UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In Re: BAYCOL PRODUCTS LITIGATIONS) MDL No. 1431
) (MJD)
) 2:00 p.m. o'clock
) March 18, 2002
) Minneapolis, MN
)

BEFORE THE HONORABLE MICHAEL J. DAVIS
UNITED STATES DISTRICT COURT JUDGE
(RULE 23(d) MOTION HEARING)

APPEARANCES:

ON BEHALF OF THE PLAINTIFFS: CHARLES ZIMMERMAN, ESQ.
STANLEY CHESLEY, ESQ.
RICHARD LOCKRIDGE, ESQ.
DIANNE NAST, ESQ.
JOHN CLIMACO, ESQ.
ROBERT HOPPER, ESQ.
JAMES DUGAN, ESQ.
RONALD GOLDSER, ESQ.

ON BEHALF OF THE DEFENDANTS: MARK FERGUSON, ESQ.
PETER SIPKINS, ESQ.
SUSAN WEBER, ESQ.
GARY MC CONNELL, ESQ.
TRACY VAN STEENBURGH, ESQ.
NORBERT BERGHOLTZ, ESQ.

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THE CLERK: Multi-District Litigation No. 1431, In Re: Baycol Products. Please state your appearances for the record.

MR. ZIMMERMAN: Charles Zimmerman, Zimmerman Reed for the plaintiffs, Your Honor.

MR. LOCKRIDGE: Richard Lockridge for the plaintiffs, Your Honor.

MS. NAST: Dianne Nast for the plaintiffs, Your Honor.

MR. HOPPER: Randy Hopper, Zimmerman Reed, for the plaintiffs, Your Honor.

MR. CLIMACO: John Climaco for the plaintiffs, Your Honor.

MR. DUGAN: Good afternoon, Your Honor, James Dugan for the plaintiffs.

MR. GOLDSER: Me, too, Your Honor, Ron Goldser, Zimmerman Reed, for the plaintiffs.

MR. SIPKINS: Peter Sipkins, Your Honor, on behalf of Bayer.

MR. MC CONNELL: Gary McConnell, Bayer, Your Honor.

MS. WEBER: Susan Weber, Bayer.

MR. SIPKINS: Your Honor, with us today is Mark Ferguson of the Bartlit Beck firm.

MR. FERGUSON: Good afternoon, Your Honor.

THE COURT: Good afternoon.

MS. VAN STEENBURGH: Good morning, Tracy Van Steenburgh on behalf of the GlaxoSmithKline.

MR. BERGHOLTZ: Norbert Bergholtz on behalf of GlaxoSmithKline.

THE COURT: All right.

MR. ZIMMERMAN: I've got a couple of housekeeping matters. Charles Zimmerman, Your Honor, for the plaintiffs. We're here to argue our Rule 23(d) motion for protection and management of the proceedings. Mr. Chesley will be arguing that. But I'll have a couple of other matters to report to the Court on.

We have been meeting and conferring on the matters that were before the Court the last time we were here that had to do with the plaintiff fact sheet, the document production deadline, and with that what we call the rolling privilege log. And I'm happy at this time to hand up to the Court a stipulation that was signed this morning between all counsel and lead counsel and liaison counsel for the plaintiffs and defendants which resolves those three issues.

We have come up with a plaintiff fact sheet that we agree to that is attached and forms of medical authorizations for those different categories of claimants, and that's attached as Exhibit A. We have come up with a

deadline for the production, the final production of documents by the defendant Bayer and the defendant GlaxoSmithKline which will be November 15, 2002. In other words, all the documents will be produced and in completed form by that date subject to possible small amendments if there are some stragglers, but that's the deadline for the finishing of production. And with that we have come up with a way to resolve the privilege log issue so we're having production of the privilege log on a rolling basis so that it doesn't hold up any production. They are going to roll those forward, and we've got dates in the proposed order for those that have been agreed upon by counsel.

Mr. Sipkins and I talked on Friday about this, and then he messengered over to my office this morning the stipulation with the attachments. I signed it and we brought it over here for Your Honor. With the Court's consent we'll hand that up.

MR. SIPKINS: Thank you, Your Honor, Peter Sipkins on behalf of defendant Bayer. Mr. Zimmerman has accurately described the document. I think the record should make clear, however, that the target dates for the production of the documents that he referenced are dates for the domestic defendants as opposed to the foreign defendants that are also named in the case.

MR. ZIMMERMAN: We have no agreement on the

foreign defendants at this time. We understand that is a slightly different problem, and we are continuing to discuss that and Mr. Sipkins is absolutely correct. The agreement is as to the domestic.

THE COURT: I will review those documents.

MR. ZIMMERMAN: Next, Your Honor, I have a letter which I would like to hand up to the Court which involves the Andy Birchfield matter and my request for a letter of resignation from the PSC as the Court requested. I have not provided copies to the defendant. I certainly can, but it's a very simple letter. If the Court wants me to, I certainly can, but it simply says that he cannot serve, essentially.

Lastly, Your Honor, at the conclusion of the argument that we make today, we would like to discuss, perhaps in chambers at the Court's discretion, some updating on the state and federal coordination process and some follow up to some communications we have had on that subject. I think we will be fairly brief, quite brief, but we would like to at least take the opportunity to discuss it if we had a chance to this afternoon.

THE COURT: Certainly.

MR. ZIMMERMAN: Thank you, Your Honor. Mr. Chesley.

MR. CHESLEY: May it please the Court, Stanley

Chesley for plaintiffs. Maybe I would have been better off to stay with Judge Sargess. But I note in passing, Your Honor, I notice the newest of electronic equipment, but having done a lot of fire cases, I see eight connections into your extension cord, and I call it to the Court's attention.

Your Honor, I would like to make my argument rather brief, and the best way I can start it is to say they protested too much.

We are here on a very simple matter, and we've been besieged by what their interpretation of the federal law or guidance is. And as you start to peel away the artichoke, I used to say onion, but it's more sophisticated someone told me to, you should peel away the artichoke, you finally see that there really is an emperor with no clothes.

Our relief that we are asking for is totally discretionary with this Court, and it's under 23(d)(2). We're not asking for a temporary restraining order. We're not asking for an injunction. We don't need the prerequisites to get that.

And one of the things I think that is interesting, Your Honor, before I get to 23(d)(2) is what has occurred in Pennsylvania is the same issue that went up on a TRO, not a 23(d)(2), and Judge Herron stated as

follows. "Well, my question, to be perfectly clear about it, has to do with whether or not this court is bound by some other court, but the fact that another court" -- and that's this court, Your Honor -- "MDL is considering it on an expedited basis, why should this court do so as well. Isn't there some economy in having one Judge labor thoughtfully on the issue in reaching a conclusion rather than having two judges laboring on the same issue at the same time, even if in one the jurisdiction is different than the other."

