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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549-4561

DIVISION OF
CORPORATION FINANCE

11005960

March 10, 2011

Paul W. Cahan

*** FISMA & OMB Memorandum M-07-16 ***

Act: 1934
Section:
Rule: 14a-8
Public
Availability: 3-10-11

Re: Johnson & Johnson
Incoming letter dated March 6, 2011

Dear Mr. Cahan:

This is in response to your letters dated March 6, 2011 and March 9, 2011 and your letters received on February 26, 2011, February 27, 2011, March 7, 2011, March 8, 2011, and March 10, 2011 concerning the shareholder proposal that you submitted to Johnson & Johnson. On February 22, 2011, we issued our response expressing our informal view that Johnson & Johnson could exclude the proposal from its proxy materials for its upcoming annual meeting. You have asked us to reconsider our position. After reviewing the information contained in your letters, we find no basis to reconsider our position.

Sincerely,

Heather L. Maples
Senior Special Counsel

cc: Elizabeth A. Ising
Gibson, Dunn & Crutcher LLP
1050 Connecticut Avenue, N.W.
Washington, DC 20036-5306

From:	PAUL *** FISMA & OMB Memorandum M-07-16 ***
Sent:	Thursday, March 10, 2011 12:27 AM
To:	shareholderproposals
Cc:	dchia@its.jnj.com
Subject:	Proxy:Attn C; KWON
Attachments:	J&JManipulatedLevaquinStudyEurope.txt; MinnTrialMotionsLevq.txt; ProxyFINAL.wpd; QuarterWatch20110001.pdf; Safeway Inc Food Label Proxy0001.pdf

Please excuse the disorganized communication.
Below are the attachments to complete my request.
It will be the last presentation of information.
Attached:

Relative to risk and 'ordinary business' discussion:

1) J&JManipulatedLevaquinStudyEurope: from Trial Transcript
2) Transcript of Tendon Rupture trial case: full day 9/28/2010
3) ProxyFinal.wpd: Separate document in body of letter
4) QuarterWatch2011 file Vital Statistics Referenced in Introduction Section
5) Safeway Proxy: from annual report, example of similar request accepted

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DUE TO FILE SIZE, THIS SENT SEPARATELY:
6) Entire Letter with page numbers on pdf file for your convenience.

I thank you all for your patience. I have not been well.
Paul Cahan

JJManipulatedLevaquinStudyEurope

Section of:
US District Court
District of Minnesota
RE: Levaquin Products Liability Litigation
File No. 08-md-1943
Minneapolis Minn.
Hon. Judge J R. Tunheim
Plaintiffs: R. Goldser, Esp
etc
Defendants: J. Dames, Etc

Section quoted below pertinent to
how J&J has conducted business related to
"risk" management of Levaquin
Manipulated Research Study on Levaquin's equivalent drug,(Tavanic) in Europe

Related to issues of
Social and Health Impact
Risk Mangement
Definition of Ususal and Customary Business

From Trial Transcript:

copy and paste from middle of transcript to bring your attention to this section:
full transcript another file document.

"They manipulated the Ingenix study for their own economic purposes. The Ingenix study started to appear in discussions in the late fall of 2001. Aventis made a proposal about the protocol. The idea was that they would respond to the French authorities. The French authorities wanted to know what was the comparative tendon toxicity between Levaquin and the other fluoroquinolones.
The Johnson & Johnson response was -- and Aventis was going to do a study that said that. Johnson & Johnson said we can't afford that study. If we end up with a bad result, we're in trouble. So they started taking control of the study from Aventis, and they slowly but surely turned the battleship around to change the focus of the study from a comparison between fluoroquinolones to talking about fluoroquinolones in general and the impact on the elderly and corticosteroids, because by that time they had already decided to include that warning in the label. And so if they found that there was a negative impact, no big deal. It was already in the label. They already had a strategy for that. So they were going to figure out a way to manage the Ingenix study so that they would get the result that they wanted. So they manipulated the one study to achieve an outcome that was in their best economic interests.

They took it over from Aventis. They controlled the study with Ingenix. I will talk about that for a second. The protocol that was written, it was drafted by Dan Fife. It was discussed between Dan Fife and John Seeger at Ingenix.
There were meetings to talk about the protocol. There were exchanges of drafts on how to do the protocol, the type of study that it was was developed by Johnson &

Johnson in discussion with Ingenix. I mean, they did the whole protocol process.

To be sure, I mean, John Seeger was involved in this, but Johnson & Johnson really controlled the protocol process. Once the protocol was set, it was just a matter of filling in the numbers by mostly administrative mechanism, although we certainly have complaints about how John Seeger did that, and I will talk about that.
They avoided comparing Levaquin with other fluoroquinolones as was requested in Europe. All the items on the bottom are references to documents, and if the hyperlink works, you could pull up the documents. They changed the desired outcome. Europe wanted to know what was the problem related to tendonitis and tendinopathy. Johnson & Johnson said we can't do that. It has got to be tendon rupture. Ostensibly the reason is because tendon rupture is better defined. It's easier to identify what constitutes a tendon rupture, but really what they're saying at that point in time is that doctors don't know how to diagnose a tendinopathy and they won't trust tendinopathy diagnoses.

Paul Van der Linden in the Netherlands whose four studies, including his PhD thesis, talked about how Floxin was worse than the rest, focused on tendinopathy and tendon rupture. He was able to distinguish between tendinopathy and its relative risk compared to other drugs and to placebo and also tendon rupture compared to other drugs and placebo.

He could do it. It was academically acceptable to people accepting his PhD thesis, but that was not good enough for Johnson & Johnson. The reason? Because there were fewer tendon ruptures than tendinopathies, and as a result the relative risk was going to show lower, they would get a better number.

They manipulated the power estimates of the study. I don't know to what extent you're conversant with the notion of power, but power tells you the ability to make accurate predictions about epidemiology studies. If you start out with power that is wrong, it's too high. If the power is at four when you're going to find a relative risk of two, what you are going to end up with as a result of that is a confidence interval that is very wide.
In order for you to have statistically significant results, the narrower the confidence interval the better, and most importantly, if the lower bound of the confidence interval is over one, you know that at worst it's still more statistically significant than random. One is random.
So when you have got a wide confidence interval that results in a lower bound being below one, you can say with honesty this is statistically not significant, but it all stems from where you started. If you start with the wrong power estimate, you end up with a wide confidence interval and no statistical significance.
If you take the trouble to go through the litany of testimony from John Seeger that is listed on that page, you will see he admits that that's true and that they knew it going in, that they picked the wrong power. It was a manipulated study.

"They created a plan to maximize profits while avoiding safety issues. Sitting around in board room 301 in the Kitano meeting, you didn't see anything in that James Kahn memo that said anything about safety issues and how do we fix the safety problems. It was how do we avoid the safety problems in order to make sure we don't lose any money. They purposely sought to avoid label changes.
I had an e-mail from Dr. Noel, one of the medical people involved in this. That's attached to this, but I highlight back for you the notion that I mentioned before about how they refuse to incorporate anything in their label change about Levaquin being worse than the other fluoroquinolones.

They knowingly decided not to share the warnings information with the public. One of the documents that I have that the defendant has finally acknowledged is a set of handwritten notes from yet another doctor, Chuen Yee, from Johnson & Johnson, sitting at the Kitano meeting, and that documents says in her handwriting, Not share with public, and it's talking about the French agency reports. Don't tell anybody about it.

They ignored their own published literature and how best to communicate warnings to doctors.....
Dr. Fife says at the end of his article, if I have it highlighted -- let's see if I can pull that up for you. He did an epidemiology study to determine what is the most effective way to communicate warnings to doctors, and what he finds in the last sentence is the most telling I think. The key characteristics of a successful drug warning appear to be specificity, prominence, brevity, no reliance on secondary information, publicity and in-person discussions. You've got to do stuff other than bury it on the lower left corner of page 2,448 of the PDR when that book comes out every year and don't tell a doctor about it. Their own doctor says, their own epidemiology department tells how you should be doing that. They ignore their own published literature and how best to communicate with doctors.

They intentionally buried the warning, as I have described to you. They failed to send a dear doctor letter. There were dear doctors letters sent, if I get the countries right, in France, Italy, Belgium, Germany, Austria, and I'm missing one. There were six of them, all in 2001 and early 2002, about the corticosteroid elderly problem. Was there one sent in the United States? No. Dr. Canabarro from Aventis was deposed, and what she said in her deposition was, she was asked, you know, why do you send out a dear doctor letter, and her response was, well, you know, we had it in the warnings. But why did you send out the dear doctor letter? Because the warning wasn't enough, and we wanted to make sure to communicate with doctors. Aventis did it. Johnson & Johnson didn't.

They deliberately did not train their sales representatives to proactively call out label changes to doctors. I deposed Teresa Turano two weeks ago. She was the 30(b)(6) corporate representative on sales training. She didn't know much, but what was clear from her was that

there was no policy to tell sales representatives that whenever there is a label change you have got to tell doctors.

.....

There were clear press releases issued about new indications that the FDA had approved, but was there any indication whatsoever that they issued a pretty release on any label changes? Not a one. They didn't undertake any seminars, public speaking engagements, lunch or learn trainings.
They didn't educate doctors in the manner that they otherwise do educate doctors about new indications. They didn't publish articles talking about the risk of tendon disorders, and I will come back to that in a little bit when I talk about the publication plan and the ghost writing.

They manipulated the Ingenix study for their own economic purposes. The Ingenix study started to appear in discussions in the late fall of 2001. Aventis made a proposal about the protocol. The idea was that they would respond to the French authorities. The French authorities wanted to know what was the comparative tendon toxicity between Levaquin and the other fluoroquinolones.
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They minimized the number of elderly contained in the study data. I know Mr. Saul will talk about that. They improperly included children in the study. Mr. Saul will talk about that. John Seeger admits that that's true. They incorrectly identified what constitutes a tendon rupture for the study by having a nonmedical doctor, Seeger, do the study.

In particular what you might pay attention to on

that slide is the bullet point saying testimony of Seeger regarding Schedin. We happened to pull out Mr. Schedin's medical record where it talks about whether he has got a tendon rupture or not a tendon rupture. It says tendon tear.

We asked Dr. Seeger, Is this a tendon rupture that would be included as a positive finding in your study. He said, no, this would not be a tendon rupture in our study. Our plaintiff here, who has clearly defined tendon ruptures and his doctors have all said so, his treating doctors have said so, was not a tendon rupture for purposes of John Seeger's study. That's how badly defined some of these tendon ruptures were.

Why? Keep them out of the study and keep the numbers low. There was a medical record review for evaluating tendon ruptures, but there was no such medical record review for tendonitis cases which was used as a covariate. It was an internally inconsistent study. Seeger is not blinded during the study. He knew which cases had fluoroquinolone use and which were not. Dan Fife, Johnson & Johnson's own witness, says that as a result the study is invalid. They destroyed abstracts. We wanted to reproduce the study. In order to reproduce the study we needed the abstracts and the medical records that they used to determine what was a tendon rupture and what was not. They have been described.
They admit it. Seeger admits that in the fall of 2006, three months after the article was published, they destroyed these documents. That's contrary to the guidelines published by the International Society of Professional Epidemiologists, ISPE, which requires that such documents be held for five years.
Normally you wouldn't think that would be such a big deal except the guidelines were written in part by Seeger's boss at Ingenix, Alec Walker. Walker said, I don't know the guidelines. Are there guidelines? These guidelines go back to 1996. Walker wrote them in 1996. They were revised in 2000, 2004 and 2007, if my memory serves me correctly.
Walker doesn't know them. Seeger doesn't know them. They destroyed the documents in contravention of guidelines that they wrote. Mind boggling. They ignored the existing scientific literature. I told you about the 16 articles. They lied to the FDA about comparative tendon toxicity of fluoroquinolones.
Finally, on the converse side, their marketing efforts. They touted Levaquin's excellent safety profile without disclosing its risk and trained its sales representatives in this manner. I have got a pile of documents that show that. The do and don't document that is on there do tout the excellent safety profile of Levaquin.
The quick tips guide that is on the bottom there, I worked with Teresa Turano and went through much of that verbatim. I said, does this paragraph have anything about safety in it? No. Does this have anything about tendon ruptures in it? No. Does this have anything about warnings on tendon ruptures? No. Does this have anything about comparative tendon toxicity? No.
All over the place there is nothing about tendon warnings, and it's all about the excellent safety profile

of Levaquin. They knowingly marketed to the elderly population. Again, the quick tips guide will tell you that. They marketed it as first line therapy. Levaquin is a good drug for certain circumstances. We don't dispute that.

For people who are seriously ill, it will do what it's supposed to, but if you're got a sinuitis or an acute bacterial exacerbation of chronic bronchitis, like John Schedin did, you don't use Levaquin. He had one trial on Zithromax. Could easily have gone back to another trial on Zithromax or another less potent antibiotic, but this was marketed like candy, samples left, right and sideways. They had millions of dollars in samples for first line therapy for these indications that were hardly severe enough to warrant them.
They did ghost writing. From 1994 to 2002, DesignWrite, their hired gun, caused to be authored two -- 144 papers on either Floxin or Levaquin, touting its benefits. Of those 144 papers, 13 of them had the word "safety" in the title, and only one of them had anything to do with tendons, and that was a published, published paper on children and tendon disorders. Nothing about the elderly. Nothing about corticosteroids. Nothing about any of the issues where Levaquin is worse than any other fluoroquinolone, and that's only through 2002.
In 2002 they spent a million dollars with DesignWrite on ghost writing alone. There was a lot more money spent with DesignWrite in that year. They used the Speakers Bureau as a promotional tool. Defendants' own expert John Segreti who is going to talk about Mr. Schedin's particular circumstances and case specific and also what you use Levaquin for.
I asked him -- he is on the Speakers Bureau, so they are bringing in a Speakers Bureau person as their expert witness, which is kind of curious. I asked him what he did when he was on the Speakers Bureau. He gave talks. I said, well, were they promotional. He said, of course they were promotional.
Well, why were they promotional? Because I was touting the use of Levaquin. It wasn't educational about disease. It was about how best to use Levaquin. They were promotional.

So at the end of the day, Judge, we have lots of good reasons why we believe defendant deliberately disregarded the rights of the plaintiffs, including John Schedin, intentionally, consciously, knowingly, willfully and with marked indifference. That's our evidence.
You don't have to, you shouldn't listen to any contrary evidence or challenges or cross-examination by defendant because that's not what the law allows or requires. We think the motion should be granted. Thank you very much.

THE COURT. Thank you, Mr. Goldser.
Mr. Saul, did you have something?

MR. SAUL: Good morning, Your Honor.

THE COURT: Good morning.

MR. SAUL: Louis Saul on behalf of plaintiffs.

Mr. Goldser talked at some length about the Ingenix study, and I will fill in the gaps. I realize our time is limited here. Just to go back, Johnson & Johnson had nothing to do with the European situation. Aventis, their trading partner in Europe, was asked to do studies because of the signal in Europe that there were tendon problems, particularly among the elderly, emphasis added, and particularly with corticosteroids.

What the defendant was hoping to avoid and worked to avoid -- may I approach -- was to have this, this warning in the label. This is the warning that eventually got into the label. This is the black box warning that got into the label in November '08. Fluoroquinolones, including Levaquin, are associated with an increased risk of tendonitis and tendon rupture. The risk is increased on those over 60 and those on concomitant therapies respiratory, heart and lung recipients.

They kept this warning from being placed in the PDR, in the package insert, for seven years. During that seven years, their sales were about 13 billion dollars. By keeping this warning out for seven years, this company earned themselves 13 million dollars, and we believe that that evidence in itself is enough to get us to the punitive damages claim.
However, how did they do it.

THE COURT: Is this the warning that is on right now?

MR. SAUL: This is the present day warning.

THE COURT: Go ahead. I will ask you a question about that later.

MR. SAUL: Sure. So what did they do? They had no interest in Europe. In fact, they told the Court during our motion practice that they had no relationship with the European authorities and they didn't want to give us documents related to that, that they actually went and took over this study. They took it away from Aventis because they said if we don't do this study and we don't get the proper results, essentially we're dead. Levaquin is off the market.

So what did they do? They hired this company called Ingenix who had done numerous other studies for them. There was a young doctor there by the name of John Seeger who had just become an employee, and they had him conduct the studies. Mr. Goldser said they designed the protocol. What did they do in the study?
If I may give you another document, Your Honor.
This was prepared by me, and this is how they intentionally manipulated the study. The first they wanted to do, the European authorities wanted to study -- the issue was among the elderly and corticosteroid use. What did Johnson & Johnson do? They intentionally left out elderly from the study.

This document that I just handed you was from the original protocol of this Ingenix study. If you will see here, table 1 talks about the UnitedHealthcare research

database population. If you'll go down to the bottom, 60 to 64 and 65 plus, you will see that in their database, there was only 4.7 percent of, let's for lack of a better term, the aging population. I'm in there. Just leave it like that.

You will see in table number 2 in the census bureau, there were 16.2 percent of the population being over 60. So they chose a data -- Aetna was going to use a different database, but they took this away and used this particular database that underrepresented the elderly. What else did they do? Levaquin was contraindicated for children, for pediatric use. Contraindicated, you can't use it for pediatric use.

You will see in the general population, there is 29 percent, and in their database there is 29 percent in approximate numbers. They included this 29 percent, the children, in the study. So what they did is, they kept the elderly out. They included children. Children can't even take Levaquin. The elderly, the focus was on the elderly. They cut that down. Okay.

So what did they do? So they intentionally excluded the elderly and included children. But then what happened? They did their study. Part of their study was to get this study published in certain journals. Those journals are the journals that most of us have heard about. For instance, in New England -- I won't go through them all. Five journals, the New England Journal of Medicine and the first line journals. They could not get this study published anywhere. What did they do? They went to -- Johnson & Johnson and Ingenix, they were members of a society, and Ingenix was the head of the society. They got it published in that society's journal. No one else would take it. The study was concluded in 2003. 2006 it got published. Lo and behold three or four months after it got published, they destroyed the data. They went and they did medical review of a certain number of the patients in this study, and you have to keep this data because once you publish something, other researchers have to be able to duplicate the study. What happened to the data? Dr. Seeger testified, we don't -- we didn't really know what happened. I'm not sure what happened, and he went on and on. Finally, we got him to admit, and I just want to read to you -- at any rate, Dr. Seeger admits, admits that under his tutelage or under his direction that he caused all the documentation to be destroyed regarding the study. This is, forms the basis also of our motion, our Daubert motion.

No one can duplicate this study. They also created an algorithm to define who was in the case. They can't find that algorithm. All the documentation is gone. That in itself, the intentional destruction of the data, they kept their product on the market for nine years or eight years, is enough to allow us to amend the, the complaint, and I believe it's enough for the jury to enter a substantial award.
I feel that our time is limited, but each of these dotted areas is covered in our brief extensively, and I would like to incorporate our motion in limine regarding Dr. Seeger into this because rather than me go on and on

about the study, I think it's all well depicted in our brief.

THE COURT: Thank you, Mr. Saul.

MR. SAUL: Thank you, Your Honor. Did you have any questions about the black box?

THE COURT: No. That's fine. I may address it later in the hearing.
Mr. Dames?

MR. DAMES: Thank you, Your Honor. Your Honor, I just want to start from, actually maybe just the simplest of all is to start from the beginning, and that is when the drug was first marketed in 1997. There has much been made so far in the arguments concerning concealment, omissions, lack of warning, refusal to include things in the warning that I would like to refocus this as to what took place in the very beginning when the drug was first marketed. From its inception, and the Court is well aware because we've said it many times, when it was first marketed, there has been a tendon rupture warning in the label. Not hidden, not in any way buried in a mass of language, prominently mentioned in the warnings.

At the time that Mr. Schedin received his prescription for Levaquin, the warnings had been updated as early as 2002 -- well, let me first go back to October of 2001. The warning was altered to include a reference to a heightened risk in the elderly, potential risk with the elderly taking corticosteroids.

That was in response to the events and the data that had been received in Europe about the experience and adverse reaction reports from the use of Tavanic, the -- Levaquin is marketed in Europe, and the company through a change is being effected, that is on its own initiative, incorporated the information that was coming from Europe to include that in the warning on its own. The FDA approved it at the company's instigation. They approved that warning. It was that warning with a very slight amendment in 2004. That was the warning the prescribing physician for Mr. Schedin received. Now, in Europe the reports, the adverse reaction reports that were received in Europe, showed variances within the different European countries. Germany had a much lower rate of reporting than did France. When those things were investigated, when the scientists and researchers looked at what were the reasons for divergence between the European countries, they determined that in France, Levaquin was prescribed and Tavanic was prescribed predominantly for upper respiratory tract infections, and there the French physicians used corticosteroids a significant percentage of the time when they used Levaquin. Now, the debate has been, you know, what significance is that. When the meeting occurred at the Kitano Hotel, not quite as luxurious. I have actually stayed there. When the meeting was held at the Kitano Hotel to evaluate the situation and determine what should be done to investigate it, now remember already in place was J & J's CBE label change -- the label change occurred in October. I'm sorry. Already --

J & J incorporated that information in October that it learned, but in addition it wanted to do an investigation and a study, as did Aventis. Aventis does their own studies, a quick and dirty analysis, it was put, to look at the situation to respond to the French and European regulatory authorities. J & J decided it wanted to use the largest database then available, the UnitedHealthcare database.

Contrary to what you have heard so far, Your Honor, the Aetna database, an alternative, was not even available to be used. They couldn't use it. Why did they use UnitedHealthcare database? Well, it afforded J & J an opportunity to have access to medical records. Not all databases that were used would give you the access to the medical records.

And as I said, it was an exceptionally large database and would provide one of the best experiences to evaluate to see what was the frequency, what was the incidence of tendon rupture on Levaquin and what was the incidence of tendon rupture on some other factors, for example, other fluoroquinolones and to evaluate -- I mean the study itself clearly was published by Dr. Seeger, included other factors besides Levaquin. It also evaluated corticosteroid use and some other predisposing factors. Now, why was tendon rupture used as a measure? Was it done to manipulate the data, to somehow hide something? No.

It was determined that the most objectively verifiable diagnosis that could be used in the study was a rupture. Not tendinopathy. Tendinopathy can be a wide variety of things. It is like 70 diagnostic codes are related to tendinopathies. So it could be confused with muscle tears. It could be confused with other kinds of diagnostic end products. So it was made, it was determined to use tendon rupture as the objectively verifiable point. The diagnosis of tendon rupture by a physician was operative. Now what is wrong with that? Very, very little. Dr. Van der Linden used tendon rupture as the outcome in his own study.

Now, I want to remind the Court that J & J was very responsible in addressing the issue head on. It wanted to do the study on its own, not because it wanted to manipulate the results. Dr. Kahn testified quite clearly that what they wanted to do was the correct study. They wanted to do it correctly. They wanted to make certain it was done right, and that's why they did the study the way they did, and that's why they did it rather than rely on any other company to do it on their behalf. What was the outcome of their investigation? What was the outcome of their research? The French and European -- well, the European regulatory authorities evaluated not only the Johnson & Johnson sponsored study that was performed, and let's make this distinction clear. It was performed by Ingenix. J & J participated in the protocol. It helped plan the protocol of this study. It did not conduct the study. That was done independently by Ingenix, and Dr. Seeger made the decisions concerning the development of the study together with other employees at Ingenix and the development of the algorithm

which defined and decided which were cases and which were not.

Much reference has been made to destruction of medical records. Dr. Seeger in the course of an office move after the study was published, as plaintiffs state, lost the medical records involved in the study. It had nothing to do with Johnson & Johnson. Johnson & Johnson certainly had no relationship to any loss of the medical records, but it was inadvertent, and it was done during the course of his office move, as he testified.
There was a reference made to whether his study was blinded. Dr. Seeger pointed out, his study, he was blinded as to which fluoroquinolones were used by the people involved in the study. We could go on and on with how the study was designed. Were the elderly intentionally excluded? That's absolutely false. Here is a classic example of how the characterization by plaintiffs is so unfair.

The UnitedHealthcare database, of course, the basis of that database are the people covered under the UnitedHealthcare. That, there would be, because of Medicaid -- because of Medicare, there would be a possible underrepresentation of the elderly. That was recognized, and that's why the elderly and a Medicare database were added to the study.

