

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

In re: MEDTRONIC, INC., SPRINT
FIDELIS LEADS PRODUCTS LIABILITY
LITIGATION

Case No. : 08-md-1905

TRANSCRIPT

OF

PROCEEDINGS

(PLAINTIFFS' MOTION TO AMEND PROTECTIVE ORDER and to
COMPEL REDACTION OF FDA DOCUMENTS)

The above-entitled matter came on for hearing
before Magistrate Judge Janie S. Mayeron, on March 30th,
2009, at the United States District Courthouse, 316 N. Robert
Street, St. Paul, Minnesota 55101, commencing at
approximately 10:45 a.m.

CALIFORNIA CSR NO. : 8674

ILLINOIS CSR NO. : 084-004202

IOWA CSR NO. : 495

RMR NO. : 065111

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

APPEARANCES

GUSTAFSON, GLUEK, PLLC, 608 Second Avenue
South, Suite 650, Minneapolis, Minnesota 55402, by DANIEL E.
GUSTAFSON, KARLA GLUEK and AMANDA WILLIAMS, Attorneys at Law;
and

RIFF, STEVENSON LAW FIRM, LLP, 2016 Bissonnet
Street, Houston, Texas 77005, by MARCUS L. STEVENSON,
Attorney at Law, appeared as counsel on behalf of Plaintiffs.

MAYER, BROWN, LLP, 71 South Wacker Drive,
Chicago, Illinois 60606, by DANIEL RING, Attorney at Law; and

BOWMAN & BROOKE, 150 South Fifth Street, Suite
3000, Minneapolis, Minnesota 55402, by JENNIFER HUELSKOETTER,
Attorney at Law, appeared as counsel on behalf of Defendants.

1 THE COURT: Good morning, everyone. We're here
2 this morning in connection with the matter of In re:
3 MEDTRONIC, INC., SPRINT FIDELIS LEADS PRODUCTS LIABILITY
4 LITIGATION, Court File Number 08-1905.

5 As you all know, the court reporter's
6 microphone is not operational, so I do want to make sure that
7 he can hear you. You'll let me know when they're at counsel
8 table, if you can't.

9 I know, when you do argument, you'll be at the
10 podium. But I do want to make sure that you speak loudly
11 enough so that he can hear.

12 All right. Let's start first with plaintiffs'
13 counsel -- actually, I'm going to have you guys identify
14 yourselves first and then we'll go to the motion.

15 MR. GUSTAFSON: Thank you, your Honor. Dan
16 Gustafson on behalf of plaintiffs. With me is Karla Gluek
17 and Amanda Williams from my office, and Marcus Stevenson from
18 the firm Riff, Stevenson firm in Houston. I gave the court
19 reporter cards, so he has all the spellings.

20 THE COURT: All right. Let me make sure.
21 Mr. Gustafson, Ms. Gluek. The third person was...?

22 MR. GUSTAFSON: Ms. Williams.

23 THE COURT: Ms. Williams.

24 MR. GUSTAFSON: And Marcus Stevenson.

25 THE COURT: Yes. Okay. And on behalf of

1 Medtronic?

2 MR. RING: Good morning, your Honor. Dan Ring
3 on behalf of Medtronic defendants. With me is Jennifer
4 Huelskoetter from the Bowman and Brooke firm.

5 MS. HUELSKOETTER: Good morning, your Honor.

6 THE COURT: Good morning to you as well.

7 All right. We are here today to address
8 plaintiffs' motion to amend the Protective Order and to
9 compel redaction of FDA documents. I have the moving papers
10 by plaintiffs; the response by the defendants. My
11 understanding is no reply was filed by plaintiffs.

12 Is that correct, Mr. Gustafson?

13 MR. GUSTAFSON: Yes. My understanding is we're
14 not allowed reply briefs in this district.

15 THE COURT: You are under my order. So under
16 the order of this case, on nondispositive motions, you are
17 allowed to do reply briefs. So check it out in terms of how
18 much I allow you by way of word length, and all of that.

19 MR. GUSTAFSON: Okay.

20 THE COURT: In any event, I just want to make
21 sure I didn't miss it.

22 MR. GUSTAFSON: You didn't miss it. I was not
23 aware of that, your Honor.

24 THE COURT: Okay. And I would also say -- now,
25 I'm speaking from memory, because it's included in all of my

1 orders -- but the MDL order -- I'll have to check to make
2 sure that it includes it as well. If it doesn't, I'll modify
3 it. But, in any event, just so you know in the future, you
4 are allowed a reply up to -- I think it's 3,500 words, so
5 long as your total doesn't exceed the total amount allowed
6 for nondispositive motions. Go ahead.

