STATE OF ILLINOIS)
) SS.
COUNTY OF COOK)

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

KARL L. SANDA,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	No. 13 L 000305
	)	
MEDTRONIC, INC.; MEDTRONIC SOFAMOR DANEK USA, INC.; NORTHWESTERN MEMORIAL HOSPITAL; NORTHWESTERN ORTHOPAEDIC INSTITUTE, LLC; and MARK T. NOLDEN, M.D.,	)	
	)	
Defendants.	)	

Report of proceedings had at the hearing in the above-entitled cause before the HONORABLE EILEEN MARY BREWER, Judge of said Court, commencing at 12:05 p.m. on the July 18, 2013.

APPEARANCES:

RAPOPORT LAW OFFICES, P.C., by
MR. MICHAEL L. TEICH

On behalf of the Plaintiff;

BAUM, HEDLUND, ARISTEI, GOLDMAN, PC, by
MR. BIJAN ESFANDIARI

On behalf of the Plaintiff;

MAYER BROWN, LLP, by
MS. EMILY M. EMERSON
MR. ANDREW TAUBER
MR. DANIEL L. RING

On behalf of the Defendants Medtronic, Inc., and Medtronic Sofamor Danek USA, Inc.;

ANDERSON RASOR & PARTNERS, LLP, by
MR. ALBERT C. LEE

On behalf of the Defendant Northwestern Memorial Hospital;

CASSIDAY SCHADE, by
MR. THOMAS A. FITZGERALD

On behalf of the Defendants Northwestern Orthopaedic Institute, LLC, and Mark T. Nolden, M.D.

THE COURT: All right. Would you like to step up, please. Could you tell me who is arguing, please.

MR. RING: Sure, your Honor. My partner Andy Tauber will be arguing on behalf of Medtronic, Inc.

THE COURT: And you are Mr. Tauber?

MR. TAUBER: Mr. Tauber, yes.

THE COURT: T A U B E R T?

MR. TAUBER: Yes -- T A U B E R, no "T" at the end.

THE COURT: Oh, no "T," Tauber?

MR. TAUBER: Yes.

THE COURT: Okay. And your first name, sir?

MR. TAUBER: Andrew.

THE COURT: Thank you.

Okay.

MR. ESFANDIARI: And Bijan Esfandiari on behalf of the Plaintiff, your Honor.

THE COURT: Bijan ...

MR. ESFANDIARI: Bijan, B I --

THE COURT: J O N.

MR. ESFANDIARI: J A N.

THE COURT: Oh, J A N. Last name, please.

MR. ESFANDIARI: Esfandiari with an "E," E as in Edward, S as in Sam, F as in Frank, A as in apple, N as in Nancy, D as in David, I A R I.

THE COURT: So you're the Plaintiff's counsel?
MR. ESFANDIARI: Yes, your Honor.
THE COURT: And everyone else is just here for the ride and performance.
MR. LEE: Well, we have separate motions up.
THE COURT: The doctor?
MR. FITZGERALD: I have the doctor, your Honor.
MR. LEE: I have Northwestern Memorial Hospital.
THE COURT: I probably will not get to them today.
MR. LEE: Okay.
MR. FITZGERALD: Okay, your Honor.
THE COURT: So would everyone else like to sit down. Is that okay?
MR. RING: At your pleasure, your Honor. Thank you.
MS. EMERSON: Thank you, your Honor.
MR. TAUBER: I'll remain, your Honor.
THE COURT: I hope so.
Would you prefer to argue from a chair?
MR. TAUBER: I'm happy right here, your Honor.
THE COURT: Okay. Good.
You too, sir, you're all right?
MR. ESFANDIARI: Yeah. This is fine. This is new for me, this setting, this type of a setting being so

close.

THE COURT: We allow this here. Are you not from Illinois?

MR. ESFANDIARI: No, from California, your Honor.

THE COURT: Okay. Where do you argue?

MR. ESFANDIARI: Typically a podium far removed from the bench. Actually I enjoy this.

THE COURT: So you can't look at our notes?

MR. ESFANDIARI: I guess not.

THE COURT: You can actually look over and try to see what I have written.

MR. ESFANDIARI: I would not do that, your Honor.

THE COURT: That's quite all right. You won't be able to read my handwriting though.

So you would like to start, I assume, Mr. Tauber.

MR. TAUBER: Yes. It's our motion. It's probably appropriate.

THE COURT: Thank you, sir.

MR. TAUBER: Okay. Good afternoon, your Honor.

No fewer than six courts considering complaints arising from the alleged off-label promotion of the Infuse device, two federal courts and four state courts including this court through Judge Flanagan in

the *Wendt* case, have held that claims substantially identical to those asserted here are both expressly and impliedly preemptive.

THE COURT: What are the names of those cases?

MR. TAUBER: The cases, your Honor, are *Caplinger* --

THE COURT: *Caplinger*?

MR. TAUBER: -- *Caplinger v. Medtronic*. That's one out of Oklahoma.

THE COURT: That's the Western District at Oklahoma.

MR. TAUBER: Yes, your Honor. Then there's the *Otis-Wisher* case --

THE COURT: Okay.

MR. TAUBER: -- from the District of Vermont. There's the *Wendt* case in this court.

THE COURT: I think we're going to get -- talk about that. I haven't -- I didn't know about an Illinois case.

MR. TAUBER: Yeah. That was decided by Judge Flanagan 3 weeks ago.

THE COURT: Okay. Go ahead.

MR. TAUBER: There's the *Coleman* case --

THE COURT: Okay.

MR. TAUBER: -- in California and the *McCormick* case in Maryland. Does that add up to six? I think so.

THE COURT: Why don't you tell me about the case that just came down here.

MR. TAUBER: Sure, your Honor. That's --

THE COURT: That's down the hallway.

MR. TAUBER: That was down the hall. That's the *Wendt* case, W E N --

THE COURT: D T.

MR. TAUBER: -- D T. Exactly. And, as in this case, the Plaintiff in *Wendt* alleged --

THE COURT: Was it Infuse?

MR. TAUBER: Yes. Yes. Exac- -- Your Honor, same device, same allegations. And we would suggest the same results should follow.

THE COURT: Same facts, it was used in a cervical operation?

MR. TAUBER: It was a posterior approach without the LT-CAGE. I am not certain whether it was a cervical or a lumbar implantation.

THE COURT: Was it brought by the same lawyers?

MR. TAUBER: No, your Honor, it was not.

THE COURT: Was it off-label?

MR. TAUBER: The allegation -- The use was

off-label, your Honor. The FDA warnings that Medtronic issues, the label -- the FDA label that's approved for the device and that Medtronic issues --

THE COURT: Have you seen that *Wendt* case?

MR. ESFANDIARI: Your Honor, yes, I have seen the *Wendt* case. And I believe it's distinguishable.

THE COURT: Okay. Go ahead, please.

MR. TAUBER: But, yes, the --

THE COURT: My -- My colleague isn't in the Appellate Court.

MR. ESFANDIARI: Correct.

THE COURT: Thank you. Go ahead.

MR. TAUBER: The use -- The alleged use was off-label in the sense that the device was implanted via a posterior rather than an anterior approach to the spine. And in that case, as in this case, the allegation was that the rhBMP-2 components, or the bone protein component, of the device was implanted without use of the LT-CAGE component. And insofar as the FDA-approved label that Medtronic issued advises doctors to use the two components together, the use of the rhBMP-2 component without use of the LT-CAGE components was an off-label use. So, yes, your Honor, it was similar allegations as here.

THE COURT: And Judge Flanagan found that the --

MR. TAUBER: Judge Flanagan found that --

THE COURT: -- that the state case was preempted?

MR. TAUBER: Yes, your Honor. She found both expressed preemption and implied preemption, just as we argue here.