Your Honor, (d)(2) -- 23(d)(2) states, orders and conduct of actions, and the conduct of an action to which this rule applies, the court may make appropriate orders, Subparagraph 2, requiring for the protection of the members of the class or otherwise for the fair conduct of the action, that notice be given in such manner as the court may direct to some, all or members in any step in the action or of the proposed extent of the judgment or of an opportunity of members to signify whether they consider the representation fair.

Your Honor, it's undisputed that we have a putative class. It is further undisputed that we are under the Rule 4.2. I notice the defendant cited some cases, but 4.2 of the Minnesota Rules of Professional Conduct, very similar in most jurisdictions, Your Honor, it says, "in

representing a client, a lawyer shall not communicate about the subject of the representation with the party the lawyer knows to be represented by another lawyer in the matter unless the lawyer has the consent of the other lawyers authorized to do so." Your Honor, the rule also applies to clients. Since a lawyer could not directly contact class members to require -- request medical releases, the party cannot directly contact them either, and I cite the Larry James, 175 F.R.D. 245.

Now, what the defendant has done is said, not our fault, Judge, we're doing -- we're following the law of the FDA. So, what I would like to do, Your Honor, is go briefly through the defendant's filings and their exhibits, and they're fascinating.

Let me start first with the affidavit of one of their experts, a Ph.D. who is a safety -- affidavit of Michael Oliver, Ph.D., Drug Safety Specialist. Item E of his affidavit, it would be 9(e). However, this is by affidavit, if the reporter is the patient or of himself or herself, that's what we're talking about, the patients, the potential members of the class, Bayer is required to attempt to follow up with the patients' treating physicians or other health care provider -- health care providers, physicians -- to obtain the medical information required for reporting. In that regard Bayer may need to contact

the patient reporter to obtain the name, address, and phone number of the patients' health care providers and patients' consents to contact them. Doesn't say anything about medical records. That's their affidavit.

And why didn't he under oath say anything about medical records? Simple, Your Honor. If we take a look at the law that we're under, we're under 314, 21 C.F.R. 314.8. I have a copy here for the Court. I think they also attached it in their materials. Your Honor, the law is single spaced, 1, 2, 3, 4 pages, all on the information, postmarked and reporting of adverse drug experiences. Your Honor, I'll pass it up to the Court and the Court's clerk. There is not one word that requires anybody to furnish medical records to the manufacturer. And what's very significant, Your Honor, here they withdrew this product from the marketplace so it isn't like they are trying to find out what they need to know so as to prevent or change the formulation of the drug or change the labeling or do something relative to the person.

They, then, Your Honor, very cleverly say, well, there are some guidelines and we've got to follow these guidelines because the guidelines are very informative as to how to follow up with additional information. And in their own papers, Your Honor, the guidelines say, attachments may include copies of hospital discharge

summaries, autopsies, biopsy reports or relevant office visits, summaries of relevant laboratory tests. In general, attachments should not include lengthy legal records, complete medical records. Should not. This is the guidelines.

Also, Your Honor, I think it's significant that the guidelines clearly state that while we have some guidelines, and it's nice to get as much information as you can, and this is the Department of Health and Human Services supplemented practices, 65 F.R. 56468, which I will hand up to the Court. It says, we agree with this comment. Guidance documents are not binding. An enforcement action may be taken only when we find a violation of statutory or regulatory requirements.

So, they put together a whole bible, or attempted to put the bible of all of these regs, all of these guidelines, but when you cut through to the chase, Your Honor, there is nothing that says that a patient is required to surrender the right to the physician to turn over their medical records of adverse reactions, because we all know as lawyers that when you get someone's medical records, there are all kinds of privacy issues, and to have the right to these medical records, then to be shared by their attorneys, there is no prohibition as to what they are going to do with these medical records. There is no

prohibition from them. You start getting doctor's notes of a person's psychological background, their emotional problems, their problems with their children, their problems with their spouses or their loved ones, their recent losses, their stress, their emotions. All of that is medical records. And, Your Honor, there is a cogent way that we are handling medical records. We just endorsed a stipulation on a form for people that are -- and that is to go through counsel. It's to be orderly and not chaotic. Those people that are making a claim must surrender their medical records. I don't have a problem with that. But there were certain caveats and certain warnings. There is no warning whatsoever on what was given to these various people, and to suggest that we, the plaintiffs, are supposed to advise them who got this is frankly bizarre.

Your Honor, I was dumbfounded shortly after our last hearing. I went to counsel for the defendant. I don't think he's in the courtroom today, Adam -- Adam's not here -- and I said, Adam, see if we can work this out. Let's call a draw and I'll withdraw our request to write an explanatory letter or a letter of cancellation or a letter advising all of these people to disregard what they sent in and void it, and you just pull it down. Just give us assurance that you are not going to do it. And I wanted the same thing on the other documents, Your Honor, which is

similar but not as severe because I'm assuming that's the refund.

Instead, Your Honor, we've been met with opposition, and one has to wonder, and I don't know whether you can take an inference, one has to wonder what are they trying to do. What are they trying to accomplish? Why are they doing this? The way -- what the FDA sets up, Your Honor, is the real burden is on the drug manufacturer to give them information.

And let me talk for a moment. If I take a look directly at the reg, which they didn't bother -- they have it attached, and it is Part 2, Department of Health and Human Services form for reporting serious adverse events and product problems with human drug and biological products and devices availability notice, and I believe, Your Honor, this is attached to their -- that's their Exhibit 3. And at Volume 58, No. 105, Page 31597, it provides for the provisions of the final form and other reporting information.

Your Honor, I can show this to you. Make it easier.

THE COURT: What was the page number?

MR. CHESLEY: 31597 on their Exhibit 3, and I'm looking at the bottom of the lefthand corner, Your Honor. It's a Roman Numeral two.

THE COURT: Let me see your -- Exhibit No. 3, you said?

MR. CHESLEY: I thought it was, Your Honor. That's what I got from them.

MR. FERGUSON: Your Honor, it's at the end of that same exhibit in a different format from the beginning part.

THE COURT: I found it.

MR. CHESLEY: Have you found it, Your Honor?

THE COURT: I got it.

MR. CHESLEY: And this is what it says, Your Honor, which is -- which goes back to the point I made at the front end of the argument, which is when you peel away the onion. Roman Numeral two, provisions of the final form and other reporting information. Both versions of the form contain identical reporting provisions for the following sections: (A) Patient Information. So, patient, identifier. (A) date of birth, sex and weight; (B) Adverse event or product problem, outcome attributed; (C) Suspect Medications; (D) Suspect Medical Device; (E) Reporter. For Version 3500, the reporter is the person who makes the report. Usually it's a health provider. It could be the patient. The reporter is the person who made the initial report of the adverse event or product problem to the user facility, distributor or manufacturer.