7 MR. GUSTAFSON: Okay. Your Honor, a reply
8 would have been helpful in this, I think.

9 THE COURT: I do too.

10 MR. GUSTAFSON: But I will check. And if that
11 was the case --

12 THE COURT: And I will check too.

13 MR. GUSTAFSON: If it turns out that we were, I
14 apologize, because we should have filed one, because I think
15 that Medtronic's opposition sort of misses our point. And,
16 so, let me go to that -- let me give you a little background
17 first. There are about a dozen FOIA requests that have been
18 filed in this case. I'm not sure of the exact number because
19 they don't file them through me. I'm lead counsel in this
20 case, as you know, but not with respect to the individual
21 cases that are filed and unfilled across the country. There
22 were several files before the MDL; there have been
23 subsequently more files after the MDL. As you know, this
24 Court stayed discovery before the MDL, waiting for the MDL to
25 rule, and, then, subsequently stayed discovery again.

1 Subsequent to the MDL consolidating the cases here in
2 Minnesota there have been three civil actions filed, one in
3 the Central District of California; one in the District of
4 Minnesota, in which, I believe, Judge Davis has been
5 assigned, if I remember right; and there is a citizens'
6 petition action filed in the Southern District of Texas.
7 It's slightly different because it also asks the FDA to
8 cancel the premarket approval of the Sprint Fidelis lead, but
9 it has a FOIA component to it.

10 In response to the FOIA, the FDA has produced
11 several thousand documents. They are in redacted form. The
12 FDA has also contacted the lawyers who have filed these --
13 lawyers and citizens who have filed these FOIA requests and
14 asked us to coordinate our efforts. As part of that, the FDA
15 has made clear to us that they do not want to take the time
16 to redact the documents if they don't have to. It's a
17 complicated -- not complicated -- it's a time-consuming
18 process. And they suggested to us that we move the Court to
19 add the language that we have proposed in this motion to
20 protect the confidentiality of this exception for
21 information, which is Medtronic's business and trade secret
22 information. It accomplishes two things: It saves the FDA,
23 obviously, administrative time and expense; and it protects
24 Medtronic from the inadvertent disclosure of the information.
25 As you see from the proposed language that we put in by way

1 of my affidavit, it would govern either a FOIA request or a
2 subpoena -- which, of course, we have not been able to file
3 here because discovery is stayed.

4 The plaintiffs' motion also solves the MDL
5 problem. As you know, of course, Judge, the MDL is designed
6 to coordinate and consolidate pretrial activities in this
7 court so that we don't have different rulings and
8 inconsistent outcomes for cases that are filed across the
9 country. For example, granting plaintiffs' motion here will
10 allow everyone access to these documents at the same time
11 rather than a haphazard approach of documents being produced
12 at different times in different courts and subject to
13 different rulings. The second thing it would do would
14 prevent the problem which will occur -- and is highlighted by
15 Medtronic's response -- if we go through the FOIA process and
16 these documents are produced after we litigate, whether they
17 are, in fact, confidential, trade secret-type information,
18 those documents will be public. And, so, some of the people
19 who get those documents in FOIA litigation will have public
20 documents. If the case is not dismissed and discovery goes
21 forward in this case, those same documents will be produced
22 here, subject to a Confidentially Agreement. And the Court
23 here, and elsewhere, will not be able to distinguish between
24 those documents because they're going to be the same
25 documents, the ones that were produced subject to a

1 Confidentially Agreement and those that were produced subject
2 to FOIA. Apart from the confusion that would create, I can
3 imagine there will be many accusations that Protective Orders
4 were violated if that becomes the case.

5 Medtronic, of course, refused to agree to
6 plaintiffs' motion. In fact, as I recall it -- I don't want
7 to put too fine a point on it -- they said they would never
8 agree under any circumstances or any type of situation. In
9 their papers, they take the position that they can't do it,
10 for several reasons. First of all, they say the stay of
11 discovery prohibits it and we're just trying to avoid the
12 stay of discovery. They suggest -- and I'm certain that the
13 Court will disagree with this -- that our failure to ask for
14 reconsideration on the stay of discovery somehow precludes us
15 from bringing this motion now. That's not my understanding
16 of what Rule 7.1(g) was intended to be. But, nonetheless,
17 that's the position they suggest in their papers.

18 Keep in mind, Judge, that the reason that this
19 court has stayed discovery is because of the burden that it
20 imposes on Medtronic. Again, I'm paraphrasing, but what the
21 Court said is that until plaintiffs plead a cognizable cause
22 of action Medtronic should not be put to the burden of having
23 to do discovery. This doesn't create any burden on
24 Medtronic. This, in fact, alleviates a burden for Medtronic.
25 If the Court amends the Protective Order, the FDA is willing

1 to produce these documents at no expense to Medtronic at all,
2 no inconvenience to Medtronic and no risk to Medtronic. They
3 can have all of their trade secret, confidential information
4 protected.