So there wasn't any intentional exclusion. They were in fact included. Then it was contrasted with whether there was an intentional inclusion of children to also skew the results of the study. Children were not intentionally included. The database includes children. There were no Levaquin cases of tendon rupture involving children. There were no skewed results because of children, but you take a database as it comes, and it includes the span of ages in the database, so of course, the age range of children who would have been included.
The tears were excluded, according to Mr. Saul, in the study. If Levaquin, if there was a tendon rupture defined as having occurred with Levaquin by the prescribing doctor, it could be defined as a complete tear, it would be included. So we are really ending up talking about and debating the merits of a scientific protocol openly arrived at, submitted to the FDA, shown to the European regulatory authorities who in turn evaluated the published literature, Aventis's own studies and the Seeger study.
And they recognized the limitations of each, including the Seeger study, and what do they come out with after the purported suggestion -- it isn't purported. It was a suggestion by one of the assessors earlier on that the label be altered to include a statement concerning a greater use in the risk of Levaquin over the other fluoroquinolones.

That was rejected after all of the evidence was in by the European regulatory authorities, and the reason it was rejected was clearly stated that the data was insufficient to make any differentiation between fluoroquinolones and tendon rupture, and it is worthwhile to remind ourselves of exactly what the European health authorities after all of the data was in, up-to-date for them, in 2003.

And it says, and this is one of Plaintiff's Exhibits, Exhibit 87. Under paragraph 8, and we mentioned it as well in our brief, Your Honor, the conclusions, it states, The morbidity and frequency of the suspected adverse reaction, that is, very rare and not fatal outcome which generally recovers, must be weighed against the nature of the benefits and indications for treatment with levofloxacin, reduction in morbidity and mortality of respiratory tract infections and other infections when considering the need for further studies and regulatory action.

They conclude, No further action -- this is on the next page -- given the rarity and nonlethality of adverse reactions, this is justified on the following grounds. Absolute risks of fluoroquinolone associated tendon rupture are very rare, and furthermore, the population attributable risk is very low. Although we cannot exclude a slightly higher risk of tendon rupture with levofloxacin or ofloxacin, currently available data are inconclusive. Such estimates are likely to be rare or very rare. SPCs, that is a labeling, for levofloxacin products have been updated with adequate warnings. Further analysis of existing data are unlikely to be helpful.

There were several things in that conclusion that are important. Even considering all of the studies, even considering the state of the animal data, considering all of the issues that plaintiff have put forth today about the adequacy of the studies, disagreeing with some, agreeing with others, the European regulatory authorities decided that the heightened risk label change was not necessary. There was no evidentiary basis for it. They also, however, said something very important in this conclusion, and that is the benefits of Levaquin in the treatment of upper respiratory infection. There are benefits to this drug, and that is in part part of the passion that arises from Dr. Kahn. The benefits of Levaquin have been proved repetitively, and they are agreed to by everyone in this litigation.

At the trial of this case, you will hear from every expert witness, plaintiffs' and defendants' alike, that Levaquin is efficacious and is very valuable. It is a good drug. Quite simply, they have testified already that it is a good drug.

We have pointed out in the brief that Dr. Zizic, one of the plaintiffs' principal experts in this case, prescribes Levaquin, uses it to this day. Uses it, in fact, under the condition -- well, let me backtrack. Dr. Zizic took it himself. It actually cured his infection, a very severe infection which he had. So he obtained the benefit of Levaquin himself. He gives it to his patients from time to time, and there is no testimony from either Dr. Zizic or any other expert witness in this case that the use of Levaquin under the conditions of use in Mr. Schedin was somehow inadequate or inappropriate.

So in the midst of all of this characterization of how there was a clear disregard of the safety of

patients, we have a unanimity of opinion as to the necessity and utility of the drug. We have a unanimity of an opinion that it should be used in the kinds of infections, upper respiratory tract infections, for which Mr. Schedin received the drug.

We have also heard about, it is not to be used as a first line of defense therapy for certain indications. Well, taking Mr. Schedin's case, for example, there will be no testimony, there is certainly none based on the expert reports of the depositions, that Mr. Schedin was not an appropriate candidate at the time he got Levaquin for Levaquin.
There are no indications in any label or any suggested indications in the label or contraindications which would minimize the use of Levaquin or have it as a second line of use. The published guidelines to this day, the Sanford Medical Guide, the Infectious Disease Society published guidelines, call for Levaquin to be used as a first line therapy initially in upper respiratory tract infections.

So the current state of medical knowledge by neutral and expert physicians, by responsible and referenced medical guides all call for the use of Levaquin. Levaquin is in fact the most efficacious, the best antibiotic for upper respiratory tract infections.
So if I can mirror, even slightly, the belief that someone like Dr. Kahn and others brought to how important the drug was to be used in the current respiratory season in his memo and to push for the right study, the correct study, the properly done study, the mischaracterization of the memo and of Dr. Kahn in this is truly horrendous.

Dr. Kahn's attempts, J & J's attempts was to do a study using the largest healthcare database then available, to use it for a measure of outcome which was the most clearly and objectively verifiable, and they hired Ingenix to perform and conduct that study. None of the data that has been developed to this day shows that Levaquin has any greater risk of tendon rupture than any other fluoroquinolone.
The data referenced by plaintiffs in their brief, the information that can be gleaned from it is, you either have data on ofloxacin. You have no reference to Levaquin and tendon rupture in those studies. You have suggestions on animal data as to comparative toxicities, but virtually none that any authority considered relevant and probative of the differential toxicities.
So how can anyone conclude that what shouldn't be in the label, what is not in the label anywhere today, was somehow the result of manipulation by J & J earlier? How can anyone conclude that something not required by any regulatory authority to this day is the by-product of a manipulation by J & J and a clear disregard of public safety by J & J earlier?
Added to that is, these attempts through marketing efforts to cloud and conceal and hide and ghost writing and detail people to call on physicians and not mention safety. Every visit that a sales representative makes upon a physician includes the prescribing information.

They don't just get it from the PDR, although that's a highly reputable source. They get it every time a sales rep calls on them. They get it prominently mentioned in the label. It's not hard to find, and the physicians, now we have taken enough prescribing physicians I've reminded the Court to this day. The physicians know about tendon rupture.

If there is one thing that we find consistently is that the prescribing physicians are aware of tendon rupture, including Dr. Beecher. He testified he knew of tendon rupture at the time he prescribed the drug to plaintiff. Plaintiffs asked, were you aware of the fact of corticosteroid and the risk of elderly, and in all fairness, Dr. Beecher said he didn't remember that he was aware of that at the time.

And this first slide will show you the history of the gross revenues that the company has earned over the years year by year on Levaquin. This is all public material. It comes from their annual report, so this is all out in the public domain.

So if our story for this motion begins in April of 2001, you can see that starting in 2001 through 2009 we're talking about roughly 13 billion dollars, so what's at stake here for the company looking forward from 2001 when our story begins is the potential of 13 billion dollars of lost revenue. That's what they needed to protect. That was their motive. It was Ortho-McNeil's number one drug.

Their actions were deliberate. The Statute 549.20 says that in order to get punitive damages, plaintiff must show a deliberate disregard for the rights and safety of others. As the Court knows, that can be shown several different ways.

One of the ways is to talk about intentional acts. The other is to talk about deliberate disregard of knowledge and facts, and you'll see that there were both that occurred here, much disregard of information that was out and available.

But before I get to those acts, what I want to talk about is the mindset that the company had, and some of the early documents that show the mindset I'm going to show those here. They felt that an adverse regulatory decision in Europe was going to be devastating. What was that? Let me tell you the story.

It starts in April of 2001, as the brief shows you, when the European, the French regulators went to Johnson & Johnson's marketing partner Aventis and said there is an increased reporting of tendon problems, particularly with Levaquin. And they wanted to know what that was about, and they wanted to know whether Levaquin was experiencing a greater tendon disorder report than any of the other drugs in the class of the fluoroquinolones. So the report started coming to Aventis, and Aventis immediately contacted Johnson & Johnson, and they started talking to each other about what would be the ultimate ramifications of this. So April of 2001 leads to July 24, 2001.

The partners come together at the Kitano Hotel in New York City. It's a beautiful place. It is located on 37th and Park Avenue, and next time you're in New York you ought to run by. It's just a gorgeous hotel, and they meet in board room 301. What is it they're talking about in board room 301?

They are talking not about safety. They are not talking about health concerns. What they're talking about is money. They're talking about the devastating potential of the adverse regulatory decision that might come out of Europe.

Now, who was there for Johnson & Johnson? One guy that was there was Dr. James Kahn. Dr. Kahn was a

medical affairs guy. He was not a marketer. He was not in sales. He was not in economics. He was the guy who gave birth to the molecule and gave birth to the science, but his whole mindset was about marketing and economics. And so as you can see from this first document, which was used in Dr. Kahn's deposition which was not marked as confidential, he says, The repercussions from an adverse regulatory decision in France, who among us can forget what happened over there to sparfloxacin, would be immediate and devastating, so let's act promptly.

MR. DAMES: I just wanted to object to something, Your Honor, and I'm sorry, Ron. The document by its own at the bottom says protected document, document subject to protective order. However we want to handle this issue, I don't want to fall pit to his argument again, but we're going to run into this.

THE COURT: Mr. Goldser?

MR. GOLDSER: As I said, this is marked as Plaintiff's MDL Exhibit Number 38. That's also on the bottom. It's part of Dr. Kahn's deposition. It is part of Larry Johnson's deposition. Those depositions were not marked as sealed, and I think counsel will agree to that fact, and so this document is already in the public domain. You never marked them as confidential, guys.

MR. DAMES: We marked the document as confidential, Your Honor. The transcript portions were not marked confidential, the transcript itself, but the document itself has been consistently marked confidential. I just think that once that issue is decided by the Court as to the confidentiality of those documents, obviously this will be one way or another resolved, but we did protect that document.

The transcript portions, the testimony, I frankly don't remember if they were or not, but I will assume that they were not.

THE COURT: They were not made confidential?

MR. DAMES: The testimonial portion.

MR. ROBINSON: No, Your Honor. The transcripts were not marked protected or confidential, but under the protective order, we had the right to mark documents as confidential. I don't think there is any requirement that we go back each time a protected document is discussed in a deposition and seal that part of the deposition. It's not a public record.

MR. GOLDSER: One other item, Your Honor. I read this very sentence to Dr. Kahn in his deposition. It's part of the transcript. That's not confidential.
THE COURT: Do you have other documents as part of this presentation that raise this same issue?

MR. GOLDSER: Yes. There will be another document, the next one, which is one of the most significant documents in the case, also authored by

Dr. Kahn, I went through it in copious detail with him, and I read most of the parts I'm going to read to you in his deposition. They're part of the transcript.

THE COURT: Anything else then besides that?

MR. GOLDSER: There will be one or two others. There is one that I am pretty sure was not used in the deposition. I can tell you which one that is when I come to it.

THE COURT: Let's address that when we come to it. Since the language was read in the deposition, which is open and not marked confidential, I will allow at least these two documents to go forward. Go ahead.

MR. GOLDSER: So let me explain the significance of that line. It's got two things of import. One is you can see that the repercussions of an adverse regulatory decision would be immediate and devastating, so let's act promptly. It tells you about the mindset of the company as of July 21, 2005, right after the Kitano meeting. The other thing that it mentions, it says in parentheses, Who among us can forget what happened over there to sparfloxacin. Sparfloxacin was another fluoroquinolone. It had phototoxicity problems. There was a contraindication given to sparfloxacin because of phototoxicity, and its use was severely restricted. So the reference, and Dr. Kahn explains this in his deposition is, we can't afford to have a contraindication to Levaquin because the same thing would happen to us in Levaquin as what happened -- as happened to sparfloxacin. Our sales would go down. That 13 billion dollars I showed you in the first slide was in jeopardy. That's the mindset. That's the deliberate disregard of patient rights. It was about money, and the statement comes from the doctor, the safety officer. It's not coming from the marketing people. What else did they say? It would have serious implications for marketing. This is the second document that I just described to you. It is James Kahn's document. It is his long memorandum that, it is his long memorandum that describes what happened at the Kitano meeting, and I hope this is readable enough on your screen. I want to go through a number of these.

These are the quotations that I read to Dr. Kahn in his deposition. I don't know that I got all of the ones that I'm about to recite, but many of them, and this document was certainly included. It was MDL 98. It was noted that way in Dan Fife's deposition, as well as being used in Jim Kahn's.

Kahn writes that the regulatory situation in France was a very worrisome regulatory situation. It has clear and serious implications for our marketing of Levaquin and could have an impact in the U. S. as early as the coming respiratory season. I believe this matter to be urgent and to require our immediate attention. That's the first paragraph. That certainly shows the mindset of Jim Kahn as he is conveying what happened at the Kitano meeting, but then if you go down to that third

paragraph, the one that I just blocked off, this has some particular importance. These data should be considered against a prevailing background perception that both ofloxacin and levofloxacin might have greater tendinopathic potential than other fluoroquinolones.

Comparative animal data had previously suggested that the two agents were more prone to induce lesions than were many other members of the class. Reporting rates for ofloxacin, ofloxacin related tendinopathies have traditionally been higher than for other FQ fluoroquinolone agents. In our U. S. post marketing Levaquin experience, we see has a higher reporting rate for tendon disorders than for virtually any other AE, adverse event, commonly regarded as part of the fluoroquinolone profile.
There is a huge amount of stuff in that paragraph. First off, in July of '01, Kahn is acknowledging that both ofloxacin and levofloxacin have a greater tendon problem than the other fluoroquinolones. They have denied that issue today. They will not say that there is a problem, but back in July of '01, they were admitting that problem.
As one of the documents that may still be subject to a confidentiality order says, and I will tell you about it without pulling it up, they specifically say they don't want to put that in the label, the greater potential. It would be a killer.

Next thing it says, there is comparative animal data that suggests that the two agents were prone to induce lesions than were many other members of the class. There is a huge argument the defense makes about you don't use animal studies to talk about whether it's predictive or not predictive. Jim Kahn says the animal studies will tell you it's predictive. It's a problem.

How can they with a straight face come here and say animal studies are not relevant? Their own doc says it's relevant. The next sentence says, Reporting rates for ofloxacin associated tendinopathies have traditionally been higher than other fluoroquinolone agents. Defense has been saying all along that Floxin is irrelevant, ofloxacin. Kahn thinks it's perfectly relevant. He's worried that the higher reporting rates for Floxin tell you something about Levaquin. He thinks it's relevant. The defense doesn't. In our U. S. post marketing Levaquin experience, we see has a higher reporting rate for tendon disorders.

What is it that they say there? They've looked at their owned SCEPTRE database. The SCEPTRE database is their database of adverse events that they maintain. Our expert Cheryl Blume has gone to a great length to evaluate the SCEPTRE database year by year, period by period to show where in the rankings tendon disorders fit.

THE COURT: What is the timing of the Kahn memo?

MR. GOLDSER: July 26th, 2001, the day after he comes back from the meetings with Aventis and Daichi.

THE COURT: Wasn't there a follow-up label change, though, right after this?

MR. GOLDSER: There was. There was a label change that occurred in October 2001. It was done by the CBE. The changes being effected procedure, so defense by that action acknowledges that CBEs are available. What they said in that label change was that there is a problem with the elderly in corticosteroids. Two problems there. Number one, it ignores the question of Levaquin worse than the other fluoroquinolone, like this paragraph is talking about. It doesn't talk about the comparative tendon toxicity whatsoever. The other problem is the adequacy of that warning, and I can talk about that somewhere along the line, but basically they put it in the PDR.

You have seen the PDR. It's an eight and a half by eleven book. The 2005 version has 3,558 pages in it. The Levaquin warning, the Levaquin part appears on page 2,445. The warning itself appears on page 2,448 in the lower left corner of three columns, and the only thing that defendant did in changing the label was to change one sentence in the middle of that paragraph on the lower left corner on page 2,448 of a 3,558 page document and say the doctor should have picked up that one sentence. They never detailed it. They never did a dear doctor letter. They never did a seminar about it. They never did any published articles about it. They never did any of those things. So, yes, Judge, there was a label change after this.

But this point has to do with the analysis of the SCEPTRE database, which apparently the defendant did, never disclosed to us in discovery, which our expert Cheryl Blume did, reproduced, and found that tendon disorders were ranked as the number one disorder and were back to 1999 and consistently thereafter.

What else did Jim Kahn write on July 26th, 2001? He says, The agencies have several options, and he goes through a list of possibilities. One of them is a concern about restricting Tavanic, which was the European name for Levaquin, to in-hospital use. That gets you to the same contraindication problem that sparfloxacin got to. Labeling changes would follow, and least onerous would be letting the company continue its current campaign of alerting doctors to the situation, which of course they were not doing.

This is the doctor talking about how to minimize the warning label so that they don't have economic, adverse economic impact. Farther down on that document they start talking about the epidemiology study that Europe wanted, and I've highlighted the section that reads, Moreover, the study envisioned struck many as very insufficient in its present design.

That's Aventis's proposed study. It might actually generate more damaging material unless careful thought were given to other fluoroquinolone and nonfluoroquinolone experience in the same database. They're worried about an adverse result if they do the proper study. They had to manipulate the study. Ultimately, they did manipulate the study in our

view. That was the Ingenix study, and we will talk about what they did with that. Mr. Saul will go into more detail than I will. You can see the precursor of manipulation of the Ingenix study right after the Kitano meeting. The proper remedy is not to fault the agent but to seek remedy in either changing medical practice or more thoroughly advising physicians of the identified risk factors. It's not Levaquin's fault. It's the doctors' fault. We have got to make sure the doctors don't use this wrong. There is nothing wrong with Levaquin. Of course, blame others. Isn't that always the case, blame the victim in situations like this?

The sine qua non of our efforts should be making the case that the European picture is distorted by medical practices and in no way implicates levofloxacin as the lone culprit. It's the doctors' fault. We need to consider doing the correct epidemiological study ourselves. We have far more at stake than does Aventis, and there would be no ambivalence clouding our commitment to doing it right. Far more at stake? Ortho-McNeil had one antibiotic. Aventis had a bunch. If Aventis lost Tavanic, Levaquin, their revenues would not suffer. If Johnson & Johnson, Ortho-McNeil, lost Levaquin, they would be losing their number one drug. They had far more at stake, and that's all for that document.

Their mindset, the entire franchise was riding on a single toss. That's what Jim Kahn said again in his deposition. The stakes have gone up, Larry Johnson wrote this, when the Germans suggested there was a problem with Levaquin. There was some discussion about contraindication occurring with the British advisor, Dr. Steven Evans, and the writing was that a contraindication would be tantamount to a withdrawal. They were worried about that. The MCA, that's the British authority, they were proposing a label change, and this could lead to a bad result, which we have already detailed. Now this document is the one that I was talking about that I don't believe was used in the deposition, but it also had the provision in it that said we cannot accept a label change that would show Levaquin having a greater potential for tendon toxicity than any other fluoroquinolone. The study could be a nightmare. That would be the Ingenix study, if it came out wrong.

And finally one of the marketing people talking to the scientists about how to manage the study said, you've got to do whatever it takes. This is the marketing people talking now about how to do science, just as the science people were talking about how to do marketing with ultimately one goal, profits over people. We have four categories of claims of bad acts that we believe are germane to this motion. First, the defendant deliberately disregarded patient rights concerning the warnings. Second, they manipulated the scientific literature for their own economic purposes. That's the Ingenix study.

Third, they deliberately disregarded existing scientific literature. There were, we count, 16 articles published by 2003 wherein either Floxin or Levaquin was shown to have a greater tendinopathic potential than other

fluoroquinolones in the class. It was out there. It was not in JAMA. It was not in the Archives of Internal Medicine.

Dr. Beecher, our family practice physician in the Schedin case working in Edina, would not be seeing these. Some of them were internal documents, like the Aventis study that as given to the MCA. There were 16 articles that Johnson & Johnson had and should have known about that they disregarded.
Then on top of that what do they do is, they turn their sales force loose, and their sales force has one mantra: Tell everybody how safe Levaquin is, touting the high safety profile of this drug. They deliberately disregarded patient rights. They created a plan to maximize profits while avoiding safety issues.
Sitting around in board room 301 in the Kitano meeting, you didn't see anything in that James Kahn memo that said anything about safety issues and how do we fix the safety problems. It was how do we avoid the safety problems in order to make sure we don't lose any money. They purposely sought to avoid label changes.
I had an e-mail from Dr. Noel, one of the medical people involved in this. That's attached to this, but I highlight back for you the notion that I mentioned before about how they refuse to incorporate anything in their label change about Levaquin being worse than the other fluoroquinolones.

They knowingly decided not to share the warnings information with the public. One of the documents that I have that the defendant has finally acknowledged is a set of handwritten notes from yet another doctor, Chuen Yee, from Johnson & Johnson, sitting at the Kitano meeting, and that documents says in her handwriting, Not share with public, and it's talking about the French agency reports. Don't tell anybody about it.

They ignored their own published literature and how best to communicate warnings to doctors. I mentioned Dr. Fife. He's one of the doctors involved with Johnson & Johnson. He's an epidemiologist. One of the epidemiology studies he published, and I'm not sure but what this article is marked confidential. Let me just take a quick look here.
No, they didn't mark this one confidential. What Dr. Fife says at the end of his article, if I have it highlighted -- let's see if I can pull that up for you. He did an epidemiology study to determine what is the most effective way to communicate warnings to doctors, and what he finds in the last sentence is the most telling I think. The key characteristics of a successful drug warning appear to be specificity, prominence, brevity, no reliance on secondary information, publicity and in-person discussions. You've got to do stuff other than bury it on the lower left corner of page 2,448 of the PDR when that book comes out every year and don't tell a doctor about it. Their own doctor says, their own epidemiology department tells how you should be doing that. They ignore their own published literature and how best to communicate with doctors.

They intentionally buried the warning, as I have

described to you. They failed to send a dear doctor letter. There were dear doctors letters sent, if I get the countries right, in France, Italy, Belgium, Germany, Austria, and I'm missing one. There were six of them, all in 2001 and early 2002, about the corticosteroid elderly problem. Was there one sent in the United States? No. Dr. Canabarro from Aventis was deposed, and what she said in her deposition was, she was asked, you know, why do you send out a dear doctor letter, and her response was, well, you know, we had it in the warnings. But why did you send out the dear doctor letter? Because the warning wasn't enough, and we wanted to make sure to communicate with doctors. Aventis did it. Johnson & Johnson didn't.

They deliberately did not train their sales representatives to proactively call out label changes to doctors. I deposed Teresa Turano two weeks ago. She was the 30(b)(6) corporate representative on sales training. She didn't know much, but what was clear from her was that there was no policy to tell sales representatives that whenever there is a label change you have got to tell doctors.

What they did do is, they handed out a copy of the package insert every time they went there, theoretically, but that doesn't mean they said to the doctor, you know, take a look here. There is a label change. I want to make sure you're aware of this. They did not do that.

They did do that with the black box. The sales force was told proactively, tell doctors about the black box. Were they told proactively to tell doctors about the black box? Were they told proactively to tell doctors about that 2001 label change? According to the corporate representative, there was no such policy.
They deliberately didn't issue press releases publicizing changes. I deposed Greg Panico last week, the corporate representative on press releases. He, too, didn't know a lot, but what he did say was there was no policy to initiate press releases about label changes. We went through a litany of documents. They kept track of every news article.

There were clear press releases issued about new indications that the FDA had approved, but was there any indication whatsoever that they issued a pretty release on any label changes? Not a one. They didn't undertake any seminars, public speaking engagements, lunch or learn trainings.
They didn't educate doctors in the manner that they otherwise do educate doctors about new indications. They didn't publish articles talking about the risk of tendon disorders, and I will come back to that in a little bit when I talk about the publication plan and the ghost writing.

They manipulated the Ingenix study for their own economic purposes. The Ingenix study started to appear in discussions in the late fall of 2001. Aventis made a proposal about the protocol. The idea was that they would respond to the French authorities. The French authorities

wanted to know what was the comparative tendon toxicity between Levaquin and the other fluoroquinolones. The Johnson & Johnson response was -- and Aventis was going to do a study that said that. Johnson & Johnson said we can't afford that study. If we end up with a bad result, we're in trouble. So they started taking control of the study from Aventis, and they slowly but surely turned the battleship around to change the focus of the study from a comparison between fluoroquinolones to talking about fluoroquinolones in general and the impact on the elderly and corticosteroids, because by that time they had already decided to include that warning in the label. And so if they found that there was a negative impact, no big deal. It was already in the label. They already had a strategy for that. So they were going to figure out a way to manage the Ingenix study so that they would get the result that they wanted. So they manipulated the one study to achieve an outcome that was in their best economic interests.

They took it over from Aventis. They controlled the study with Ingenix. I will talk about that for a second. The protocol that was written, it was drafted by Dan Fife. It was discussed between Dan Fife and John Seeger at Ingenix.
There were meetings to talk about the protocol. There were exchanges of drafts on how to do the protocol, the type of study that it was was developed by Johnson & Johnson in discussion with Ingenix. I mean, they did the whole protocol process.