THE COURT: Okay. How is that distinguished?

MR. ESFANDIARI: First of all, your Honor, the decision was with leave to amend. So it wasn't a final ruling. It was with leave to amend. That complaint, your Honor, is nowhere near the same level of detail that our complaint is. Indeed that Judge Flanagan in that case agreed that if you have proper allegations that the defendant violated federal law and those are parallel to state law, then you are not preempted. And that is what we believe we have here in this case, your Honor.

THE COURT: Okay.

MR. TAUBER: Your Honor, I mean, there is no dispute between the parties that if the complaint adequately alleges a specific federal violation and adequately alleges an identical state law and moreover alleges causation from the predicate federal violation, then that sort of claim would escape expressed

preemption. It might still be --

THE COURT: As long as it -- As long as it ran parallel to the underlying federal regulations, correct?

MR. TAUBER: Exactly. But there must be --

THE COURT: Okay. Can you go give me an example of that?

MR. TAUBER: Absolutely. Yes. Sure. Probably the easiest example and the one that would be most relevant to the claims asserted here, which are at bottom failure to warn claims, would be if the FDA in granting premarket approval to the device required the manufacturer to distribute a label containing certain warnings and the manufacturer then failed to distribute a label with such warnings and a Plaintiff was injured as a result of that failure, then a state law failure-to-warn claim would escape federal preemption because there was the clear federal duty to distribute this warning, the identical state law duty to distribute that warning, and there was a violation of those two identical duties and causation in the hypothetical. So that would be an example of a state law claim that escaped --

THE COURT: So that's --

MR. TAUBER: -- preemption.

THE COURT: So that's if the FDA required a label with certain warnings on it and the manufacturer chose to distribute the product without that requisite label?

MR. TAUBER: Yes. Yes, your Honor. That --

THE COURT: Okay.

MR. TAUBER: -- sort of claim would escape preemption.

THE COURT: Thank you. Go ahead, sir.

MR. TAUBER: Now, in the filing that Mr. Esfandiari made a couple of days ago in response to our submission of the *Wendt* case to this court --

THE COURT: I have not read it.

MR. TAUBER: On July, I think it was, 5th, we submitted a notice of supplemental authority to your Honor bringing the *Wendt* decision.

THE COURT: You didn't get permission to do this.

MR. TAUBER: We did it on consent -- And I'm turning to my associate Emily here.

MS. EMERSON: It was consent. It --

THE COURT: Consent by whom? Not by me.

MR. RING: We contacted your clerk about the process for doing so. And the suggestion was that we had consent. We could file a suppl- -- a notice of supplemental --

THE COURT: Oh. You can file, but that doesn't mean I'm going to read it.

MR. TAUBER: Fair enough, your Honor.

THE COURT: Go ahead.

MR. TAUBER: In -- We brought the *Wendt* --

THE COURT: And, in addition, I can't imagine how, you know, the *Wendt* decision would affect me. It wouldn't affect me whatsoever. I greatly respect Judge Flanagan for both her high intelligence and her great court sense. However, she's a -- she's a trial judge just like I. And it certainly would not constitute any kind of authority to me.

MR. TAUBER: Your Honor, I'm not suggesting that it's binding on your Honor in any way. I fully understood --

THE COURT: Thank you.

MR. TAUBER: -- it's not. What I was getting to was that Mr. Esfandiari in a response to that filing suggested that this case is distinguishable, he suggested, because purportedly in this case he alleged that the LT-CAGE component had not been used with --

THE COURT: Okay. Thanks. You know what, I don't even want to -- you know, I don't want to discuss *Wendt*.

MR. TAUBER: Okay.

THE COURT: *Wendt* isn't relative to me. What I want to discuss is the briefs that were filed in this case.

MR. TAUBER: Certainly.

THE COURT: Thank you, sir. So do you want to talk about expressed preemption --

MR. TAUBER: Yes. Gladly.

THE COURT: -- pursuant to *Riegel*?

MR. TAUBER: Yes, that's exactly where I'm going to start.

THE COURT: Thank you. Let's go.

MR. TAUBER: The claims are preempted by 21 U.S.C. 360k(a) as construed in *Riegel* which held that where, as here, the FDA has granted premarket approval to a device, no state may, through tort law or otherwise, impose requirements on that device that are different from or in addition to the federal requirements imposed by the FDA through the premarket approval process. Any claim that would impose a state law requirement different from or in addition to the federal requirements is expressly preempted.

Here, Plaintiff's claims would impose requirements different from or in addition to the federal requirements --

THE COURT: Why don't you tell me about those claims.

MR. TAUBER: Certainly. Plaintiff's claims are, as Plaintiff admits at page 15 of the opposition, at bottom failure-to-warn claims. Plaintiff alleges in essence that Medtronic failed to warn of risks alleg- --

THE COURT: Counsel was looking at you. That's with why I'm smiling. He's frowning.

MR. TAUBER: Well, I understand why he's frowning, because that concession --

THE COURT: Because of your argument, correct?

MR. TAUBER: Yes. Exactly. That concession, your Honor, his concession at page 15 of the opposition is dispositive of this case because Plaintiff alleges that Medtronic failed to warn of risks allegedly associated with the off-label use of the Infuse device. But, and this is absolutely essential, Plaintiff does not allege that Medtronic failed to provide any of the warnings required by the FDA through the premarket approval process. Thus, Plaintiff's claims --

THE COURT: I'm sorry. Could you go back to that?

MR. TAUBER: Sure.

THE COURT: Plaintiff -- Plaintiff -- The last sentence.

MR. TAUBER: He does not -- Plaintiff does not allege that Medtronic failed to distribute the warnings that were required by the FDA through the premarket approval process. And the premarket --

THE COURT: But that premarket approval process did not apply to cervical surgery, correct?

MR. TAUBER: No, your Honor, that's not correct. The process for approving devices is a process that approves devices, not uses.

THE COURT: Well, I thought for certain uses.

MR. TAUBER: No. That's Plaintiff's assertion. But it's simply wrong on the facts and wrong on the law. If your Honor would look at, for example, pages 7 to 8 of our reply brief, we respond to erroneous assertion with respect to the approval of uses.

When the FDA approves devices, it approves devices, not uses. And under the statute, 21 U.S.C. Section 396, the FDCA expressly protects a doctor's right to use any approved device in any manner that the doctor believes medically appropriate. And in many areas of medicine, off-label use is in fact the standard of care. In case after case, the *Buckman* case, for example, from the Supreme Court, which we cite, your Honor, in our briefs; the *Cooper* case from the

4th Circuit, which we cite in our briefs, all specifically hold that physicians are free to use approved devices in any manner that they see fit. So the fact that Mr. Sanda's doctor exercised his discretion and chose to use the device in an off-label manner does not in any way affect the preemptive effect of the FDA's approval of the device.

Now, your Honor is absolutely correct that the label that Medtronic distributed with the device, the FDA-approved label, in other words, the label that Medtronic was required to distribute with the device, warned physicians against cervical use. No question about that. But that was Medtronic's duty, to distribute that warning. It fulfilled that duty. And Plaintiff does not allege otherwise.

The fact that the doctor then chose to disregard that warning is within the doctor's discretion if it does not affect the preemption analysis because the FDA, as I say, approves devices, not uses. In the cases I -- you know, I point your Honor to at pages 7 to 8 of our reply stand for that proposition.

THE COURT: Okay. Why don't we -- I would like you to respond to that point, sir.

MR. ESFANDIARI: Certainly, your Honor. Mr. Tauber

is completely incorrect. The FDA specifically approves indications. That's what the law provides. And an indication is a specific use. In this case, the Infuse was approved only for a specific indication, the anterior approach in the lumbar spine.

