-*Medtronic* case); *Connelly v. Iolab Corp.*, 927 S.W.2d 848, 853 (Mo. 1996), cert. dismissed, ___ U.S. ___, 117 S. Ct. 2429 (1997); c.f. *Hernandez v. Coopervision, Inc.*, 691 So.2d 639, 641 (Fla. Dist. Ct. App. 1997). The views of these courts are summarized in *Sowell*:

[T]he mere fact that a product has received a PMA, a procedure that was instituted with the purpose of benefitting and protecting consumers, is not a reason to forever shield its distributors from State tort actions based on harm caused by the product. Indeed, it is inconceivable that Congress would have provided for such a draconian result without making itself more explicit.

Sowell, 656 N.Y.S.2d at 21. Or as the pre-*Medtronic* opinion in *Kennedy* said: “Premarket approval is supposed to benefit consumers, not create a rose garden, free from liability, for manufacturers.” *Kennedy*, 67 F.3d at 1460.

The courts that have considered whether the less rigorous, though still specific, IDE — investigational device exemption — process results in preemptive requirements are evenly divided. Four have given IDE approval preemptive effect. *Chambers v. Osteonics Corp.*, 109 F.3d 1243, 1247-1248 (7th Cir. 1997) (negligent manufacturing claims, however, were not preempted); *Martin v. Telectronics Pacing Sys., Inc.*, 105 F.3d 1090, 1097 (6th Cir. 1997), cert. denied, ___ U.S. ___, 1988 W.L. 15431 (January 20, 1998) (“Unlike the general federal requirements discussed in *Medtronic*, the regulations governing investigational devices are essentially device specific.”); *Chmielewski v. Stryker Sales Corp.*, 966 F. Supp. 839, 843 (D. Minn. 1997) (“Given the intense nature of the IDE approval process, most courts agree that it imposes device-specific federal requirements.”) (negligent manufacturing claims, however, were not preempted); *Berish v. Richards Medical Co.*, 937 F. Supp. 181, 185 (N.D.N.Y. 1996) (IDEs are subject to regulations that “‘set forth detailed procedures for determining whether [IDEs] are safe and effective’” and that are “‘promulgated for application, not generally to all devices, but to IDEs specifically.’” (citation omitted)). Four have not. *Shea v. Oscor Medical Corp.*, 950 F. Supp. 246 (N.D. Ill. 1996); *Niehoff*

v. Surgidev Corp., 950 S.W.2d 816 (Ky. 1997); *Connelly v. Iolab Corp.*, 927 S.W.2d 848 (Mo. 1996), *cert. dismiss'd*, ___ U.S. ___, 117 S. Ct. 2429 (1997); *Baird v. American Medical Optics*, 693 A.2d 904 (N.J. Super. Ct. App. Div. 1997).

Thus, the post-*Medtronic* decisions are divided over whether FDA premarketing approval alone is a specific federal preemptive requirement, but the majority view is that such approval is preemptive of at least some state requirements.

2

Complicating the matter further, however, the FDA has recently expressed its own disagreement with this view of a majority of the courts. On December 12, 1997, the FDA published for comment a proposed rule on MDA preemption to amend or replace section 808.1 of its existing regulations, 21 C.F.R. § 808.1 (1997), “to clarify and codify the agency’s longstanding position that available legal remedies, including State common law tort claims, generally are not preempted under the [FDCA].” 62 Fed. Reg. 65384, 65384, 65388 (Dec. 12, 1997). Noting the conflict in the courts over the preemptive effect of the PMA and IDE processes, the FDA stated:

FDA believes that its general regulatory review and approval processes provide a significant measure of protection against the marketing of dangerous or defective medical devices. FDA does not believe, however, that those processes can guarantee the safety of such devices. Accordingly, compliance with general FDA requirements should not broadly preempt State common law remedies, which provide an important (and frequently the only) mechanism for persons to seek redress for injuries resulting from defective medical devices. FDA notes below several situations in which the agency's regulatory activities will typically not preempt State law remedies.