Your Honor, there is not one word in there that says the reporter, if it's the individual, or the medical provider has to furnish the medical records of the person. And I believe that's for a purpose, Your Honor. And the purpose is to protect the privacy of the individual. There is no screening. If a person were to fill in that form, someone from Bayer would go to the doctor and get a xerox copy of the medical records of that patient. There are no checks, no balances, no monitoring. There is, while it says in there, as to the medical attention for the use of this Bayer product, that there is no screening ability -- availability. We don't know who is going to meet with the doctor. We're assuming no one is going to meet with the doctor. The doctor is going to get a blank form. His nurse is then going to take that form. The doctor will never see it, and then he sends all the records of that individual, the best that the nurse could possibly see.

THE COURT: Why don't you move to comparing what Daniel E. Troy sent out. Did you see the letter that Mr. Troy sent from the FDA?

MR. CHESLEY: No, I have not, Your Honor.

THE COURT: You have not seen this? Why don't we take a ten-minute break so you can take a look at it. Do you need copies?

MR. SIPKINS: Your Honor, for the record it was

delivered to Mr. Zimmerman's office about 9:30 this morning.

MR. ZIMMERMAN: I never saw it. Was that with the package of other stuff by messenger?

MR. SIPKINS: Yes.

MR. ZIMMERMAN: It wasn't there.

THE COURT: We'll make some copies.

MR. CHESLEY: Your Honor, I'll read it.

THE COURT: If you don't want any time, that's fine. Continue.

MR. CHESLEY: Your Honor, this is a standard letter that I've seen before from the FDA and that's very nice the chief counsel -- if one were to take a look, and I'm not trying to be perjorative, but if you were to track the records over the last seven general counsels of the FDA have gone to work they have for the most part gone to drug companies or counsel for drug companies.

Your Honor, it cites 21 C.F.R. 314.8 which you have. It cites U.S.C. 355(k) which says nothing about medical records. What they have attempted to do is to bootstrap 314.80 and put a little glamour on a very, very weak argument.

There is nothing in this letter -- while the letter says Your Honor, we would like you to consider this, and consider that you may be -- we want to help this drug

company gather information, there are ways this drug company can gather information. There are some how many thousands of lawyers have cases? How many lawyers presently have cases?

MR. ZIMMERMAN: In the MDL we know over 97.

MR. CHESLEY: Ninety-seven. How many around the country, lawyers.

MR. ZIMMERMAN: Equally as many.

MR. CHESLEY: So you got over two to three hundred lawyers that I know of, Your Honor, that they can contact. You have an infinite amount of number cases that have been filed. They have never come to us, nor have they gone to any other lawyer in any other state and said will you help us with this project and would you voluntarily try and get medical records.

Your Honor, while I respect Mr. Troy and that's very nice to get the FDA to try and help them in their cause and bootstrap it, when one reads it, and they cite the Porter v. Warner Holding Company, 325 U.S., Your Honor, I believe that case is even before my practice of law. That case is about, I think forty-some years old relative to a Court's inherent equitable powers may be limited by a clear and now legislative command.

To suggest that Mr. Troy is writing to this Court, and he's speaking on behalf of the FDA, I think is

totally inappropriate because there is no command. The only command there be can be, Your Honor, is the command as set forth in the statute, and if the United States Congress wanted medical records to be part and parcel of the reporting process, they would have so written it. There is not one word.

Candidly, Your Honor, I'm glad I saw the letter now because if I had seen the letter earlier this morning, I probably would have been more angry and a little less gentle. The nerve of this defendant who is in litigation in which there are class actions pending to avoid 4.2 of the Minnesota Rules and Codes of Ethics, and to avoid 23(d)(2), which is an inherent power that Your Honor has and has been given to you. And to ignore your power as the MDL Article III Judge by suggesting and citing to you a case that suggests that you better know what your inherent powers are, and you better deliver them on command. I would like to have Mr. Troy come here and I'd love to put him under cross examination and ask him some questions that he's volunteering letters on March 15.

This matter incidentally, Your Honor, now has been in two courts, Oklahoma and Pennsylvania, two state courts, and here. We had a hearing in your court -- when was that?

MR. ZIMMERMAN: About two weeks ago.

MR. CHESLEY: About two weeks ago. One can imagine, Your Honor, one can imagine how much lobbying it took to get this letter written on March 15 delivered to us at 9:30 this morning. Is this a persuasive letter? No, Your Honor. Is it persuasive to me? Absolutely not. It's a self-serving combination of counsel working hand in hand with drug companies and it's been going on as long as I've been practicing drug and medical device law. I only wish that the General Counsel of the FDA would be as concerned about the general public and the patients and their privacy as they are of Bayer getting records that they know how to get by asking attorneys. All they have to do is ask us. That's what our form is going to be. Right now we're at a sensitive area.

Your Honor, this class is a ward of the court. This class is your ward. We are nothing but guardians appointed by you an interim basis. And as a ward of this court, they are no different than infants. They are no different than minors. They are no different from people that have mental disabilities. They have to be protected during this interim period and they have to know what their rights are. And their rights are not to give a blanket letter giving their doctor carte blance to send in records.

Let me read -- thank you for looking, that's what

you have when you have other bodies working on a case -- the first paragraph of Mr. Troy's letter, which, incidentally, Your Honor, I notice of interest because it's not to you. The agency understands that the plaintiffs in this case are seeking an emergency -- I'm now reading -- ruling from the Court that would prohibit the holder of the new drug application, Bayer, from collecting data or reporting adverse drug experiences.

Your Honor, that's not what this ruling is about. That's a falsehood. That's an absolute embellishment. We are not attempting to prevent them from getting medical records from people that have claims in an orderly, less chaotic process. We are not asking the Court to stop collecting the data. We are asking the Court to prevent the overreaching. And when one reads this, one has to question who went to Mr. Troy and what Mr. Troy really knew about the facts. I notice, and I guess that's one of the beauties of the cross examination in the Court process. I notice Mr. Troy is not here. I assume he's not here. I guess I can go take his deposition, Your Honor, although we don't want to extend this.

Your Honor, we are not asking for an emergency ruling. We're asking for intermim relief and protection. And, now, Your Honor, if they want to play a little bit hardball, we want something else. We want a list of who

they sent it to, and want a corrective letter. You know -- and a corrective letter, and the corrective letter has got to state why we would attempt to get such information. You are under no obligation to get it, and you have legal rights and there is a legal case moving forward, and there are many class actions of which you could very well be a participant in. That's fair, Your Honor. They are not willing to do that.

Your Honor, I think I've stayed more than my welcome, and I think the Troy letter -- don't get me started, Your Honor. I only wish that the FDA cared as much about the public. Thank you, Your Honor.

THE COURT: Please.

MR. FERGUSON: If it pleases the Court, Your Honor, Mark Ferguson on behalf of Bayer. I've got some of the documents on my computer which I'm going to run through the screen so that we can look specifically at the sections which Bayer has cited and look at them in the context of Mr. Chesley's remarks.

But before I get into what I had prepared, I want to do one thing. I want to do one thing as so as to kind of set the record straight, set the background and correct it so that we can then look at these issues under what the law actually says and what the regulations actually say.