However, Medtronic realized that that is -- there is not a big market for that. So it began an illegal off-label promotion campaign where it promoted and encouraged physicians to use the device for other uses, therefore turning the product into a billion-dollar-a-year product. That is what this case is about, is that illegal off-label promotion. If Medtronic wanted to legally promote Infuse for cervical surgeries, it was required to obtain FDA approval for that specific use. And the law that provides that, your Honor, is two C.F.R. regulations. One is 21 C.F.R. 814.39(a), which is cited in our briefs.

THE COURT: What page have you cited?

MR. ESFANDIARI: This is going to be, your Honor, on pages -- primarily page 7, your Honor.

THE COURT: Page 7, I'm there.

MR. ESFANDIARI: Okay.

THE COURT: Is it the first full paragraph, "By approving a device..."?

MR. ESFANDIARI: It starts earlier, but --

THE COURT: Where do you want me to start?

MR. ESFANDIARI: On the last line of page 6.

THE COURT: Okay. I will go there.

21 C.F.R. Section 814.39(a)?

MR. ESFANDIARI: Correct, your Honor.

THE COURT: And the citation is, quote, "After FDA's approval of a PMA, comma, an applicant shall submit a PMA supplement for approval by the FDA before making a change affecting the safety or effectiveness of the device for which the applicant has an approved PMA... While the burden for determining whether a supplement is required is primarily on the PMA holder, changes for which an applicant shall submit a PMA supplement include, but are not limited to, the following types of changes if they affect the safety or effectiveness of the device." And it's No. 1 "New indications for use of the device." Okay.

MR. ESFANDIARI: Exactly, your Honor. So if they wanted to legally promote Infuse for cervical surgeries, under this regulation, they were required to obtain FDA approval for that indication. The only indication that they had was for the lumbar anterior surgery.

THE COURT: Okay.

MR. ESFANDIARI: So that's --
THE COURT: I think you've answered -- I think you've answered my question, sir.
MR. TAUBER: Your Honor, I realize I misspoke when I directed your attention to page 7 and 8 of our reply brief. It's actually the footnotes around there. It's pages 10 to 11 that I intended to direct your Honor to. I apologize. So there --
THE COURT: Okay. So what did you -- And which supports your argument that Medtronic did not need to have the off-label use --
MR. TAUBER: I would --
THE COURT: -- approved by the FDA or another PMA certification or regulation?
MR. TAUBER: I would point to the cases cited at Footnote 8 on page 11 starting with --
THE COURT: Footnote 8 on page 11.
MR. TAUBER: Yes, your Honor.
(Continuing.) -- starting with *Nightingale*, which specifically says that the F- --
THE COURT: This is a Southern District of Indiana case?
MR. TAUBER: Yes, your Honor.
THE COURT: Okay. This is from -- This is just --

This is case law?

MR. TAUBER: Yes, your Honor, this is case law obviously interpreting the FDCA. And it says that the FDA does not approve or disapprove the use of medical devices for specific treatments.

Then the cases further on in that footnote, for example, the 4th Circuit, U.S. Court of Appeals for the 4th Circuit says, "Once the FDA has cleared a device...physicians may use the device in any manner they determine to be best for the patient..." --

THE COURT: Do you want to respond to Footnote 8?

MR. ESFANDIARI: Yes, your Honor. Exactly. What this is talk- -- I mean, Medtronic is placing itself in the position of a physician. A physician is permitted to do whatever it wants -- that he or she wants to do with it.

THE COURT: Is *Nightingale* a physician, *Nightingale Home Healthcare*?

MR. ESFANDIARI: But that, I mean, it's an unpublished decision --

THE COURT: *Cooper* looks like a physician.

MR. ESFANDIARI: -- from Indiana, your Honor.

THE COURT: *Cox* is a physician.

MR. ESFANDIARI: And this off-the-cuff quote, I'm

not even sure what it's saying. The law is that the FDA approves --

THE COURT: I know. You just read -- You just read me the federal regulation --

MR. ESFANDIARI: Exactly.

THE COURT: -- which I don't think is superseded by *Nightingale Home* or *Cooper* v. Smith or *Cox v. Deputy*.

MR. TAUBER: Your Honor, Mr. --

MR. ESFANDIARI: And the FDA specifically and federal law specifically prohibits pharmaceutical companies and medical device companies from promoting their devices for off-label uses. There have been million-dollar settlements, hundreds of million-dollar settlements --

THE COURT: Sir, I think -- I think your -- the brief that you filed in this case, which contained 21 C.F.R. Section 814 answers my question. Thank you, sir. I don't need any more argument on that point. Let's go.

MR. TAUBER: Your Honor, two points --

THE COURT: Let's go with the next point, sir.

MR. TAUBER: What Mr. Esfandiari just said was absolutely false. There is no truth to what Mr. Esfandiari already said that --

THE COURT: You mean what he said about the C.F.R. regulation?

MR. TAUBER: -- off label -- Well, I will go back to that. I just wanted to hit his last falsehood. When he says that it is illegal for the Medtronic to promote off-use devices, he is simply ignoring, absolutely ignoring the recent case in the United States Court of Appeals, the 2nd Circuit --

THE COURT: The *Caplinger* case?

MR. TAUBER: No, the *Caronia* case, your Honor.

THE COURT: But that -- that case is -- is about the First Amendment. That is a case about drugs, not about a medical device.

MR. TAUBER: Your Honor --

THE COURT: I don't think that case is directly on point for us.

MR. TAUBER: If I may respond, your Honor --

THE COURT: It doesn't really offer me guidance on this issue.

MR. TAUBER: If I could explain why it does, your Honor. The approval process for drugs and medical devices is in this regard the same. There are some differences. But for here, there are no relevant differences. In *Caronia*, the 2nd Circuit was

interpreting the FDCA, precisely the same provision, 21 U.S.C. Section 352(f), which is the provision that Mr. Esfandiari relies on for the proposition that off-label promotion is illegal. So the 2nd Circuit in *Caronia* was interpreting precisely the statutory provision at issue hear, like I say, 21 U.S.C. 352(f) and --

THE COURT: It talks about mis- -- It talks about misbranding.

MR. TAUBER: Yes, your Honor. And that's precisely the hook that Mr. Esfandiari hangs the purported illegality of off-label promotion on. And the 2nd Circuit looked at that specific provision, the provision at issue in this case, and held that contrary to Mr. Esfandiari's assertion and contrary to the position that was taken by the government in that case, Section 352(f) does not prohibit off-label promotion, as we've argued in our briefs to this court. And to the fact that they were -- it's talking about perhaps truthful off-label promotion rather than the alleged false off-label promotion at issue here, that is not relevant because under clear binding United States Supreme Court precedent, for example, in the *Clark* case that we've cited to your Honor --

THE COURT: I would like to stay on *Caronia*.

MR. ESFANDIARI: May I respond, your Honor?

THE COURT: Yeah, please.

MR. ESFANDIARI: Of course, your Honor. First of all, *Caronia* was a criminal trial. Second of all, the issue there was that the sales rep for the drug company was engaged in truthful off-label promotion. So the 2nd Circuit said we're not going to find someone criminally liable for engaging in truthful discussion pursuant to the First Amendment.

What we have here, your Honor, first of all, it's a civil case. Second of all, Plaintiff's allegations are that the off-label promotion that Medtronic engaged in was not truthful. They did not have any adequate reasoning or clinical trials to support their off-label promotion of Infuse cervical fusions. And in *Caronia*, the majority opinion specifically said -- you know, they reserved for another day when it comes to the issue of falsehoods and the First Amendment and illegal off-label promotion.