First, FDA's general clearance and approval processes, such as the clearance for marketing under section 510(k) of the act [21 U.S.C. § 360(k)]; the grant premarket approval under section 515 of the act [21 U.S.C. § 360e]; or the grant of an IDE under section 520(g) of the act [21 U.S.C. § 360j(g)], do not, by themselves, preempt State common law claims. Section 521 of the act [21 U.S.C. § 360k] provides for preemption of a State common law duty only if it imposes a requirement that is different from, or in addition to, a specific substantive requirement pertaining to the particular device that has been imposed by or under the act. FDA's action in clearing a product for marketing or granting an application for a PMA or an IDE signifies that the manufacturer's proposal for marketing or use of the device in question satisfies the relevant statutory and regulatory criteria for the clearance, approval, or exemption. It does not signify, however, that Congress or FDA has established a specific Federal requirement (e.g., with respect to the design of the device) that supplants a State common law duty.

Second, FDA's notification of deficiencies in, or proposal of modifications to, an application for a PMA or an IDE does not, as a general matter, create specific Federal requirements that have preemptive effect.

62 Fed. Reg. at 65387. The FDA added, however, that it does not view the proposed rule as a change in its position regarding MDA preemption:

This proposed rule would make no change in the agency's prior or current construction of the scope of section 521 of the act. Rather, the rule would simply clarify and codify the agency's longstanding interpretation of the scope of section 521 of the act as generally not preempting available legal remedies, including State common law tort claims.

Id.

As we have noted, *Medtronic* requires only that the scope of MDA preemption be informed by FDA regulations, not that courts completely defer to them. Preemption is determined by Congress, not the FDA. *Medtronic* itself accepted from section 808.1 only the limitation that federal and state requirements be “specific”. Nevertheless, we are mindful of the view of a majority of the Supreme Court that the FDA is in a unique position to determine the scope of preemption because of its role in the creation of preemptive federal requirements. Accordingly, we conclude that while a majority of courts since *Medtronic* have viewed PMA and IDE requirements as preemptive, largely irrespective of the details of those requirements, we must look more closely to determine whether such requirements have preemptive effect with respect to a particular device.

3

Prior to *Medtronic*, most courts held that the FDA’s approval of Zyderm preempted claims that it was unsafe. *Mitchell v. Collagen Corp.*, 67 F.3d 1268 (7th Cir. 1995), *cert. granted & judgment vacated*, 518 U.S. ___, 116 S. Ct. 2576 (1996); *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 510 U.S. (1993); *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, 510 U.S. 824 (1993); *Blanchard v. Collagen Corp.*, 909 F. Supp. 427 (E.D. La. 1995); *Tucker v. Collagen Corp.*, 1994 WL 87367 (N.D. Ill. 1994); *Mears v. Marshall*, 909 P.2d 212 (Or. Ct. App. 1996); 905 P.2d 1154 (Or. Ct. App. 1995), *vacated*, 921 P.2d 966 (Or. 1996), *on remand*, 944 P.2d 984, 993 (Or. Ct. App. 1997)(post-*Medtronic* opinion). *Contra Kennedy v. Collagen*

Corp., 67 F.3d 1453 (9th Cir. 1995), *cert. denied*, ___ U.S. ___, 116 S. Ct. 2579 (1996); *Fiore v. Collagen Corp.*, 930 P.2d 477 (Ariz. Ct. App. 1996).

Since *Medtronic*, most courts have continued to hold that federal requirements on Zyderm preempt most state claims of personal injuries caused by the product. *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997); *Steele v. Collagen Corp.*, 63 Cal. Rptr. 2d 879 (Cal. Ct. App. 1997); *Green v. Dolsky*, 685 A.2d 110 (Pa. 1996), *cert. denied*, ___ U.S. ___, 117 S. Ct. 1695 (1997). *Contra Rodriguez-Suris v. Montesinos*, 935 F. Supp. 71, 75 n. 3 (D. Puerto Rico 1996) (court denied summary judgment based upon MDA preemption grounds); *Mears v. Marshall*, 944 P.2d 984 (Or. Ct. App. 1997).