The first thing I want to do is address Rule 4.2

which deals with communications between lawyers and persons represented by counsel. Mr. Chesley said that a client can't do what a lawyer is prohibited from doing under Rule 4.2. That is not the case, and I've got -- I've got one copy of it here, but this is a copy of the Minnesota Annotated statutes, which if I may, Your Honor, I would like to read and then hand it out.

What it says is in the comment, "parties to a matter may communicate directly with each other, and a lawyer having independent justification communicating with the other party isn't permitted to do so." So, the first thing is it is not the case that a party can't do what a lawyer can't do. A lawyer can't use a party as its agent, but a party can communicate directly, and there are other exceptions that I would like to get to in a moment. But the first thing I would like to do is hand this up if I may. I've highlighted that comment at the bottom, Your Honor, that I have just read.

MR. CHESLEY: Do you have a copy of that?

MR. FERGUSON: That's my only copy. I didn't expect that argument.

Secondly, to make it clear, Mr. Chesley cited the Larry James Oldsmobile case, and the actual quote from that case reads as follows. "Secondly, an attorney may not do through a third person what he may not do himself." It has

nothing to do with what a client can do. It's a situation where an attorney says, well, I can't make the contact myself. I'll direct someone else to do it. That's what the Larry James Oldsmobile case deals with, and that's what the rule is addressed to, a lawyer using either directly or indirectly the superior position that a lawyer has to influence or otherwise take advantage of a party.

The second thing I want to address, Your Honor, is this assertion that no where in the regulations is there any mention of the need for medical records. Now, I should take a step back here because I think the argument I kept hearing was an argument as to whether or not the regulations require individuals to turn over their medical records. And that's not what's at issue here because we're not doing anything that requires individuals to do anything. We are sending out a request as the regulations seek to have us do. And just as an example, because it was the one that Mr. Chesley had in front of him on that Page 31597, Item 2 on that page, he skipped over this part. But in Subparagraph B where it says adverse events or product problem, one of the things it asked for is, "description of an event or problem, relevant tests or laboratory data and other relevant history." Now, if that's not medical records, I don't know what is. That's specifically what's in these regulations. In essence, Your Honor, the

plaintiffs argument is based --

THE COURT: The vast majority of the cases dealing with that type of reaction whether it's death or disability or those people who are going to be represented by attorneys, and you would be certainly at a minimum to contact the attorneys to get the medical records which you set down now in written form that you agreed to get the medical records and in an orderly fashion. And you're going to have to re-argue this issue that a party can do something that no one else can do in contacting someone that's been injured.

MR. FERGUSON: I want to get to that issue right now, Your Honor. The rules in which -- the rule that addresses counsel contact with a represented party is designed so as to avoid a lawyer taking advantage of that party without that person's ability to have the input of his own counsel. This is a --

THE COURT: Then, also implicit in that, I like the Turner phrase, the class is a ward of this court. I'm here, the ward of this class, and not to make sure that anything happens to this class that will not occur otherwise.

MR. FERGUSON: Let me address that if I may. The first thing is there is no class yet. It's a putative class. And I don't mean to say that this Court has no

authority. In fact, the case makes clear that the Court has authority to prevent abuse even as it may relate to a putative class.

What I'm saying is that when -- and I'll go through these regulations piece by piece in a moment. When the regulations direct Bayer to take adverse event reports, to investigate those reports, to report on them, to provide follow up reports, to evaluate them in periodic reports. Those you are all things that the FDA itself has said dictate investigation, dictate actually approaching health care providers so as to find out those things such as what I just read to you from the regulations. The thing besides just what the reporter, if it be the consumer, besides what the reporter might know, other medical history, other, for example, interactive drug situations, all kinds of possible issues that would go to the drug manufacturer's ability to evaluate the report, decide whether to categorize it as serious or not and to evaluate, analyze and report on it as the regulations require the drug manufacturers to do.

None of those things present the difficulty that's inherent when, for example, just to take some of the other cases, when a party in a class action goes out and tries to solicit opt-outs. For example, the Kleiner case involving a bank which had in many cases existing lending relationships which went out and tried to solicit its

existing loan customers and others to opt-out of the class. The court found that that was an abuse of the process and usurped the court's own ability to manage the class action process.

Similarly, there is a case involving the Cotter and Company Cooperative -- excuse me, Cooperative Hardware Organization, the Hampton case, I think is the name of the plaintiff. In that case Cotter and Company wrote all of its members, who in essence is the class, and said by suing us, you are suing yourself. You're just costing yourself money. It's a bad idea. You really shouldn't do this. And, again, the court said that's not something I'm going to allow to be done ex parte because that undermines my ability, the court's ability to manage the class to see that it's done properly.

I'm sure Your Honor has read some other cases. There are similar instances of abuse of people making accusations of class counsel, calling of names, saying they are not effective and so on and so forth, instances such as that. Those are the kinds of situations where the court has found a need to come in and issue remediation.

What we have here is an FDA-mandated program. It wasn't put together for Baycol, this particular drug. It was a procedure that Bayer has used for all of its drugs across the board for a period of time. It's completely

neutral as respect to litigation. It sends, and, Your Honor, I can show the letter if you haven't got it right there in front of you. It is in no way misleading.

MR. CHESLEY: Is this the Troy letter.

MR. FERGUSON: The letter I'm showing, Your Honor, is one of the exhibits to the declaration of Dr. Oliver, and I'll tell you which one in a moment. This is Exhibit C, Your Honor, to the Oliver declaration, and the Oliver declaration is Exhibit 2 to the Bayer's brief. And you have it on the screen now. If I may, I'll blow it up some so we can read it a little bit better.

Here's the letter, Your Honor, and what it does is it references the reporter's notification, mentions the type of problems that had been referenced to Bayer. It then goes on to said simply, in order to obtain more information about those events, Bayer would like to contact the doctor that prescribed the medicine. Asks the recipient to complete a form and makes clear that this will authorize Bayer to contact the doctor and request medical information. It doesn't say you have to. And it makes absolutely clear who's getting this information and why.

The next page, which I now have up, again, sets forth what it is that the reporter is being asked to do, that is, give permission for Bayer Corporation to contact the physician and collect further information about the

adverse events. And it says, I also grant permission for the physician to release that information. Now, there is nothing misleading there. It is precisely what the regulations require Bayer to do. Again, in order to do the review, consideration, categorization and analysis of these individual adverse experience reports.

Now, I want to get to that now and talk about those regulations. I have on the screen now, Your Honor, 21 C.F.R., Part 314.8. Again, I'll try to zoom in on it a little bit more.

What we see here, Your Honor, is the beginning of this reporting requirement section. And just to make clear, go back for a second. This is the beginning section that I've just put on the screen. This is at Page 1 at the introduction. And I'm going to highlight this section that I've got in yellow. It says here that this is what the agency advises is its current position on the requirements for reporting of adverse drug events. And this guideline, among other things, references what I have just shown you, 314.8.