And a further point, if Mr. Tauber -- Mr. Tauber's primary preemption argument, your Honor, when you remove it all -- strip it from all of the fancy language, is that they're prohibited from issuing

warnings that the FDA has not allowed to. That's basically what his argument is, that they're prohibited from issuing warning that the FDA has not allowed them to -- that the FDA has not specifically authorized.

If he stands here and he says the First Amendment and *Caronia* gives him a right to engage in off-label promotion, if the First Amendment gives him a right to engage in off-label promotion, then the First Amendment likewise gives him a right to provide warnings regarding those very same off-label uses that it is promoting.

MR. TAUBER: Your Honor, may I respond, please?

MR. ESFANDIARI: That is basically what we're here for, your Honor. Medtronic engaged in the illegal off-label promotion of Infuse for cervical devices and failed to provide adequate warnings regarding those, failed to inform physicians that the off-label use of Infuse for cervical uses was neither effective nor safe.

MR. TAUBER: Unfortunately, Mr. Esfandiari simply does not know constitutional law, your Honor, because it is well established under Supreme Court precedent in, for example, *Clark v. Martinez*, 543 U.S. 371 at 377-82 which we cite to your Honor, and similarly in *Leocal v. Ashcroft*, 543 U.S. 11 Note 8, it is well

established that a statutory construction adopted in a criminal case for constitutional purposes such as the statutory construction of 21 U.S.C. 352(f) adopted in *Caronia* applies not only to criminal cases and not only to the particular category of conduct at issue in that case, but to all categories of conduct so long as the statute at issue does not distinguish between those categories. And Section 352(f) does not distinguish between truthful and untruthful promotion. It simply does not. So under well-established Supreme Court precedent that statutory construction --

THE COURT: Supreme Court. Supreme Court precedent.

MR. TAUBER: United States Supreme Court precedent.

THE COURT: This is 2nd Circuit.

MR. TAUBER: Which is clearly subject to the Supreme Court, your Honor. It is bound by Supreme Court precedent. But the point is the 2nd Circuit --

THE COURT: You're talking about a 2nd Circuit case now saying a Supreme Court case.

MR. TAUBER: No. No. No. The 2nd Circuit construed 21 U.S.C. Section 352(f) in *Caronia*. We can all agree on that. The ques- -- Mr. Esfandiari is arguing to your Honor that that statutory construction

does not apply to this case because (A) this case is a civil case rather than a criminal case and (B) because the off-label promotion at issue here was allegedly false whereas in *Caronia* it was concededly truthful. What I'm suggesting to your Honor is that those two distinctions that Mr. Esfandiari is attempting to draw simply do not work because under Supreme Court precedent neither of those distinctions is relevant to the statutory construction.

THE COURT: Thank you. Let's -- Let's move on.

MR. TAUBER: Your Honor, even if, even if off-label promotion were illegal under federal law -- And *Caronia* says this is most distinctly not illegal. But even if off-label promotion were illegal under federal law, Mr. Esfandiari still has not stated a parallel claim that escapes expressed preemption. Because to state a parallel claim that escapes preemption under *Riegel*, he must do three things. He must point to a predicate federal violation. He must point to an identical state law violation and must show that the alleged injuries were caused by the predicate federal violation.

So even if we were to assume for purpose of argument that off-label promotions were prohibited by federal, he still --

THE COURT: Well, I think No. 3 sounds like it is best dealt with in a summary judgment motion or a trial.

MR. TAUBER: I would disagree, your Honor, because --

THE COURT: 1 and 2, yes, I can understand it on a motion to dismiss level. But 3, if he's alleged those, you know, the facts in his complaint, I don't rule on 3. I can rule on 1 and 2.

MR. TAUBER: But, your Honor, on the face of the complaint -- We don't have to even go outside the complaint. Your Honor, we have submitted to you the FDA-approved labeling. We do believe your Honor is entitled to take judicial notice of that both under 2-615 and 2-619. But even if --

THE COURT: Great. I read the briefs. Go ahead.

MR. TAUBER: But even if you ignore the FDA labeling, on the face of Plaintiff's own complaint, it is apparent that they cannot establish causation. On the face of their complaint, they recite the relevant warnings which we asked your Honor to take judicial notice of. On the face of their compliant, they admit that in 2006 -- Now, remember, the surgery at issue here took place in 2011. They admit on the face of their complaint that in 2006 an article was published in *The*

Spine Journal warning of precisely these risks. They further admit that in 2008 a medical study was published at a medical conference warning of precisely these warnings. Moreover, in their complaint, again staying within the four corners of their complaint, they admit that in 2008 the FDA issued a public health notification warning surgeons of precisely the sort of risks alleged here in connection specifically with cervical use of rhBMP-2. So even --

THE COURT: And your client -- And your client chose to continue to promote the use of that device for cervical surgical -- I'm sorry -- cervical surgery --

MR. TAUBER: That's the allegation that they make.

THE COURT: -- despite the FDA warning.

MR. TAUBER: Your Honor -- Again, your Honor, that's their allegation. We can test the allegation that we did engage in such promotion. But even if one assumes that's true, it does not change the fact either, as we argued before, that off-label promotion is not illegal, moreover, even ignoring that, the fact that a doctor is, as we've established, entitled to use an approved medical device in any way that he or she sees fits, as indeed Plaintiff's doctor chose to use the device here notwithstanding the FDA warning and

notwithstanding the FDA public health notification.

THE COURT: Right. I know your argument is the FDA warning informed the surgeon and he had notice.

MR. TAUBER: Yes, your Honor.

THE COURT: So, therefore, the Plaintiff can't establish that -- You made that argument in your reply brief?

MR. TAUBER: Yes. And --

THE COURT: I thought it -- I thought it was very interesting -- I thought that argument very interesting that 2 years before the injury, the FDA warned that the unauthorized use of the Infuse in cervical operations could cause swelling and other symptoms, which the Plaintiff allegedly suffered from. And then despite that, the Infuse continued to market the case -- allegedly continued to market this product for off-label use, the use that has specifically been questioned by the FDA.

MR. TAUBER: That's the allegation, your Honor. But --

THE COURT: That's the allegation.

MR. TAUBER: But precisely because, your Honor, that information was publicly available, Plaintiff as a matter of law, as a matter of law had not established

requisite causation.

THE COURT: Okay. Why don't we get to your next argument, sir.

MR. TAUBER: Well, it was the middle argument, your Honor, which is they cannot point to a parallel state law duty. Remember, under *Riegel* and under *Lohr*, in order to state a parallel claim that escapes expressed preemption under 360k(a), they must point to not only a federal violation, but they also must point to the violation of a state law duty that imposes the identical requirement.

THE COURT: Right. And that's what triggers -- That was -- That is the second prong of the test --

MR. TAUBER: Yes, your Honor.

THE COURT: -- in which I must decide what state requirements relate to this device's safety and effectiveness and constitute requirements different from already issued federal requirements.

MR. TAUBER: Yes, your Honor, that is --

THE COURT: Okay. So I've got that -- I've got that down. So what next do you want to go to?

MR. ESFANDIARI: Should I respond to that point, your Honor? Or do you want Mr. Tauber to finish?

THE COURT: No. Let's -- Let's just keep going,

please.

MR. TAUBER: Well, your Honor, under that point, as the *Caplinger* court explained in great detail and as the other courts have recognized --

THE COURT: The *Caplinger* court, the Western District of Oklahoma.

MR. TAUBER: The Western District of Oklahoma which has issued what I would say is the most comprehensive decision in --

THE COURT: Which is based on -- Which is based on the *Buckman* case, correct?

MR. TAUBER: Both -- It's both *Riegel* and *Buckman,* your Honor. *Caplinger*, like Judge Flanagan, *Caplinger* found both that these claims were expressly preempted under *Riegel* and 360k(a) and --

THE COURT: Now, was *Buckman* -- I'm sorry. Now, *Buckman* was decided before *Riegel*; is that correct?

