IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ARDIS McCUTCHEON, Plaintiff,	)	
v.	)	No. 06 C 6256
ZIMMER HOLDINGS, INC., et al., Defendants.	)	

MEMORANDUM OPINION AND ORDER

Ardis McCutcheon ("McCutcheon") brought this product liability action against Zimmer Holdings, Inc., Zimmer US, Inc., Zimmer, Inc., Zimmer Daniel Associates and Zimmer Smith Associates (collectively "Zimmer," treated here as a singular noun to avoid awkwardness in this opinion's verb usage), asserting that Zimmer had defectively designed and manufactured an artificial knee replacement device known as the Natural Knee II ("N-K II") that was implanted in McCutcheon's knee in 1998. As a result of the N-K II's assertedly defective nature, McCutcheon says she experienced pain and suffering and incurred significant medical expenses associated with a second knee replacement surgery she was forced to undergo in 2004.

Zimmer has now moved for summary judgment under Fed. R. Civ. P. ("Rule") 56. For the reasons stated in this opinion, its motion is granted.

Summary Judgment Standards

Every Rule 56 movant bears the burden of establishing the

absence of any genuine issue of material fact (Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986)). For that purpose courts consider the evidentiary record in the light most favorable to nonmovants and draw all reasonable inferences in their favor (Lesch v. Crown Cork & Seal Co., 282 F.3d 467, 471 (7th Cir. 2002)). But to avoid summary judgment a nonmovant "must produce more than a scintilla of evidence to support his position" that a genuine issue of material fact exists (Pugh v. City of Attica, 259 F.3d 619, 625 (7th Cir. 2001)) and "must set forth specific facts that demonstrate a genuine issue of triable fact" (id.). Ultimately summary judgment is warranted only if a reasonable jury could not return a verdict for the nonmovant (Anderson v. Liberty Lobby, Inc., 466 U.S. 242, 248 (1986)).

This District Court has implemented Rule 56 through its LR 56.1, which requires both sides to submit factual statements supported by record evidence. As to any nonmovant (such as McCutcheon) who seeks to avoid summary judgment, LR 56.1(b)(3)(B) calls for "a response to each numbered paragraph in the moving party's statement, including, in the case of any disagreement, specific references to the affidavits, parts of the record, and other supporting materials relied upon." In addition LR 56.1(b)(3)(C) requires the nonmovant to submit "a statement, consisting of short numbered paragraphs, of any additional facts [not set out in the movant's papers] that require the denial of

summary judgment...."

McCutcheon and her counsel have not complied with LR 56.1. They did not file the required response to Zimmer's LR 56.1(a)(3) statement, nor did they file a statement of additional facts. Instead they have merely sprinkled various asserted facts into a memorandum that is otherwise wholly dedicated to advancing legal arguments as to why Zimmer's motion should be denied. Even more critically, they have not supported any of those asserted facts with admissible evidence such as exhibits or affidavits.

Put simply, McCutcheon's response--or nonresponse, really--to Zimmer's 56.1(a) statement is wholly inadequate. Under LR 56.1's enforcement provision, "[a]ll material facts set forth in the statement required of the moving party will be deemed to be admitted unless controverted by the statement of the opposing party." And our Court of Appeals has "consistently held that a failure to respond by the nonmovant as mandated by the local rules results in an admission" of facts (Smith v. Lamz, 321 F.3d 680, 683 (7th Cir. 2003)). What follows then is a summary of the facts as advanced by Zimmer in its LR 56.1 statement.[1]

Factual Background

N-K II is an artificial knee replacement device designed and

[1] This opinion cites to Zimmer's LR 56.1(a)(3) statement and exhibits as "Z. St. ¶--" and "Z. Ex. --" and to Zimmer's memorandum as "Z. Mem. --." McCutcheon's responsive memorandum will be cited "M. Mem. --."

manufactured by Zimmer (Z. Mem. 1, Z. St. ¶11). It has been classified by the Food and Drug Administration ("FDA") as a Class III medical device and was approved by the same agency through an extensive process known as premarket approval (Z. St. ¶¶7-8).

Zimmer began the premarket approval process on January 12, 1994 when it submitted an application to the FDA regarding the Natural-Knee® System with Cancellous Structured Titanium™ ("Natural-Knee")(Z. St. ¶9). On May 21, 1996 Zimmer tendered an amendment to its pending application, seeking to expand it so that it would include the N-K II as well (Z. St. ¶10).