We believe the details of the FDA’s premarketing approval of Zyderm — as opposed to the PMA process in general — are sufficiently specific to have preemptive effect. Collagen’s submissions to the FDA state in detail how the product is manufactured, what its typical immunogenic effect is, what data has resulted from clinical and serological tests, what instructions are given physicians for using the product, what instructions are given patients concerning the product. As we have already noted, Collagen’s eight volumes of material were reviewed for over a year by the FDA’s panel of experts. The FDA then approved Zyderm, subject to certain detailed conditions. Announcing the order granting approval, the FDA stated that Zyderm “had been shown to be safe and effective”. 46 Fed. Reg. 46394 (1981). Ten years later the FDA again reviewed the product and again found it to be safe. As with other products, the FDA prohibited the manufacture or marketing of the product in a manner inconsistent with these conditions. 21 C.F.R. § 814.80 (1997). Given the specificity of Collagen’s presentation to the FDA, the specificity of the FDA’s conditions in granting approval, the amount of time required to obtain approval, the recurrence of the investigation a decade later, the prohibition against deviation from the conditions of approval, and the specific finding by the FDA that Zyderm was “safe and effective”, we conclude that the FDA’s requirements concerning Zyderm are entitled to preemptive effect under the MDA as construed and applied in *Medtronic*.

B

We must next consider whether Worthy's claims are preempted. As we have explained, Worthy's claims are solely for violations of the DTPA. Although these are statutory claims, they are similar to common law claims for negligence, breach of warranty, and products liability. In fact, as we noted, Worthy asserted the latter claims earlier in the litigation. *Medtronic* specifically refers to state common law claims rather than claims for violation of a state consumer statute. We see no difference in substance between the two, at least in these circumstances.

Worthy's petition alleges that Collagen represented that Zyderm (and a related product, Zyplast) was safe for her use as a cosmetic device, and that such representations were false, misleading, and deceptive because Worthy developed serious immunological damage and injuries, including autoimmune injuries and damage, and physical deformities and injuries. Worthy alleged that Collagen violated the DTPA by misrepresenting the uses, benefits, standard, quality, and grade of goods; by failing to disclose pertinent information to induce Worthy to use Zyderm; and by breaching the implied warranty that Zyderm was fit for its ordinary purposes. Worthy also alleged that Collagen's conduct was unconscionable.

In essence, Worthy claims that Zyderm was not safe for her use. She does not contend that Zyderm was manufactured, marketed, or injected in her in any way other than that approved by the FDA. To prevail, therefore, Worthy must prove that Zyderm as approved by the FDA is not safe. This contradicts not only the FDA's specific finding to the contrary but also the manufacturing, distribution, and labeling protocols approved by the FDA. Collagen cannot both market Zyderm in compliance with FDA requirements and not market Zyderm because it is unsafe. This is not the situation that existed in *Medtronic*. There the plaintiff could obtain a finding that Medtronic's pacemaker was unsafe that did requirements specifically and directly contradict what Worthy must prove in order to prevail in her action.

Moreover, we believe that even if the federal requirements for Zyderm could be viewed as not directly conflicting with a judgment favorable to Worthy in her action, claims like hers "stand[]

as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,” *Medtronic*, ___ U.S. at ___, 116 S. Ct. at 2261 (Breyer, J., concurring) (citation omitted), as those purposes and objectives relate to this one product. One purpose of Congress is that there be a federal determination whether a device is safe “with respect to the persons for whose use the device is represented or intended, with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.” 21 U.S.C. § 360c(a)(2) (subdivision designations omitted). If an action like Worthy’s is not preempted, then we are unsure what kind of action would ever be preempted.

As we have previously noted, most courts since *Medtronic* that have considered the issue have concluded as we do that suits challenging the safety of Zyderm are preempted.

* * * * *

For the reasons we have explained, the judgment of the court of appeals is

Affirmed.

Nathan L. Hecht
Justice

OPINION DELIVERED: February 13, 1998