MR. TAUBER: Yes, your Honor.

THE COURT: So then *Riegel* would supersede *Buckman*.

MR. TAUBER: No, your Honor, because they address two entirely different areas. *Buckman* is an implied preemption case, and *Riegel* is an expressed preemption case.

THE COURT: Okay. Thanks. Let's move along, sir.

MR. TAUBER: Okay. And it's well established under the *Geier* decision, for example, and *Buckman* itself that a claim might escape expressed preemption --

THE COURT: Okay. I've read both cases. Let's move along, sir. Thank you.

MR. TAUBER: The second prong they have to meet is the fact that there is no parallel state -- Their point is that there is no parallel state law claim. The very concept of off-label anything, be it off-label use or off-label promotion, is strictly a creature of federal law. There is no concept under state law of off-label use. And there is no prohibition in Illinois law against off-label use or off-label promotion. And, therefore, insofar as they say that the predicate federal violation is off-label promotion, they cannot establish a parallel claim because they cannot point to an identical state requirement that one refrain from off-label promotions. There simply is no parallelism.

MR. ESFANDIARI: Can I respond?

THE COURT: That -- That argument doesn't fly.

Go, sir, please.

MR. ESFANDIARI: All right. If it doesn't fly, then, your Honor, I --

THE COURT: No. Go ahead. You can respond for the

record.

MR. ESFANDIARI: To respond to that specific argument, your Honor, what we're arguing here, whether you want to call it off-label promotion or whatever the case may be, Medtronic promoted a device for a use that it knew was neither safe nor effective. If there was no FDA, there was no FDCA, there was nothing, under Illinois law, when you promote a product that is neither effective nor safe and promote that to physicians to implant in patients, that triggers a common law right of action, not only for strict liability, but for negligence and potentially even fraud.

So for Mr. Tauber to argue that the State of Illinois doesn't provide a remedy for that kind of action, for that kind of harm, for that kind of conduct that paralyzes a man, I'm not sure what universe he's living in.

MR. TAUBER: Very simply, your Honor, I can explain very clearly because Mr. Esfandiari is operating at a far too high level of generality. One has to look at the particular requirements and the particular conduct. Sure, there's causes of action for all sorts of torts in Illinois law, but --

THE COURT: I'm -- I'm a little -- I'm a little

mixed up. I thought that the Plaintiff was alleging that there was a violation of federal regulations; is that correct?

MR. ESFANDIARI: We are addressing that, yes, your Honor.

THE COURT: So you're claiming that because there weren't state regulations, therefore the Plaintiff doesn't have a cause of action?

MR. TAUBER: It doesn't turn on state regulation or state tort --

THE COURT: But you're telling me that because there isn't an exact provision such as the FDA provision, the Plaintiff -- the Defendant could not have violated any kind of state law.

MR. TAUBER: What I'm telling you is that because the State of Illinois does not prohibit off-label promotion either by statute or regulation or recognize a state tort claim for off-label promotion, the requirements that Mr. Esfandiari through his tort claims are trying to enforce are not identical to the federal requirements and, therefore, are expressly preempted by it. Now --

THE COURT: I thought that -- I thought that. And I certainly was well explained in the *Bausch* case that a

valid Illinois action that permits negligence findings for violations of laws, regulations, and ordinances. So Illinois treats a violation of a statute or ordinance designed to protect human life or property as prima fascia evidence of negligence.

MR. TAUBER: Your Honor, in the *Bausch* case, the allegation was that the manufacturer violated --

THE COURT: I just want to discuss that -- that -- that statement of law. I mean, is that correct or isn't it correct? I'm asking you.

MR. TAUBER: That is too general. So it's not correct because it's too general. If I could explain.

THE COURT: Okay. Go ahead.

MR. TAUBER: Yes. In *Bausch*, the allegation was that the manufacturer violated a specific FDA manufacturing requirement. And the claim brought was a manufacturing defect claim. So there was a state law --

THE COURT: In *Bausch*?

MR. TAUBER: In *Bausch*. So in *Bausch,* the parallelism was on the one hand the allegation of a predicate federal violation of a particular manufacturing requirement and on the other hand this allegation of a state law duty to not manufacture the device in that particular way. There was a one-to-one

correspondence. Here, by contrast --

MR. ESFANDIARI: And the same one-to-one correspondence --

MR. TAUBER: If I may finish my sentence, your Honor --

MR. ESFANDIARI: -- is here, your Honor, in the sense that here we have -- we're alleging off-label promo- -- illegal promotion from -- promoting a device for uses that are neither safe nor effective. And state law provides a remedy for that under strict liability. I mean, your Honor read my mind when your Honor went to *Bausch* because that was going to be my response.

THE COURT: Well, I would also like to point out that in *Riegel*, the courts said that 360k does not prevent the state from providing a damages ready for claims premised on a violation of FDA regulations --

MR. TAUBER: That's absolutely true, your Honor. But --

THE COURT: -- in which case the state duties parallel rather than add to federal requirements. So this, I think, Plaintiff is arguing is -- is that parallel.

MR. TAUBER: Exactly. But it has -- But -- Your Honor, that's a general statement which is generally

true, but it has to be looked at specifically because that section of *Riegel* cites to the *Lohr* decision from 1996. And *Lohr* clearly explains that in order for the state law claim to be parallel, it must rest on -- and this is the quote -- substantially equivalent -- sometimes it says equiv- -- excuse me -- identical -- Let's try again. Sorry. I got tongue tied. The *Lohr* case, which *Riegel* cites at that point, says for a state law claim to be parallel and therefore to escape expressed preemption, the state law duty upon which that claim rests must be identical to the federal requirement that is allegedly violated here.

THE COURT: So the *Lohr* case says it must be absolutely identical? Is that their words?

MR. TAUBER: Identical, yes. Identical is used at 795. Substantially identical is what it uses at 796. And, for example, the United States Court of Appeals of the 7th Circuit sitting here in this city has taken that to mean genuinely equivalent. Similarly, the 11th Circuit in *Wolicki-Gables* was recit- --

THE COURT: So your argument now -- I didn't -- I just want to make sure I get this -- is that in order for Plaintiff's claim to survive this motion to dismiss or in order for him to allege a claim, he must be

claiming that the actions of the Defendants violated a specific state statute that went to the off-label marketing.

MR. TAUBER: It needn't be a statute. If the state recognized --

THE COURT: Or regulation.

MR. ESFANDIARI: Common law.

MR. TAUBER: It could be common law. You know, if as a matter of Illinois common law prior to the FDCA it were illegal to engage in off-label promotion, then that would be sufficient. It doesn't have to be a statute. It can be common law. But the importance is that it must be an identical duty. And what Mr. Esfandiari does is he says the federal violation is off-label promotion but then the state tort duty is a duty to warn. But those are not identical requirements.

THE COURT: Okay. Thanks. Let's move on here. You wanted to specifically respond to that.

MR. ESFANDIARI: Respond to that, yes, your Honor. Our claim is, whether you call it off-label or what, that they promoted for a use that was neither safe nor effective. That's simply -- And Illinois law recognizes a claim for that. It has for centuries, your Honor.

If I go outside and I, you know, start selling

snake oil and somebody gets harmed, they can sue me. And that's basically what Medtronic did here, your Honor. They can sue me.

MR. TAUBER: Let me --

MR. ESFANDIARI: Medtronic never had approval for the use of Infuse in the cervical set- -- in the cervical spine. Yet it heavily promoted that use, made billions of dollars as a result of that promotion, and stands here and says the health of Mr. Sanda, he isn't entitled to any remedies.

THE COURT: Sir -- Sir, I don't need the emotional argument here, please.

MR. ESFANDIARI: I apologize. But that's basically what's going on here.