To be sure, I mean, John Seeger was involved in this, but Johnson & Johnson really controlled the protocol process. Once the protocol was set, it was just a matter of filling in the numbers by mostly administrative mechanism, although we certainly have complaints about how John Seeger did that, and I will talk about that.
They avoided comparing Levaquin with other fluoroquinolones as was requested in Europe. All the items on the bottom are references to documents, and if the hyperlink works, you could pull up the documents. They changed the desired outcome. Europe wanted to know what was the problem related to tendonitis and tendinopathy. Johnson & Johnson said we can't do that. It has got to be tendon rupture. Ostensibly the reason is because tendon rupture is better defined. It's easier to identify what constitutes a tendon rupture, but really what they're saying at that point in time is that doctors don't know how to diagnose a tendinopathy and they won't trust tendinopathy diagnoses.

Paul Van der Linden in the Netherlands whose four studies, including his PhD thesis, talked about how Floxin was worse than the rest, focused on tendinopathy and tendon rupture. He was able to distinguish between tendinopathy and its relative risk compared to other drugs and to placebo and also tendon rupture compared to other drugs and placebo.

He could do it. It was academically acceptable to people accepting his PhD thesis, but that was not good enough for Johnson & Johnson. The reason? Because there were fewer tendon ruptures than tendinopathies, and as a

result the relative risk was going to show lower, they would get a better number.

They manipulated the power estimates of the study. I don't know to what extent you're conversant with the notion of power, but power tells you the ability to make accurate predictions about epidemiology studies. If you start out with power that is wrong, it's too high. If the power is at four when you're going to find a relative risk of two, what you are going to end up with as a result of that is a confidence interval that is very wide. In order for you to have statistically significant results, the narrower the confidence interval the better, and most importantly, if the lower bound of the confidence interval is over one, you know that at worst it's still more statistically significant than random. One is random.
So when you have got a wide confidence interval that results in a lower bound being below one, you can say with honesty this is statistically not significant, but it all stems from where you started. If you start with the wrong power estimate, you end up with a wide confidence interval and no statistical significance.
If you take the trouble to go through the litany of testimony from John Seeger that is listed on that page, you will see he admits that that's true and that they knew it going in, that they picked the wrong power. It was a manipulated study.

They minimized the number of elderly contained in the study data. I know Mr. Saul will talk about that. They improperly included children in the study. Mr. Saul will talk about that. John Seeger admits that that's true. They incorrectly identified what constitutes a tendon rupture for the study by having a nonmedical doctor, Seeger, do the study.

In particular what you might pay attention to on that slide is the bullet point saying testimony of Seeger regarding Schedin. We happened to pull out Mr. Schedin's medical record where it talks about whether he has got a tendon rupture or not a tendon rupture. It says tendon tear.

We asked Dr. Seeger, Is this a tendon rupture that would be included as a positive finding in your study. He said, no, this would not be a tendon rupture in our study. Our plaintiff here, who has clearly defined tendon ruptures and his doctors have all said so, his treating doctors have said so, was not a tendon rupture for purposes of John Seeger's study. That's how badly defined some of these tendon ruptures were.

Why? Keep them out of the study and keep the numbers low. There was a medical record review for evaluating tendon ruptures, but there was no such medical record review for tendonitis cases which was used as a covariate. It was an internally inconsistent study. Seeger is not blinded during the study. He knew which cases had fluoroquinolone use and which were not. Dan Fife, Johnson & Johnson's own witness, says that as a result the study is invalid. They destroyed abstracts. We wanted to reproduce the study. In order to reproduce the

study we needed the abstracts and the medical records that they used to determine what was a tendon rupture and what was not. They have been described.
They admit it. Seeger admits that in the fall of 2006, three months after the article was published, they destroyed these documents. That's contrary to the guidelines published by the International Society of Professional Epidemiologists, ISPE, which requires that such documents be held for five years.
Normally you wouldn't think that would be such a big deal except the guidelines were written in part by Seeger's boss at Ingenix, Alec Walker. Walker said, I don't know the guidelines. Are there guidelines? These guidelines go back to 1996. Walker wrote them in 1996. They were revised in 2000, 2004 and 2007, if my memory serves me correctly.
Walker doesn't know them. Seeger doesn't know them. They destroyed the documents in contravention of guidelines that they wrote. Mind boggling. They ignored the existing scientific literature. I told you about the 16 articles. They lied to the FDA about comparative tendon toxicity of fluoroquinolones.
Finally, on the converse side, their marketing efforts. They touted Levaquin's excellent safety profile without disclosing its risk and trained its sales representatives in this manner. I have got a pile of documents that show that. The do and don't document that is on there do tout the excellent safety profile of Levaquin.
The quick tips guide that is on the bottom there, I worked with Teresa Turano and went through much of that verbatim. I said, does this paragraph have anything about safety in it? No. Does this have anything about tendon ruptures in it? No. Does this have anything about warnings on tendon ruptures? No. Does this have anything about comparative tendon toxicity? No.
All over the place there is nothing about tendon warnings, and it's all about the excellent safety profile of Levaquin. They knowingly marketed to the elderly population. Again, the quick tips guide will tell you that. They marketed it as first line therapy. Levaquin is a good drug for certain circumstances. We don't dispute that.

For people who are seriously ill, it will do what it's supposed to, but if you're got a sinuitis or an acute bacterial exacerbation of chronic bronchitis, like John Schedin did, you don't use Levaquin. He had one trial on Zithromax. Could easily have gone back to another trial on Zithromax or another less potent antibiotic, but this was marketed like candy, samples left, right and sideways. They had millions of dollars in samples for first line therapy for these indications that were hardly severe enough to warrant them.
They did ghost writing. From 1994 to 2002, DesignWrite, their hired gun, caused to be authored two -- 144 papers on either Floxin or Levaquin, touting its benefits. Of those 144 papers, 13 of them had the word "safety" in the title, and only one of them had anything to do with tendons, and that was a published, published paper on children and tendon disorders. Nothing about the elderly. Nothing about corticosteroids. Nothing about any of the issues where Levaquin is worse than any other

fluoroquinolone, and that's only through 2002.
In 2002 they spent a million dollars with DesignWrite on ghost writing alone. There was a lot more money spent with DesignWrite in that year. They used the Speakers Bureau as a promotional tool. Defendants' own expert John Segreti who is going to talk about Mr. Schedin's particular circumstances and case specific and also what you use Levaquin for.
I asked him -- he is on the Speakers Bureau, so they are bringing in a Speakers Bureau person as their expert witness, which is kind of curious. I asked him what he did when he was on the Speakers Bureau. He gave talks. I said, well, were they promotional. He said, of course they were promotional.
Well, why were they promotional? Because I was touting the use of Levaquin. It wasn't educational about disease. It was about how best to use Levaquin. They were promotional.

So at the end of the day, Judge, we have lots of good reasons why we believe defendant deliberately disregarded the rights of the plaintiffs, including John Schedin, intentionally, consciously, knowingly, willfully and with marked indifference. That's our evidence.
You don't have to, you shouldn't listen to any contrary evidence or challenges or cross-examination by defendant because that's not what the law allows or requires. We think the motion should be granted. Thank you very much.

THE COURT. Thank you, Mr. Goldser.
Mr. Saul, did you have something?

MR. SAUL: Good morning, Your Honor.

THE COURT: Good morning.

MR. SAUL: Louis Saul on behalf of plaintiffs.
Mr. Goldser talked at some length about the Ingenix study, and I will fill in the gaps. I realize our time is limited here. Just to go back, Johnson & Johnson had nothing to do with the European situation. Aventis, their trading partner in Europe, was asked to do studies because of the signal in Europe that there were tendon problems, particularly among the elderly, emphasis added, and particularly with corticosteroids.

What the defendant was hoping to avoid and worked to avoid -- may I approach -- was to have this, this warning in the label. This is the warning that eventually got into the label. This is the black box warning that got into the label in November '08. Fluoroquinolones, including Levaquin, are associated with an increased risk of tendonitis and tendon rupture. The risk is increased on those over 60 and those on concomitant therapies respiratory, heart and lung recipients.

They kept this warning from being placed in the PDR, in the package insert, for seven years. During that seven years, their sales were about 13 billion dollars. By keeping this warning out for seven years, this company earned themselves 13 million dollars, and we believe that that evidence in itself is enough to get us to the punitive

damages claim.
However, how did they do it.

THE COURT: Is this the warning that is on right now?

MR. SAUL: This is the present day warning.

THE COURT: Go ahead. I will ask you a question about that later.

MR. SAUL: Sure. So what did they do? They had no interest in Europe. In fact, they told the Court during our motion practice that they had no relationship with the European authorities and they didn't want to give us documents related to that, that they actually went and took over this study. They took it away from Aventis because they said if we don't do this study and we don't get the proper results, essentially we're dead. Levaquin is off the market.

So what did they do? They hired this company called Ingenix who had done numerous other studies for them. There was a young doctor there by the name of John Seeger who had just become an employee, and they had him conduct the studies. Mr. Goldser said they designed the protocol. What did they do in the study?
If I may give you another document, Your Honor.
This was prepared by me, and this is how they intentionally manipulated the study. The first they wanted to do, the European authorities wanted to study -- the issue was among the elderly and corticosteroid use. What did Johnson & Johnson do? They intentionally left out elderly from the study.

This document that I just handed you was from the original protocol of this Ingenix study. If you will see here, table 1 talks about the UnitedHealthcare research database population. If you'll go down to the bottom, 60 to 64 and 65 plus, you will see that in their database, there was only 4.7 percent of, let's for lack of a better term, the aging population. I'm in there. Just leave it like that.

You will see in table number 2 in the census bureau, there were 16.2 percent of the population being over 60. So they chose a data -- Aetna was going to use a different database, but they took this away and used this particular database that underrepresented the elderly. What else did they do? Levaquin was contraindicated for children, for pediatric use. Contraindicated, you can't use it for pediatric use.

You will see in the general population, there is 29 percent, and in their database there is 29 percent in approximate numbers. They included this 29 percent, the children, in the study. So what they did is, they kept the elderly out. They included children. Children can't even take Levaquin. The elderly, the focus was on the elderly. They cut that down. Okay.

So what did they do? So they intentionally excluded the elderly and included children. But then what

happened? They did their study. Part of their study was to get this study published in certain journals. Those journals are the journals that most of us have heard about. For instance, in New England -- I won't go through them all. Five journals, the New England Journal of Medicine and the first line journals. They could not get this study published anywhere. What did they do? They went to -- Johnson & Johnson and Ingenix, they were members of a society, and Ingenix was the head of the society. They got it published in that society's journal. No one else would take it. The study was concluded in 2003. 2006 it got published. Lo and behold three or four months after it got published, they destroyed the data. They went and they did medical review of a certain number of the patients in this study, and you have to keep this data because once you publish something, other researchers have to be able to duplicate the study. What happened to the data? Dr. Seeger testified, we don't -- we didn't really know what happened. I'm not sure what happened, and he went on and on. Finally, we got him to admit, and I just want to read to you -- at any rate, Dr. Seeger admits, admits that under his tutelage or under his direction that he caused all the documentation to be destroyed regarding the study. This is, forms the basis also of our motion, our Daubert motion.

No one can duplicate this study. They also created an algorithm to define who was in the case. They can't find that algorithm. All the documentation is gone. That in itself, the intentional destruction of the data, they kept their product on the market for nine years or eight years, is enough to allow us to amend the, the complaint, and I believe it's enough for the jury to enter a substantial award.
I feel that our time is limited, but each of these dotted areas is covered in our brief extensively, and I would like to incorporate our motion in limine regarding Dr. Seeger into this because rather than me go on and on about the study, I think it's all well depicted in our brief.

THE COURT: Thank you, Mr. Saul.

MR. SAUL: Thank you, Your Honor. Did you have any questions about the black box?

THE COURT: No. That's fine. I may address it later in the hearing.
Mr. Dames?

MR. DAMES: Thank you, Your Honor. Your Honor, I just want to start from, actually maybe just the simplest of all is to start from the beginning, and that is when the drug was first marketed in 1997. There has much been made so far in the arguments concerning concealment, omissions, lack of warning, refusal to include things in the warning that I would like to refocus this as to what took place in the very beginning when the drug was first marketed. From its inception, and the Court is well aware because we've said it many times, when it was first marketed, there has been a tendon rupture warning in the label. Not hidden, not in any way buried in a mass of language, prominently mentioned in the warnings.

At the time that Mr. Schedin received his prescription for Levaquin, the warnings had been updated as early as 2002 -- well, let me first go back to October of 2001. The warning was altered to include a reference to a heightened risk in the elderly, potential risk with the elderly taking corticosteroids.

That was in response to the events and the data that had been received in Europe about the experience and adverse reaction reports from the use of Tavanic, the -- Levaquin is marketed in Europe, and the company through a change is being effected, that is on its own initiative, incorporated the information that was coming from Europe to include that in the warning on its own.
The FDA approved it at the company's instigation.
They approved that warning. It was that warning with a very slight amendment in 2004. That was the warning the prescribing physician for Mr. Schedin received.
Now, in Europe the reports, the adverse reaction reports that were received in Europe, showed variances within the different European countries. Germany had a much lower rate of reporting than did France. When those things were investigated, when the scientists and researchers looked at what were the reasons for divergence between the European countries, they determined that in France, Levaquin was prescribed and Tavanic was prescribed predominantly for upper respiratory tract infections, and there the French physicians used corticosteroids a significant percentage of the time when they used Levaquin.
Now, the debate has been, you know, what significance is that. When the meeting occurred at the Kitano Hotel, not quite as luxurious. I have actually stayed there. When the meeting was held at the Kitano Hotel to evaluate the situation and determine what should be done to investigate it, now remember already in place was J & J's CBE label change -- the label change occurred in October. I'm sorry. Already --
J & J incorporated that information in October that it learned, but in addition it wanted to do an investigation and a study, as did Aventis. Aventis does their own studies, a quick and dirty analysis, it was put, to look at the situation to respond to the French and European regulatory authorities. J & J decided it wanted to use the largest database then available, the UnitedHealthcare database.

Contrary to what you have heard so far, Your Honor, the Aetna database, an alternative, was not even available to be used. They couldn't use it. Why did they use UnitedHealthcare database? Well, it afforded J & J an opportunity to have access to medical records. Not all databases that were used would give you the access to the medical records.

And as I said, it was an exceptionally large database and would provide one of the best experiences to evaluate to see what was the frequency, what was the incidence of tendon rupture on Levaquin and what was the incidence of tendon rupture on some other factors, for example, other fluoroquinolones and to evaluate --
I mean the study itself clearly was published by Dr. Seeger, included other factors besides Levaquin. It

also evaluated corticosteroid use and some other predisposing factors. Now, why was tendon rupture used as a measure? Was it done to manipulate the data, to somehow hide something? No.

It was determined that the most objectively verifiable diagnosis that could be used in the study was a rupture. Not tendinopathy. Tendinopathy can be a wide variety of things. It is like 70 diagnostic codes are related to tendinopathies. So it could be confused with muscle tears. It could be confused with other kinds of diagnostic end products. So it was made, it was determined to use tendon rupture as the objectively verifiable point. The diagnosis of tendon rupture by a physician was operative. Now what is wrong with that? Very, very little. Dr. Van der Linden used tendon rupture as the outcome in his own study.

Now, I want to remind the Court that J & J was very responsible in addressing the issue head on. It wanted to do the study on its own, not because it wanted to manipulate the results. Dr. Kahn testified quite clearly that what they wanted to do was the correct study. They wanted to do it correctly. They wanted to make certain it was done right, and that's why they did the study the way they did, and that's why they did it rather than rely on any other company to do it on their behalf.
What was the outcome of their investigation?
What was the outcome of their research? The French and European -- well, the European regulatory authorities evaluated not only the Johnson & Johnson sponsored study that was performed, and let's make this distinction clear. It was performed by Ingenix. J & J participated in the protocol. It helped plan the protocol of this study. It did not conduct the study. That was done independently by Ingenix, and Dr. Seeger made the decisions concerning the development of the study together with other employees at Ingenix and the development of the algorithm which defined and decided which were cases and which were not.

Much reference has been made to destruction of medical records. Dr. Seeger in the course of an office move after the study was published, as plaintiffs state, lost the medical records involved in the study. It had nothing to do with Johnson & Johnson. Johnson & Johnson certainly had no relationship to any loss of the medical records, but it was inadvertent, and it was done during the course of his office move, as he testified.
There was a reference made to whether his study was blinded. Dr. Seeger pointed out, his study, he was blinded as to which fluoroquinolones were used by the people involved in the study. We could go on and on with how the study was designed. Were the elderly intentionally excluded? That's absolutely false. Here is a classic example of how the characterization by plaintiffs is so unfair.

The UnitedHealthcare database, of course, the basis of that database are the people covered under the UnitedHealthcare. That, there would be, because of Medicaid -- because of Medicare, there would be a possible underrepresentation of the elderly. That was recognized,

and that's why the elderly and a Medicare database were added to the study.

So there wasn't any intentional exclusion. They were in fact included. Then it was contrasted with whether there was an intentional inclusion of children to also skew the results of the study. Children were not intentionally included. The database includes children. There were no Levaquin cases of tendon rupture involving children. There were no skewed results because of children, but you take a database as it comes, and it includes the span of ages in the database, so of course, the age range of children who would have been included.
The tears were excluded, according to Mr. Saul, in the study. If Levaquin, if there was a tendon rupture defined as having occurred with Levaquin by the prescribing doctor, it could be defined as a complete tear, it would be included. So we are really ending up talking about and debating the merits of a scientific protocol.openly arrived at, submitted to the FDA, shown to the European regulatory authorities who in turn evaluated the published literature, Aventis's own studies and the Seeger study.
And they recognized the limitations of each, including the Seeger study, and what do they come out with after the purported suggestion -- it isn't purported. It was a suggestion by one of the assessors earlier on that the label be altered to include a statement concerning a greater use in the risk of Levaquin over the other fluoroquinolones.

That was rejected after all of the evidence was in by the European regulatory authorities, and the reason it was rejected was clearly stated that the data was insufficient to make any differentiation between fluoroquinolones and tendon rupture, and it is worthwhile to remind ourselves of exactly what the European health authorities after all of the data was in, up-to-date for them, in 2003.
And it says, and this is one of Plaintiff's Exhibits, Exhibit 87. Under paragraph 8, and we mentioned it as well in our brief, Your Honor, the conclusions, it states, The morbidity and frequency of the suspected adverse reaction, that is, very rare and not fatal outcome which generally recovers, must be weighed against the nature of the benefits and indications for treatment with levofloxacin, reduction in morbidity and mortality of respiratory tract infections and other infections when considering the need for further studies and regulatory action.

They conclude, No further action -- this is on the next page -- given the rarity and nonlethality of adverse reactions, this is justified on the following grounds. Absolute risks of fluoroquinolone associated tendon rupture are very rare, and furthermore, the population attributable risk is very low.
Although we cannot exclude a slightly higher risk of tendon rupture with levofloxacin or ofloxacin, currently available data are inconclusive. Such estimates are likely to be rare or very rare. SPCs, that is a labeling, for levofloxacin products have been updated with adequate warnings. Further analysis of existing data are unlikely to be helpful.

There were several things in that conclusion that are important. Even considering all of the studies, even considering the state of the animal data, considering all of the issues that plaintiff have put forth today about the adequacy of the studies, disagreeing with some, agreeing with others, the European regulatory authorities decided that the heightened risk label change was not necessary. There was no evidentiary basis for it.
They also, however, said something very important in this conclusion, and that is the benefits of Levaquin in the treatment of upper respiratory infection. There are benefits to this drug, and that is in part part of the passion that arises from Dr. Kahn. The benefits of Levaquin have been proved repetitively, and they are agreed to by everyone in this litigation.

At the trial of this case, you will hear from every expert witness, plaintiffs' and defendants' alike, that Levaquin is efficacious and is very valuable. It is a good drug. Quite simply, they have testified already that it is a good drug.

We have pointed out in the brief that Dr. Zizic, one of the plaintiffs' principal experts in this case, prescribes Levaquin, uses it to this day. Uses it, in fact, under the condition -- well, let me backtrack. Dr. Zizic took it himself. It actually cured his infection, a very severe infection which he had. So he obtained the benefit of Levaquin himself. He gives it to his patients from time to time, and there is no testimony from either Dr. Zizic or any other expert witness in this case that the use of Levaquin under the conditions of use in Mr. Schedin was somehow inadequate or inappropriate.

So in the midst of all of this characterization of how there was a clear disregard of the safety of patients, we have a unanimity of opinion as to the necessity and utility of the drug. We have a unanimity of an opinion that it should be used in the kinds of infections, upper respiratory tract infections, for which Mr. Schedin received the drug.

We have also heard about, it is not to be used as a first line of defense therapy for certain indications. Well, taking Mr. Schedin's case, for example, there will be no testimony, there is certainly none based on the expert reports of the depositions, that Mr. Schedin was not an appropriate candidate at the time he got Levaquin for Levaquin.
There are no indications in any label or any suggested indications in the label or contraindications which would minimize the use of Levaquin or have it as a second line of use. The published guidelines to this day, the Sanford Medical Guide, the Infectious Disease Society published guidelines, call for Levaquin to be used as a first line therapy initially in upper respiratory tract infections.

So the current state of medical knowledge by neutral and expert physicians, by responsible and referenced medical guides all call for the use of Levaquin.

Levaquin is in fact the most efficacious, the best antibiotic for upper respiratory tract infections. So if I can mirror, even slightly, the belief that someone like Dr. Kahn and others brought to how important the drug was to be used in the current respiratory season in his memo and to push for the right study, the correct study, the properly done study, the mischaracterization of the memo and of Dr. Kahn in this is truly horrendous.

Dr. Kahn's attempts, J & J's attempts was to do a study using the largest healthcare database then available, to use it for a measure of outcome which was the most clearly and objectively verifiable, and they hired Ingenix to perform and conduct that study. None of the data that has been developed to this day shows that Levaquin has any greater risk of tendon rupture than any other fluoroquinolone.
The data referenced by plaintiffs in their brief, the information that can be gleaned from it is, you either have data on ofloxacin. You have no reference to Levaquin and tendon rupture in those studies. You have suggestions on animal data as to comparative toxicities, but virtually none that any authority considered relevant and probative of the differential toxicities.
So how can anyone conclude that what shouldn't be in the label, what is not in the label anywhere today, was somehow the result of manipulation by J & J earlier? How can anyone conclude that something not required by any regulatory authority to this day is the by-product of a manipulation by J & J and a clear disregard of public safety by J & J earlier?
Added to that is, these attempts through marketing efforts to cloud and conceal and hide and ghost writing and detail people to call on physicians and not mention safety. Every visit that a sales representative makes upon a physician includes the prescribing information.

They don't just get it from the PDR, although that's a highly reputable source. They get it every time a sales rep calls on them. They get it prominently mentioned in the label. It's not hard to find, and the physicians, now we have taken enough prescribing physicians I've reminded the Court to this day. The physicians know about tendon rupture.

If there is one thing that we find consistently is that the prescribing physicians are aware of tendon rupture, including Dr. Beecher. He testified he knew of tendon rupture at the time he prescribed the drug to plaintiff. Plaintiffs asked, were you aware of the fact of corticosteroid and the risk of elderly, and in all fairness, Dr. Beecher said he didn't remember that he was aware of that at the time.
I asked him, Did you have this label, and I read him that label, and he said, yes, I did have that prescribing information at the time. More importantly, in this case, the actual prescribing physician turned to the plaintiff who was there and said to him, I'm very sorry. This is all my fault. Not the drug company misled me, not based upon what you have told me to this day and what plaintiffs' attorneys have told me do I feel like the

company consciously disregarded your safety, not that I felt I was manipulated by anyone, not that I looked at any other information from any other source and was misled, none of that.

It was, this was my fault. Am I blaming the doctor? Frankly, no. The doctor did the proper thing. Mr. Schedin was cured of his infection. He suffered an adverse reaction, but that is not the sign or the sole reason to hold any drug company culpable when it has adequately warned and the company did. Hardly a case for punitive damages. Hardly a case showing an intentional disregard for the safety.
Now, I just want to summarize and conclude, Your Honor, that plaintiffs claim that there was a plan to conceal and failed to disclose the heightened risk. There was no plan documented anywhere here. There is no level of agreement or anything that can diagram an effort to conceal and disregard the public safety. They document no such plan.

Plaintiffs also failed to demonstrate evidence of a heightened risk. As I have said repetitively, no expert or regulatory agency has concluded there is a greater risk to this day. The only ones to offer that opinion, the only ones that will come to the Court and discuss heightened risk are plaintiffs' retained experts who actually learned of the information and read the literature available on the drug for the first time, by and large, when they were retained.