5 Secondly, Medtronic says that FOIA doesn't
6 permit -- and they cite a handful of cases, six or eight
7 cases. First of all, this isn't the FOIA case. This is
8 the MDL proceeding, where the Court is charged with the
9 responsibility of coordinating and managing pretrial
10 proceedings. True enough, the cases that Medtronic cites
11 suggests that FOIA doesn't provide an opportunity for the
12 Court to enter a Protective Order and essentially re-secret
13 or reclassify FOIA-produced documents as confidential. But
14 the cases that Medtronic cites are not Section (sic) 6 cases.
15 All of them are cases in which the Government had an interest
16 in keeping the information privileged or secret. They were
17 national defense cases, which is Exemption 1, they were law
18 enforcement cases, which is Exemption 7, and they were
19 personal privacy cases, which are Section 6 -- or --
20 Exemption 6. All of those cases have a common theme. The
21 agency that was being asked to produce the documents was
22 opposed to producing them for reasons unrelated to the FOIA
23 procedural aspects. Here, we have a different case. We have
24 a circumstance in which the FDA wants to produce the
25 documents under a Protective Order because it doesn't want to

1 be burdened with trying to redact the thousands of documents
2 that are at issue here.

3 Now, whether we did it as a FOIA request or as
4 a subpoena seems to make a difference under these cases. We
5 didn't, because I was working under the assumption that we
6 couldn't do a reply brief. But the Vioxx litigation -- which
7 I'm sure the Court is familiar with -- had this very same
8 issue come up, and they reached an agreement with FDA and
9 they produced the Vioxx documents via subpoena. So this is
10 not a --

11 THE COURT: This was a subpoena to the FDA?

12 MR. GUSTAFSON: A subpoena to the FDA.

13 THE COURT: And when you say an agreement was
14 reached, between who?

15 MR. GUSTAFSON: As I understand the -- it's not
16 an order, it's a Confidentially Agreement. As I understand
17 it, it's an agreement between Merck, the defendant, and the
18 plaintiffs and the FDA to produce the documents, subject to
19 the Confidentiality Order (sic) -- which is what we've
20 suggested here. Obviously we couldn't issue a subpoena to
21 the FDA because there's a stay of discovery, although I
22 understand -- I don't know this to be the case, but I
23 understand that there are some state-law cases which, for
24 various reasons, can't be removed -- an MDL -- which have now
25 either filed for a subpoena with the FDA or intend to file

1 subpoena with the FDA -- which sort of highlights the issue
2 of coordination that I mentioned earlier.

3 I was only able to find one case, Judge, that
4 talked about Section 4 issues with respect to a Protective
5 Order, it's *Public Citizen Health Research Group v. FDA*. It
6 deals with the Paxil drug, if you're familiar with Paxil.
7 It's 953 F.Supp. 400.

8 THE COURT: 953...?

9 MR. GUSTAFSON: F.Supp. 400. It's out of the
10 District of Columbia -- the District of the District of
11 Columbia, 1996. In that case, the Court did exactly what we
12 were asking, under different facts. It issued a Protective
13 Order to protect FDA documents that had been released via the
14 FOIA process. Now, it's a different set of facts because the
15 documents were released by the FDA and, then, the defendant,
16 who I believe was Abbott Laboratories, came back and said:
17 You should not have released these documents. They were
18 confidential. And they went to the Court, and the Court
19 said: I'm going to enter a Protective Order so that nobody
20 can release these to the public. But they had been released
21 by FDA pursuant to a FOIA request under Section 4. And the
22 court -- not citing to FOIA, because I agree there's no
23 provision in FOIA for Protective Orders -- but citing to the
24 Court's inherent authority to manage the litigation before it
25 entered a Protective Order and precluded public disclosure of

1 the documents. I think that the fact that this court is an
2 MDL court illustrates that its use of its inherent authority
3 here to issue a Protective Order would be appropriate. It's
4 an unusual situation in that you've been asked to manage
5 litigation from all over the country. What we're asking here
6 doesn't inconvenience anyone. If the notion of the stay of
7 discovery here is to prevent access to information, then this
8 motion should be denied. If the notion here is to prevent an
9 inconvenience to Medtronic or the burden and expense of
10 producing discovery to Medtronic before the case has gone
11 forward past the motion to dismiss, then there are a lot of
12 options for this court to allow these documents to be
13 produced in a confidential manner. It protects FDA, it
14 protects Medtronic, and it allows documents that would
15 otherwise be public to be produced to the plaintiffs.

16 Thank you, your Honor.

17 THE COURT: If you could -- one of the
18 arguments that's made by Medtronic has to do with what I'm
19 calling their "selective dissemination argument," that if, in
20 fact, the FDA were to release these documents in an
21 unredacted form, that basically it would be required to
22 produce those documents to any other member of the public,
23 regardless of what they wanted, in an unredacted form.

24 MR. GUSTAFSON: I think that there are cases
25 that stand for that proposition. I think that the *Citizen*

1 *Public Group (sic)* case I cited to you stands for the
2 opposite proposition. But that's easily resolved if you
3 allow us to issue a subpoena to the FDA and we resolve it in
4 that fashion. Because that clearly is an argument that only
5 applies under FOIA.