MR. TAUBER: Your Honor, let me --

THE COURT: Let's get to your next argument.

MR. TAUBER: Let me take Mr. Esfan- --

THE COURT: Please let's get to your next argument. Thank you.

MR. TAUBER: Let me take Mr. Esfandiari's snake oil example. The tort duty that --

THE COURT: I don't want to talk about snake oil, sir. Could we -- Could we please stick to your argument. Let's go.

MR. TAUBER: Yes, your Honor. What Mr. Esfandiari is asking us to do as a matter of state law is to issue warnings that we were not required to issue by the FDA and that we were affirmatively prohibited from issuing. It would have been illegal for us to issue the warnings that Mr. Esfandiari says. Precisely, the regula- --

THE COURT: I'm sorry. How could you -- How could you have issued any kind of FDA warnings --

MR. TAUBER: We couldn't. That's pre- --

THE COURT: -- regarding the off-label because you never submitted your product to this PMA -- this PMA approval?

MR. TAUBER: Your Honor, the precise regulation that --

THE COURT: It doesn't make any sense.

MR. TAUBER: What doesn't make sense is Mr. Esfandiari's argument, your Honor, because the regulation he cites, 21 C.F.R. 814.39, Medtronic was affirmatively prohibited, not just -- we were affirmatively prohibited from issuing the sorts of warnings that Mr. Esfandiari says as a matter of state tort law we were required to give because, as he told this court, we cannot change our label without FDA permission. We couldn't do what he wanted us to do.

THE COURT: How could you have changed the label legally --

MR. TAUBER: We couldn't.

THE COURT: -- when you didn't go through the supplementary PMA?

MR. TAUBER: But, your Honor, if -- if the claim is that we violated Illinois law by not submitting a PMA supplement, that claim is plainly expressly preempted and impliedly preempted under the United States Court of Appeals decision *McMullen*, which we've cited to this court. The state cannot require what the FDA merely permits. And under 814.39, a manufacturer may submit the PMA supplement under certain circumstances. But there's never any requirement that it do so. So if the assertion here --

MR. ESFANDIARI: The statute uses the word "shall," the one that we quoted on page 8.

THE COURT: Yeah, I saw that.

Go ahead, sir.

MR. TAUBER: I direct your Honor's attention to the *McMullen* case, which we cite in our case, which clearly --

THE COURT: Thank you. Let's -- Let's go on to the next argument, sir.

MR. TAUBER: Your Honor, even if, even if these claims were not expressly preempted, which of course we believe they are, they nevertheless are impliedly preempted as was found in the *Caplinger* court, as found by Judge Flanagan in *Wendt*. These -- The *Buckman* case holds in Section -- 21 U.S.C. Section 337(a) states that all claims to enforce the FDCA shall be brought by and in the name of the United States government. There is no private right of action. And insofar --

THE COURT: Okay. Now -- Now, I didn't understand this case to be an attack on the regulations.

MR. TAUBER: It's not an attack on the regulations, your Honor. But what they're doing is saying an absolute necessary predicate for their --

THE COURT: It doesn't seem to be an enforcement action. I thought *Buckman* was an enforcement action. Am I incorrect?

MR. TAUBER: No, your Honor, *Buckman* was a private suit.

THE COURT: Suit. I'm sorry. Let me get to that.

MR. TAUBER: Yes.

THE COURT: Right. I'm sorry. But it didn't -- Wasn't the holding in regard to enforcement? Hold on. I have notes on that somewhere.

MR. ESFANDIARI: Your Honor, in *Buckman*, it was a fraud on the FDA cause of action that the court was addressing. And we have not alleged fraud on the FDA. We don't have a cause of action for fraud on the FDA here. But I'll let Mr. Tauber continue his argument, your Honor.

THE COURT: Just one second.

MR. TAUBER: Yes.

THE COURT: I thought the point in *Buckman*, as you said, was that Section 337(a) creates no private cause of action to enforce the FDCA.

MR. TAUBER: That is correct, your Honor.

THE COURT: But I didn't think this case was an enforcement case. I thought this was a case for damages.

MR. TAUBER: As was *Buckman*. Your Honor, in *Buckman*, as Mr. Esfandiari --

THE COURT: So you think that what Counsel is trying to do -- what the Plaintiff is trying to do is create a private cause of action to enforce the FDA?

MR. TAUBER: Implicitly, yes, your Honor, exactly as in *Buckman*. In *Buckman*, the Plaintiff brought a suit saying I was harmed by manufacturer's fraud vis-à-vis the FDA and I, the private plaintiff, am entitled to

recover civil damages as a result. The United States Supreme Court said no. The mere fact that there was a violation or an alleged violation of the FDCA does not permit you to bring a state law tort claim precisely because Section 337(a) says you may not. And the holding in *Buckman* was that 337(a) does not only bar fraud on the FDA claims, which is the particular state law claim at issue in *Buckman*, but it bars any state law claim in which the violation of a federal regulation is, and I quote, a critical element of the Plaintiff's case. *That's Buckman*, 531 U.S. at 353. Here --

THE COURT: Then how do you -- how do you get around the *Elmore v. Smith* case, which is a case that just was decided by the Northern District of Illinois on April 19th, 2013? And the *Elmore* case distinguished *Buckman* and rejected the argument for implied preemption because the tort claims related to health and safety are distinct from a plaintiff alleging fraud on a federal agency.

MR. TAUBER: Well, your Honor, that --

THE COURT: How do you handle *Elmore*?

MR. TAUBER: I say that that is wrongly decided insofar as it's ignoring the Supreme Court decision in *Mensing -- Pliva v. Mensing*, which we've also cited to

your Honor, in which the Supreme Court itself said what *Buckman* was about. And it said *Buckman* is about its communications with the FDA. It doesn't limit it to fraud on the FDA claims. It's any claim that involves a plaintiff's allegation that the defendant should have done -- made some other communication to the FDA is impliedly preempted.

THE COURT: I'm sorry. You've got to -- You've got to move a little more quickly. I've got a 12:30 pretrial.

MR. TAUBER: I mean, that's it, your Honor.

THE COURT: Do you have any other -- anything else?

MR. TAUBER: No, your Honor.

THE COURT: We did everything?

MR. TAUBER: Yes, your Honor.

THE COURT: Okay. Thank you.

Sir, do you want to respond?

MR. ESFANDIARI: Your Honor, I will respond to *Buckman* first off because that is what we were just discussing. Your Honor is absolutely correct that *Elmore* rejected the arguments that Mr. Tauber is making. And *Elmore* is in the majority. The New Jersey Supreme Court and Court of Appeal in *Cornett* -- we site this on page 16 of our brief -- likewise says it distinguishes

Buckman when you have a traditional state tort law claim being brought, which is what we have here. *Cornett*, mind you, was also, your Honor, an off-label promotion case.

MR. TAUBER: Your Honor, if I could stop him right there. Your Honor, *Cornett* has been rejected in this very context. In the *Otis-Wisher* case that we brought to your Honor's attention, the court says at no point it's out there, not persuaded. Analysis in *Caplinger,* also in this direct context, is the persuasive analysis. And these claims are impliedly preempted.

THE COURT: Thank you.

MR. ESFANDIARI: *Cornett* was a New Jersey Supreme -- It was affirmed by the New Jersey Supreme Court. *Bausch*, the other case that your Honor has cited at length during the hearing, likewise rejected the *Buckman* argument and said when you have a state tort law claim that is distinguished from a *Buckman* case.

And another case on page 16 that we cited, which is actually a Medtronic case, *Medtronic Implantable Defibrillators*, the court stated *Buckman* did not preempt -- the court stated states may not be concerned about protecting federal agencies, but states have a strong interest in protecting their citizens from

fraud and personal injuries and therefore rejected *Buckman*.