They didn't have the level of experience and knowledge that could have afforded them the opportunity to have that opinion before it. Regulatory agencies have specifically reviewed the data as I have suggested that plaintiffs claim and cannot establish and deny that there is a greater risk and have never suggested that J & J should have put that in its label.
Plaintiffs argue that simply -- they argue that what that really shows, and I've heard this before, is actually how well the plan worked. The fact that no one has taken any action to show them that our unidentified plan has actually had its intended purpose, met its intended purpose.

Any efforts made by the company to investigate the issue, submit the results to the regulatory agency and publish the results are claimed by plaintiffs to be part of this illicit and unidentified plan. The very act that J & J wished and did a study, sponsored a study by Ingenix and wanted to do the correct study is taken as an effort to conceal the truth.
It is almost a bit Orwellian that an effort by the company to find out what it believed to be would be the most reliable and correct answer to date is taken as conduct to justify the imposition of punitive damages, for a product which remains on the market and is to this day considered to be a premier antibiotic with an ample warning about tendon rupture.

So it is difficult to conceive of a less appropriate situation and a less appropriate drug to find that the defendant acted in intentional disregard of the

public's safety. The public's safety has been benefitted by this drug. That is the final irony. The public safety is what has benefitted and benefitted by the marketing of this drug, exactly as Dr. Kahn had hoped it would be. Thank you, Your Honor.

THE COURT: Thank you, Mr. Dames.
Did you have anything else, Mr. Goldser?

MR. GOLDSER: Briefly, Your Honor. I once again thank Mr. Dames for a preview of his closing argument to the jury, but as I said in my opening remarks, what he says about the evidence in that fashion this Court must disregard.

In reaching a determination about punitive damages, the Court makes no credibility awards, does not consider any challenge by cross-examination or otherwise to plaintiffs' proof. So the spin that Mr. Dames puts on it has nothing to do with this Court's determination at this point in time. This Court has to decide whether from the plaintiffs' evidence there is a prima facie showing of deliberate disregard.

I could go on for a long time responding seriatim to each of the points that Mr. Dames makes. Let me pick up a couple of them. For example, he says, tendon ruptures were used as a measure because they were the most objectively verifiable test. Then why was it when the algorithm was completed that there were far more Levaquin tendon ruptures discarded as nonviable cases than Cipro tendon ruptures?

Even when you get to the level of tendon rupture as they claim was the gold standard, their algorithm resulted in a manipulation that substantially threw out more Levaquin cases than Cipro cases. That was part of the manipulation that was involved.
Mr. Dames says, and the Medicare database was added. Indeed it was. There were three drafts of the study that were promulgated over time. The Medicare data was added in the second draft. The problem is, it was the first draft that was sent to the European agencies, and it was the first draft that caused the European agencies to back down.

That first draft did not have the Medicare data in it, and so the fact that the Medicare data was in the second draft did nothing to influence the European agencies to back down from their proposed warning. Mr. Dames says there are children in the database, and that was just normal and it doesn't matter, but you've got to think about what the impact of the children being in the database was. They had no tendon ruptures because they weren't taking Levaquin. So if you have children in the database and you have got 100 people in the database as a result of the children being in the database and there is one tendon rupture in the adults, that's a 1 in 100 rate.
But if you throw out the children and let's say 90 percent of them were children, and obviously I'm using an extreme example, but you only have 10 adults in the database and one of those adults has a tendon rupture, you have a rate of 1 in 10. That's 10 percent. Children in

the database mattered substantially because they skewed the numbers. It's not quite as easy as Mr. Dames would like to suggest.

I'm intrigued by the extensive argument that Mr. Dames makes about how no foreign regulatory authority took any legal action to change the label, and yet time after time after time in oral argument and in briefs in this court, defense has said you can't consider what the legal actions were that were taken by foreign agencies. We're not allowed to do that, they say, with Dr. Blume and her evidence.

There is a motion, the Daubert motions, their Daubert motion specifically addresses that. We can't do that, so well, why can they? Either those legal actions taken by the regulatory authorities are in or they're out. Not good for the goose, not good for the gander. It's our burden to show you based on our evidence and our spin of that evidence that a jury could find that punitive damages are warranted.

I understand Mr. Dames's spin. He has given us that from the get-go. I hardly agree with it, but that doesn't matter for today. Mr. Saul had a comment he wanted to make.

THE COURT: Go ahead, Mr. Saul.

MR. SAUL: Very briefly, Your Honor, I must say I was somewhat disappointed in Mr. Dames and some of the things he said, particularly about the issue of destruction of the documents. He said that they were somehow destroyed in an office move.

It is just one minute of testimony of Dr. Seeger. I'm taking the examination. And who made the decision to destroy them?

Mr. Saul.
I don't recall exactly, but it could have been one of a couple of scenarios. Either somebody asked me if I could, if these could be discarded and I said yes, or it's possible that the default was to get rid of things unless somebody stepped forward, and I did not step forward to not discard them.

Everything was discarded unless someone said save it?

That's right.

And it was your responsibility to determine in this particular project what was saved and what was thrown away?

That was a possible scenario.

What?

That was a possible scenario. Yes.

That was a question. Was it or was it not your

decision as the project manager in this particular project to save or destroy documents?
It was my decision, and I followed one of those two scenarios that I laid out.
What Mr. Dames said was not what the testimony was. Thank you.

THE COURT: Mr. Robinson?

MR. ROBINSON: Thank you, Your Honor. Bill Robinson for the defendants. I will be brief. First with respect to Mr. Goldser's comments about the fact that the algorithm used in the Seeger study found more ciprofloxacin cases than levofloxacin cases, he did not tell you Dr. Seeger's answer when he was asked that at the deposition.
In fact, Dr. Seeger did a separate post hoc study of that issue, and it's very clear that doctors were misdiagnosing tendon ruptures in Levaquin patients, and that's in the published article. Basically that's why there were more ciprofloxacin cases. There was a diagnostic bias found in the study against levofloxacin and tendon ruptures.
Secondly, with respect to the Medicare database, the testimony is pretty straightforward. The Medicare population was not available for the database when the initial protocols were done. As soon as it was available, it was added. The Medicare patients were included in the final study results and in the published paper results and in the results given to all the regulators.
The question of the children in the database, Dr. Seeger's comment to that was why would you exclude children from the database? You're looking at a study of the use of levofloxacin. Some doctors do use levofloxacin off label use for children. In fact, you're probably going to hear a lot about some of the studies done with children in the course of the trial.

As it turned out, there were no cases in the study of any children with an Achilles tendon rupture that were included in the data. That doesn't skew the data, the fact that they found no cases, because it's a case control study. You're comparing to controls. You're not looking at total numbers of cases in that sense.
In terms of the destruction of documents, Mr. Saul has referred to that on a couple of occasions here. Just for the record to be very clear what was destroyed, Dr. Seeger selected 328 random sample potential cases of Achilles tendon rupture, sent people out to get records, do abstraction forms. Those are the records that were destroyed.

It's important to note Dr. Seeger was asked a question, well, could you reproduce this study without those records. He said, yes, you could. It would take some time and effort and money, but you could do that because they still have the code numbers for all those patients.

Those records have nothing to do with the final case selection process which was done by the algorithm, and I will just note, Your Honor, the algorithm was blinded to all fluoroquinolone exposure of any type, all antibiotic

exposure. So the final computer program that picked the cases that were the cases included in the data analysis for the study was totally blinded to drug exposure, which fluoroquinolone, which antibiotic or whether any was used. It wasn't there.
Thank you.

THE COURT: Thank you, Mr. Robinson. Okay.
Thank you, Counsel. The Court will take the motion under advisement and issue a written order quickly. Let's take a five-minute break before the other motions.

THE CLERK: All rise.

(Recess taken.)

(In open court.)

THE COURT: You may be seated. Okay. You may be seated. Okay. Let's take the other motions.
Ms. Van Steenburgh.

MS. VAN STEENBURGH: Your Honor. We're going to narrow the focus a little bit and look just at the complaint in the Schedin case, although we have included as our motion the other bellwether cases. Before I begin, Mr. McCormick informed me prior to my approaching the podium here that the plaintiffs are going to withdraw their claims on the Deceptive Trade Practices Act. That happens to be embedded in Count Number VI. There are two claims in there, but they will withdraw that one, so I will just restrict my comments.

MR. MCCORMICK: That's correct, Your Honor. We decided from the seven complaints that are at issue, six complaints that are at issue in this motion. Thank you, Your Honor.

THE COURT: Very well. Go ahead.

MS. VAN STEENBURGH: So we're moving today for motion on judgment on the pleadings in partial. There are three claims we're not moving on, strict liability, negligence and fraud. But there are seven causes of action that we believe are subject to dismissal, and they can be grouped into three areas: Consumer fraud, the warranty claims and the unjust enrichment claim.
Each of those is deficient in terms of its pleading and are subject to dismissal. What I would like to do is turn to the consumer fraud claims initially. That would be Counts VI, VII, VIII and IX. I'm not going to spend really any time on Count VII, that's the handicapped and elderly provision, and that's derivative of the other consumer fraud statutes.
But as to the consumer fraud statutes in themselves, the basis of the motion is that the plaintiffs cannot show any public benefit. As the Court well knows, there is no private cause of action under those statutes, and in order to bring a claim, a plaintiff has to invoke Section 8.31 under the Minnesota Statutes, and the purpose of that is to allow a private litigant to stand in the shoes of the Attorney General.
And the purpose of the statute is to expand

efforts to stop or prevent fraudulent business practices. Well, just as the Attorney General would have to do that for the benefit of the public, a private litigant has to show that in fact they are operating to benefit the public when they bring such a cause of action.
Now the plaintiffs have taken the position here that as long as their complaint alleges deceptive trade practices aimed at the public at large, they have satisfied the public benefit requirement under the case law and the statutes. They rely on the Collins versus Minnesota School of Business case, and that case cannot be read so narrowly. There was a narrow issue in that case involving District Court interpretation of a public benefit saying that maybe the number of plaintiffs was too small, and the Court said no, you need to focus more on what the representation was that it was a larger, it was made to the public.

But really the Collins case is consistent with the other case law having to do with the public benefit because the real issue is, what's the remedy and whether the lawsuit would change the behavior of defendant, whether you're going to stop deceptive trade practices or not. The Collins case, the minute the lawsuit was started, the television ads and the presentations that the Minnesota School of Business were presenting in order to attract students stopped immediately, and so the kind of behavior was immediately stopped by the lawsuit.
This case is very different. Mr. Schedin has brought an action. He brought an action three years after he took Levaquin. This is a classic products liability action. It involves products liability negligence, and the remedy is an individual remedy.

There are a series of cases, Judge Montgomery and Magistrate Judge Erickson have rendered decisions in which they looked at that remedy, and when it's an exclusively individual remedy, they have held that that does not accrue to the public benefit. Mr. Schedin is seeking damages for himself, pain and suffering, past medical expenses, future expenses. Those are not for the public benefit.
If you also look at the representation, the issue in this case, and you look at the cases that look at that, for example, this case, the Swenson case, the horrible security case involving ADT Securities, and also Judge Magnuson on the Tuttle case, the issues there were, what are those representations?

What is happening? Are those still out there? Are they continuing? Is there something about this lawsuit that is going to change behavior? If you look at this case, this case involves the 2002 with the minor modification, the 2004 label. That label does not exist anymore. That label is not out in the public domain. There is nothing about that label.

We are litigating something in the past. It's like the childproof lighters in Pecarina that Judge Montgomery said they're not on the market. They're not going to change behavior. In Tuttle Judge Magnuson said that the plaintiff wanted to bring consumer fraud claims because she wanted to warn other consumers about smokeless tobacco. The label had already been put on by the FDA.

The whole situation here is again, the claim is, was the label in 2004 adequate, and the plaintiff has lots of arguments as to why it wasn't. There wasn't sufficient information. We didn't send out dear doctor letters. It was confusing. In the end, if there is ever a verdict form, it's going to say was the label inadequate. It's not going to do anything about this label because that label doesn't exist anymore.

So the Consumer Fraud Act claims just do not apply because there is no public benefit by virtue of those claims in this lawsuit.
Turning now to the warranty claims, I'm going to just spend a brief moment, Your Honor, because I think those are pretty straightforward. They're in Count III. There is an implied breach of warranty claim. This Court has addressed that issue before. Strict liability in Minnesota preempts an implied warranty of merchantability, and so as long as there is a strict liability claim, there cannot be an implied warranty claim.
With respect to breach of express warranty, I'm amazed. There was lots of rhetoric in the plaintiffs' brief about how Minnesota recognizes an express warranty claim. Great. That's true. But the question is, what is that warranty that is the basis of the claim in this lawsuit, and you look at page 19 of the plaintiffs' brief, they don't explain that at all.

They just fuss it up. They don't identify anything with respect to what that warranty is, and if you look at the complaint, paragraph 136 of their complaint where that warranty should be, all it says is that it wasn't safe. That's no different than an implied warranty, safe for its intended purpose.
So it's duplicative of the implied warranty.
That one should also be dismissed. If it's an implied warranty, it's preempted under Minnesota law relative to strict liability. Finally, with respect to Count X, the unjust enrichment, I think that has been well briefed as well. As long as there is an adequate remedy at law, the equitable claims do not stand, and there are cases that have been, that so hold.

The plaintiffs do cite to a case by Judge Davis where he allowed an unjust enrichment claim, but if the Court notes those facts, there were lots of equitable claims in that set of facts. This was not in an alternative. Here there are plenty of adequate remedies at law under the strict liability, the negligence, the fraud claims.
The unjust enrichment claim is an equitable claim that should be dismissed. If there is nothing further?

THE COURT: Let me ask you one question, Ms. Van Steenburgh.

MS. VAN STEENBURGH: Yeah.

THE COURT: Back to the question about the public benefit.

MS. VAN STEENBURGH: Mm-hmm.

THE COURT: Do you think there is anything to an argument that although this is an action that is seeking damages that are personal to Mr. Schedin, and most of these cases do relate to that, is there an argument that because particularly his case is coming first as a bellwether trial in an MDL it affects a lot of potential future plaintiffs or current plaintiffs in other cases that that can somehow confer a public benefit by participating in the trial in that way?

MS. VAN STEENBURGH: I don't think so for a couple of reasons. Every single one of these cases really is an individual case. They just happen to be collected here for pretrial discovery as part of an MDL. All of these cases may involve different labels. Mr. Schedin's case involves a 2004 label, so there may be one that involves a 2002. We have got a 2007. We have got a 2008, so you can't necessarily say that Mr. Schedin's case involving this particular label, which does not exist anymore, could somehow confer a public benefit with respect to any of those others. The adequacy of any of those others in any of those cases has to be litigated separately.

THE COURT: Thank you.

MS. VAN STEENBURGH: Yes.

MR. MCCORMICK: Almost afternoon, Your Honor. Good morning. Still there.

THE COURT: You're close.

MR. MCCORMICK: Hopefully I will be done before afternoon, Your Honor. Your Honor, your last question I think goes to the heart of the public benefit issue, which is where does the public benefit begin to run or when does a public benefit stop running for an individual bringing a claim under these Minnesota statutes?

For every Pecarina case and every Berczyk case that Ms. Van Steenburgh can cite to you, I can cite your ADT case, which you know better than I do. I can cite to you the Weigand versus Walser case, which is a Minnesota state court case. I can cite to you the Kinetic versus Medtronic, all those cases where conduct may have stopped during the course of the lawsuit.

The public benefit still was seen, and there still was an enforceable case underneath the consumer fraud statutes using the Private Attorney General Act.

THE COURT: What about this argument that simply bringing these claims now inside of an MDL with a potential impact on others? I mean is that a theory that would support a public benefit? Do you know of any cases that addressed the issue in that way?

MR. MCCORMICK: I do not, Your Honor, but I think if you go back and look -- I spent more time on Minnesota law in the past three months than I ever thought I would. If you go back and look at legislative reading and you go back and you look at the Ly versus Nystrom case and what led from that, I think that the way the defendants would

have you read the public benefit is to basically shut down the consumer fraud statutes to almost any individual trying to bring, seek redress under those cases.
So I think that while there is not a case specifically on point, I think if you look at the line of cases that we have versus the line of cases that the defendants would rely on, I believe that this case is closer to the Collins line than it is to the other line of cases.

THE COURT: Recognizing that there is not injunctive relief sought and I think that the public benefit issue is more complicated than just injunctive relief versus personal damages, the current label, the November '08 label which I have a copy here in front of me, is that an adequate label?

MR. MCCORMICK: Your Honor, we would argue it's not an adequate label.

THE COURT: Does that affect the public benefit issue?

MR. MCCORMICK: I would believe it would. If, for example, in your ADT case if that is the issue, we should be able to amend the complaint to add the inadequacy of the November 2008 label, but looking back at the November 2004 label, Mr. Schedin's complaint was filed before the November 2008 label, but our argument all along and always will be, I believe, that the new label is not adequate, either.

THE COURT: Okay.

MR. MCCORMICK: Your Honor, I think I can be as brief with the implied warranty and the express warranty claims as defendant was. All of the cases that the defendants rely on for their citations to the express warranty -- well, let me stay with the breach of implied warranty.
At this point dismissing that claim on a motion for judgment on the pleadings is premature. We should be able to present that case to the jury. Then in a jury instruction if you decide at the end of the trial whether we're going to present it or if you say the jury instructions are going to be confusing, then we withdraw that case.
Doing it right now before we get to the case, the actual trial, would be premature. All of the cases that they rely on are distributor cases. This is a case that involves a manufacturer. The express warranty claim is, again, I believe that their argument is misplaced here. This is a motion for judgment on the pleading.
If they felt like our express warranty does not expressly -- what we're complaining about is not in the complaint, they should have filed a motion for summary judgment and said your evidence isn't there.
At this point we have taken discovery for two and a half years. There is discovery that we could point to, express warranties over and over amongst the defendants' labels, the representations they have made to physicians, the detailing that they hand out. So --

THE COURT: But do we have evidence in these individual, what are we dealing with, five separate motions here?

MR. MCCORMICK: Six.

THE COURT: Six, that express warranties were made to patients or their doctors in these cases? Is there anything that has developed?

MR. MCCORMICK: Your Honor, I think under the Minnesota law, a general statement made by the company that may have made it down to the physician or the patient is enough, but I don't know the specifics of these cases, but Mr. Goldser could better answer that question, Your Honor.

THE COURT: That's fine.

MR. MCCORMICK: As to the unjust enrichment claim, Your Honor, it is similar to our breach of implied warranty claim which is that this is a premature motion. While we have adequate theories of law, the unjust enrichment claim is not ready to be dismissed. We should be able to try a case like that.
If at the end of the trial we decide that there is no evidence or if you decide that the case then is unworthy, we should drop it out then before you give us your jury instruction.

THE COURT: On the implied warranty claim, when do you choose between that and strict liability?

MR. MCCORMICK: I would think when we have a charging conference, Your Honor, and you say what cases are you going to charge the jury on, and we say this or this.

THE COURT: We can probably make that clear to a jury at the end of the case, but it may get confusing during the trial.

MR. MCCORMICK: I would think that we would be able to provide evidence on both claims to the jury. To be honest, I think probably the same elements would go in, so I don't know if the jury would understand until they receive two different instructions on the same elements. Thank you, Your Honor.

THE COURT: Thank you.

MR. GOLDSER: May I, Your Honor?

THE COURT: Sure, Mr. Goldser.

MR. GOLDSER: I remember Professor Marshall from the University law school, dearly departed, I don't know if you had any experiences with him.

THE COURT: Oh, yes.

MR. GOLDSER: Wonderful man. When we were talking about the purpose, the public policy behind tort law, I hope this is going to work, that one of the public policies behind tort law was to change behavior of the

defendant, and so I think you are exactly right when you say it's more complicated than simply whether or not there is injunctive relief.
Tort damages, tort cases for damages can get you there. I spent a long time earlier this morning talking about one of the theories of liability, and that is that Levaquin is worse than other fluoroquinolones in terms of comparative tendon toxicity. That is not in the warning. Never has been. Defendant denies it to this day. It's certainly not in the black box warning.

That, if we can convince a jury that there is inadequate warning on that, is in fact a public benefit. Of course one would hope that defendant would learn from the tort decision on an individual remedy case that they need to change their warning to address the question of the comparative tendon toxicity of Levaquin versus other fluoroquinolones, which dovetails exactly into the express warranty issue.

And what I have up in front of you at the moment are the call notes that were provided to us by defendant where the defendants' sales representatives called on Dr. Beecher, and the one that you see right in front of you, and it actually scrolls up a little bit, this page, as you can see is July 2, 2002, it's Dr. Beecher.
Monica Sadar over here is the name of the sales representative, and when she is done with the call, she writes in this box down here what occurred in the call. And you can see that she described to Dr. Beecher on July 2, 2002, the safety of Levaquin versus other quinolones, versus Augmentin as well, and I don't understand what that last tag phrase is IN SIN, but she was there talking to Dr. Beecher that day about how Levaquin compares in safety to other fluoroquinolones.

I can promise you she didn't say to Dr. Beecher, well, you know, Levaquin is worse than other fluoroquinolones in terms of the tendon toxicity. Quite the opposite. This call might suggest that it is in fact safer than other fluoroquinolones, which is a misrepresentation, and it's also an express warranty.
I can find for you several other references to descriptions of tolerability and safety. You can see that over on the right. This call note I believe was created on the top of the page July 12, 2002.
There were several others that look very similar that talked about safety as Monica Sadar or other sales reps referenced specifically to Dr. Beecher, the doctor in this case. We have not only an express warranty just generally out there, we have got a specific express warranty that was made to Dr. Beecher that we can see in the call notes.
Thank you.

MR. SAUL: Just one thing, Your Honor?

MS. VAN STEENBURGH: I'm getting triple teamed here. Seems unfair.

THE COURT: Go ahead, Mr. Saul.

MR. SAUL: 60 seconds.

THE COURT: We can give Mr. Dames and
Mr. Robinson a chance.
Go ahead, Mr. Saul.

MR. SAUL: During depositions I specifically
asked the defendants' experts as well as their employees,
did they agree or disagree with the black box warning,
which is now in effect, and across the board, they either
disagree with it in whole or in part.
So in terms of the public benefit, you have it
there in testimony throughout the litigation.

THE COURT: Thank you.
Ms. Van Steenburgh?

MS. VAN STEENBURGH: Well, first, let me bring us
back to the fact that we're here for a motion for judgment
on the pleadings. Mr. Goldser has now just introduced a
bunch of evidence that I wasn't aware that those were the
express warranties. We looked at the complaint. The
complaint says nothing. Paragraph 136 just says including
plaintiff and physicians that Levaquin had been shown by
scientific study to be safe for its intended use.
Their brief in response when we said there isn't
an express warranty, as to express warranties, the various
complaints make it clear with factual affirmations and
product descriptions of Levaquin that form the basis of
additional express warranties.

There is never any representation as to what
warranty, where, who or what, other than it's safe, and
even as Mr. Goldser said, the warranty that was given
Dr. Beecher is, it was safe. That's an implied warranty.
So there is nothing different about the express warranty
claim than there is the implied warranty claim.
Now, stepping back to that, what I'm hearing is,
they don't want to make a decision about whether they're
going to stick with their strict liability claim now or
later. If they get rid of the strict liability claim,
negligence merges in with the implied warranty, so that
goes away anyway at trial.

So whether we get rid of it now or later it is
not going to make any difference if they decide to drop
their strict liability claims. Strict liability, and
negligence is equal to the implied warranty, and under
Minnesota law, you have to get rid of the implied warranty
claim. So the decision is actually subject now. Strict
liability as long as it stays in the complaint preempts
implied warranty.
The final thing I wanted to say is, there seems
to be some confusion about this issue of the public
benefit. The question was, do the plaintiffs believe that
the 2008 label is adequate? That isn't the subject of
Mr. Schedin's lawsuit, nor any of the other bellwether
plaintiffs.
The adequacy of the 2008 label is not at issue.
The issue is the adequacy of the 2004 label, and that's
what is going to be litigated in this case, and that label
doesn't exist.
Now I hear Mr. Goldser saying, well, they still
don't have two times endotoxic in the future label. Well,

is that the only thing that is ever going to be litigated as part of the 2004 label? No. They have identified all kinds of deficiencies.
There is nothing that -- about the 2008 label that somehow can be brought back to the 2004 label, and if you look at Pecarina, you look at the Tuttle case, and it's distinguished from the Swenson case because in that case it was unclear whether there was national sales literature and installation literature still out there such that the impact of the lawsuit might impact the behavior. The 2004 label doesn't exist.