6 THE COURT: I'm sorry, "that only applies...?"

7 MR. GUSTAFSON: "Under FOIA." There are cases
8 that suggest, once the Government has released FOIA documents
9 pursuant to FOIA, that they then have to make them available
10 to anyone else who asks for them. I don't dispute that.

11 The *Citizen Public Group* case stands for a
12 different proposition or, you know, stands contrary to that
13 proposition. But there's no doubt that if the FDA responded
14 to a subpoena instead of a FOIA request that concern would be
15 evaporated.

16 THE COURT: But obviously I don't have a
17 subpoena in front of me, nor do I have a motion, for example,
18 to lift the stay to allow for a subpoena. In other words,
19 what I've got in front of me is to amend the Protective Order
20 to not only protect these FOIA-produced documents under the
21 Protective Order but also to go so far as to say that
22 Medtronic can't object to them being produced in an
23 unredacted form. And what I hear Medtronic saying is, Judge,
24 if you grant this and the FDA then produces them in an
25 unredacted form, they are not going to be able to --

1 basically they are not going to be able -- meaning the FDA --
2 is going to be permitted to redact them for any other member
3 of the public who comes forward and makes a FOIA request for
4 these same documents. And maybe I've misstated Medtronic's
5 argument, but that's what I understand their kind of
6 selective dissemination argument is about.

7 MR. GUSTAFSON: That's how I understand it
8 also.

9 THE COURT: And, then, this Protective Order
10 really has no meaning, because the FDA will be required to
11 produce those documents in an unredacted form, having
12 produced them here.

13 MR. GUSTAFSON: I think that is their argument,
14 and I think that their cases stand for that proposition,
15 except for they're not Section 4 cases and they're contrary
16 to *Citizen Public Watch* (sic) case.

17 But to the extent that this problem can be
18 solved with a subpoena to the FDA, I mean, I'm happy to make
19 that motion. It seems to me that the job of the MDL court
20 here is to try to find a solution to a problem that FDA has
21 asked us to solve and the plaintiffs have asked us to solve.
22 If it takes another motion, we're happy to make that motion.
23 We think here that the Court has the power to resolve this
24 issue.

25 THE COURT: All right.

1 MR. GUSTAFSON: Thank you.

2 THE COURT: Thank you. Mr. Ring.

3 MR. RING: Thank you, your Honor. Let me start
4 with our position on the Court's prior order of February 5th.
5 Our position is that that order not only entered and
6 continued the stay but dealt with this very dispute, which
7 was presented in the January 22nd Joint Status Report as
8 plaintiffs' request for the production of unredacted FDA
9 documents or, ordering Medtronic to consent to their
10 production. We opposed that. It was before the Court, and
11 the Court, in broadly declining to allow discovery -- and
12 that's what that really is, it is discovery by any other name
13 -- said: No. We're not going to have discovery before
14 plaintiffs are able to state a viable claim -- which they
15 have not done. And while it's true that the ruling is, in
16 part, based on the burden of discovery, it's also based on
17 the very basic and practical proposition that discovery
18 follows the statement of a viable claim. It doesn't precede
19 it.

20 As to the issue of this court's authority under
21 the MDL, I think the February 5th ruling was the ruling by
22 this court, coordinating discovery and saying, no, it's not
23 going to happen, whether through FOIA or any other means,
24 until there's a viable claim stated -- which hasn't happened
25 yet.

1 On the issue of selective disclosure, the case
2 law we have cited broadly states the proposition, consistent
3 with FOIA, that disclosure to one is disclosure to all. It's
4 not driven by which exemption is in dispute. And, in fact,
5 as to what authority governs here, the Eighth Circuit, in
6 1978, in a case called *State of North Dakota v. Andres* --
7 which we've cited -- 581 F2d 177 -- dealt with this very
8 situation. The Government in that case had produced material
9 to the *Audobon Society* with a Confidentially Agreement. And,
10 then, in the case before the Eighth Circuit, with the State
11 of North Dakota asking for those same documents, the FDA
12 said: Wait a minute, our selective disclosure was pursuant
13 to a Confidentially Agreement. That means that we can still
14 maintain our position, that we don't have to produce them
15 under FOIA now to North Dakota. The Eighth Circuit said --
16 quite emphatically -- that's wrong. Once they're disclosed,
17 the Government cannot withhold them from production pursuant
18 to an identical FOIA request to another party. That's
19 contrary to FOIA. There's no provision in FOIA -- and I
20 think counsel agrees -- there's no provision in any aspect of
21 FOIA or any of the exemptions for production pursuant to a
22 Confidentially Agreement. So even if the FDA is now saying
23 -- and, of course, they're not here -- and they're not taking
24 that position before this court, nor have they agreed to be
25 bound by any Protective Order to prevent them from changing

1 their mind later -- the courts have uniformly said: Even if
2 the FDA wanted to take that position, as they did in 1978,
3 they can't take that position. They're not permitted under
4 FOIA to make selective disclosures to one party, whether
5 pursuant to a Confidentially Agreement or otherwise.