MR. TAUBER: The case that Mr. Esfandiari just cited is from 2006. He is well aware of the fact that in 2008 the 8th Circuit, which was the controlling circuit for that case, rejected that analysis specifically and held that *Buckman* stands for the proposition that private plaintiffs may not through private tort suits, such as this, enforce requi- -- regulations of the FDCA such as the purported prohibition on off-label promotion. It's not good law.

MR. ESFANDIARI: The fact is, and I'm sure -- I mean, I'll challenge Mr. Tauber that the majority of the courts who have addressed the *Buckman* issue, your Honor, have found that *Buckman* does not preempt these type of claims.

Your Honor actually allowed me an opportunity to respond to many of Mr. Tauber's arguments. I'm not going to take too much of the court's time to go through my personal outline. I will make one point, your Honor. In 1999 the Supreme Court of the State of Illinois in a specific Class III PMA case, such as the case here, rejected preemption. That is a case called *Weiland v. Telectronics Pacemaker* [sic] *Systems*. And that was

decided in 1999. We addressed this case in our brief. Mr. Tauber, in his opening brief in a passing footnote, says that that case is no longer good law and cites to a district court case here in -- I believe it was a Federal District court case. Before we even address all of the arguments that we've addressed here, your Honor, the court would have to specifically rule that that Supreme Court decision from the State of Illinois has been overruled by *Riegel*. And no court has specifically -- No Illinois State court has yet to do that. There's no published decision saying that *Weiland* is no long good law. However, even if your Honor decides that *Weiland* is no longer good law in light of --

THE COURT: That's *Weiland v. Telectronics* --

MR. ESFANDIARI: Exactly, your Honor.

THE COURT: -- 188 Ill. 2d 415.

MR. ESFANDIARI: Exactly. So if --

THE COURT: End of quote, the starting point for our analysis is the presumption that historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.

MR. ESFANDIARI: And also on page -- Your Honor, on

page 14, there is a block quote specifically from *Weiland* right in the center there.

THE COURT: Yes, sir.

MR. ESFANDIARI: When -- I'm happy to read it. It states, "The premarket approval process allows the FDA to assure minimal safety devic- -- of medical devices which are marketed for human consumption; the premarket approval process simply does not address the appropriate standards of liability once the medical device enters the market. There is simply no support for defendant's assertion that Congress intended to preempt almost all state common law claims against the manufacturers of medical devices which received premarket approval from the FDA."

So before your Honor --

MR. TAUBER: Your Honor, this is plainly --

MR. ESFANDIARI: -- needs to address -- even if we go into this off-label parallel claims and so forth, your Honor would have to specifically hold that this case has been overruled.

MR. TAUBER: And indeed it has, your Honor, by the *Riegel* case in 2008. United States Supreme Court precedent plainly trumps contrary Illinois law from 1999. And as to the presumption against preemption that

Mr. Esfandiari just pointed to from that case, the Supreme Court expressly addressed that in *Riegel*, as we tell your Honor at pages 2 to 3 of our reply brief. The U.S. Supreme Court in *Riegel* expressly rejected the notion that a presumption against preemption applies in this context. And, moreover, in the 2001 *Buckman* decision, the U.S. Supreme Court expressly rejected the notion that a presumption against preemption applies with respect to medical devices and implied preemption. So Mr. Esfandiari is simply not telling this court the correct law. The correct law is found in the United States Supreme Court in *Riegel*, the United States Supreme --

THE COURT: Thank you. Got it.

MR. ESFANDIARI: And even if your Honor holds that *Weiland* has been rejected or superseded, for all the arguments we've made here today, your Honor, *Riegel* specifically allowed parallel claims to proceed. And what we have here is a parallel claim. Cases that support that, your Honor, are the *Bausch* decision from the 7th Circuit, which we find as the most persuasive, as well as the Supreme Court's *Cornett* decision out of New Jersey.

Furthermore, in Infuse cases, there have been

two decisions written by courts in California and Colorado. One is the *Cabana v. Stryker* case in which the court said -- identical case as Infuse off-label case -- the court rejected *Buckman*, rejected *Riegel*, and said in light of the off-label promotion, Plaintiff was allowed to proceed with her claims. We are actually about to have trial coming up on November 6th in that case, your Honor. That is an Infuse case as well as state court in Colorado, the *Huggins* decision, which likewise rejected Medtronic's arguments.

I'm not going to rehash everything that I've already said, your Honor, and that's already in the briefs. I will simply step -- want to step back for a second from a public policy perspective, your Honor.

The FDCA was passed in 1933 to protect patients. They realized that drug manufacturers were out there selling drugs that were neither effective or safe. And they felt that there was regulations necessary to promote them, to make sure that they go through an approval process before they're promoting for those specific indications.

In 1976 when we had the Dalcon Shields contraceptive tragedies where numerous patients were harmed, the MDA was passed, the Medical Device

Amendments were passed, again to protect patients. And the whole purpose, your Honor, was that products be placed through a rigorous approval process for the specific indication and before a defendant is allowed to market them. Medtronic never did that vis-à-vis the cervical use of Infuse in this case, your Honor. And because they chose not to do that, because they never obtained FDA approval for cervical use, it can't hide behind a shield of immunity.

In essence, Medtronic is turning a regulation that was designed to protect patients and give greater remedies and protection to patients to say no, that is not a shield and you're not allowed to sue and too bad for you for all the injuries you suffered as a result of our negligence and --

MR. TAUBER: Your Honor, you have to --

THE COURT: I'm ready to rule. I've obviously read the briefs. I've read the case cited. I don't need to hear any more argument here.

I am denying the Defendants' motion. I am denying it based first on the United States Supreme Court *Riegel v. Medtronic*, 128 S. Ct. 999. This court has required me to apply the two-part test. The court required me to determine whether the FDA has imposed a

device-specific requirements on this device. Certainly it has, but not for the off-label use.

Two, I must decide whether the state requirements that relate to the device's safety and effectiveness and constitute requirements different from or in addition to the federal requirements. I have been asked to look at that. And I will find or have found -- As you can certainly tell from what my comments have been throughout this oral argument, what I found is that these requirements are not in addition to federal requirements but run parallel to it.

I already noted the language I found in *Riegel.* I mentioned this before in which the court pointed out that Section 360k does not prevent a state from providing a damages claims remedy for claims premised on a violation of FDA regulations in which the state duties parallel rather than add to federal requirements.

I also relied on the *Bausch* case. That's *Bausch*, B A U S C H, *v. Stryker*, S T R Y K E R, *Corporation*, 630 F.3d 546. It's a 7th Circuit 2010 case. In this case, the 7th Circuit found that the Plaintiff Bausch's claims that she was injured by defendants' alleged violations of federal law were not

preempted. And I would like to read the very persuasive rationale provided by the 7th Circuit in this case:

Quote, "The idea that Congress would have granted civil immunity to medical device manufacturers for their violation of federal law that hurt patients is, to say the least, counter-intuitive. Nevertheless, manufacturers in this case and in others have asserted this theory of defense. As we explain below, the manufacturer's theory tries to stretch the Supreme Court's decisions in this field beyond the boundaries that were made clear in these decisions. Medical device manufacturers who subject their Class III devices to the rigorous premarket approval process are protected by federal law from civil liability so long as they *comply* with federal law. That protection does not apply where the patient can prove that she was hurt by the manufacturer's *violation* of federal law."

The court also noted that there was a valid Illinois action that permitted negligence findings for violations of laws, regulations, and ordinance. The court noted that Illinois treats a violation of statute or ordinance designed to protect human life or property as prima facia evidence of negligence though the violation may not always be conclusive on the issue of

negligence.