As required by the FDA, Zimmer's premarket approval application contained detailed information as to the design, operation, manufacturing methods and processes, quality control procedures, marketing and distribution of the N-K II (Z. St. ¶¶9, 11). It also contained descriptions of all clinical and non-clinical laboratory studies concerning the N-K II, copies of all proposed labeling, operating instructions, literature and advertising for the device and a bibliography of published reports concerning its safety and effectiveness (id.). And in response to questions later posed by the FDA, Zimmer provided the agency with even more data, information and supporting documents (Z. St. ¶12).

On March 21, 1997 the FDA approved Zimmer's premarket approval application for both the Natural-Knee and the N-K II (Z.

St. ¶13). Since that time the FDA has subjected both devices to several post-marketing requirements (Z. St. ¶14). For instance, Zimmer must submit (1) a premarket approval supplement that the FDA reviews before Zimmer can make any changes to the design, manufacturing or warnings of the devices, (2) annual FDA post-approval reports that satisfy the regulations in 21 C.F.R. §814.84 and (3) in some specified circumstances, adverse reaction and device defect reports (id.). Zimmer must also complete a post-approval survivorship study designed to evaluate the nine-year survivorship of its two devices (Z. St. ¶15). As part of that last requirement, Zimmer must provide the FDA with a post-approval study protocol and, continuing through the end of the post-approval study, annual progress reports summarizing survivorship data and patient accounting (id.).

On August 10, 1998 McCutcheon underwent knee replacement surgery during which the N-K II device was implanted in her right knee (Z. St. ¶3). Six years later (on September 10, 2004) that device was surgically removed from McCutcheon's knee (Z. St. ¶4). According to McCutcheon, that removal was necessary to "repair and prevent further osteolysis" caused by the 1998 knee replacement (Z. St. ¶5).

Manufacturing records for the specific N-K II implanted in McCutcheon show that all of its components were manufactured according to FDA-approved specifications (Z. St. ¶18). In

addition, during the time that McCutcheon was implanted with the N-K II the device remained an approved Class III medical device under continuing FDA supervision and in compliance with all relevant requirements in 21 U.S.C. §§360c-360k, part of the Medical Device Amendments of 1976 ("MDA") to the Federal Food, Drug and Cosmetic Act (21 U.S.C. §§301-399a)(Z. St. ¶17). As of March 7, 2008--the date Zimmer filed its motion for summary judgment--the N-K II remained an approved medical device (Z. St. ¶16).

Nearly two years after the 2004 surgery, McCutcheon brought this product liability action in Illinois state court, alleging that the N-K II was defectively designed and manufactured using materials "prone to wear" and that Zimmer was liable under theories of strict liability, negligence and breach of warranties (Z. St. ¶¶1, 5-6).[2] Zimmer removed the action to this District Court on the premises (1) that federal jurisdiction was conferred by the requisite diversity of the parties' citizenship[3] and (2) that venue was proper in this judicial district because McCutcheon resided in Palatine, Illinois (Z. St. ¶2). Zimmer later filed the current motion.

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[2] Those theories are part of a single claim--see NAACP v. American Family Mut. Ins. Co., 978 F.2d 287, 291-93 (7th Cir. 1992).

[3] See Appendix.

McCutcheon's State Law Claim Pre-empted by MDA

Zimmer asserts that McCutcheon's state law claim against it is pre-empted by an MDA provision, 21 U.S.C. §360k ("Section 360k"), as interpreted this past Term in Riegel v. Medtronic, Inc., 128 S.Ct. 999 (2008). Despite valiant efforts by McCutcheon's counsel to contend otherwise, Riegel compels the granting of Zimmer's motion for summary judgment.

Section 360k(a) of the MDA states:

> Except as provided in subsection (b) of this section [inapplicable here], no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

Riegel, 128 S.Ct. at 1006, 1011 held that the quoted language expressly pre-empts common-law claims if (1) the FDA has established federal requirements that apply to the device in question and (2) the asserted common-law claims are based on state requirements "that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness" (id. at 1006).