6 Now, the issue of the subpoena has come up,
7 although not really argued and presented to the Court. I
8 don't think we agree that a subpoena resolves this problem.
9 Other parties have attempted to use subpoenas to do end-runs
10 around FOIA requests and disclosures. That issue itself
11 would have to be litigated and briefed. But we don't agree
12 that simply the mechanism of a subpoena would obviate all the
13 FOIA considerations. The parties have tried that before. I
14 don't think the law says that that's a simple way around the
15 problem.

16 So where we come down to it is the request here
17 is nothing about rendering burdens or inconvenience to
18 Medtronic a nonissue. In fact, it creates worse burdens,
19 because a selective disclosure under these circumstances
20 would not prohibit the FDA from disclosing them. And
21 parties, including competitors and other members of the
22 public, would be entitled, and would have every right to
23 argue, that once they're disclosed, they become public
24 documents and have to be disclosed generally. And under
25 the evolving standards of electronic FOIA, they might even

1 have to be posted on the FDA's Web site for all to see --
2 competitors and the public alike. That is not permitted by
3 FOIA. It's not called for by any of the cases the plaintiffs
4 cite. They cite not one for the proposition that the FDA can
5 enter into -- in fact, the proposed Protective Order here
6 isn't even the FDA entering into it, it's the parties before
7 this court entering into a modification of a Protective Order
8 the FDA is not even bound by. Those cases uniformly prohibit
9 the use of Protective Orders because of FOIA's basic
10 proposition, it is designed to compel the production of
11 public government documents, and what the FDA produces or
12 what a government agency produces then becomes public. It's
13 selective disclosure or attempts to delineate between this
14 group or that group -- it may reduce the FDA's burden, but,
15 in fact, that's the burden it has under FOIA. In fact, even
16 one of the cases that the plaintiffs cited -- *Uniroyal* --
17 involved a situation where the party with the interest in the
18 documents had tendered to the government agency a redacted
19 version of the documents, saying, This is our version of what
20 you, the Government, should produce. The court there said:
21 No. It's the Government's burden to go through the documents
22 and make its own determination. It is not enough for the
23 Government to avoid disclosure by saying, The private party
24 submitted it and we're going to just do that.

25 So in terms of reduction of the Government's

1 burden, it sounds simple, but it's not a basic proposition
2 that a Protective Order is going to obviate the legal burden
3 imposed by FOIA for the FDA to respond to the requests.

4 From our position, the FDA-stated position in
5 the litigation, at least that's been cited to this court, is
6 these requests, pursuant to the case law that's developed
7 primarily in the District of Columbia, should be stayed and
8 put in the queue, where many other requests are before
9 theirs. And that's how the FDA and other government agencies
10 deals with the overwhelming burden of FOIA requests.

11 THE COURT: So what does that mean in terms of
12 the -- I saw that in the FDA answers. And part of what
13 they're saying is this litigation should be stayed and put in
14 the "queue." What does that mean?

15 MR. RING: As a practical matter, what it means
16 is this. Because the FDA and other government agencies get
17 so many FOIA requests, they process them on a first in, first
18 out basis. And what the courts have said is we're not going
19 to let somebody who sues jump the queue and force us to act
20 faster. Because you can see what would happen then,
21 everybody would be filing suit, taking up the Government's
22 time responding to the suits, trying to get their requests
23 higher in the line. And as long as the government agency is
24 acting with reasonable diligence, pursuant to the budget and
25 the amount of time they have and the amount of staff and

1 resources they have, courts have said: That's right. The
2 only thing we can force them to do is act in a first in,
3 first out basis on a timely fashion, and we're not going to
4 let litigation jump ahead of the other requests.

5 And that's the basic doctrine you see espoused
6 in the Government's answer here is that, in the ordinary
7 course, they respond to these by saying, Put a place holder
8 here. We'll get to yours, but your case is behind a lot of
9 others who have an equal demand on our time and resources.

10 THE COURT: But hasn't the FDA, in fact, gone
11 ahead -- they've gone ahead and responded. They've produced
12 documents. They've now produced them in a redacted formed.
13 And as I understand, part of the litigation -- well,
14 depending on which suit we're talking about -- part of it had
15 to do with they hadn't responded at all, and that I
16 understand the issue of put in a stay, let us respond in a
17 timely fashion. But it seemed that other litigation had to
18 do with the fact that plaintiffs' view was information was
19 wrongfully withheld, meaning, we've got documents now. We're
20 looking at them. They're redacted. We think they're
21 redacted improperly. And, so, putting it in the ordinary
22 queue is no longer what the issue is.

23 MR. RING: Well, I think it still is, at least
24 from what I understand has happened, based on the record
25 that's before the court, is that the FDA has produced more

1 documents -- and maybe that's the prod of litigation doing
2 that -- but it's also the case that they seem to have
3 produced documents to different people at different times
4 and, as Mr. Gustafson said, they now realize they have more
5 than one party asking for the same things and demanding the
6 same documents. And, so, I'm not aware of any litigation
7 over the scope of the redactions the FDA has made or any
8 resolution as to that issue.