It is not going to have an effect. It is more like Tuttle where the label has changed, and now we're litigating something in the past. And whether Mr. Schedin is entitled to damages for past medical expenses, pain and suffering as a result of the alleged inadequacy of the label is the issue before the Court.
There is no public benefit with respect to that label, and thus there can be no consumer fraud claims.
Thank you, Your Honor.

THE COURT: Thank you, Ms. Van Steenburgh. Do you want some backup?

MR. DAMES: She apparently doesn't need it.

MR. ROBINSON: We have our batting helmets.

THE COURT: Okay. Did you have anything else, Mr. McCormick?

MR. MCCORMICK: Your Honor, just one quick thing, and it brings me back to the express warranty, which is at this point in time a motion for judgment on the pleadings as opposed to a Rule 12 motion. If they felt like our express warranties were not there and not in the complaint, they should have brought a motion for summary judgment to have that opportunity, and they didn't do it.
As to the public benefit argument, I think my argument stands in that if you would read the public benefit as narrowly as defendants would have you do in an MDL setting, it would defeat the purpose of an MDL and setting law and following law and setting a group going forward for the rest of these cases.
Thank you, Your Honor.

MR. GOLDSER: So the records are clear, we move to amend the complaint to incorporate the express warranties set forth in the call notes that I described to you.

THE COURT: Speaking of the call notes, Mr. Goldser, where in the record is what you showed us there? Can you cite to the record so that we can look that up?

MR. GOLDSER: I don't believe it's in the record. Because this was a judgment on the pleadings, we didn't submit any evidence. I'm happy to send them to you if you would like.

THE COURT: I see. Okay. Anything else on the

motions? Okay. Very well. Okay. Let's talk a little bit about scheduling. We have, I believe, I believe it's next week, Wednesday, the Daubert motions, the 6th? We have inquired about the advisability of splitting them up somehow. I am of a couple of minds about that. I thought I would raise that anyway.
I guess it depends in part on the length of arguments that you wish to do on the Daubert motions. If it's lengthy argument involving all of them, then -- I want to make sure. I've got a trial going on next week. I want to make sure I have enough time to prepare for all of them and to be able to prepare for arguments.
What's anticipated right now? Maybe each of you have thoughts on this.

MR. GOLDSER: I'm not sure that we have gone into a great deal of detail yet about what we want to argue and how we want to argue it. I have the concern about the longer we go before we get a ruling, the closer we are to trial, of course.
But I like to with, with due humility and respect, suggest a possible solution. It may impose a greater burden on the Court, however. There is a procedure that is used in California courts, both state and federal, where the Court issues what is called a tentative ruling. I don't know if you're familiar with that.
I have experienced it a few times. It's pretty wonderful from a litigant's perspective. The Court actually issues a proposed order, and the litigants get it when they walk into court that morning.
THE COURT: Judge Renner did something like that on a regular basis. He would announce his tentative decision and ask lawyers to tell him where he was wrong. He was rarely wrong.

MR. GOLDSER: I find that to be true certainly as well when I have been in California, but from my perspective it's really wonderful. It cuts down the amount of time for the argument, and it focuses the argument. Of course, it puts a tremendous burden on the Court to have tentative rulings done.
One court, I wish I could recall who it was, handed out a list of questions, as opposed to what the tentative ruling would be, so that the arguments could be really focused. I went on at great length because I wanted to tell you the story. It was the first time I think we have had the chance. You have now seen it, and you have read a lot about it in the Daubert briefs, so I don't know that we have that great need to go there.
I want to focus on what you need to know to make those decisions. If you can help us with that, I think we can get it done in one day.

MR. DAMES: We don't have an objection to having one day to hear all the motions. I think that really is going to be your calendar for the preparation time if you feel that you need to do --

THE COURT: What are you anticipating for the argument time?

MR. DAMES: You know, we haven't discussed it, Your Honor, but at some point the issues, I mean, clearly

the first arguments are going to be longer than the later arguments, I suspect. The Seeger lay argument will probably be one of the longer arguments. The -- We have the Waymack/Blume arguments will probably be quite significant, and I should tell the Court that we're going to have John Winter, who is an attorney with Patterson Belknap, come and argue those motions.

THE COURT: Mm-hmm.

MR. DAMES: It's hard to say, but none of them will be particularly short.

MR. ROBINSON: Your Honor, if the Court will entertain possibilities here, we could do as much as we could on the 6th and then perhaps have another date on the 13th if that's convenient for the Court as suggested to finish up if we need it.

THE COURT: Well, I mean, we will issue the order just as quickly as possible. It will be, obviously we know the trial is coming up, and it goes to the top of the list, so, you know, maybe that is the best way to proceed. If I can give the parties some direction in advance, I will do so, but I'm not promising anything right now. I'm starting this other trial on Monday, and that will involve a lot of -- it's a bench trial, too. So -- but we can -- Go ahead.

MR. DAMES: I think that for some of the motions, I've had experience in California with the, with that procedure. It isn't a bad procedure to utilize if you think the oral argument isn't going to clarify things or if oral argument is going to have a substantial benefit. I think on the Daubert motions, oral argument probably will have a substantial benefit so that, I mean, because a lot of arguments foreclose with that kind of a preliminary decision in practice, and I just think that it might be the least appropriate method, time to use that procedure if you do it with the Daubert motions.

THE COURT: Well, go ahead, Mr. Saul.

MR. SAUL: Your Honor, we suggest, plaintiffs suggest you do one plaintiff, one defendant, back and forth between the motions.

MR. ROBINSON: That's fine with us if the Court wants to set some kind of schedule.

THE COURT: We'll let you know. We'll try to get to that, you know, a day or two in advance so you know exactly how we are going to proceed, and I think the suggestion, we'll do what we can on the 6th, and if we can't get it all done, we'll just schedule another day shortly thereafter.

MR. ROBINSON: Your Honor, originally when we had talked about the schedule, we had reserved October 7th. I take it that is not going to happen now, and I just want to be clear about that.

THE COURT: Well, let's look here and see what we have got. I think we should probably continue to hold that for now, but I do have this other trial. It's just the other trial. That's all I have going on other than a sentencing.
I do have time available that day if we need to spill over. So I think let's hold it for now. Okay?

MR. ROBINSON: Yes, sir.

THE COURT: Okay. Anything else we need to discuss today?

MR. GOLDSER: I don't think so, Your Honor.

THE COURT: Okay. Very good.

MR. DAMES: Thank you, Your Honor.

MR. ROBINSON: Thank you, Your Honor.

THE COURT: The Court is in recess. Thanks for the arguments today.

THE CLERK: All rise.

(Court was adjourned.)
* * *
I, Kristine Mousseau, certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.
Certified by: s/ Kristine Mousseau, CRR-RPR
Kristine Mousseau, CRR-RPR

Messages in this topic (4)

2b. Re: You have got to read this: Yet another reason why the numbers do
Posted by: "Jim Webb" jfwebb@gmail.com smartassrj
Date: Tue Jan 4, 2011 9:09 pm ((PST))

That names some good names as well.

On Tue, Jan 4, 2011 at 10:45 PM, david <Fqresearch@aol.com> wrote:

>
>
> SEE:
>
> mnd.uscourts.gov/MDL-Levaquin/Transcripts/2010/092810.pdf
>
> For those who do not have Adobe Reader here is the text version:
>
> KRISTINE MOUSSEAU, CRR-RPR
> (612) 664-5106
> 1
> UNITED STATES DISTRICT COURT
> DISTRICT OF MINNESOTA
> ---

>)
> In Re: Levaquin Products)
> Liability Litigation,) File No. 08-md-1943
>) (JRT/AJB)
>)
>)
>) Minneapolis, Minnesota
>) September 28, 2010
>) 10:10 A.M.
>)
> ---
> BEFORE THE HONORABLE JOHN R. TUNHEIM
> UNITED STATES DISTRICT COURT JUDGE
> (MOTIONS HEARING)
> APPEARANCES
> For the Plaintiffs: RONALD S. GOLDSER, ESQ.
> LEWIS J. SAUL, ESQ.
> BRIAN McCORMICK, ESQ.
> For the Defendants: JOHN DAMES, ESQ.
> WILLIAM H. ROBINSON, JR., ESQ.
> WILLIAM ESSIG, ESQ.
> TRACY J. VAN STEENBURGH, ESQ.
> Court Reporter: KRISTINE MOUSSEAU, CRR-RPR
> 1005 United States Courthouse
> 300 Fourth Street South
> Minneapolis, Minnesota 55415
> (612) 664-5106
> Proceedings recorded by mechanical stenography;
> transcript produced by computer.
> 10:10 A.M.
>
> (In open court.)
> THE COURT: Good morning. You may be seated.
> This is civil case number 08-1943, In Re: Levaquin
> Products Liability Litigation. That's the MDL number. We
> have a number of motions this morning.
> Let's see. Let's have counsel note appearances
> first.
>
> MR. GOLDSER: Good morning, Your Honor. Ron
> Goldser for plaintiffs.
>
> MR. SAUL: Good morning, Your Honor. Louis Saul
> for plaintiffs.
>
> MR. MCCORMICK: Brian McCormick, Your Honor.
>
> MR. DAMES: John Dames for the defendants.
>
> MR. ESSIG: Bill Essig for the defendants.
>
> MR. ROBINSON: William Robinson for the
> defendants.
>
> MS. VAN STEENBURGH: Tracy Van Steenburgh for the
> defendants.
>
> THE COURT: Good morning to all of you.
>
> MR. GOLDSER: Your Honor, I thought what we would
> do is take the punitive damages motion first and then the
> judgment on the pleadings with your permission.
>

> MR. DAMES: I don't have any disagreement, but I
> wanted to just raise an issue before we got started with
> the specifics on the oral argument. We have a reporter in
> the gallery here, and there are going to be matters that
> are -- that have been to date confidential and are
> confidential, some documents embedded in the presentation,
> and my concern is that we don't wish to waive that. The
> motion hasn't yet been decided by the Court.
>
> THE COURT: Okay. Very well.
>
> MR. GOLDSER: We certainly oppose any action
> taken with regard to that. We think this is an open
> courtroom. The documents that we're going to be using have
> all been used in depositions, and none of the depositions
> have been marked as confidential ever, except minor parts
> dealing with individual personal finances, so the documents
> even though they may have a confidential stamp on them
> aren't even confidential anymore.
> Presumption, strong presumption in favor of an
> open courtroom.
>
> THE COURT: Let's address that when we get to it.
> Let's start with the punitive damages motion.
>
> MR. GOLDSER: Okay. Thank you, Your Honor. The
> way we will divide up the punitive damages is, my
> presentation that is before you is designed to be a bullet
> point presentation. These are what we considered to be the
> bad acts, all of which have been substantiated by
> voluminous filings in the briefs.
>
> I will highlight those bad acts for you. I will
> call your attention to several documents. I am not going
> to be going through a lot of documents. The presentation
> has a lot of hyperlinks on them. Mr. Essig tells me that
> unfortunately the copy I gave to him, the hyperlinks
> weren't working. I don't know if that was true of the
> Court's copy or not. Obviously I hope they were working.
> I'm on my laptop. I know they work. At least
> they did an hour ago. So we will see where that takes us.
> There are a few in particular that I want to call to the
> Court's attention. Mr. Saul will follow me on this and
> focus on the Ingenix study, although I will cover it fairly
> quickly.
>
> The whole notion of the punitive damages motion,
> to start off with, there are a couple of preliminary legal
> issues that I want to address and get out of the way right
> away. First, the question of choice of law, that's been
> briefed extensively. We think there is little doubt that
> Minnesota law applies to this question. Even if it
> doesn't, we think we have met the New Jersey standard, and
> I'm quite perplexed by the defense posture.
>
> To suggest that New Jersey law would apply,
> because as federal courts have rejected the McDarby
> decision out of the New Jersey appellate court, if you
> decide that New Jersey law applies and that McDarby is no
> longer good law in light of Wyeth, I think they have just
> opened themselves up to a whole punitive damages claim in
> New Jersey in state court that they don't anticipate. So I
> don't think they really want to go there, and I don't think

> they're really serious about it.
>
> Secondly, the law is quite clear to me that what
> you consider on this record is plaintiffs' prima facie
> proof that defendant doesn't have the right to
> cross-examine it. They don't have the right to challenge
> it. They don't have the right to present any of their own
> evidence, and so to the extent that the defense wants to
> present documents to you today, I don't think you consider
> them. I don't think they're part of the prima facie case
> at this point.
>
> I mean, I'm glad to have had their brief because
> I now see what their closing argument is in front of the
> jury, and it's very nice, but they don't get to make that
> argument today. So for us what matters is what does the

Vote FOR adding a phrase to all Levaquin tablet bottles and injection solutions that direct patients to pay close attention to all information (the "monogram" and the Patient Guide) .

Suggested phrase for bottles of Levaquin:

CAREFULLY READ PRODUCT INFORMATION
BEFORE USING, AND DO NOT DISCARD INFORMATION

There is no information on Levaquin bottles of recent new warnings, and no indication that small adverse reactions can build-up in the body and later start cellular events that can be very painful and irreversible. If one has a MINOR reaction, sometimes it does NOT slowly worsen while one completes the prescribed dose. It can stabilize or decrease giving the patient a false sense of security. (This is what happened to me in 1998; Levaquin is Floxin's "mirror" drug; Floxin was discontinued in 2009.) If patients read the fine print and inserts they may know this, if they do not, many could be danger.

Current communication is failing. There have been over 159,000 adverse reactions reported to the FDA on Levaquin and Floxin, and over 37,000 individual safety reports. Complaints are "the tip of the iceberg." The delayed reaction mechanism is different than other medicines with black box warnings, and Levaquin **has the highest tendon rupture rate within the floroquinolone "class"**.

Everyone needs to see something on the bottle so they fully understand the consequences of any minor initial reaction during the course of treatment. Pharmacists cannot offer advise on medical issues. They only say: "Do you have any questions about this medicine?" Everyone has a right to know "up-front" the unique delayed reaction mechanism that can cause permanent pain. The 2008 Medication Guides are primarily not reaching the majority of patients, most only receive the fine print in the monogram.

To add one phrase may take consulting with the FDA and companies that provide labeling services that are automatically generated when a prescription is filled. A possible decrease in sales will be offset by fewer lawsuits.

Information on the **bottle of Levaquin 500 mg. Tablets**:

"Medication should be taken with plenty of water.

Take this medication at least 2 hours before or 2 hours after magnesium or aluminum containing antacids, or other products containing calcium, iron, or zinc.

Avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication. May cause dizziness.

This medicine is dispensed as a(n) PEACH, OBLONG-SHAPED, FILM COATED TABLET with LEVAQUIN imprinted on one side and 500 imprinted on the other side. "

No mention of the dangers on the bottle, often the only information read by patients, especially those with lower reading abilities, difficulty seeing or do not speak English.

There is no cure for permanent reactions that damage tendons, cartilage, nerves, etc. Help decrease company liability, be compassionate towards public health, and decrease preventable government expenses for the disabled.

Sincerely,
Paul W. Cahan

Holding 51 Shares

At the 2004 and 2005 Annual Meetings, similar proposals were defeated by votes of approximately 66% and 80%, respectively, against the proposal.

In view of the strong oversight mechanisms the Company already has implemented, the Board does not believe it is necessary to mandate a separation of the positions of Chairman and Chief Executive Officer through a Bylaw amendment. In fact, the Board believes that imposing such an absolute rule would be unwise and not in the best interests of stockholders because it would eliminate the Board's flexibility to determine whether the positions should be held by the same person or by separate persons based on the circumstances and individuals available at any particular point in time. The Board believes at the present time the interests of the Company and its stockholders are best served by the leadership and direction provided by a single Chairman and Chief Executive Officer.

THE BOARD UNANIMOUSLY RECOMMENDS A VOTE "AGAINST" THE ADOPTION OF THIS STOCKHOLDER PROPOSAL, and your Proxy will be so voted unless you specify otherwise.

PROPOSAL 7

STOCKHOLDER PROPOSAL REGARDING LABELING PRODUCTS OF CLONING OR GENETIC ENGINEERING

The Company has been notified by the Adrian Dominican Sisters, 1257 East Sienna Heights Drive, Adrian, MI 49221-1793, which owns 150 shares of Common Stock, that it intends to present, jointly with ASC Investment Group, Bon Secours Health System, Inc., Boston Common Asset Management, LLC, the Dominican Sisters of Oxford, MI, the Dominican Sisters of Springfield Illinois and the General Board of Pension and Health Benefits of the United Methodist Church, the following proposal for consideration at the Annual Meeting:

Label Products of Cloning or Genetic Engineering
2007 Safeway

RESOLVED: Shareholders request that the Board of Directors adopt a policy to identify and label all food products manufactured or sold by the company under the company's brand names or private labels that may contain genetically engineered (GE) ingredients or products of animal cloning.

Supporting Statement

- The right to know is a fundamental principle of democratic societies and market economics.
- The Food and Drug Administration is expected to make a decision regarding the sale of milk and meat from cloned animals by the end of 2006 (WA Post 10/17/06).
- Safeway products contain corn, rice and soy, all of which potentially could be the genetically engineered variety.
- Safeway's O Organic line could be impacted by contamination from genetically engineered ingredients.
- Labeling is an indicator of due diligence of product ingredients.
- The global alliance Action by Churches Together took a stand supporting the "right to know" whether there are genetically engineered ingredients in the food purchased or in the seeds sown. (ReliefWeb 6/28/06)
- 132 countries, parties to the Cartagena Protocol, have agreed to documentation requirements for the export and import of genetically engineered organisms. (Financial Times 3/29/06)
- As of May 19, 2005, Alaska law requires that genetically engineered salmon be labeled as such.

Indicators that genetically engineered organisms can be difficult to control, and may be harmful to financial markets as well as to humans, animals and the environment include:

- Illegal unapproved Liberty Link long-grain rice, planted in field trials no later than 2001, was discovered to have contaminated U.S. rice supplies. (Reuters 8/28/06) This prompted Japan to suspend imports of US Rice, and the European Commission to require that rice imports be certified as free of unauthorized grain, greatly disrupting the US rice export market.
- Between 2001-2004, approximately 15,000 hectares (150 square kilometers) in four US states were planted with unapproved Bt10 corn. (New Scientist 3/23/2005)
- December 2006, U.N. Secretary General Annan cautioned that the international community lacks safeguards to prevent bioterrorism and accidental harm from biotechnology advances.
- The report *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects (National Academy of Sciences] 7/2004)* states: ..."there remain sizable gaps in our ability to identify compositional changes that result from genetic modification of organisms intended for food... (p.15)
- Federal District Court ruled (8/10/06) that USDA's permitting of drug-producing genetically engineered crops in Hawaii violated the Endangered Species Act and the National Environmental Policy Act.
- Genetically engineered creeping bentgrass, not yet approved commercially, escaped into wild as far as three miles from the test plot. (8/9/06)
- Five major US agricultural weeds have developed resistance to glyphosate, the herbicide used with genetically engineered Roundup Resistant crops. Addressing this problem includes use of additional herbicides.
- Research (*Environmental Health Perspectives 6/2005*) has shown that Roundup, increasingly needed on Roundup Ready crops, is toxic to human placental cells at concentrations lower than agricultural use.

Board Recommendation

The Board of Directors recommends a vote "AGAINST" this proposal for the following reasons:

The Company shares and actively supports our customers' interest in food safety. The Company's policies regarding food products manufactured or sold under its own brand names and private labels that contain genetically modified ingredients are based on a number of factors, including the following:

To date, the Food and Drug Administration (FDA), the United States Department of Agriculture (USDA) and the Environmental Protection Agency (EPA) have identified no significant health, food, safety or environmental issues or concerns associated with human consumption of genetically modified ingredients or approved food products containing those ingredients. Additionally, the FDA has expressed concern that special labeling for foods containing ingredients improved through modern biotechnology may be misleading to consumers because many would interpret such a label as a warning when, in fact, there is no scientific basis to suggest such foods are in any meaningful way different from their non-biotech counterparts.

To date, no significant studies by the EPA have documented or confirmed environmental concerns with respect to genetically modified crops. While the EPA has established a 20% non-Bt crop planting requirement (Bt crops contain certain proteins used as an alternative to conventional chemical insecticides) we note the EPA set this threshold while it continues its plant incorporated protectorant (PIP) studies which, to date, have shown no negative environmental impacts. While the reports noted in support of the proposal reference planting incursions, they do not support the proposition that harm has occurred to humans, animals or the environment.

It is also noteworthy that the U.S. government promotes the cultivation of genetically modified food and the international sale of such products (including seeds), citing the benefits of these products to developing countries.

Consistent with most U.S. national brand products, approximately 75% of Safeway's private label products contain genetically modified ingredients. The Company has determined that to label these products as genetically modified would be impractical from a detection and marketing perspective as well as cost-prohibitive. Neither is

it feasible to identify and label the approximately 25% of the Company's private label food products that might qualify as being free of genetically modified ingredients. Such an undertaking would require establishing and maintaining a costly supplier audit and certification program.

In addition, the Board does not believe that the policy requested by the proposal is feasible, given the current practices of multi-vendor sourcing prevalent in the United States food distribution system. The Company produces and markets thousands of different products, and uses large volumes of various raw materials. The Board believes it would be difficult and costly, in the absence of federal laws and regulations, for the Company to require its numerous suppliers to identify crops and raw materials derived from modern biotechnology.

Because of the difficulty in determining which crops and raw materials used by the Company may contain genetically engineered ingredients, any label would likely state that foods produced by the Company from such crops and raw materials "may" contain genetically engineered ingredients. Because the labeling of genetically engineered ingredients is not generally required, a universal label such as the foregoing would not further a consumer's understanding of which foods contain genetically engineered ingredients, but may create confusion among consumers and potentially place the Company at a competitive disadvantage relative to those companies that do not label their products in such a manner.

The Company also notes that consumers' interest in non-genetically modified food products is tempered by their higher cost. Research shows these consumers, in fact, purchase non-genetically modified food products only if the cost of such food products is comparatively the same or only slightly higher than the comparable genetically modified food products.

As a more practical and cost-effective means of providing consumers a choice of foods free from genetically modified ingredients, the Company previously has introduced and continues to expand its *O* ORGANICS brand, which offers organic produce and food products. By law, food items designated as "organic" must be free of genetically modified ingredients. The Company has determined this approach presents a better and more competitive alternative than focusing efforts on the monitoring, labeling and/or removal of private label food products containing such ingredients.

As noted by the proponent, the FDA is investigating the safety of animal clones and products derived from animal clones. While the FDA is finalizing its report, it has requested a voluntary moratorium against the sale of cloned products. As a result of the moratorium, the Company does not currently carry any products of animal cloning. Consequently, there are currently no products for the Company to label in response to this proposal.

The FDA issued a draft report entitled "*A Risk-Based Approach to Evaluate Animal Clones and Their Progeny*" in December 2006 that summarizes the FDA's analysis of the safety of animal clones and products derived from animal clones. The draft report concludes that "[e]dible products derived from the progeny of clones pose no additional food consumption risk(s) relative to corresponding products from other animals based on underlying biological assumptions, evidence from model systems, and consistent empirical observations." The draft report also concludes that "[e]xtensive evaluation of the available data has not identified any food consumption risks or subtle hazards in healthy clones of cattle, swine, or goats. Thus, edible products from healthy clones that meet existing requirements for meat and milk in commerce pose no increased food consumption risk(s) relative to comparable products from sexually-derived animals." The proponent has offered no support to address safety issues with regard to the products of animal cloning, and, in fact, nothing in the proponent's supporting statement addresses animal cloning.

Additionally, in the event that products derived from animal clones did enter the marketplace, because scientific analysis indicates that cloned animals are genetically identical to the original animals, it would be highly impracticable, if not impossible, for the Company to test and identify whether a product originated from a cloned animal or from a non-cloned animal. Therefore, it would not be possible for the Company to identify and label products that may contain products from animal cloning.

Further, in the event that products of animal cloning did enter the food supply and a legitimate concern arose with respect to human, animal or environmental safety, there is a recognized mechanism to address this issue, which would be a recall of the affected products.

Accordingly, the Company believes this stockholder proposal is impracticable and, even if the proposed policy were implemented, the effort would be inordinately expensive with no significant resulting stockholder benefit.

Similar proposals were presented at the Company's 2004 and 2006 Annual Meetings and were defeated by votes of over 94% and 93%, respectively.

THE BOARD UNANIMOUSLY RECOMMENDS A VOTE "AGAINST" THE ADOPTION OF THIS STOCKHOLDER PROPOSAL, and your Proxy will be so voted unless you specify otherwise.