Okay, so when we talk about these guidelines and the question of whether or not they are required, what the FDA has made clear is that is its view. This is what is required. Now, just to go back to where I was, if I may.

THE COURT: You may.

MR. CHESLEY: Excuse me, I don't mean to interrupt. Can we agree what an applicant is? The applicant is Bayer, correct?

MR. FERGUSON: In this case it is, yes.

MR. CHESLEY: Not the patient.

MR. FERGUSON: That's correct. The reporter would be the individual consumer. So when you see reporter in these guidelines, that would be the person who reports to the applicant. Bear with me, Your Honor. I'm sorry. I've got to get this.

So, back to the actual regulations. What it says here, Your Honor, is that in reviewing adverse drug experiences, a prompt reporting requirement for things deemed to be serious adverse drug experiences. Among other things, the -- what the statute shows, the regulation shows is that there is a requirement both of -- excuse me, a follow up, and then as I've got highlighted here, a narrative summary and an analysis of the information in the report, both from the 15-day reports, which are the serious reports, and from the periodic reports which deal with all others. In order to do that, analysis, investigation and reporting. That's why -- that's what the FDA has said requires that Bayer go -- all applicants go to health care providers, to the prescribing physicians. And what they have done is provide the guidance that I've began to show

you, and I will go into more detail now.

And now here's the section of the guidelines that specifically deals with how the reporting under Section 314.80 should be carried out with respect to consumer reports. And you see that it says, "generally, additional information should be sought from the treating health care provider." And then it says, "and this is for those serious adverse experiences. A determined effort should be made to obtain additional details from health professionals for all serious reactions initially reported by consumers."

There is no question at all that this guidance which applies to actual regulations state the FDA's view that what is needed in order to comply with the appropriate analysis and reporting regulations. And that's the only reason that it's carried out by Bayer. And that's why it was put into place. It was put into place long before the Baycol litigation ever happened. And that's the purpose for which it is being carried out today.

Now, back to the letter that Mr. Chesley kind of ridiculed from the chief counsel of the FDA. I don't think there is anything ambiguous about it. What it shows is that the FDA recognizes all these regulatory requirements, in particular 314.80, as imposing the need to investigate before one does the analysis and the reporting that the

regulations require. And, of course, it makes sense. It would be very difficult to report on why you think something happened or how you think something happened or what other factors might have been involved if you didn't get enough medical information. That's exactly why it's there. And, so, when Mr. Troy quotes that same set of regulations, and then he goes to the 2001 draft guidance, which he spoke to the top of his letter and says essentially the same thing, the applicant should actively pursue contacting the health care professionals, it's all for the the same purpose. And, so, that's why, not I don't think because of any, I don't know, improper ties between pharmaceutical companies and the FDA and people like Mr. Troy. It's for that reason that he says very clearly that the FDA would urge that the Court not enter any order that would prevent us from making this investigation.

THE COURT: Certainly, I have not heard anyone saying that you shouldn't be stopped from collecting the data. It is just the form and fashion for collecting that data, and that's through the process of the Court and through the discovery through the attorneys in this matter and --

MR. FERGUSON: Your Honor, much as we would like to think otherwise, I suspect that the FDA does not view the timing and all the interplay that goes on in litigation

as being something they want interjected into their regulatory process. And, in fact, I think that there is a reason why it would interfere because there are all kinds of issues of admissibility, issues of relevance that lawyers will, and I think probably, correctly, as they try to do their jobs, attempt to make judgments on, which if you put them into the regulatory context, would in essence put lawyers in the position of making medical judgments, making pharmacological judgments about things on which they have no training. And the reason why --

THE COURT: But what do consumers, including attorneys, mean?

MR. FERGUSON: That is -- just so you know, that is what the FDA wants Bayer to do -- when they've got an attorney as the reporting person. In other words, there are times when an adverse drug event is reported by an attorney rather than by the consumer directly. In those situations they treat that as a consumer report under the regulations. That's why it says including attorney. It's not meaning to suggest that in all cases what should happen is that attorneys should be brought into the loop. There are cases where attorneys are already there and that's fine. But there are also cases where attorneys are not there.

THE COURT: Even if the attorneys are there, the

process is the same, turning in the information to the FDA, isn't that correct?

MR. FERGUSON: Well, I suppose that the answer would be yes the attorneys can decide to either do it or not, just as the individual reporter can decide whether to do it or not. And, so, what I guess I was suggesting was that using the discovery process in a case like this as the mechanism by which absent class members, putative class members in all fifty states are -- which becomes the only conduit through which Bayer can collect any information from absent class members or putative class members in all fifty states, some of who may have no interest in pursuing at all. And to suggest that the conduit to which those people have to deal is the set of class representatives in this case, prior to there even being a certification order, I don't think is correct from the litigation side or the Rule 23 side. And to suggest that that is an efficient and prompt way in which all of those people all over the United States can get information to Bayer for the reporting process and, therefore, into the hands of the FDA for reviewing analysis, I just don't think is true. I don't think that is any kind of effective way to convey the information to the ultimate regulatory body so that they can do what they might with what is still an ongoing new drug approval for Baycol. Although it's been withdrawn by

Bayer, the FDA has not demanded and required that it be taken off. So that application remains there and they continue to have this reporting duty associated with it.

THE COURT: Go to the second page of C dealing with the consent form. Isn't that too broad?

MR. FERGUSON: I'm sorry?

THE COURT: The consent form of 2(c), Page 2.

MR. FERGUSON: I'm not sure I follow Your Honor. Broad in what sense?

THE COURT: Broad in the sense that they are asking for all the medical records.

MR. FERGUSON: Well, it says, "give permission for Bayer Corporation to contact my physician to collect further information about the adverse events I experienced during the use of Baycol." So, I say it's fairly closely targeted to what is necessary. I don't think that it asks, demands, suggests, or coerces in any way the kinds of irrelevant medical records that Mr. Chesley suggests might be turned over and, in fact --

THE COURT: I'm just looking at it now and looking at the last sentence which is different from the first sentence. It says experience during the use of Baycol. And the last sentence says regarding the adverse events. It does not qualify to being that of the events of Baycol.

MR. FERGUSON: Well, I think, Your Honor, when it says the adverse events, it's referring back to where it says the adverse events --

THE COURT: I understand what you think, but I'm looking at a physician saying adverse events, I'll send the whole medical records.

MR. FERGUSON: You know, I don't think that Bayer would have any difficulty changing that sentence in the future to address that. My own view is that I think that most physicians would understand the purpose of this, but I understand that there is not the same verbiage in the last part of the last sentence. I don't think that the intent is to try to get things that don't relate to the Baycol event. And I think most doctors reading this would understand. But, again, I also don't think that Bayer would have any problem making the modification you just suggested.