As to the first criterion, Riegel, id. at 1007 concluded that premarket approval--the process used by the FDA to sanction

the balloon catheter device at issue there--imposes federal "requirements" within the meaning of the MDA as that term had already been defined in Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996). Riegel, id. so held because premarket approval "is specific to individual devices," because "the FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness" and because the agency "requires a device that has received a premarket approval to be made with almost no deviations from the specifications in its approval application."

In addressing the second criterion, Riegel, id. easily concluded that the New York law applicable to the catheter "relates to the safety or effectiveness of the device" because "[s]afety and effectiveness are the very subjects of the Riegels' common-law claims." Having so decided, the Court then turned its attention to the separate issue whether a state's "tort duties constitute 'requirements' under the MDA" (id.). They do, Riegel held (id. at 1008, internal citations omitted):

> Absent other indication, reference to a State's 'requirements' includes its common-law duties. As the plurality opinion said in Cipollone [v. Liggett Group, Inc., 505 U.S. 504 (1992)], common-law liability is 'premised on the existence of a legal duty,' and a tort judgment therefore establishes that the defendant has violated a state-law obligation. And while the common-law remedy is limited to damages, a liability award "'can be, indeed is designed to be, a potent method of governing conduct and controlling policy.'"

And with respect to the New York tort laws at issue there,

Riegel, id. concluded that those laws clearly qualified as "requirements" under the analysis it had just set forth:

> In the present case, there is nothing to contradict this normal meaning. To the contrary, in the context of this legislation excluding common-law duties from the scope of pre-emption would make little sense. State tort law that requires a manufacturer's catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect.

As already stated, that line of analysis applies with equal force here. And as such, it dooms McCutcheon's common-law claims.

First, just like the balloon catheter device at issue in Riegel, the N-K II device implanted in McCutcheon's knee underwent the same extensive premarket approval process that under Riegel qualifies as proof that the FDA has established federal requirements applicable to the device. Second, the Illinois tort laws McCutcheon relied on in bringing her original action in the state court qualify as "requirements" for purposes of Section 360k(a). Moreover, McCutcheon has advanced no argument as to why those laws, unlike New York's, are not "different from, or in addition to" those established by the FDA, and in the absence of such a contention this Court must assume that the Illinois tort laws at issue here are more than just carbon copies of the relevant federal regulations. It follows that McCutcheon's state law claim is expressly pre-empted by Section 360k(a), and her product liability action must be

dismissed.

McCutcheon advances a number of contentions in an effort to stave off dismissal. Each, however, fails to survive analysis.

To begin with, M. Mem. 2-3 argues against pre-emption on the ground that Zimmer did not fully and honestly disclose to the FDA all potential risks associated with the N-K II that were known at the time of the premarket approval process. Without all the available information at its disposal, McCutcheon contends, the FDA was not able to assess accurately whether the N-K II warranted premarket approval.

That argument fails for two reasons. First, it has already been noted that McCutcheon has produced no evidence in response to Zimmer's motion. That leaves a vacuum in the record by way of substantiation of any purported failure to disclose known risks to the FDA. Second, even if that had not been so, McCutcheon's argument remains barred by the holding in Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 348 (2001) that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, the federal law [the MDA]." Although McCutcheon has not formally asserted that Zimmer violated some kind of Illinois prohibition against fraudulent representations to the FDA, her argument that Zimmer failed to disclose all relevant information to the agency essentially equates to that. Under Buckman, then, she cannot prevail.

M. Mem. 3-5 separately argues that Riegel does not control the outcome here because McCutcheon asserts defects in the N-K II--specifically, complications associated with the materials used in its design and manufacture--that were not discovered until after the FDA had granted premarket approval. By contrast, any injuries suffered by Charles Riegel (the patient whose medical complications gave rise to Riegel) were caused by "defects" of the catheter that came to light during the premarket approval process and that were clearly printed on the device's labeling (128 S.Ct. at 1005).[4] McCutcheon points to this footnote to Justice Ginsburg's one-Justice dissent in Riegel, 128 S.Ct. at 1013 n.1 as providing the necessary legal support for her argument:

> The Court's holding does not reach an important issue outside the bounds of this case: the pre-emptive effect of §360k(a) where evidence of a medical device's defect comes to light only after the device receives premarket approval.