PROPOSAL 8

STOCKHOLDER PROPOSAL REGARDING SUSTAINABILITY REPORT

The Company has been notified by the City of New York Office of the Comptroller, 1 Centre Street, New York, NY 1007-2341, on behalf of the New York City Teachers' Retirement System, the New York City Police Pension Fund, the New York City Fire Department Pension Fund and the New York City Board of Education Retirement System, which, in the aggregate, own 1,343,039 shares of Common Stock, that it intends to present the following proposal for consideration at the Annual Meeting:

WHEREAS:

Investors increasingly seek disclosure of companies' social and environmental practices in the belief that they impact shareholder value. Many investors believe companies that are good employers, environmental stewards, and corporate citizens are more likely to be accepted in their communities and to prosper long-term. According to Innovest, an environmental investment research consultant, major investment firms including ABN-AMRO, Neuberger Herman, Schroders, T. Rowe Price, and Zurich Scudder subscribe to information on companies' social and environmental practices.

Sustainability refers to development that meets present needs without impairing the ability of future generations to meet their own needs. The Dow Jones Sustainability Group defines corporate sustainability as "a business approach that creates long-term shareholder value by embracing opportunities and managing risks deriving from economic, environmental and social developments."

Globally, approximately 1,900 companies produce reports on sustainability issues (www.corporateregister.com), including more than half of the global Fortune 500 (KPMG International Survey of Corporate Responsibility Reporting 2005).

Companies increasingly recognize that transparency and dialogue about sustainability are elements of business success. For example, Unilever's Chairman stated in a 2003 speech, "So when we talk about corporate social responsibility, we don't see it as something business "does" to society but as something that is fundamental to everything we do. Not just philanthropy or community investment, important though that is, but the impact of our operations and products as well as the interaction we have with the societies we serve."

An October 6, 2004 statement published by social research analysts reported that they value public reporting because "we find compelling the large and growing body of evidence linking companies' strong performance addressing social and environmental issues to strong performance in creating long-term shareholder value... We believe that companies can more effectively communicate their perspectives and report performance on complex

SAFEWAY

SAFEWAY INC.
5918 Stoneridge Mall Road
Pleasanton, CA 94588-3229

NOTICE OF ANNUAL MEETING OF STOCKHOLDERS

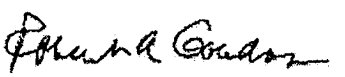
NOTICE IS HEREBY GIVEN that the Annual Meeting of Stockholders of Safeway Inc., a Delaware corporation (the "Company"), will be held at the corporate offices of Safeway Inc., 5918 Stoneridge Mall Road, Pleasanton, California, on Wednesday, May 16, 2007 at 1:30 p.m. Pacific time for the following purposes:

1. To elect nine directors of the Company to serve for a term of one year and until their successors are elected and qualified;
2. To consider and vote upon the approval of the Safeway Inc. 2007 Equity and Incentive Award Plan;
3. To consider and vote upon the approval of the Amended and Restated Capital Performance Bonus Plan for Executive Officers and Key Employees of Safeway Inc.;
4. To ratify the appointment of Deloitte & Touche LLP as the Company's independent registered public accounting firm for fiscal year 2007;
5. To consider and vote upon five stockholder proposals, if properly presented at the Annual Meeting, which are opposed by the Board of Directors; and
6. To transact such other business as may properly come before the meeting and any adjournments or postponements.

Only stockholders of record at the close of business on March 19, 2007 will be entitled to receive this notice and to vote at the Annual Meeting. A complete list of stockholders entitled to vote at the Annual Meeting will be open to the examination of any stockholder present at the Annual Meeting and, for any purpose relevant to the Annual Meeting, during ordinary business hours for at least ten days prior to the Annual Meeting, at the corporate offices of the Company at the address indicated above.

Whether or not you plan to attend the Annual Meeting in person, we urge you to ensure your representation by voting by proxy as promptly as possible. You may vote by completing, signing, dating and returning the enclosed proxy card by mail, or you may vote by telephone or electronically through the Internet, as further described on the proxy card. A return envelope, which requires no postage if mailed in the United States, has been provided for your use. If you attend the Annual Meeting and inform the Secretary of the Company in writing that you wish to vote your shares in person, your proxy will not be used.

By Order of the Board of Directors,



ROBERT A. GORDON
Secretary

Pleasanton, California
Dated: April 4, 2007

DEF 14A 1 ddef14a.htm DEFINITIVE PROXY STATEMENT

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D. C. 20549

SCHEDULE 14-A

(Rule 14a-101)

INFORMATION REQUIRED IN PROXY STATEMENT
SCHEDULE 14A INFORMATION
Proxy Statement Pursuant to Section 14(a) of the Securities Exchange Act of 1934

Filed by the Registrant ☒

Filed by a Party other than the Registrant ☐

Check the appropriate box:

☐ Preliminary Proxy Statement
☒ Definitive Proxy Statement
☐ Definitive Additional Materials
☐ Soliciting Material Pursuant to §240.14(a)-12

☐ **Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))**

Safeway Inc.

(Name of Registrant as Specified In Its Charter)

(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

Payment of Filing Fee (Check the appropriate box):

☒ No fee required.

☐ Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11.

(1) Title of each class of securities to which transaction applies:

(2) Aggregate number of securities to which transaction applies:

(3) Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11 (set forth the amount on which the filing fee is calculated and state how it was determined):

(4) Proposed maximum aggregate value of transaction:

(5) Total fee paid:

☐ Fee paid previously with written preliminary materials:

☐ Check box if any part of the fee is offset as provided by Exchange Act Rule 0-11(a)(2) and identify the filing for which the offsetting fee was paid previously. Identify the previous filing by registration statement number, or the Form or Schedule and the date of its filing.

(1) Amount Previously Paid:

(2) Form, Schedule or Registration Statement No.:

(3) Filing Party:

March 9, 2011

TO: Securities and Exchange Commission

FROM: Paul Cahan

RE: Johnson & Johnson Shareholder Proxy
Request to Appeal Proxy Decision with New Information

Dear Ladies and Gentlemen:

INTRODUCTION

Please find below, reasons why I request that you reconsider your decision about allowing the Shareholder Proxy about Levaquin to be denied access to a Shareholder Vote. Also for SEC and Johnson & Johnson consideration, is a revised Proxy that I hope the SEC will consider and suggest to Johnson & Johnson to use, and allow to go forth to shareholder vote.

The proposal was re-phrased with suggested change taken directly from the Company's own bottles of over-the-counter Tylenol, of course a much safer product than Levaquin. Another example of a common over-the-counter medication Excedrin adds: 'keep box for important information" which is a common phrase with OTC medicines.

(See photos attached)

UPDATED LEVAQUIN TOXICITY INFORMATION

Attachment: "Quarterwatch 2010 pdf.

QuarterWatch: 2010 Quarter 2

Monitoring MedWatch Reports

January 27, 2011

INSTITUTE FOR SAFE MEDICATION PRACTICES

http://www.ismp.org/QuarterWatch/2010Q2.pdf

The QuarterWatch report states not only was Levaquin suspect in more reports of serious injury than any other antibiotic, but substantially at much higher incidence levels then other drugs within the same class.

The serious injuries not only involved tendon rupture but muscle, tendon, and joint/ ligament injuries. The current safety label also warns of potential for irreversible nerve damage that can impact the musculoskeletal system. The warnings fail to warn of the degenerative nature of such types of serious injury. While all drugs in this class carry a UNIFORM BLACK BOX Warning this does not disclose the higher frequency of which these serious adverse events are being reported with Levaquin.

2011 Quarterly Newsletter from the Institute for Safe Medication Practices supports the data of findings of regulatory agencies globally whose documents were provided in the original proxy. Significantly higher incidence of serious safety report signals impact public health globally.

Third Exhibit:

"While antibiotics rank among the safest drugs we monitor, levofloxacin (LEVAQUIN) was suspect in more reports of serious injury than any other antibiotic."

The proposal in essence asks the shareholders to vote for disclosure of the risks of Levaquin, which are now found to have a higher incidence of serious safety concerns. This significantly impacts Public Health Globally. The public and shareholders have the right to be informed, and vote that everything be done to encourage patients receiving Levaquin to read and understand all current and future disclosures; and thus help to limit legal liabilities of the Company.

Staff Legal Bulletin 14 July 2001

"We analyze the prior no-action letters that a company and a shareholder cite in support of their arguments and, where appropriate, any applicable case law. We may also conduct our own research to determine whether we have issued additional letters that support or do not support the company's and shareholder's positions.

The proxy relates to only ONE product, Levaquin. It is undisputably the most dangerous of any antibiotic on the market. (See latest article, January 2011)

Re-worded Shareholder Proxy for SEC consideration to propose to Johnson & Johnson for inclusion in this years' Annual Meeting:

Vote FOR adding a phrase to all Levaquin tablet bottles and injection solutions that direct patients to pay close attention to all information (the "monogram" and the Patient Guide.)

Suggested phrase to put on bottles of Levaquin:

CAREFULLY READ PRODUCT INFORMATION BEFORE USING, DO NOT DISCARD INFORMATION

There is no information on Levaquin bottles of recent new warnings, and no indication that small adverse reactions can build-up in the body and later start cellular events that can be painful and irreversible. If one has a MINOR reaction, sometimes it does NOT slowly worsen while one completes the prescribed dose. It can stabilize or decrease giving the patient a false sense of security. This is what happend to me in 1998; Levaquin is Floxin's "mirror" drug; Floxin was discontinued 2009) If patients read the fine print and inserts they may know this, otherwise many could be in danger.

Current communication is failing. There have been over 159,000 adverse reactions reported to the FDA on Levaquin and Floxin, and over 37,000 individual safety reports. Complaints are "the tip of the iceberg." The delayed reaction mechanism is different than other medicines with black box warnings, and Levaquin has the highest tendon rupture rate within the floroquinolone "class".

Everyone needs to see something on the bottle so they fully understand the consequences of any minor initial reaction during the course of treatment. Pharmacists cannot offer advise on medical issues. They only say: "Do you have any questions about this medicine?" Everyone has a right to know "up-front" the unique delayed reaction mechanism that can cause permanent pain. The 2008 Medication Guides are primarily not reaching the majority of patients, most only receive the fine print in the monogram.

To add one phrase this may take consulting with FDA and companies that provide the computerized services that are automatically generated when a prescription is filled. A possible decrease in sales would likely be offset by fewer lawsuits.

Information on the bottle of Levaquin 500 mg. Tablets:

"Medication should be taken with plenty of water.

Take this medication at least 2 hours before or 2 hours after magnesium or aluminum containing antacids, or other products containing calcium, iron, or zinc.

Avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication. May cause dizziness.

This medicine is dispensed as a(n) PEACH, OBLONG-SHAPED, FILM COATED TABLET with LEVAQUIN imprinted on one side and 500 imprinted on the other side. "

No mention of dangers on the bottle, often the only information read by patients, especially those with lower reading abilities, difficulty seeing, or do not speak English.

There is no cure for permanent reactions that damage tendons, cartilage, nerves, etc.. Help decrease shareholder liability, be compassionate towards public health, and decrease preventable government expenses for the disabled.

Sincerely,

Paul W. Cahan

* FISMA & OMB Memorandum M-07-16 ***

Holding 51 Shares

The Numbers Updated:

A Socially Significant Health Issue

Date Range: November 1, 1997 - Feb 2, 2010 (12+ years)

	Total Reactions	Deaths	Individual Safety Reports
Levaquin	130,578	1,600	30,735
Floxin	29,201	595	6,496
Total	159,779	2,195	37,231

Note: Statistics from Director of Statistics at FDA Mr. H. Stepper and include both Trade Name and all drugs that contain Levaquin or Floxin in the compound.

These numbers do not reflect the 'real' numbers, unknown.

Former FDA Commissioner Dr. David Kessler is cited as concluding that only about one percent (1%) of serious adverse reactions are ever reported to the FDA (8th paragraph,website)

http://occupational-therapy.advanceweb.com/Article/Is-Med-Watch-Looking-for-You.aspx

It is important to note again, that the proposal does not seek a true 'label' change, but only that a phrase be added that calls attention to already provided information.

Details about Phrase that Proxy suggests to add:

It is quite ironic, that on the Tylenol bottle, an over the counter, commonly used medication, in fact a household name, a phrase that is prominently on the bottle says:

READ THE LABEL

there are arrows in both directions to the left and the right of these three words.

Also, on the Excedrin label it says:

"READ ALL PRODUCT INFORMATION BEFORE USING

KEEP BOX FOR IMPORTANT INFORMATION"

Is it still assumed that physicians, when they write a prescription, review adverse effects with patients?

Is it assumed that pharmacists tell people about the adverse effects of Levaquin, and tell them to carefully read everything?

Do patients read all the fine print when they are given a prescription medication?

NO to both of these, in this day and age.

So why are over the counter medications asking people to make sure they read all information, and it's not asked of patients who take the most dangerous medications? If only George Orwell were still alive.

This letter requesting the reconsideration of your decision will provide updated information that will prove the Shareholder Proxy transcends ordinary business; it will discuss a newly discovered example of a similar Shareholder Proxy about labels and how they are sold, which was allowed to go to a shareholder vote at Safeway Inc.. regarding disclosure of genetically engineered food products. The public needs far more awareness than is currently of general knowledge from people who are prescribed Levaquin in the US. It is indeed a significant social policy issue global in nature and the proposal seeks to only begin to remedy this serious education gap.

An important part of the proxy statement:

"... and **Levaquin has the highest tendon rupture rate** within the floroquinolone class of antibiotics." From the 2011 Institute for Safe Medication Practices:

http://www.ismp.org/QuarterWatch/2010Q2.pdf

The QuarterWatch report states not only was Levaquin suspect in more reports of serious injury **than any other antibiotic,** but substantially at much higher incidence levels then other drugs within the same class. The serious injuries not only involved tendon rupture but muscle, tendon, and joint ligament injuries. The current safety label also warns of potential for irreversible nerve damage that can impact the musculoskeletal system. The warnings fail to warn of the degenerative nature of such types of serious injury. While all drugs in this class carry a UNIFORM BLACK BOX Warning, it **does not disclose the higher frequency** of which these serious adverse events are being reported with Levaquin.

2011 Quarterly Newsletter from the Institute for Safe Medication Practices supports the data of findings of regulatory agencies globally whose documents were provided in the original proxy. Significantly higher incidence of serious safety report signals impact public health globally.

The public and shareholders have the right to be informed, and vote on such disclosure, and in the long run protects shareholders from shareholder lawsuits against the company in cases where they were not told ahead of time what was happening to patients, non-disclosure of serious adverse events (ie: Merck's Viiox) can result in high legal costs that reduce shareholder value and lead to other lawsuits, lowering shareholder value even further.

http://www.law.cornell.edu/supct/html/08-905.ZO.html

The SEC rules indicate that proposals are not excludable where the underlying subject matter of a proposal:

- transcends the day-to-day business matters of the company;
- raises policy issues so significant that it would be appropriate for a shareholder vote; and
- poses sufficient nexus between the nature of the proposal and the company

When a pharmaceutical company's ordinary business operations include suppressing important data for whatever reasons, consequences will inevitably follow, as evidenced historically with drugs that have posed significant serious harm to public health globally. The public in general and shareholders in particular have the right to be informed. Investors seek disclosure of company practices in the belief that they impact shareholder value.

Black Boxed Tendon Rupture Warnings remain inadequate. They do not report the significantly higher reaction incidence for Levaquin. The higher serious incidence reports for Levaquin do not just pertain to tendon rupture, but tendons, muscle, joints, ligaments. While the black box warnings state that concomitant steroid use increases such risk, this does not convey to the public or prescribing physicians that utilizing corticosteroids to treat such reactions once they occur, may place patients at higher risk as ruptures are known to occur months after exposure. (With or without concomitant steroid use)

The Black Box warning for tendons **fails to disclose the degenerative nature of such events and/or the degenerative nature of serious events that impact both tendons, the musculoskeletal system, and peripheral nerves.** The Company's credo of patient safety falls short, when the higher incidence of such serious reactions are not disclosed to shareholders and the public.

Unless all patients are directed to **make sure that they read all the fine print information they possibly can, despite it's insufficiencies, then we are accessories to a possible serious assault on each and every patients health and well being.**

(Please see attachments of the fine print information on the Patient "monographs" that they are given at the point of purchase.)

Since the elderly, those on corticosteroids, and those having received transplants are highlighted, it could lead many patients who even read the black box warning, to take the warning less seriously who are not in those medical or demographic groups. These people are less likely to question their physician on the need for the most risky antibiotic to treat their infection, since they do not know that it is such a risky product to begin with. If they do not read the material, they are less likely to even call their physician with a minor symptom. (which all antibiotics have to some extent.) People are used to taking antibiotics and having a mild stomach ache, but it went away when the course of antibiotics was over.

What else can account for the ongoing high rate of tendon ruptures? Please note also, there are likely MORE injuries that have multiple tendon tears and chronic tendinosis than actual tears, and unfortunately these people are not being chosen in current class-action suits; there are more people suffering than accountable for.

PROOF: A study from the Netherlands mentioned this point. This quote is from the Minnesota trial transcript from last year, when John Schedin sued J&J for his tendon ruptures:

"Paul Van der Linden in the Netherlands whose four studies, including his PhD thesis, talked about how Floxin (Levaquin's "mirror' drug) was worse than the rest, focused on tendinopathy and tendon rupture. **He was able to distinguish between tendinopathy and its relative risk compared to other drugs and to placebo and also tendon rupture compared to other drugs and placebo. He could do it. It was academically acceptable to people accepting his PhD thesis, but that was not good enough for Johnson & Johnson. The reason? Because there were fewer tendon ruptures than tendinopathies,** and as a result the relative risk was going to show lower, they would get a better number. They manipulated the power estimates of the study.

http://www.mnd.uscourts.gov/MDL-Levaquin/Transcripts/2010/092810.pdf

Also: see abbreviated transcript attached with most relevant information.

The current Black Box talks a lot about elderly, those on corticosteroids, and recent transplant patients' increased risk. This can be misleading to a lot of patients who read it.

The article below addresses the problem of floroquinolones among young athletes. Having young people affected, is certainly proof that this is a significant public policy/health issue and the Black Box Warning is not doing it's job. Studies point out that many people are given Levaquin, the most dangerous antibiotic, inappropriately. See this utilization study please:

http://www.archinte.ama-assn.org/cgi/reprint/163/5/601.pdf

Staff Legal Bulletin 14 July 2001

"We analyze the prior no-action letters that a company and a shareholder cite in support of their arguments and, where appropriate, any applicable case law. We may also conduct our own research to determine whether we have issued additional letters that support or do not support the company's and shareholder's positions.

Similar Shareholder Proxy

that was successfully brought to a vote:

SAFEWAY INC 2007 SHAREHOLDER PROXY

THAT WAS ACCEPTED BY SEC 2007

PROPOSAL 7

STOCKHOLDER PROPOSAL REGARDING LABELING PRODUCTS OF CLONING

OR GENETIC ENGINEERING

The Company has been notified by the Adrian Dominican Sisters, 1257 East Sienna Heights Drive, Adrian, MI 49221-1793, which owns 150 shares of Common Stock, that it intends to present, jointly with ASC Investment Group, Bon Secours Health System, Inc., Boston Common Asset Management, LLC, the Dominican Sisters of Oxford, MI, the Dominican Sisters of Springfield Illinois and the General Board of Pension and Health Benefits of the United Methodist Church, the following proposal for consideration at the Annual Meeting:

Attachment: SafewayIncFoodLabelProxypdf.

Label Products of Cloning or Genetic Engineering

2007 Safeway

RESOLVED: Shareholders request that the Board of Directors adopt a policy to identify and label all food products manufactured or sold by the company under the company's brand names or private labels that may contain genetically

engineered (GE) ingredients or products of

animal cloning.

Supporting Statement

- The right to know is a fundamental principle of

  democratic societies and market economics.

- The Food and Drug Administration is expected to make a decision regarding the sale of milk and meat from cloned animals by the end of 2006

- Safeway products contain corn, rice and soy, all of which potentially could be the genetically engineered variety.

Staff Legal Bulletin 14 July 2001

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Supporting Statement

- The right to know is a fundamental principle of democratic societies and market economics.
- The Food and Drug Administration is expected to make a decision regarding the sale of milk and meat from cloned animals by the end of 2006
- Safeway products contain corn, rice and soy, all of which potentially could be the genetically engineered variety.

• Safeway's O Organic line could be impacted by contamination from genetically engineered ingredients.

• Labeling is an indicator of due diligence of product ingredients.

• The global alliance Action by Churches Together took a stand supporting the "right to know" whether there are genetically engineered ingredients in the food purchased or in the seeds sown. (ReliefWeb 6/28/06)

• 132 countries, parties to the Cartagena Protocol, have agreed to documentation requirements for the export and import of genetically engineered organisms. (Financial Times 3/29/06)

• As of May 19, 2005, Alaska law requires that genetically engineered salmon be labeled as such.

Indicators that genetically engineered organisms can be difficult to control,and may be harmful to financial markets as well as to humans, animals and the environment include:

• Illegal unapproved Liberty Link long-grain rice, planted in field trials no later than 2001, was discovered to have contaminated U.S. rice supplies. (Reuters 8/28/06) This prompted Japan to suspend imports of US Rice, and the European Commission to require that rice imports be certified as free of unauthorized grain, greatly disrupting the US rice export market.

• Between 2001-2004, approximately 15,000 hectares (150 square kilometers) in four US states were planted with unapproved Bt10 corn. (New Scientist 3/23/2005)

• December 2006, U.N. Secretary General Annan cautioned that the international community lacks safeguards to prevent bioterrorism and accidental harm from biotechnology advances.

• The report Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects (National Academy of Sciences] 7/2004) states: ..."there remain sizable gaps in our ability to identify compositional changes that result from genetic modification of organisms intended for food.

• Federal District Court ruled (8/10/06) that USDA's permitting of drug-producing genetically engineered crops in Hawaii violated the Endangered Species Act and the National Environmental Policy Act.

• Genetically engineered creeping bentgrass, not yet approved commercially, escaped into wild as far as three miles from the test plot.

• Five major US agricultural weeds have developed resistance to glyphosate, the herbicide used with genetically engineered Roundup

Resistant crops. Addressing this problem includes use of additional herbicides.

• Research (Environmental Health Perspectives 6/2005) has shown that Roundup, increasingly needed on Roundup Ready crops, is toxic to human placental cells at concentrations lower than agricultural use.

The SEC recommend that the above Proxy be voted on by the shareholders of Safeway Inc. in 2007.

The supporting statement of this Proxy on "Label Products of Cloning or Genetic Engineering" was concerned with:

- the right to know
- FDA information:

  Johnson & Johnson did not voluntarily warn doctors and patients about tendon ruptures, see Exhibit E Rebuttal and

(Public citizen v. FDA,DDC No. 08-cv-005). The Attorney General of Illinois also submitted a citizen's petition to the FDA seeking action on the same issue.

"Labeling is an indicator of due diligence of product ingredients"

- This issue with Safeway Inc. Proxy is completely parallel to Levaquin regarding other countries taking measures that the US has not. Other countries have implemented more stringent safety requirements. (See attachment (EuropeanLimitedUse)

To quote from J. Schedin trial in Minnesota 2010:

(attachment pdf file)

Page 21 line 15 of trial transcript Sept. 28, 2010:

Ronald Goldser, Esq:

"They intentionally buried the warning, as I have described to you. They failed to send a dear doctor letter. There were dear doctor letters sent, if I get the countries right, in France, Italy, Belgium Germany, Austria, and I'm missing one. There were six of them, all in 2001 and early 2002, ... Was there one sent in the United States? No."

What the Safeway Proxy was afraid of was how consuming genetic engineered food was going to affect humans; and that consumers in Europe WERE being warned and made aware of genetic engineered food they were purchasing.

The entire concept of Safeway Proposal 7 that was accepted by the SEC in 2007, was that consumers have the right to know what they are purchasing, especially if, in the future, there is any evidence of negative effects of genetically engineered food products.

Socially Significant Policy Issue additional information:

There isn't a definition of what constitutes a socially significant policy issue, however, I think that the new data stated earlier on the First Quarter Report from Medwatch showing Levaquin leads in adverse reactions would be sufficient.

Updated statistics on reported adverse events to the FDA are below:

Date Range: November 1, 1997 - Feb 2, 2010 (12+ years)

	Total Reactions	Deaths	Individual Safety Reports
Levaquin	130,578	1,600	30,735
Floxin	29,201	595	6,496
Total	159,779	2,195	37,231

Note: Statistics from Director of Statistics at FDA Mr. H. Stepper and include both Trade Name and all drugs that contain Levaquin or Floxin in the compound.