9 So I think where Medtronic comes out, and what
10 our position is -- I think amply supported by the law -- is
11 that, first, this issue was already before the Court and
12 resolved in the February 5th ruling, where the Court decided
13 that no discovery would take place before a viable claim was
14 stated. Second, that FOIA doesn't permit selective
15 disclosures, whether or not pursuant to a Protective Order.
16 And that even if the Government was stating that position
17 here before you, the Eighth Circuit case we've cited and the
18 other courts we've cited have rejected that proposition. And
19 while I understand if the FDA were here making that its
20 formal position, that they may well be arguing it, would
21 relieve our burden. The courts have said: No, you can't do
22 it. And the burden then falls on Medtronic. If this is
23 permitted, the protection that FOIA recognizes -- and it's
24 important to recognize what Exemption 4 is for. It's for
25 trade secrets, confidential commercial and financial

1 information -- which, for a device company, is its lifeblood.
2 There's a very good policy reason why the Government would
3 have such documents through the course of approving medical
4 devices. And FOIA recognizes that -- twofold, we want to
5 protect that intellectual property; and we want to continue
6 to encourage parties who have it to be able to submit it to
7 the Government without fear that it's going to be disclosed
8 publicly, making that information valueless or, to the
9 contrary, making it really valuable to competitors. And
10 those two policy reasons are why Exemption 4 is so important
11 and why, unlike the general rule, FOIA requires public
12 disclosure, Exemption 4 recognizes that those materials that
13 properly fit within Exemption 4 should not be disclosed.
14 And, so, the case law that recognizes you can't do selective
15 disclosure is in tandem with that policy reason why a
16 Protective Order wouldn't be appropriate here.

17 Thank you, your Honor.

18 THE COURT: I don't have any other questions.

19 Mr. Gustafson.

20 MR. GUSTAFSON: Very briefly, your Honor?

21 THE COURT: Yes.

22 MR. GUSTAFSON: My memory isn't what it once
23 was -- and it wasn't that good to start with -- but my
24 recollection is Judge Kyle told us to bring this issue to you
25 at the last conference, when we discussed it. I don't think

1 his ruling covers this issue. I'd have to look at the
2 transcript to be sure. But my recollection is that I asked
3 about whether I should bring this subpoena -- I mean this
4 Protective Order issue to you, and he directed me to bring it
5 to your Honor. So I disagree that he decided this issue with
6 respect to his order reaffirming the stay of discovery.

7 The second thing --

8 THE COURT: Are we talking about the February,
9 2008 order? Are you referring to the same order that
10 Mr. Ring is talking about?

11 MR. GUSTAFSON: I think he's talking about the
12 order that starts out denying our rebuts for reconsideration.

13 MR. RING: That's right.

14 MR. GUSTAFSON: And then it goes on?

15 MR. RING: The February 5th, 2009 order.

16 MR. GUSTAFSON: The February 5th, 2009 order.

17 MR. RING: You're right, though, that the stay
18 of discovery goes back long before that. But most recently
19 that's the order reaffirming that no discovery will be had.

20 MR. GUSTAFSON: But the suggestion that we
21 argued this issue in front of the Judge I think is wrong. If
22 you look at the -- and I will, I'll look at the transcript --
23 but I believe he told us to bring this issue to you. So I
24 don't think it's been decided.

25 With respect to the *Andres* case out of the

1 Eighth Circuit, I don't think the recitation of the facts is
2 correct. I think if you look at the facts on the *Andres*
3 case, you'll see that the Government was subject to a
4 discovery order in an unrelated case, not a FOIA request, and
5 that they voluntarily produced those documents as part of a
6 settlement discussion. And, then, the Eighth Circuit said:
7 Well, look, if you're voluntarily producing them as part of
8 that settlement discussion, you can't withhold them and say
9 their confidential work product or sort of the Government
10 equivalent of privilege. So I don't believe the *Andres* case
11 stands for the proposition for which it was put forth.

12 THE COURT: You're saying that the *Andres* case
13 does not involve the FOIA requests.

14 MR. GUSTAFSON: I think the waiver that was
15 found by the Eighth Circuit in *Andres* was a Government waiver
16 that was unrelated to FOIA, that's correct. It was a subject
17 to a discovery dispute. I believe the documents were
18 produced to the other side there as part of an effort to
19 settle the litigation. The issue there was whether it was
20 essentially Government work product. They call it, you know,
21 memorandum in process, or something like that. But it's
22 essentially work product. And the Eighth Circuit said: You
23 can't claim work product after you voluntarily gave it up in
24 related litigation.