But that footnote does not aid McCutcheon's attempt to

[4] To be clear, Riegel's death was not caused by "defects" associated with the catheter inserted into his coronary artery shortly after he suffered a heart attack, but rather by his doctor's failure to use that device properly. Riegel's doctor inserted the catheter into his "diffusely diseased and heavily calcified" right coronary artery, even though "the device's labeling stated that use was contraindicated for patients with diffuse or calcified stenoses" (128 S.Ct. at 1005). In addition the doctor ignored the fact that "[t]he label also warned that the catheter should not be inflated beyond its rated burst pressure of eight atmospheres," inflating it instead "to a pressure of 10 atmospheres" (id.).

distinguish Riegel, once again owing to a lack of admissible evidence that would support her version of the facts. McCutcheon has provided no evidentiary support for her ipse dixit (M. Mem. 4) that "significant discoveries" regarding the N-K II's shortcomings were made after the premarket approval process. Instead her Mem. 4-5 contains nothing more than a cursory discussion of three studies that, she claims, cast doubt on the safety of the materials used in the N-K II device at the time of her implant and hence provided the impetus for changes Zimmer later made to the N-K II's composition.

But no copies (let alone authenticated ones) of those studies are attached to McCutcheon's memorandum, nor has she produced any affidavits or deposition testimony from opinion witnesses attesting to the content of the studies or to the FDA's unawareness of the problems associated with the N-K II that the studies purportedly address.

With no evidence to support McCutcheon's claim that the facts of her case are materially distinguishable from those in Riegel, this Court has no choice but to accept the version of the facts advanced by Zimmer: that it fully complied with the requirements of the premarket approval process and that the N-K II remains an FDA-approved Class III medical device. Under that version of the facts, Riegel controls and McCutcheon's claim is

pre-empted.[5]

Finally, McCutcheon advances two other contentions that can be dispatched readily. This opinion turns to those arguments.

First, M. Mem. 5-7 urges that this Court should give weight to the state court decision in Weiland v. Telectronics Pacing Sys., Inc., 188 Ill.2d 415, 721 N.E.2d 1149 (1999), which held that the MDA's premarket approval process did not pre-empt state tort actions. But even in diversity cases where Erie v. Tompkins generally commands adherence to state law, the Constitution's Supremacy Clause dictates that state caselaw "does not control the resolution of issues governed by federal statute" (Budinich v. Becton Dickinson & Co., 486 U.S. 196, 198 (1988)). Instead state court precedents may at best provide no more than persuasive authority on matters of federal law (RAR, Inc. v. Turner Diesel, Ltd., 107 F.3d 1272, 1276 (7th Cir. 1997))--but here, where the pre-emption doctrine derives directly from the Supremacy Clause (Fifth Third Bank v. CSX Corp., 415 F.3d 741, 745 (7th Cir. 2005)), the question whether a federal statute pre-empts state law stems from federal law and is therefore governed by federal and not state court decisions.

So Weiland's potential for "persuasive" authority amounts to

[5] There is no reason then to decide one of the issues that the parties' memoranda dispute heavily: whether Justice Ginsburg's footnote accurately portrays the scope of Riegel as limited to situations where a device's defect at issue came to light during the premarket approval process.

no real authority at all here, given its direct conflict with the definitive decision in Riegel (see also Mitchell v. Collagen Corp., 126 F.3d 902 (7th Cir. 1997), holding that the premarket approval process can have pre-emptive effect under the MDA[6]).

Lastly M. Mem. 7-8 urges this Court to act, not as taught by Riegel and Mitchell, but rather according to a bill recently introduced in the House of Representatives that, if enacted, would overturn Riegel. But it would of course be irresponsible to ignore controlling Supreme Court and Seventh Circuit precedent in favor of prospective legislation. That final argument by McCutcheon is legally bankrupt.

Conclusion

There is no genuine issue of material fact, so that Zimmer is entitled to a judgment as a matter of law. Its Rule 56 motion is granted, and this action is dismissed with prejudice.

Milton I. Shadur
Senior United States District Judge

Date: August 6, 2008

[6] Although Weiland, 188 Ill.2d at 422-23, 721 N.E.2d at 1153-54 expressed the Illinois Supreme Court's freedom to differ with the Seventh Circuit's opinion in Mitchell (Riegel had not yet been decided), this Court is of course bound to follow our Court of Appeals (and, a fortiori, to follow the Supreme Court).