And, finally, I looked to the latest case decided in my federal district that I mentioned before. And that was *Elmore v. Smith & Nephew*. That's 2013 U.S. District Lexus 56 to 75 (phonetic). And that's an April 19th, 2013 decision in which the plaintiffs' Illinois negligence and strict liability claims were not expressly preempted. Like the strict liability and negligence claims in *Bausch*, plaintiffs' claim ran parallel to the underlying federal regulations. As I read before from this case, the *Elmore* District Court distinguished *Buckman* and rejected the defendants' arguments for implied preemption because tort claims related to the health and safety are distinct from a claim alleging fraud on a federal agency.

So there we are as to these motions to dismiss.

What I do want to get to -- we can do this very quickly -- is I think the complaint does need to be cleaned up.

MR. ESFANDIARI: Yes, your Honor.

THE COURT: Okay. Let's go to the complaint.

I think you have a number of compound paragraphs in here. By compound, I mean, you know, a

number of different facts and claims asserted in one paragraph.

For example, there's one in Number 13 on page 3.

Page 4, Number 14 is a problem.

Number 15, you seem to be discussing failure to inform and then you begin discussing the fact that there's no informed consent. Those seem to be different claims.

Number 26, you need a statute citation in paragraph 26.

Okay. Page 8, from paragraph 29 to 34, you need a history -- you provide me with a history of spine surgery. Do we need that? That, you can make a decision on. I don't know why I needed a history of spine surgery.

Let's see. Page 16, Number 57, is that relevant?

Paragraph 59, I need a date.

Okay. Page 25, Number 90, is that needed? I don't really know what that is.

Okay. Page 27, that seems to include a number of compound --

MR. TEICH: Which paragraph on page 27?

THE COURT: Paragraph 94, I would look at.

And look at paragraph 95. That hit me because you were claiming negligence and recklessness in regard to researching and manufacturing. That doesn't seem to be at issue here, the research and manufacturing. Would you look at that, manufacturing especially?

MR. ESFANDIARI: Certainly, your Honor.

THE COURT: Now, this isn't written in stone here. Now, I might -- I would just ask you to take a look at it and make a decision as to whether it should be in there.

MR. ESFANDIARI: I'll clean it up, your Honor.

THE COURT: There might be a reason for it to be in there. I don't know.

Again, page 31 at the top of the page, you use the words "manufactured" and "designed."

Okay. Page 38, Count V, this goes to Northwestern and to the doctor. You seem to make legal conclusions of agency. I think you need to flesh that out.

That's all I have to say now.

Gentlemen, thank you go so much for your terrific arguments. Your briefs were tremendous.

MR. ESFANDIARI: Thank you, your Honor.

THE COURT: And I was so pleased to be able to read them, to read the case law you cited. It is delightful for me to be able to use my federal courts class that I took so many years ago with Professor Fallon, Richard Fallon. He was great. He has written a book on -- actually, has written a book on federal courts. And I was very, very happy to be an allower and able to listen to these arguments and to read federal law, especially United States Supreme Court cases. Thank you so much for giving me the opportunity and for doing such a terrific job.

ATTORNEYS: Thank you, your Honor.

THE COURT: Especially defendants.

MR. RING: I suspect you will have another opportunity before we're done.

THE COURT: Maybe you should ask that it be transferred -- Maybe you should have these consolidated with Judge Flanagan. Are they the exact same cases, same device, same allegations?

MR. RING: Same device, both cervical. Although, as it was pointed out, different firms and different doctors and hospitals as well. But, yeah, there are now two. There may be a third now in this court.

MR. ESFANDIARI: And I don't want to speak out of

school, but it's my understanding that the *Wendt* case also plaintiffs might be dismissing it voluntarily. I'm not sure, your Honor, just from the --

THE COURT: Were you the attorneys on it?

ATTORNEYS: We are.

THE COURT: So you were able to prevail in such a way that the plaintiff is now dismissing?

MR. RING: I don't think that's going to happen.

MR. ESFANDIARI: I may be speaking out of school.

MR. RING: But if he wants to whisper, that's always accepted. So ...

MR. FITZGERALD: Your Honor, there was one more thing.

THE COURT: Yes, sir.

MR. FITZGERALD: We also have a motion to dismiss an institutional negligence claim because there was no 622 report addressing that.

THE COURT: You're going to need it.

MR. TEICH: Well, we do have a 622 report, your Honor.

THE COURT: What about the institutional negligence?

MR. TEICH: Well, your Honor, the 622 report states a claim against the defendant hospital. This is a

motion by the defendant hospital. And I want to -- Basically, what I would like to do, your Honor, is file a written response. The 622 report, according to the Illinois Supreme Court case -- now I'm getting to federal courts too -- *Sullivan* specifically describes the 622 report as a ticket to get into the courtroom as long as the report applies to the defendant, and this one does. Then we don't need to be able to support every one of our theories by the 622 report. It does not have to reach that level of specificity.

THE COURT: Well, you have to support claims against a particular defendant.

MR. TEICH: And we have. And even if they win this, those defendants will still be in. Nobody is going to get out of this case.

MR. FITZGERALD: On agency as opposed to a direct claim for institutional negligence. They've never addressed that.

MR. TEICH: Well, if we could file a written response, I would like to do that.

THE COURT: I can tell you that I agree with Counsel on this case. Mr. Fitzgerald, I agree that he needs a 622 on the particular negligence of Northwestern. This isn't just respondeat superior.

This is --

MR. FITZGERALD: There's both.

THE COURT: There's both. That's what I'm saying. This is actually institutional negligence.

MR. FITZGERALD: And I point out they already have had the 90-day extension from 622.

MR. TEICH: Well, we're not going to be seeking to amend the report. What we would like to do is have an opportunity to file a written response to convince the court that the case law provides that the report that we have filed is sufficient to maintain this cause of action.

THE COURT: You can file what you want. But I'll tell you which way I'm leaning here. I think it's only fair to know exactly what you did wrong.

In particular, do you know what you did wrong, you, the hospital?

MR. LEE: Well, actually, I have the hospital. And so far I have been agreeing with everything that Mr. Fitzgerald has said. I'm looking at the 262 right now. I don't see anything that goes to institutional negligence itself. There's agency issues brought up.

THE COURT: Which is different than the institutional negligence. They state separate claims.

MR. TEICH: May I have 7 days to file a written response?

THE COURT: Fine. Why don't you set up some kind of a schedule and get it to us, please.

When do I see you next, gentlemen?

MR. TEICH: We don't have a date to come back.

THE COURT: When do you want to come back, 28 days?

MR. TEICH: 28 days to clean up the complaint.

THE COURT: And then how much time to respond? Are you going to file the same set of briefs or similar briefs?

MR. RING: Your Honor, we'll take under due notice what you've said. But we'll see what it looks like when it's cleaned up. So how about 28?

THE COURT: Whatever you need, let me know.

MR. LEE: So considering that the complaint is being amended, we also have a separate motion to dismiss based on 2-603. And so could we just enter and continue that depending on how the amended complaint looks?

THE COURT: Sure. Thank you.

All right. Thank you.

(Which were all the proceedings had in the above-entitled cause.)

STATE OF ILLINOIS)
) SS.
COUNTY OF COOK)

Sharon Valli, being first duly sworn, on oath says that she is a Certified Shorthand Reporter doing business in the City of Chicago, County of Cook and the State of Illinois;

That she reported in shorthand the proceedings had at the foregoing hearing;

And that the foregoing is a true and correct transcript of her shorthand notes so taken as aforesaid and contains all the proceedings had at the said hearing.

_____
SHARON VALLI, CSR

CSR No. 084-004551

SUBSCRIBED AND SWORN TO
before me this 20th day of
July, A.D., 2013.

_____
NOTARY PUBLIC