25 But this whole notion about the queue -- you

1 know, you don't have to sue under FOIA. You can make your
2 FOIA requests and you can do what you will with what they
3 give you. Only three of the dozen or so people have sued
4 under this. The people who sue get to pursue their lawsuit.
5 They don't get put away by the queue of who filed their
6 letters first. And just so you know, Judge, the FDA has
7 coordinated this production. Everybody gets the same
8 documents regardless of the order in which they submitted
9 their initial FOIA requests. It seems to me here that there
10 are technical defenses that can be made, depending on how you
11 view this. And if the objective here is to keep the
12 information that Medtronic submitted to the FDA private, we
13 can find a way to do that. If the objective here is to avoid
14 the burden on as many people as possible and coordinate the
15 activities for everyone so that everyone gets a consistent
16 outcome and the FDA gets the smallest burden possible and
17 Medtronic gets the smallest burden possible, there's a way to
18 do it and that's to amend this Protective Order and grant
19 plaintiffs the opportunity to get these documents unredacted.

20 Thank you.

21 THE COURT: All right. Mr. Ring, anything
22 further?

23 MR. RING: Just briefly. The Court mentioned
24 this at the beginning, that the proposed amendment would
25 actually, then, impose on Medtronic the burden to review

1 documents, which -- I should note for the record, we don't
2 know what the FDA has produced, so we don't have the
3 thousands of documents. But review those documents,
4 designate them, and now we're going to litigate whether the
5 confidentiality designation was appropriate. I can't think
6 of anything that more closely resembles the discovery process
7 that the Court, on February 5th, said shouldn't go forward
8 until we have a viable claim here. I think the *Andres* case
9 is an example -- and we've cited many others and their
10 related propositions, both selective disclosure under FOIA
11 or, any other disclosure by the Government will waive the
12 argument that the documents should be exempt from disclosure.
13 So however it happens, whether through FOIA requests or the
14 FOIA requests of North Dakota arguing that the prior
15 disclosure, even pursuant to a Confidentially Agreement,
16 could not be used by the Government to object to a FOIA
17 request. The case law is uniform in saying the Government
18 can't do that. And thus, while I understand plaintiffs want
19 to say there's some mechanism here that will work that will
20 protect Medtronic, the proposed motion and amendment of a
21 Protective Order won't do that. And it's premature. And
22 unless and until they can establish a viable claim, it's
23 discovery by any other name.

24 Thank you, your Honor.

25 THE COURT: Let me just make sure I understand.

1 When you talk about the burden to Medtronic, you're saying if
2 I were to agree to add what are proposed paragraphs 26
3 through 28 of the Protective Order to address the FDA
4 documents, the burden to Medtronic -- let's assume -- so now
5 the FDA produces them unredacted to the individuals who have
6 made the FOIA requests or to the steering committee. You're
7 saying that the burden to Medtronic will be to do what with
8 those documents, to review them to decide whether they need
9 to be designated as confidential under the Protective Order?
10 I want to make sure I understand.

11 MR. RING: That's what I understood the
12 proposal to be is that we would then have 30 days to review
13 them all and designate them under the Protective Order and,
14 then, the plaintiffs would then litigate with us whether or
15 not they are subject to protection or not.

16 In addition, there's the related burden, of
17 course, that, in our view of the law, now when the FDA is
18 presented with a FOIA request for those documents which were
19 previously produced in redacted form and which are subject to
20 Exemption 4, we'll have to litigate whether or not the
21 Exemption 4 still is available, given the production. And,
22 so, we're going to have a future burden every time those are
23 requested, to try to protect the Exemption 4 -- which the law
24 doesn't, in our view, give the FDA the ability to protect,
25 once it makes a disclosure.

1 Thank you, your Honor.

2 THE COURT: Thank you. Mr. Gustafson, you were
3 shaking your head when I was asking Mr. Ring about the burden
4 of Medtronic if the FDA were to produce the documents
5 unredacted, and he indicated, yes, there would be a burden.
6 They'd have to review the documents. They'd have 30 days to
7 designate which ones should be marked confidential under the
8 Protective Order. And, then, if plaintiffs disagreed,
9 obviously there would be the meet and confer, and litigation
10 over it. And you were shaking your head, suggesting that
11 wasn't true, side to side.

12 MR. GUSTAFSON: I was. And I don't agree that
13 the Protective Order in this case -- I mean I assume they'll
14 designate them all confidential. They designate everything
15 they've ever produced confidential in any litigation I've
16 ever been in with Medtronic or any other defendant. And why
17 would we challenge their designation. We would be able to
18 use them anyway under the Protective Order. So I don't think
19 there's any burden at all.

20 I think that the 30-day provision is put in the
21 papers so they could designate things as not confidential.
22 But I would be skeptical that anything that the FDA produced
23 would be not confidential in their view. So I don't see a
24 burden.

25 THE COURT: All right. And the last question

1 -- one of the points that Mr. Ring made in his earlier
2 argument was that this Protective Order is an order of this
3 court that actually arises out of a stipulation signed by the
4 parties but is addressed to the parties here. In other
5 words, the FDA is not party to this Protective Order.
6 They're not party even to this motion. And, so, to the
7 extent that I were to grant the motion and allow them to be
8 produced and protected here, on what basis would this be
9 binding on the FDA?