What I want to get to, though, is the relief that has been sought, and there was at least one point and time when the plaintiffs were seeking to have this process stopped. The idea of having some kind of curative notice is only something that comes into play under the case law dealing with the Court's inherent authority under Rule 23 when there has been a violation that needs to be cured. And as I've indicated before, Section 4.2 is not the source

of any violation. This is not something that falls under the gamut of Section 4.2 under any reading, including -- particularly, I should say, given the comments that applies as I handed up in the Minnesota version. There hasn't been anything misleading or confusing at all about these letters. What they do is to simply make very clear that they are following up on the reported adverse events, and it is Bayer Corporation asking for the information, and that it is going to be used by Bayer to review and learn further about the medical circumstances surrounding the adverse event.

The Supreme Court case that addresses what the court should do in order to -- before it could find that that kind of order is necessary is Gulf Oil v. Bernard. And what that court said was that you can't have speculation or conjecture about possible future injury. You have to have evidence showing that some putative class members have either been misled or that there is an imminent threat that they will be misled. And the courts that have picked up on the Bernard ruling have said there may be an instance where something is so inherently abusive that you don't have to put in actual evidence. But those are situations, as I said, again, where, for example, there have been one-sided presentations of the merits of the case, for example, in the asbestos litigation where in the

Impervious Paint case where individual discovery, the threat of individual discovery against class members was kind of played up in a defendant's communication with, I guess they were absent class members. The class had been certified at that point. Those kinds of things where some curative notice is required so that it levels the playing field relating to litigation.

Here what we are talking about is a request for medical information, a request which is directed to obtaining the information necessary and to carry out the regulatory process.

THE COURT: Refresh my memory. How many letters have gone out?

MR. FERGUSON: I don't know, Your Honor. I can't give you number. There have been a number, a large number of adverse event reports, and this is part of a standard process that takes place when getting the information from the health care provider meets that first step. In other words, if it's an individual making the report, they just simply say I have these problems, these are the kinds of things that take place as a follow up. My answer is, and I'm sorry not to be more precise, it is a subset of, but not all of the adverse event reports that are out there.

THE COURT: Guesstimate.

MR. FERGUSON: Frankly, Your Honor, I don't know

enough about the number of claims that are out there to give you a guesstimate. Maybe one of my co-counsel can do that, but I'm not able to.

THE COURT: So, no one knows what the universe of --

MR. CHESLEY: Your Honor, I was under the impression that house counsel was at the table. Maybe he can be of some help to us.

MR. MC CONNELL: Your Honor, it's my understanding we have received approximately 15,000 adverse event reports since the time the drug was taken off the market. I don't know where they are in the process of working through those.

MR. FERGUSON: One of the other things, Your Honor, the sheer number has kind of overburdened the system which is why we can't say 15,000, fifteen days later all of these have gone out.

In order to have a need for a curative notice, there has to have been a violation. There has been no violation here. In fact, the FDA believes -- Bayer believes, and I think the regulations show that this communication is something that is required by regulations, is required by law.

I want to raise, again, the second part of Rule 4.2, which specifically excepts from this prohibition

communications otherwise authorized by laws. And, again, I suggest, Your Honor, this is one of the clearest cases where the kind of communication at issue, even if it had been initiated by lawyers, which it wasn't, would otherwise be permitted by law.

There hasn't been any showing of anyone actually having had unrelated medical records submitted. There hasn't been even a showing of a strong likelihood or any likelihood that the physicians who read this notice actually believe that they should send in records other than those relating to the adverse drug event. And, in essence, there is no showing that anyone has been misled at all, coerced or otherwise threatened by it.

There is nothing to remedy, and to suggest that there ought to be a curative notice, particularly one that comes from Bayer, runs into the problem that the Gulf Oil case addressed and which had also been addressed more broadly, more generally in the Great Rivers Cooperative case in the Eighth Circuit, 59 F.3d 764, about enforced speech. Enforced speech is to generally be avoided. And this is a situation in which absent any problem, any kind of curative notice, whether it's a notice that suggests something was done wrong, which I don't think it was, a notice which suggests that there is a pending litigation and that people should be aware of that, any kind of speech

like that is a cure, a forced speech cure where there has been no violation, no problem, no abuse.

And, in particular, the idea of notifying people in fifty states of the pendency of a single class litigation runs into the problem that there are class litigations all over the place, not just here in the federal court, but in a number of states around the country. And there would be a tremendous competition among the class-appointed lawyers who got their action on the notice, how it was portrayed, who got what notices. I think that's a matter of management that the Court wouldn't be able to effectively manage, this court or any other court, because of the plurality, the proliferation, I guess I should say, of different lawyers involved in this litigation around the country in different forums.

Your Honor, what I believe the record shows, the regulations show is that there is no basis for any relief here. There is certainly not the kind of showing that the Bernard v. Gulf Oil case would require. And that the FDA-mandated procedure that Bayer has been following up to now should be allowed to continue unfettered. And that's all I have to said at this point, Your Honor.

THE COURT: Let me ask you a question. Dealing with the adverse reports that have come in and the possibility of the letters that have gone out, is there any

way that Bayer can do a cross reference of those individuals with a list of the named plaintiffs?

MR. FERGUSON: What I'd say, Your Honor, is two things. As I understand it, when the initial report that Bayer has received was an actual complaint, then the communication went to the lawyer who filed the complaint. Otherwise, I don't know that Bayer has any other indication of who all may have counsel around the country, who all may be represented by counsel, but those that have come to Bayer in the form of a complaint have resulted in communications to the lawyer who filed the complaint.

THE COURT: Well, correct me if I'm wrong, Bayer now has the names of all plaintiffs that have filed suits, is that correct?

MR. FERGUSON: To the extent that their name is on a complaint, the answer is yes.

THE COURT: With that, is there any way that there can be a cross reference dealing with the letters that were sent out?

MR. FERGUSON: I just have to ask.

MR. MC CONNELL: Your Honor, it is the policy of the medical safety people, drug safety people to follow up on these to try and cross check if they have enough information to do that. That effort is being done currently. Now, it may not be perfect in it because they

may not be able to identify from a complaint an adverse event report, but that effort is currently under way and has been all along.

THE COURT: And when that is -- when there is a match, what is done? Then the letter is sent --

MR. MC CONNELL: To the lawyer.

THE COURT: I'm just thinking out loud. I'm trying to figure out -- it seems like both sides are trying to get to the same point, whether or not it depends on how quickly the information is gathered. It seems to me if the lawyers are involved, the information is going to be gathered more quickly and be sent to the FDA. If someone is sending a form to my house, it might go in the junk mail.

So, the information, what we are trying to do is get to the FDA so that your process with the FDA can continue. I don't want to in any way interfere with that. And, in fact, if we can do this in an orderly fashion that would make it more quicker for the FDA to get the information, I think everybody is served by that.