Also of note regarding Social Significance:

There are endless websites in the US and abroad that where patients worldwide are reporting and discussing their reactions on-line seeking help. The same stories being reported to Medwatch are the same stories patients around the world are posting to a wide variety of forums and websites. The anecdotal reports by patients on-line, are the same as reports shown in regulatory databases. They convey that their physicians fail to warn them, fail to recognize their reactions, pain, and don't know how to treat them and cure them. The patients themselves, many come to the sites quite desperate, wanting to know how to get better, and ask why the possibility of these devastating disabling outcomes that impact multiple systems was never disclosed to them in the first place.

These websites have grown over the years, and only reflect a very small percent of the true victims of adverse effects.

It's logical to hypothesize that most victims do not find these support sites... Age, socio-economic statistics, medical condition, and long-term victims 'give up'.

A physician, Dr. Todd Plumb of Utah, experienced an adverse reaction to Levaquin. He composed a letter that patients could bring to their physicians. This letter has been used countless times, is a public document, and helps bridge the gap of knowledge, but it is used unfortunately after it's too late by patients who are experiencing great problems after taking Levaquin. When patients have to seek outside medical advise and are forced to give their own doctors information about a new malady that was caused by a medicine, that is a very significant indication of a most serious societal health problem.

IMPORTANT ADDITIONAL INFORMATION

THAT IS A SOCIALLY SIGNIFICANT ISSUE

BEYOND NORMAL BUSINESS OPERATIONS:

It is an extraordinary situation where hundreds, perhaps thousands of patients become ill, do not heal, and need to bring their own information to their physicians. Dr. Plumb wrote this letter in response to the request from people on the floroquinolone social websites, whose physicians are unaware of the adverse effects of Levaquin or do not know how to deal with it.

LETTER WRITTEN BY DR. TODD PLUMB

ST. GEORGE, UTAH

TO HELP PATIENTS EXPLAIN TO THEIR DOCTORS THE ADVERSE REACTIONS CAUSED BY

FLOROQUINOLONE ANTIBIOTICS

Dear Doctor,

As you are probably aware, the fluoroquinolone class of antibiotics is useful for certain serious infections. Unfortunately, fluoroquinolones also have a long history of serious adverse drug reactions, many of them long term. (1) As a consequence of these reactions, several of these drugsbave been removed from clinical practice or their use severely restricted. Besides the severe life threatening immediate reactions, those of a more chronic nature may occur.

The spectrum of these adverse reactions is extremely broad. Patients suffering from these reactions are often misdiagnosed, referred for a psychiatric consult or even unfairly labeled as "difficult patients."

Many physicians have not been properly educated about the severe nature of these chronic adverse reactions, some of which result in life-long disabilities. Post-marketing studies of several flouroquinolones have shown an incidence of adverse reactions much higher than were originally reported in pre-clinical studies. (1,2,3)

You are probably aware that the fluoroquinolones are eukaryotic DNA gyrase and topoisomerase inhibitors very similar to many antineoplastic agents. Because of their similar mechanisms of action, it's no surprise that fluoroquinolones and many antineoplastic agents share similar toxicity profiles. Studies have even been conducted using fluoroquinolones to inhibit neoplastic chondrocyte growth in chondrosarcoma. (4)

There are many patients who have a syndrome of associated symptoms that include, but are not limited to: CNS agitation, depression, insomnia, new-onset anxiety and panic attacks, and even elevated intracranial pressure and visual abnormalities. They may also present with peripheral neuropathy usually of the small fiber type with temperature and pain sensory aberrations, but also often

involving larger sensory and motor nerves. Spontaneous muscle activity with fasciculations, myokymia and myoclonic jerks may also occur. Many have musculoskeletal damage with degeneration of cartilage and tendons often leading to tendon rupture and severe ongoing musculoskeletal pain long after therapy has been discontinued. (1,2,3,4,5,6, 7,8)

This complex symptomatology does not usually resolve after discontinuation of the inducing fluoroquinolone and may in fact worsen. Many patients go on to have disability that may persist for years. (1) Unfortunately, such patients are often seen by many physicians from multiple specialties who, given the complex symptomatology, fail to recognize a unifying diagnosis.

The mechanism of injury is not fully apparent, but several studies have been conducted and researchers have implicated the following possible mechanisms:

1. Inhibition or disruption of the CNS GABA receptor. (9)
2. Depletion of magnesium and disruption of cellular enzymatic function. (10)
3. Disruption of mitochondrial function and energy production. (11,12)
4. Oxidative injury and cellular death. (14)

This seems to be a functional disorder and structural abnormalities are not usually seen on radiological studies. (13) Patients may have abnormal EMG/NCV studies, abnormal skin punch neurologic density and morphology, abnormal vasomotor and sudomotor function on autonomic testing, and abnormal degeneration of tendons and cartilage on MRI. (13) There may be a large number of these patients with coexisting endocrine abnormalities including: antithyroid antibodies and abnormal thyroid function, abnormal adrenal function with either hyper or hypocortisolism, hypogonadism, hypo or hyperglycemia and possibly impaired pituitary function. (13)

Most patients suffering from these side effects have a very clear onset of symptoms temporally related to a course of fluoroquinolone antibiotic. (13) They were often given the fluoroquinolone in conjunction with a corticosteroid or NSAID. Both of these classes of medications are associated with an increased incidence of adverse drug reaction from fluoroquinolones. (10,13)

As of yet no scientifically proven effective treatment is known, however patients will definitely benefit from your caring support and appropriate informed care. Of course, other diseases with similar symptoms need to be carefully ruled out.

There exists a large community of these patients who share information on the World Wide Web. Their numbers grow as the prescription of fluoroquinolones increases. Many of these patients are professionals like myself who have been affected by these drugs.

Thank you for your time and consideration.

Todd R. Plumb MD

15

References:

Please see attachment for copy of article, and full list of scientific references.

ALSO OF SOCIAL SIGNIFICANCE IS THE

EXTENT OF PAINFUL SMALL NERVE DAMAGE THAT

IS NOT DISCLOSED OR DIAGNOSED BUT IS OFTEN A PAINFULLY CHRONIC MALADY

Dr. Plumb's letter discusses peripheral neuropathy being typically of small nerve fiber type. Typically patients being evaluated for PN often only have EMG and Nerve Conduction studies that do not detect small fiber neuropathies that are noted in the current warning where it says (small fiber nerves).

Many patients' painful nerve damage to small fiber nerves goes undiagnosed and not disclosed in their medical records There are tests (small fiber Skin Punch Biopsy) which detects small fiber nerve density loss but unfortunately this test is only done at a few facilities in the USA, therefore many patients nerve damage is not documented. It can be done at Johns Hopkins, Massachusettes General Hospital, and a few others.

Social Significant Issue Continued:

VICTIMS SEEK MEDICAL HELP
FROM THOUSANDS OF MILES AWAY

In addition, many victims of Levaquin toxicity have gone to great lengths to try and get help. Many have flown to see an expert in Dr. Flockhart, in Indianna. Many have gone to the Mayo Clinic. No-one has walked away with a cure, I can safely say that nearly all have walked away from these appointments with great disappointment.

Note: All the bottles of floroquinolones have the same label and phrases in terms of no added indicators regarding the importance of reading the fine print information that is given to them by the pharmacies. If Levaquin helps the situation, other companies may follow suit. A ripple effect can follow globally. (Cipro information below)

Date Range: November 1, 1997 - Feb 2, 2010 (12+ years)

	Total Reactions	Deaths	Individual Safety Reports
Levaquin	130,578	1,600	30,735
Floxin	29,201	595	6,496
Total	159,779	2,195	37,231
Cipro	136,388	2,461	30,647

(Cipro not manufactured by Johnson & Johnson)

Hopefully any improvement in the education process of patients who are given Levaquin will spread to other floroquinolone antibiotics, such as Cipro and Avelox. (See Attachments: Monogram Other Floroquinolones)

Note: Statistics from FDA Representative Mr. H. Stepper and include both Trade Name and all drugs that contain Levaquin or Floxin in the compound. The numbers in reality, are much higher, and unknown. Former FDA Commissioner Dr. David Kessler is cited as concluding that only "about one percent (1%) of serious adverse reactions are ever reported to the FDA " (8th paragraph,website)

http://occupational-therapy.advanceweb.com/Article/Is-Med-Watch-Looking-for-You.aspx

World Health Organization Alert:
http://www.who.int/medicines/publications/newsletter/en/news2002_1.pdf

Discussion of RISK and ORDINARY BUSINESS

Staff Legal Bulletin No 14E (CF)
Oct. 27, 2009

B) "To the extent that a proposal and supporting statement have focused on a company minimizing or eliminating operations that may adversely affect the environment or the public's health, we have not permitted companies to exclude these proposals under Rule 14a-8 (I) (7)

" On a going-forward basis, rather than focusing on whether a proposal and supporting statement relate to the company engaging in an evaluation of risk, we will instead focus on the subject matter to which the risk pertains or that gives rise to the risk."

In particular relative to the issue at hand, the "ordinary business" definition, there is ample proof of a long-standing trend of Johnson & Johnson hiding the risk of Levaquin from doctors and patients, they have acted most probably irresponsibly and put profits above their Corporate Credo. This is likely reprehensible behavior influencing decision models throughout the executive level of the company, and has likely increased shareholder risk by illegal recalls, high litigation fees, altering research results on Levaquin in Europe (attachment) and defective manufacturing practices that temporarily closed more than one plant, etc. What is most despicable, is what they did NOT say about this drug, and it's predecessor for so long, when at the same time the people of Europe were being warned. They have taken a risky path indeed; and shareholders share the burden of that risk as well as patients.

~~17~~

I hope that the SEC acknowledges the relevance of the context in which Levaquin was a part of the corporate culture of high risk at the company, and is thus of the highest Social Concern. Information that has been left out for years has injured countless patients, and has been fully or partially responsible for many deaths.

I am not asking for the drug to be totally banned; but that eventually it be used much more conservatively; our goal should be patient safety, Levaquin should be used after safer antibiotics are found to be ineffective against a particularly difficult medical situation. (See attachment:Ireland Medical Paper.

In fact;

In 2007, the Chairman of Pharmaceuticals , Christine Poon personally said to me, after a shareholder meeting I attended, 'These medications should not be used for common infections." Ms. Poon is now Dean of Ohio Business School. (Transcript of my speech was in first Rebuttal)

At this stage, I am humbly requesting that people simply be reminded how important full disclosure is with this medicine, as soon as they get the medicine, and every time they open the top of the bottle and take out a pill.

Hopefully this might make a small dent in decreasing the great tragedy that bestows thousands who are prescribed Levaquin, impacting the lives of patients, their friends, employers, and families.

One last note to ponder "Normally the quinolone class of drugs is used in patients who have failed at least one prior therapy. The patients tend to be fairly ill and require relatively acute care that often may be the last step before they are admitted into the hospital. ...By the time the physicians get to this classification, they tend to have a good idea of what bacteria is involved, what antibiotic is the most potent for the bacteria and which penetrates that particular body side the best. ...These drugs are often the last step before admission into the hospital..." Jim Hoover, for Bayer Corporation, Alaska Pharmacy and Therapeutics Committee March 19, 2004

http://www.hss.state.ak.us/dhcs/PDL/minutes_meetings_pdl/minutes_031904_pdl.pdf

~~18~~

13 Attachments:(Sent by multiple emails; computer limitations)
THANK YOU FOR YOUR PATIENCE WITH ATTACHMENTS

SECTuesdayMar8b.wpd

TykenolBottleWarning0001.pdf

SafeMedPactices20110001.pdf

EDFQUtilization Study.pdf

Illiteracy statistics.txt

FinePrintProblemAll0001.pdf

DowJonesJ&JProblemList0001.pdf

Plumb_Dear_Doctor_Letter.doc

LabelIsMonogramFinePrnt30001.pdf

ProxyTwoA.wpd

Replace: Latest sent ProxyFINALwpd

QuarterWatch20110001 pdf

SafewayIncFoodLabelProxy0001 pdf
SEC RECONSIDER pdf
J+J Trial Transcipt

From:	PAUEISMA & OMB Memorandum M-07-16 ***
Sent:	Tuesday, March 08, 2011 10:04 PM
To:	shareholderproposals
Cc:	dchia@its.jnj.com
Subject:	Exhibit Recall/ Substitution
Attachments:	LabelIsMonogramFinePrnt30001.pdf

TO: Mr. Charles Kwon:
Please accept this "recall" of a
previous exhibit. The attached, corrected, is
not upside down as previously sent.
Demonstrates the great difficulty of
reading any of the warning
information on Levaquin, Cipro, or
Avelox. They all have the same problems:
insufficient information on the bottle,
the inserted detail information put in the bag of
medicine is both visually difficult and
discouraging for a consumer to begin to read.
The "warning" section does not even say
the highest warning level words: "black box"
to gain attention.
cc: D. Chia

GENERIC NAME: LEVOFLOXACIN (lee-voe-FLOX-a-sin)

COMMON USES: This medicine is a quinolone antibiotic used for treating infections caused by certain bacteria. It may also be used to prevent or slow anthrax after exposure. This medicine is not effective for treating fungal infections or viral infections (such as the common cold).

BEFORE USING THIS MEDICINE: WARNING: This medicine is associated with an increased risk of tendon problems. These include pain, swelling, inflammation, and possible breakage of tendons. The risk of tendon problems is greater in patients who are over 60 years old, patients who take corticosteroids (eg, prednisone), and in those who have received kidney, heart, or lung transplants. The Achilles tendon in the back of the foot/ankle is most often affected. However, problems may also occur in other tendons (eg, in the arm, hand, or shoulder). Problems may occur while you take this medicine or up to several months after you stop taking it. Signs of tendon problems may include pain, soreness, redness, or swelling of a tendon or joint; bruising right after an injury in a tendon area; hearing or feeling a snap or pop in a joint or tendon area; or inability to move or bear weight on a joint or tendon area. TELL YOUR DOCTOR RIGHT AWAY if you experience any of these symptoms while you take this medicine or within several months after you stop taking it. Some medicines or medical conditions may interact with this medicine. INFORM YOUR DOCTOR OR PHARMACIST of all prescription and over-the-counter medicine that you are taking. DO NOT TAKE THIS MEDICINE if you are taking cisapride or certain antiarrhythmics (eg, amiodarone, procainamide, quinidine, sotalol). ADDITIONAL MONITORING OF YOUR DOSE OR CONDITION may be needed if you are taking antiarrhythmics, arsenic, astemizole, dofetilide, droperidol, haloperidol, imidazoles (eg, ketoconazole), macrolides (eg, erythromycin), methadone, paliperidone, phenothiazines (eg, chlorpromazine), pimozide, ranolazine, serotonin receptor antagonists (eg, dolasetron), telithromycin, terfenadine, ziprasidone, insulin, oral diabetes medicines (eg, glyburide), corticosteroids (eg, prednisone), anticoagulants (eg, warfarin), nonsteroidal anti-inflammatory drugs (NSAIDs) (eg, ibuprofen), theophylline, or serotonin norepinephrine reuptake inhibitors (SNRIs) (eg, duloxetine). DO NOT START OR STOP any medicine without doctor or pharmacist approval. Inform your doctor of any other medical conditions, including stomach infection, brain or nervous system problems, muscle problems (eg, myasthenia gravis), increased pressure in the brain, Alzheimer disease, brain blood vessel problems, allergies, pregnancy, or breast-feeding. Tell your doctor if you have a history of severe or persistent diarrhea; skin sensitivity to the sun; diabetes; low blood potassium levels; chest pain; angina; heart problems (eg, enlarged heart, heart failure); heart attack; irregular heartbeat (eg, QT prolongation); seizures; bone, joint, or tendon problems; rheumatoid arthritis; liver problems; kidney problems or decreased kidney function; or heart, kidney, or lung transplant. Tell your doctor if you have a family member with a history of fast, slow, or irregular heartbeat (eg, QT prolongation). Tell your doctor if you participate in strenuous physical work or exercise. USE OF THIS MEDICINE IS NOT RECOMMENDED if you have a certain type of irregular heartbeat (QT prolongation, long QT syndrome) or low blood potassium levels. Contact your doctor or pharmacist if you have any questions or concerns about using this medicine.

HOW TO USE THIS MEDICINE: Follow the directions for taking this medicine provided by your doctor. This medicine comes with a MEDICATION GUIDE approved by the U.S. Food and Drug Administration. Read it carefully each time you refill this medicine. Ask your doctor, nurse, or pharmacist any questions that you may have about this medicine. TAKE THIS MEDICINE BY MOUTH WITH OR WITHOUT FOOD. Drinking extra fluids while you are taking this medicine is recommended. Check with your doctor for instructions. DO NOT TAKE A PRODUCT that has magnesium or aluminum, calcium, zinc, or iron in it within 2 hours before or 2 hours after you take this medicine. Examples of these products include antacids, multivitamins, quinapril, and calcium-fortified orange juice. Check with your doctor or pharmacist if you have a question about whether you should separate this medicine from a certain food or product. IF YOU ALSO TAKE sucralfate or didanosine, do not take them within 2 hours before or 2 hours after taking this medicine. Check with your doctor if you have questions. STORE THIS MEDICINE at room temperature, between 59 and 86 degrees F (15 and 30 degrees C). Store away from heat, moisture, and light. Do not store in the bathroom. This medicine works best if it is taken at the same time each day. TO CLEAR UP YOUR INFECTION COMPLETELY, take this medicine for the full course of treatment. Keep taking it even if you feel better in a few days. Do not miss any doses of this medicine. IF YOU MISS A DOSE of this medicine, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take 2 doses at once.

CAUTIONS: DO NOT USE THIS MEDICINE if you are allergic to any ingredient in this medicine or to any other quinolone antibiotic (eg, ciprofloxacin). LAB TESTS, including liver function, kidney function, and complete blood cell counts, may be performed while you use this medicine. These tests may be used to monitor your condition or check for side effects. Be sure to keep all doctor and lab appointments. This medicine may interfere with certain LAB TESTS. Be sure your doctor and lab personnel know you are taking this medicine. THIS MEDICINE MAY CAUSE DIZZINESS OR LIGHTHEADEDNESS. These effects may be worse if you take it with alcohol or certain medicines. Use this medicine with caution. Do not drive or perform other possibly unsafe tasks until you know how you react to it. MILD DIARRHEA IS COMMON WITH ANTIBIOTIC USE. However, a more serious form of diarrhea (pseudomembranous colitis) may rarely occur. This may develop while you use the antibiotic or within several months after you stop using it. Contact your doctor right away if stomach pain or cramps, severe diarrhea, or bloody stools occur. Do not treat diarrhea without first checking with your doctor. TELL YOUR DOCTOR RIGHT AWAY if you experience pain or swelling of a tendon or weakness or loss of use of a joint area. Rest the area and avoid exercise until further instruction from your doctor. THIS MEDICINE MAY CAUSE YOU TO BECOME SUNBURNED MORE EASILY. Avoid the sun, sunlamps, or tanning booths until you know how you react to this medicine. Use a sunscreen or wear protective clothing if you must be outside for more than a short time. IF YOU ARE SCHEDULED TO RECEIVE A TYPHOID VACCINE while you are taking this medicine, talk with your doctor. This medicine may decrease the effectiveness of the vaccine. BEFORE YOU BEGIN TAKING ANY NEW MEDICINES, either prescription or over-the-counter, check with your doctor or pharmacist. Use this medicine with caution in the ELDERLY; they may be more sensitive to its effects (eg, tendon problems), especially if they take corticosteroids (eg, prednisone). They may also be more sensitive to other effects (eg, irregular heartbeat, liver problems). This medicine should be used with extreme caution in CHILDREN younger than 18 years old; they may be more sensitive to its effects, especially joint and tendon problems. FOR WOMEN: If you become pregnant, contact your doctor. You will need to discuss the benefits and risks of using this medicine while you are pregnant. This medicine is found in breast milk. Do not breast-feed while taking this medicine. DIABETES PATIENTS: This medicine may affect your blood sugar. Check blood sugar levels closely. Ask your doctor before you change the dose of your diabetes medicine.

POSSIBLE SIDE EFFECTS: SIDE EFFECTS that may occur while taking this medicine include constipation; diarrhea; dizziness; gas; headache; lightheadedness; nausea; or stomach pain. If they continue or are bothersome, check with your doctor. CONTACT YOUR DOCTOR IMMEDIATELY if you experience bloody or tarry stools; chest pain; decreased or painful urination; fainting; fast or irregular heartbeat; fever, chills, sore throat, or unusual cough; hallucinations; inability to move or bear weight on a joint or tendon area; moderate or severe sunburn; mood or mental changes (eg, agitation, confusion, depression, nervousness, new or worsening anxiety, restlessness, sleeplessness); muscle pain or weakness; new or worsening nightmares; pain, soreness, redness, swelling, weakness, or bruising of a tendon or joint area; red, swollen, blistered, or peeling skin; seizures; severe or persistent diarrhea; severe or persistent dizziness, lightheadedness, tiredness, or weakness; severe or persistent stomach pain/cramps; shortness of breath; suicidal thoughts or actions; symptoms of high or low blood sugar (eg, dizziness; fainting; fast breathing; flushing; increased sweating; increased thirst, hunger, or urination); vision changes; symptoms of liver problems (eg, dark urine, loss of appetite, pale stools, yellowing of the skin or eyes); symptoms of nerve problems (eg, changes in perception of heat or cold; decreased sensation of touch; unusual burning, numbness, tingling, pain, or weakness of the arms, hands, legs, or feet); tremors; unusual bruising or bleeding; vaginal discharge, irritation, or odor; vision changes; or wheezing. AN ALLERGIC REACTION to this medicine is unlikely, but seek immediate medical attention if it occurs. Symptoms of an allergic reaction include rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue; or unusual hoarseness. If you notice other effects not listed above, contact your doctor, nurse, or pharmacist. This is not a complete list of all side effects that may occur. If you have questions about side effects, contact your healthcare provider. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

OVERDOSE: If overdose is suspected, contact your local poison control center or emergency room immediately.

ADDITIONAL INFORMATION: DO NOT SHARE THIS MEDICINE with others for whom it was not prescribed. DO NOT USE THIS MEDICINE for other health conditions. KEEP THIS MEDICINE out of the reach of children and pets.

The information in this monograph is not intended to cover all possible uses, directions, precautions, drug interactions, or adverse effects. This information is generalized and is not intended as specific medical advice. If you have

CVS/pharmacy
200 BROADWAY, VAN HOUTEN AVE
PASSAIC, NJ
07055
#2724 Ph: 973.594-4041
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PATIENT PRESCRIPTION INFORMATION
IF YOU HAVE ANY QUESTIONS ABOUT YOUR MEDICATION, PLEASE CONTACT YOUR PHARMACIST:
MOON KIM,RPh.

03/06/2011
Presbr: MILTON LEONARD WARNBERG
Refills: 0

*** FISMA & OMB Memorandum M-07-16 ***

AVELOX 400 MG TABLET
SCHERING CORP.

TAKE AS DIRECTED FOR 1 DOSE

This is a DULL RED, OBLONG-shaped TABLET imprinted with M400 on the front and BAYER on the back.