10 MR. GUSTAFSON: Well, the FDA is bound by the
11 obligation that it's bound by under FOIA and other
12 regulations, to keep confidential the information of
13 Medtronic. The fact that they produced them to this court
14 would sort of put them in the, you know, yard of this court.
15 And, so, the people who were bound by that order couldn't
16 disclose them to the press or anyone else. But FDA is
17 governed by, you know, statutes and its own regulations. It
18 wouldn't have the ability to disclose these documents outside
19 the law just because it burdens them here.

20 The argument is that there was somehow a waiver
21 or something. That's a different issue. But they wouldn't
22 be able to just disclose them to The New York Times, for
23 example, because they weren't bound by this Protective Order.
24 The FDA is covered by all sorts of regulations, including
25 FOIA.

1 THE COURT: All right. So just so I'm clear --
2 so let's assume The New York Times then makes an identical
3 FOIA request for the identical documents that were made by
4 the 12 plaintiffs here, and these documents have now been
5 disclosed in an unredacted form here in this litigation and
6 are protected under this Protective Order, and now the FDA --
7 you're saying they obviously can't look to this agreement
8 here between Medtronic and the plaintiffs. They'll have to
9 look to the FDA -- what regulations govern them for FOIA
10 requests as to whether they could disclose the documents to
11 The New York Times in an unredacted form.

12 MR. GUSTAFSON: Right. But you can put it in a
13 different way. Let's say the FDA gives the documents here
14 because you grant the motion and amend the Protective Order.
15 The New York Times can't come here and get them. They can't
16 come here and get them. They can ask the FDA, through FOIA
17 or any other statutes that apply --

18 THE COURT: If the FDA determines it's governed
19 by the Eighth Circuit law arising out of the *Audobon Society*
20 case, that once they've closed it in an unredacted form here
21 that they then must disclose it to any other party who makes
22 the same request -- they'll do it.

23 MR. GUSTAFSON: They'll do what they do. I can
24 assure you that Medtronic will take the opposite position in
25 that litigation. When The New York Times makes a FOIA

1 request and says that it's been waived by this court getting
2 the documents here, I can assure you that Medtronic will
3 stand up and say there hasn't been a waiver and that they
4 can't produce those documents to The New York Times. But it
5 will be what it will be.

6 THE COURT: All right.

7 MR. GUSTAFSON: Thank you, your Honor.

8 THE COURT: Thank you. Mr. Ring, anything
9 further?

10 MR. RING: Just briefly on what our position
11 will be, Judge. Our position will be what the law is, which
12 is that once disclosed that's -- his example is exactly a
13 highlight of the burden that's imposed on Medtronic here.
14 The FDA won't be able to, whether it wants to or not -- and
15 it's not just the Eighth Circuit. It's the U.S. Supreme
16 Court that says the Government can't do selective
17 disclosures. It's the Seventh Circuit. It's the Ninth
18 Circuit. It's the DC Circuit. Uniformly the Government
19 cannot make selective disclosures. And even if the FDA -- of
20 course, it's not bound to -- another point, just to
21 illustrate it, it's not bound to say, Well, we produced them
22 confidentiality. Office of general counsel, under the Obama
23 administration -- which has instructed agencies to be more
24 open and forthcoming and to do so promptly -- would quite
25 easily be able to say, We're not bound by that order. We're

1 going to disclose because we have disclosed, and the law says
2 we can't be selective.

3 And, so, I think that actually highlights the
4 problem here.

5 THE COURT: All right. I will take the matter
6 under advisement. Thank you very much.

7 MR. GUSTAFSON: Thank you, your Honor.

8 THE COURT: All right.

9 (Court stood in recess at approximately 11:30
10 a.m., on March 30th, 2009).

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

1 STATE OF MINNESOTA)

2)ss.

3 COUNTY OF HENNEPIN)

4

5 I, Ronald J. Moen, Official Shorthand Reporter, CSR,
6 RMR, and a Notary Public in and for the County of Hennepin,
in the State of Minnesota, do hereby certify:

7 That the said proceeding was taken before me as an
Official Shorthand Reporter, CSR, RMR, and a Notary Public at
8 the said time and place and was taken down in shorthand
writing by me;

9 That said proceeding was thereafter under my direction
10 transcribed into computer-assisted transcription, and that
the foregoing transcript constitutes a full, true and correct
11 report of the transcript of proceedings which then and there
took place;

12 That I am a disinterested third person to the said
13 action;

14 That the cost of the original has been split equally
15 between the parties who ordered the transcript of
proceedings, and that all parties who ordered copies have
16 been charged at the same rate for such copies.

17 That I reported pages 1 through 33.

18 IN WITNESS THEREOF, I have hereto subscribed my hand
this 6th day of April, 2009.

19

20 s/ Ronald J. Moen
21 RONALD J. MOEN,
Official Court Reporter,
CSR, RMR

22

23

24

25