MR. FERGUSON: There is one important consideration here that relates to those people who are not named representatives or otherwise directly represented by counsel. That is for all of the -- all of those who the class lawyers here or any other class proceeding across the

country purport or seek to represent and who could not -- don't have any contact with these lawyers, the FDA regulations also prohibit an applicant from providing patient identifying information at all, and that is so as to protect the privacy of those individuals who have submitted information in response to requests like this. That is how Bayer handles all of this information. And, so, for all of these absent class members, there isn't a lawyer that we can hand it to and say here we go. And we are not allowed to say to one of the class plaintiff's lawyers, would you go find this person. That's not appropriate. Patient identifying information is strictly controlled by the FDA regulations and for good reason. I guess --

THE COURT: What have you done in the past when the class hasn't been certified.

MR. FERGUSON: Well, it hasn't really related to these issues that I'm aware of.

THE COURT: Bayer?

MR. FERGUSON: Well, I have not represented Bayer in these matters for all of eternity. In fact, I'm new to this case, and I don't know of any instance in which Bayer has turned over patient identifying information in a context such as that. There will be, I'm sure, requests from the plaintiffs to get information that relate to these

adverse event reports. And how those regulations will be reconciled is another issue. But that will happen, I would suspect, in a way that could be regulated itself by the Court and also without --

THE COURT: I guess I'm getting back to the whole issue of me being -- the putative class being a ward of the Court. I'm trying to see where the harm is if I make it in an organized fashion here. I'm not hearing anything from you saying that you are going to be harmed, that the process of the FDA is going to be harmed in any way, that anything that the plaintiffs would do with these would slow down the process that I could not rectify --

MR. FERGUSON: Well, I have a couple of things that I should cite to address that. The first is that I don't think it is appropriate for any court to presume that absent class members in a non-certified class action prefer to be represented and prefer to have their medical histories turned over to putative class representative counsel, and I think that's one place where the FDA regulations apply most particularly.

We don't know as to any of the non-representative -- excuse me, non-represented absent class members whether they want to sue, and if they do want to sue, who do they want to represent them and whether they want anybody in this room to have anything to do with their

private business. That's the first point.

The second point is that one of the areas in which the courts have said the Rule 23 oversight process needs to focus is on the avoidance of things that would create a means by which the class representative lawyers have a way to go out and start soliciting additional clients. I'm not suggesting anything about anybody here in this room, but that is one thing that the courts have focused on in trying to avoid, and that's a problem in doing it that way.

THE COURT: I would agree with that.

MR. FERGUSON: Your Honor, I guess what I'm suggesting is that the -- what is in place now is a system that the FDA has set up and has given explicit guidelines on which is being carried out by Bayer solely for that purpose and without any actual evidence or even clear threat of any kind of abuse, and it's working. And the idea that the simple fact of requesting medical records for this reporting purpose threatens potential harms, none of which I heard very clearly articulated is not enough, I think, to create a need to come in and change the system and try to now start to have to deal with all of these other issues that come up once you try to project a different procedure.

The FDA, in their considered judgment, has come

up with this reporting system. It is working and that's what's appropriate to leave in place.

MR. CHESLEY: Can you leave that on?

MR. FERGUSON: Absolutely.

MR. CHESLEY: Your Honor, --

THE COURT: Let me ask you this. What is wrong if we have in place Bayer -- if I fashioned a ruling that Bayer is to do cross-referencing. You are to provide them with the information dealing with each and every plaintiff so they can do their cross reference, so they can go ahead on those cases where an adverse report has been sent and notified with the plaintiff that that information be sent immediately to the lawyers. That issue dealing with class certification comes before me, I rule upon that. If that goes in your favor, then they will have to turn over more information.

MR. CHESLEY: Your Honor, let me address that. I assume the question is asked of me, is that correct?

THE COURT: That is correct.

MR. CHESLEY: Yes, Your Honor, I will answer it and I will tell the Court why it is inappropriate and not the way to go in this matter.

I think it's significant, Your Honor, that my esteem counsel was unable to answer the Court as to how many adverse claims there are and how many letters went

out. It wasn't until I suggested that house counsel was here and he called on house counsel.

Your Honor, in two weeks we have attempted to find out how many letters have gone out. 15,000 letters have gone out, not as junk mail, Your Honor, as certified mail. What does a recipient of certified mail believe when they get something? They believe that they are either in trouble, they owe debt, or the Government is looking for them.

Your Honor, I represent to this Court that I have represented plaintiffs in medical cases for twenty-two years against Pfizer, against Copley, against -- let me give three others, American Home Produces. I have never seen a release of documents like this. To suggest that what's on the computer in front of you gives them a license to get medical records which are privileged. Your Honor, that's the part -- if you will take a look at the Minnesota statute. To begin with, the rule does not prohibit communication with a party or an employer or agent of a party concerning matters outside the representation.

Your Honor, this is part of the representation. And if you go to Item 4, contacts by plaintiff's attorney with former managerial employees of corporate defendant did not violate the rule prohibiting ex parte contacts where attorney informed former employees that his representation

of the plaintiff did not ask either of them to discuss matters that would be privileged. Medical records are privileged.

Your Honor, I represent to this Court that they have no intention of taking all of these bulk medical records that they received and send them to the FDA. What they will do is they will pick and choose and take certain abstracts from them.

I represent to this Court, Your Honor, that a doctor's nurse reading the letter with medical care and the condition we're in now, doctors do not read these kinds of letters, their nurses do. And I represent to the Court that if you take a look at Page 1 of their letter, very cleverly designed, and let me just get it. I had it in front of me. It says, "any information you could provide will assist us in monitoring the safety of our drugs." And the representation was made here today, Your Honor, that they withdrew it from the market but they weren't forced to withdraw. I dare them to put it back on the market because then the FDA would issue an order to take it off. That's the standard operating procedure of our drug industry today. When in trouble, withdraw the drug or price it out of the market place. That's what they did with Bendectine so they avoid an absolute recall. They don't need this information.

And, Your Honor, sometimes you ask for something that you wish you didn't get. Defendants' complaint is there is no certified class. I'll make a recommendation, Your Honor. Simple. They knew how to send 15,000 letters. That didn't boggle their system. And what I would ask the Court to do or think about doing, Your Honor, is to -- because they keep talking about all the problems and all the states and the contact and so forth and so on. I would ask two things, Your Honor. That this -- because I thought this was a simple issue. A representation has been made that the FDA command you to do this. This is the best reg they can put out, Your Honor, and there is not one word of medical records in it. Generally, additional information should be sought from the treating health care provider. No command, no demand. A determined effort, that's an effort, should be made to obtain additional detailed information from health professionals for all serious reactions initially reported by consumers.

What does that mean, Your Honor? Does that mean medical records? Does that mean complete medical records? Does that mean these defendant are going to turn over medical records. Your Honor, I can take a deposition and prove to this Court that they have no intention of taking these 14,000 of medical records and turning them over to the FDA because the FDA doesn't want it. They can't

warehouse it. They'll pick, they'll choose. Look for symptomatic. They'll try and disprove a causal connection. That's what they will do with the medical records. And that's why in twenty-two years I have never seen a letter quite like this. They asked for it and maybe they ought to get it, Your Honor.

What this Court could do for order and process, Rule 23 is a procedural vehicle only. And Rule 4.2 gives this Court the right to certify any issue. I would ask the Court to immediately certify but one common issue that affects 15,000 people and appoint a Special Master. We do -- we, these lawyers that they're concerned about, do not need to seek a Special Master that both sides can pay, Your Honor. And Bayer can issue and pay for the notice to these 15,000 people. If they have sent medical records, they should be in touch with this Special Master appointed by the Court.

Your Honor, in the appear Copley case and other cases, we never got the names and addresses of the people. We gave it to a certified medical company whose job it is to write and send these addresses. We don't need to see the addresses. The Special Master -- all this Court needs to do is issue a Rule 23, interim, conditional Rule 23, Your Honor, not even a permanent, a conditional Rule 23 because they complained that there is no class. This is

only a putative class.

And, Your Honor, let me read Judge Bartle, Judge Harvey Bartle of the Eastern District of Pennsylvania's opinion. In Dondore v. NGK Metals Corp., 2001 U.S. District Lexis 4267, 2001 U.S. District Lexis 4267, an unreported opinion in which the court considered the impact of Pennsylvania's virtually identical 4.2 rule in a case involving pre-certification contact by defense counsel with members of a putative class in a mass toxic tort. The court held that putative class members could not be interviewed without the consent of class action -- without the consent of class action counsel and that Rule 4.2 prohibits conctact by opposing counsel with putative class members. The quote, truly representative nature of a class action suit affords putative members certain rights and protection, including, we believe, the protections contained in 4.2.

But I'll answer their question, Your Honor. Let it not be a putative class as for this single issue. It should not be precedential as to whether or not we get a class for any other purpose. And once this Court issues an interim conditional class order, it can be drafted, and we will help draft it and get it to you within two days or get it to the other side. It's to just -- so that this class of people, 15,000 people are protected. We don't want to

know, but this Court as a ward of this class needs to know what was sent and who it was sent to.

Isn't it strange to send a certified letter. Show me anything. And, Your Honor, I know, I looked at Mr. Troy's letter again during the break, and while I was listening to counsel. And, you know what, (a) there is not one word in here about medical records, and (b) I agree with what he says. In fact, if you take a look at the last paragraph, he said FDA recognizes that a court may exercise its equitable power, and goes on, FDA would, therefore, urge you to seek an order that is cognizant of the language of the FDCA and its implementing regulations.

Your Honor, I think the order should be a class action appointing a Special Master to get to the bottom. (A) make independent -- hire an independent expert by this Court under the powers of 706 to determine what they will do with these medical records and how they will be used and where they will be sent and who is reviewing them.

Number 2, find out exactly how many have been sent and how many have been received.

Number 3, find out how many they sent to lawyers. Your Honor, I would venture to say they probably sent less than a hundred to lawyers. This is a very pervasive abuse of power attempting to hide under the auspices of the FDA.

I think they should get those records, but I think they should be under the control of this Court. And they should report to the Court what they are going to do with them. If their intention is to send all of these records to the FDA, fine, Your Honor. The Special Master can do that. Or the Special Master can meet with the FDA and go to Washington, D.C.

Your Honor, I would also be curious as to whether or not Mr. Troy, who wrote this letter to Mr. Bass, whether or not Mr. Bass ever gave him a copy of the two letters that went to the consumers, the letter and the attached form. I would be interested in an affidavit from Mr. Bass as to whether or not Mr. Troy was supplied those form letters. And if so, when.

I'd be interested in what communication was made with Mr. Troy and by whom, what lobbyist? What public relations firm?

Thank goodness we are here, Your Honor, because you were one hundred percent right. We are attempting to take the chaos out of this case. This looked to me like a very, very simple issue and the more -- time finished? Done. Thank you, Your Honor.

MR. FERGUSON: If I may address just a couple of points, Your Honor. If it's not necessary --

THE COURT: I don't know what you are going to

address. I have certain powers.

MR. FERGUSON: I won't be long. Quick point. It is not that we have obtained or sought to obtain medical records from 15,000 people so that we can send those to the FDA. Number one, the number 15,000 is not the number of sets of medical records we have asked for. It is, I take it, an estimate of the number of total adverse drug event reports that have come since the Baycol litigation started.

Separately, when Bayer asked for medical records, it's so they can look at, analyze and carry out the reporting, obviously. Of course, you are not going to send piles and piles of documents to the FDA, but it's part of the regulations that that analysis be done.

A couple of quick points and then I will be done. What counsel says he's never seen and what counsel represents from other cases are not a record sufficient to create the need for remedial communication or other remedy here. Evidence of actual abuse or evidence of the threat of imminent harm is what's required. We have not gotten that here, and as a result, no remedy changing this whole reporting requirement is necessary. Thank you, Your Honor.

MR. CHESLEY: May I make just one observation from my chair? I was the one -- it was originally

addressed to Your Honor that they had a duty to get these medical records so they can give them to the FDA. I go back to my point of that of a Special Master. Let the Special Master determine with the FDA what's going to happen with these medical records because they are never going to see the FDA, Your Honor. Thank you.

THE COURT: I'm going to take this under advisement. What I want in two days is counsel to meet and give me a proposal dealing with the Special Master and -- give me three names that you all agree on and who the Special Master should be and what the conditions of the duties of the Special Master should be. I'm going to take it under advisement. I'm not going to say I'm going that route, but I would like to see your proposals. And if there has been an agreement from both sides. And if you can't agree, you both submit your proposal on what a Special Master would do in this matter.

I know what Bayer is going to say -- nothing. But certainly they would want to respond to what things a Special Master would do. Let's do that. I'll take this matter under advisement. And I want it two days from today's date which would be Wednesday by 4:30.

MR. SIPKINS: If I could, Your Honor, could I address that? I think that Your Honor hit the nail on the head. At the current state of affairs, Bayer's position

would be a Special Master should do nothing. I suspect the plaintiffs will propose something. We would like an opportunity to respond to it.

THE COURT: All right. Plaintiffs have theirs in by Wednesday at 4:30. Bayer respond by Friday at 4:30.

MR. ZIMMERMAN: To the Court or to Bayer.

THE COURT: They don't want to meet with you on this issue. Send it to me what your proposal is and also send it to Bayer. They will respond to what you have to say. And, again, that doesn't mean in any shape or form that I'm going to accept that, but I'm intrigued by that concept. So, I want to take a closer look at it.

All right, anything else that we need to do out here? If not, let's take a ten-minute break. Those of you that are going to meet with me in chambers, come on back.

REPORTER'S CERTIFICATE

I, Brenda E. Anderson, Official Court Reporter, in the United States District Court for the District of Minnesota, do hereby certify that the foregoing transcript is a true and correct transcript of the proceedings in the above-entitled matter.

CERTIFIED: _____

_____
Brenda E. Anderson, RPR