MOXIFLOXACIN - ORAL - (mox-ih-FLOX-uh-sin)
COMMON BRAND NAME(S):
Avelox
WARNING:
This medication may rarely cause tendon damage (e.g., tendinitis, tendon rupture) during or after treatment. Your risk for tendon problems is greater if you are over 60 years of age, if you are taking corticosteroids (such as prednisone), or if you have had a kidney, heart or lung transplant. Stop exercising, rest, and seek immediate medical attention if you develop joint/muscle/tendon pain or swelling.
USES:
Moxifloxacin is used to treat a variety of bacterial infections. This medication belongs to a class of drugs called quinolone antibiotics. It works by stopping the growth of bacteria. This antibiotic treats only bacterial infections. It will not work for virus infections (e.g., common cold, flu). Unnecessary use or overuse of any antibiotic can lead to its decreased effectiveness.
HOW TO USE:
Read the Medication Guide and, if available, the Patient Information Leaflet provided by your pharmacist before you start using moxifloxacin and each time you get a refill. If you have any questions regarding the information, consult your doctor or pharmacist. Take this medication by mouth with or without food, usually once daily or as directed by your doctor. The dosage and length of treatment is based on your medical condition and response to treatment. Drink plenty of fluids while taking this drug unless your doctor tells you otherwise. Take this medication at least 4 hours before or 8 hours after taking any drugs that contain magnesium or aluminum. Some examples include quinapril, certain forms of didanosine (chewable/dispersible buffered tablets or pediatric oral solution), vitamins/minerals, and antacids. Follow the same instructions if you take bismuth subsalicylate, sucralfate, iron, and zinc. These medications bind with moxifloxacin and prevent its full absorption. Antibiotics work best when the amount of medicine in your body is kept at a constant level. It is important not to miss a dose. To help you remember, take this medication at the same time every day. Continue to take this medication until the full prescribed amount is finished, even if symptoms disappear after a few days. Stopping the medication too early may allow bacteria to continue to grow, which may result in a return of the infection. Tell your doctor if your condition persists or worsens.
SIDE EFFECTS:
See also Warning section. Nausea, diarrhea, dizziness, lightheadedness, headache, weakness, or trouble sleeping may occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly. Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor immediately if any of these unlikely but serious side effects occur: mental/mood changes (e.g., anxiety, confusion, hallucinations, depression, rare thoughts of suicide), shaking (tremors). Tell your doctor immediately if any of these rare but very serious side effects occur: unusual bruising/bleeding, severe/persistent headache, signs of a new infection (e.g., new/persistent fever, persistent sore throat), unusual change in the amount of urine, signs of liver problems (e.g., unusual tiredness, stomach/abdominal pain, persistent nausea/vomiting, yellowing eyes/skin, dark urine). Seek immediate medical attention if any of these rare but very serious side effects occur: severe dizziness, fainting, fast/irregular heartbeat, seizures. Moxifloxacin may rarely cause serious nerve problems that may be reversible if identified and treated early. Seek immediate medical attention if you develop any of the following symptoms: pain/numbness/burning/tingling/weakness in any part of the body, changes in how you sense touch/pain/temperature/body position/vibration. This medication may rarely cause a severe intestinal condition (Clostridium difficile-associated diarrhea) due to a type of resistant bacteria. This condition may occur during treatment or weeks to months after treatment has stopped. Do not use anti-diarrhea products or narcotic pain medications if you have any of the following symptoms because these products may make them worse. Tell your doctor immediately if you develop: persistent diarrhea, abdominal or stomach pain/cramping, blood/mucus in your stool. Use of this medication for prolonged or repeated periods may result in oral thrush or a new vaginal yeast infection. Contact your doctor if you notice white patches in your mouth, a change in vaginal discharge, or other new symptoms. A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any of the following symptoms of a serious allergic reaction: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US - Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.
PRECAUTIONS:
Before taking moxifloxacin, tell your doctor or pharmacist if you are allergic to it; or to other quinolone antibiotics (e.g., ciprofloxacin, levofloxacin); or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details. Before using this medication, tell your doctor or pharmacist your medical history, especially of: diabetes, heart problems (e.g., recent heart attack), joint/tendon problems (e.g., tendonitis, bursitis), liver disease, nervous system disorder (e.g., peripheral neuropathy), seizure disorder, conditions that increase your risk of seizures (e.g., brain/head injury, brain tumors, cerebral atherosclerosis). Moxifloxacin may cause a condition that affects the heart rhythm (QT prolongation). QT prolongation can infrequently result in serious (rarely fatal) fast/irregular heartbeat and other symptoms (such as severe dizziness, fainting) that require immediate medical attention. The risk of QT prolongation may be increased if you have certain medical conditions or are taking other drugs that may affect the heart rhythm (see also Drug Interactions section). Before using moxifloxacin, tell your doctor or pharmacist if you have any of the following conditions: certain heart problems (heart failure, slow heartbeat, QT prolongation in the EKG), family history of certain heart problems (QT prolongation in the EKG, sudden cardiac death). Low levels of potassium or magnesium in the blood may also increase your risk of QT prolongation. This risk may increase if you use certain drugs (such

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PATIENT PRESCRIPTION INFORMATION

IF YOU HAVE ANY QUESTIONS ABOUT YOUR MEDICATION, PLEASE CONTACT YOUR PHARMACIST:
MOON KIM,RPh.

03/06/2011
Prescr: MILTON LEONARD WARNER
Refills: 0

*** FISMA & OMB Memorandum M-07-16 ***

CIPROFLOXACIN HCL 500 MG TAB
WATSON LABS
TAKE AS DIRECTED FOR 1 DOSE

This is a WHITE, OBLONG-shaped TABLET imprinted with LOGO on the front and CR 500 on the back.

CIPROFLOXACIN - ORAL - (sip-row-FLOX-ah-sin)
COMMON BRAND NAME(S):
Cipro
WARNING:
This medication may rarely cause tendon damage (e.g., tendonitis, tendon rupture) during or after treatment. Your risk for tendon problems is greater if you are over 60 years of age, if you are taking corticosteroids (such as prednisone), or if you have a kidney, heart or lung transplant. Stop exercising, rest, and seek immediate medical attention if you develop joint/muscle/tendon pain or swelling.
USES:
This medication is used to treat a variety of bacterial infections. Ciprofloxacin belongs to a class of drugs called quinolone antibiotics. It works by stopping the growth of bacteria. This antibiotic treats only bacterial infections. It will not work for virus infections (e.g., common cold, flu). Unnecessary use or overuse of any antibiotic can lead to its decreased effectiveness.
HOW TO USE:
Read the Medication Guide provided by your pharmacist before you start using ciprofloxacin and each time you get a refill. If you have any questions, consult your doctor or pharmacist. This medication may be taken with or without food, usually twice a day in the morning and evening or as directed by your doctor. The dosage and length of treatment is based on your medical condition and response to treatment. Drink plenty of fluids while taking this medication unless your doctor tells you otherwise. Take this medication at least 2 hours before or 6 hours after taking other products that may bind to it, decreasing its effectiveness. Ask your pharmacist about the other products you take. Some examples include: quinapril, vitamins/minerals (including iron and zinc supplements), and products containing magnesium, aluminum, or calcium (such as antacids, didanosine solution, calcium supplements). Calcium-rich foods, including dairy products (such as milk, yogurt) or calcium-enriched juice, can also decrease the effect of this medication. Take this medication at least 2 hours before or 6 hours after eating calcium-rich foods, unless you are eating these foods as part of a larger meal that contains other (non-calcium-rich) foods. These other foods decrease the calcium binding effect. Ask your doctor or pharmacist about safely using nutritional supplements/replacements with this medication. Antibiotics work best when the amount of medicine in your body is kept at a constant level. It is important not to miss a dose. To help you remember and to keep the drug at a constant level, take it at the same times every day. Continue to take this medication until the full prescribed amount is finished, even if symptoms disappear after a few days. Stopping the medication too early may allow bacteria to continue to grow, which may result in a return of the infection. Tell your doctor if your condition persists or worsens.
SIDE EFFECTS:
See also Warning section. Nausea, diarrhea, dizziness, lightheadedness, headache, or trouble sleeping may occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly. Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor immediately if any of these unlikely but serious side effects occur: mental/mood changes (e.g., anxiety, confusion, hallucinations, depression, rare thoughts of suicide), shaking (tremors), skin that sunburns more easily (sun sensitivity). Ciprofloxacin may rarely cause serious nerve problems that may be reversible if identified and treated early. Seek immediate medical attention if you develop any of the following symptoms: pain/numbness/burning/tingling/weakness in any part of the body, changes in how you sense touch/pain/temperature/body position/vibration. Tell your doctor immediately if any of these rare but very serious side effects occur: unusual bruising/bleeding, severe/persistent headache, signs of a new infection (e.g., new/persistent fever, persistent sore throat), unusual change in the amount of urine, change in color of urine (red/pink urine), signs of liver problems (e.g., unusual tiredness, stomach/abdominal pain, persistent nausea/vomiting, yellowing eyes/skin, dark urine), vision changes. Seek immediate medical attention if any of these rare but very serious side effects occur: severe dizziness, fainting, fast/irregular heartbeat, seizures. This medication may rarely cause a severe intestinal condition (Clostridium difficile-associated diarrhea) due to a type of resistant bacteria. This condition may occur during treatment or weeks to months after treatment has stopped. Do not use anti-diarrhea products or narcotic pain medications if you have any of the following symptoms because these products may make them worse. Tell your doctor immediately if you develop: persistent diarrhea, abdominal or stomach pain/cramping, blood/mucus in your stool. Use of this medication for prolonged or repeated periods may result in oral thrush or a new vaginal yeast infection. Contact your doctor if you notice white patches in your mouth, a change in vaginal discharge, or other new symptoms. A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any of the following symptoms of a serious allergic reaction: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US - Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.
PRECAUTIONS:
Before taking ciprofloxacin, tell your doctor or pharmacist if you are allergic to it; or to other quinolone antibiotics such as norfloxacin, gemifloxacin, levofloxacin, moxifloxacin, or ofloxacin; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details. Before using this medication, tell your doctor or pharmacist your medical history, especially of: diabetes, heart problems (e.g., recent heart attack), joint/tendon problems (e.g., tendonitis, bursitis), kidney disease, liver disease, nervous system disorder (e.g., peripheral neuropathy), seizure disorder, conditions that increase your risk of seizures (e.g., brain/head injury, brain tumors, cerebral atherosclerosis). Ciprofloxacin may cause a condition that affects the heart rhythm (QT prolongation). QT prolongation can infrequently result in serious (rarely fatal) fast/irregular heartbeat and other symptoms (such as severe dizziness, fainting)

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For faster refills, phone in 24 hours in advance

Keep Out of Reach of Children

CVS Item# 715078

IMPORTANT DISCLAIMER: The side effects listed above are not all of the possible risks that could be caused by this medication. For further information, please consult with your physician about the uses, precautions and risks of the medication specific to your health. This information is obtained from First DataBank for use as an educational aid.

that require immediate medical attention. The risk of QT prolongation may be increased if you have certain medical conditions or are taking other drugs that may affect the heart rhythm (see also Drug Interactions section). Before using ciprofloxacin, tell your doctor or pharmacist if you have any of the following conditions: certain heart problems (heart failure, slow heartbeat, QT prolongation in the EKG), family history of certain heart problems (QT prolongation in the EKG, sudden cardiac death). Low levels of potassium or magnesium in the blood may also increase your risk of QT prolongation. This risk may increase if you use certain drugs (such as diuretics/"water pills") or if you have conditions such as severe sweating, diarrhea, or vomiting. Talk to your doctor about using ciprofloxacin safely. This medication may rarely cause serious changes in blood sugar levels, especially if you have diabetes. Watch for symptoms of high blood sugar including increased thirst and urination. Also watch for symptoms of low blood sugar such as nervousness, shakiness, fast heartbeat, sweating, or hunger. Check your blood sugar regularly as directed by your doctor and report any changes. If you experience symptoms of low blood sugar, you may raise your blood sugar by using glucose tablets/gel or eating a quick source of sugar such as table sugar, honey, or candy, or drink fruit juice or non-diet soda. Tell your doctor immediately about the reaction and the use of this product. To help prevent low blood sugar, eat meals on a regular schedule, and do not skip meals. This drug may make you dizzy. Do not drive, use machinery, or do any activity that requires alertness until you are sure you can perform such activities safely. Limit alcoholic beverages. This medication may make you more sensitive to the sun. Avoid prolonged sun exposure, tanning booths, and sunlamps. Use a sunscreen and wear protective clothing when outdoors. Caution is advised when using this drug in children because they may be more sensitive to its possible side effects (e.g., joint/tendon problems). Discuss the risks and benefits with the doctor. Kidney function declines as you grow older. This medication is removed by the kidneys. Therefore, older adults may be more sensitive to its side effects such as tendon problems (especially if they are also taking corticosteroids such as prednisone or hydrocortisone) or heart problems. Discuss the risks and benefits with your doctor. During pregnancy, this medication should be used only when clearly needed. Discuss the risks and benefits with your doctor. This medication passes into breast milk. Consult your doctor before breast-feeding.

DRUG INTERACTIONS:

See also the How to Use section. The effects of some drugs can change if you take other drugs or herbal products at the same time. This can increase your risk for serious side effects or may cause your medications not to work correctly. These drug interactions are possible, but do not always occur. Your doctor or pharmacist can often prevent or manage interactions by changing how you use your medications or by close monitoring. To help your doctor and pharmacist give you the best care, be sure to tell your doctor and pharmacist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products) before starting treatment with this product. While using this product, do not start, stop, or change the dosage of any other medicines you are using without your doctor's approval. Some products that may interact with this drug include: live bacterial vaccines (e.g., typhoid, BCG), "blood thinners" (e.g., warfarin), corticosteroids (e.g., prednisone, hydrocortisone), cyclosporine, drugs removed from your body by certain liver enzymes (such as clozapine, duloxetine, phenytoin, ropinirole, tacrine), drugs for diabetes (e.g., glyburide, insulin), methotrexate, nonsteroidal anti-inflammatory drugs (NSAIDs such as ibuprofen, naproxen), probenecid, sevelamer, strontium, tizanidine, theophylline, urinary alkalinizers (e.g., potassium/sodium citrate). Many drugs besides ciprofloxacin may affect the heart rhythm (QT prolongation), including amiodarone, dofetilide, quinidine, procainamide, sotalol, certain macrolide antibiotics (e.g., erythromycin, clarithromycin), and certain antipsychotic medications (e.g., pimozide, thioridazine, ziprasidone), among others. Also report the use of drugs that might increase seizure risk when combined with this medication such as isoniazid (INH), phenothiazines (e.g., chlorpromazine), or tricyclic antidepressants (e.g., amitriptyline), among others. Consult your doctor or pharmacist for details. Avoid drinking large amounts of beverages containing caffeine (coffee, tea, colas), eating large amounts of chocolate, or taking over-the-counter products that contain caffeine to keep you awake and alert. This drug may increase and/or prolong the effects of caffeine. Although most antibiotics probably do not affect hormonal birth control such as pills, patch, or ring, some antibiotics may decrease their effectiveness. This could cause pregnancy. Examples include rifamycins such as rifampin or rifabutin. Be sure to ask your doctor or pharmacist if you should use additional reliable birth control methods while using this antibiotic. This document does not contain all possible drug interactions. Keep a list of all the products you use. Share this list with your doctor and pharmacist to lessen your risk for serious medication problems.

OVERDOSE:

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US National Poison Hotline at 1-800-222-1222. Canada residents can call a provincial poison control center.

NOTES:

Do not share this medication with others. This medication has been prescribed for your current condition only. Do not use it later for another infection unless told to do so by your doctor. A different medication may be necessary in those cases. Laboratory and/or medical tests (e.g., kidney function, blood counts, cultures) should be performed periodically to monitor your progress or check for side effects. Consult your doctor for more details.

MISSED DOSE:

If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE:

Store at room temperature below 86 degrees F (30 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product.

drug may make you dizzy. Do not drive, use machinery, or do any activity that requires alertness until you are sure you can perform such activities safely. Limit alcoholic beverages. This medication may make you more sensitive to the sun. Avoid prolonged sun exposure, tanning booths, and sunlamps. Use a sunscreen and wear protective clothing when outdoors. Caution is advised when using this drug in children because they may be more sensitive to its possible side effects (e.g., joint/tendon problems). Discuss the risks and benefits with the doctor. Older adults may be more sensitive to the side effects of this medication such as heart problems or tendon problems. The risk for tendon problems is higher if they are also taking corticosteroids (e.g., prednisone, hydrocortisone). During pregnancy, this medication should be used only when clearly needed. Discuss the risks and benefits with your doctor. It is unknown if this drug passes into breast milk. Consult your doctor before breast-feeding.

DRUG INTERACTIONS:

See also How to Use section. Your doctor or pharmacist may already be aware of any possible drug interactions and may be monitoring you for them. Do not start, stop, or change the dosage of any medicine before checking with them first. This drug should not be used with the following medication because very serious interactions may occur: strontium. If you are currently using the medication listed above, tell your doctor or pharmacist before starting moxifloxacin. Many drugs besides moxifloxacin may affect the heart rhythm (QT prolongation), including amiodarone, dofetilide, procainamide, quinidine, sotalol, certain macrolide antibiotics (e.g., erythromycin, clarithromycin), and certain antipsychotic medications (e.g., pimozide, thioridazine, ziprasidone), among others. Therefore, before using moxifloxacin, report all medications you are currently using to your doctor or pharmacist. Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: live bacterial vaccines (e.g., typhoid, BCG), corticosteroids (e.g., prednisone, hydrocortisone), drugs for diabetes (e.g., glyburide, insulin), nonsteroidal anti-inflammatory drugs (NSAIDs such as ibuprofen, naproxen), warfarin. Also report the use of drugs that might increase seizure risk when combined with this medication such as isoniazid (INH), phenothiazines (e.g., chlorpromazine), theophylline, or tricyclic antidepressants (e.g., amitriptyline), among others. Consult your doctor or pharmacist for details. Although most antibiotics probably do not affect hormonal birth control such as pills, patch, or ring, some antibiotics may decrease their effectiveness. This could cause pregnancy. Examples include rifamycins such as rifampin or rifabutin. Be sure to ask your doctor or pharmacist if you should use additional reliable birth control methods while using this antibiotic. This document does not contain all possible interactions. Therefore, before using this product, tell your doctor or pharmacist of all the products you use. Keep a list of all your medications with you, and share the list with your doctor and pharmacist.

OVERDOSE:

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US National Poison Hotline at 1-800-222-1222. Canada residents can call a provincial poison control center.

NOTES:

Do not share this medication with others. This medication has been prescribed for your current condition only. Do not use it later for another infection unless told to do so by your doctor. A different medication may be necessary in that case. Laboratory and/or medical tests (e.g., liver function, complete blood count, blood glucose) should be performed periodically to monitor your progress or check for side effects. Consult your doctor for more details.

MISSED DOSE:

If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE:

Store at room temperature at 77 degrees F (25 degrees C) away from light and moisture. Brief storage between 59-86 degrees F (15-30 degrees C) is permitted. Do not store in the bathroom. Keep all medicines away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product.

From:	PAUBMA & OMB Memorandum M-07-16 ***
Sent:	Tuesday, March 08, 2011 4:25 PM
To:	shareholderproposals
Cc:	dchia@its.jnj.com
Subject:	Third Page Proxy: Paul Cahan
Attachments:	FinePrintProblemAll0001.pdf; DowJonesJ&JProblemList0001.pdf; Plumb_Dear_Doctor_Letter.doc

Proxy Reconsideration Continued.
attachments.
Problem industry-wide
2011 Report of Corporate problems
Social Significant Issue: Letter patients have to use who have adverse reactions when seeing their own doctors.

CVS/pharmacy
1350 BROADWAY, VAN HOUTEN AVE
PASSAIC, NJ
07055

#2724 Ph: 973.594-4041
www.cvs.com

PATIENT PRESCRIPTION INFORMATION
IF YOU HAVE ANY QUESTIONS ABOUT YOUR MEDICATION, PLEASE CONTACT YOUR PHARMACIST:
MOON KIM,RPh.

*** FISMA & OMB Memorandum M-07-16 ***

03/06/2011
Prescr: MILTON LEONARD WEISBERG
Refills: 0

CIPROFLOXACIN HCL 500 MG TAB
WATSON LABS

TAKE AS DIRECTED FOR 1 DOSE

This is a WHITE, OBLONG-shaped TABLET imprinted with LOGO on the front and CR 500 on the back.

CIPROFLOXACIN - ORAL - (sip-row-FLOX-ah-sin)
COMMON BRAND NAME(S):
Cipro
WARNING:
This medication may rarely cause tendon damage (e.g., tendonitis, tendon rupture) during or after treatment. Your risk for tendon problems is greater if you are over 60 years of age, if you are taking corticosteroids (such as prednisone), or if you have a kidney, heart or lung transplant. Stop exercising, rest, and seek immediate medical attention if you develop joint/muscle/tendon pain or swelling.
USES:
This medication is used to treat a variety of bacterial infections. Ciprofloxacin belongs to a class of drugs called quinolone antibiotics. It works by stopping the growth of bacteria. This antibiotic treats only bacterial infections. It will not work for virus infections (e.g., common cold, flu). Unnecessary use or overuse of any antibiotic can lead to its decreased effectiveness.
HOW TO USE:
Read the Medication Guide provided by your pharmacist before you start using ciprofloxacin and each time you get a refill. If you have any questions, consult your doctor or pharmacist. This medication may be taken with or without food, usually twice a day in the morning and evening or as directed by your doctor. The dosage and length of treatment is based on your medical condition and response to treatment. Drink plenty of fluids while taking this medication unless your doctor tells you otherwise. Take this medication at least 2 hours before or 6 hours after taking other products that may bind to it, decreasing its effectiveness. Ask your pharmacist about the other products you take. Some examples include: quinapril, vitamins/minerals (including iron and zinc supplements), and products containing magnesium, aluminum, or calcium (such as antacids, didanosine solution, calcium supplements). Calcium-rich foods, including dairy products (such as milk, yogurt) or calcium-enriched juice, can also decrease the effect of this medication. Take this medication at least 2 hours before or 6 hours after eating calcium-rich foods, unless you are eating these foods as part of a larger meal that contains other (non-calcium-rich) foods. These other foods decrease the calcium binding effect. Ask your doctor or pharmacist about safely using nutritional supplements/replacements with this medication. Antibiotics work best when the amount of medicine in your body is kept at a constant level. It is important not to miss a dose. To help you remember and to keep the drug at a constant level, take it at the same times every day. Continue to take this medication until the full prescribed amount is finished, even if symptoms disappear after a few days. Stopping the medication too early may allow bacteria to continue to grow, which may result in a return of the infection. Tell your doctor if your condition persists or worsens.
SIDE EFFECTS:
See also Warning section. Nausea, diarrhea, dizziness, lightheadedness, headache, or trouble sleeping may occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly. Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor immediately if any of these unlikely but serious side effects occur: mental/mood changes (e.g., anxiety, confusion, hallucinations, depression, rare thoughts of suicide), shaking (tremors), skin that sunburns more easily (sun sensitivity). Ciprofloxacin may rarely cause serious nerve problems that may be reversible if identified and treated early. Seek immediate medical attention if you develop any of the following symptoms: pain/numbness/burning/tingling/weakness in any part of the body, changes in how you sense touch/pain/temperature/body position/vibration. Tell your doctor immediately if any of these rare but very serious side effects occur: unusual bruising/bleeding, severe/persistent headache, signs of a new infection (e.g., new/persistent fever, persistent sore throat), unusual change in the amount of urine, change in color of urine (red/pink urine), signs of liver problems (e.g., unusual tiredness, stomach/abdominal pain, persistent nausea/vomiting, yellowing eyes/skin, dark urine), vision changes. Seek immediate medical attention if any of these rare but very serious side effects occur: severe dizziness, fainting, fast/irregular heartbeat, seizures. This medication may rarely cause a severe intestinal condition (Clostridium difficile-associated diarrhea) due to a type of resistant bacteria. This condition may occur during treatment or weeks to months after treatment has stopped. Do not use anti-diarrhea products or narcotic pain medications if you have any of the following symptoms because these products may make them worse. Tell your doctor immediately if you develop: persistent diarrhea, abdominal or stomach pain/cramping, blood/mucus in your stool. Use of this medication for prolonged or repeated periods may result in oral thrush or a new vaginal yeast infection. Contact your doctor if you notice white patches in your mouth, a change in vaginal discharge, or other new symptoms. A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any of the following symptoms of a serious allergic reaction: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US - Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.
PRECAUTIONS:
Before taking ciprofloxacin, tell your doctor or pharmacist if you are allergic to it; or to other quinolone antibiotics such as norfloxacin, gemifloxacin, levofloxacin, moxifloxacin, or ofloxacin; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details. Before using this medication, tell your doctor or pharmacist your medical history, especially of: diabetes, heart problems (e.g., recent heart attack), joint/tendon problems (e.g., tendonitis, bursitis), kidney disease, liver disease, nervous system disorder (e.g., peripheral neuropathy), seizure disorder, conditions that increase your risk of seizures (e.g., brain/head injury, brain tumors, cerebral atherosclerosis). Ciprofloxacin may cause a condition that affects the heart rhythm (QT prolongation). QT prolongation can infrequently result in serious (rarely fatal) fast/irregular heartbeat and other symptoms (such as severe dizziness, fainting)

Continued on reverse side.

Dear Doctor,

As you are probably aware, the fluoroquinolone class of antibiotics is useful for certain serious infections. Unfortunately, fluoroquinolones also have a long history of serious adverse drug reactions, many of them long term . (1) As a consequence of these reactions, several of these drugs have been removed from clinical practice or their use severely restricted. Besides the severe life threatening immediate reactions, those of a more chronic nature may occur.

The spectrum of these adverse reactions is extremely broad. Patients suffering from these reactions are often misdiagnosed, referred for a psychiatric consult or even unfairly labeled as "difficult patients."

Many physicians have not been properly educated about the severe nature of these chronic adverse reactions, some of which result in life-long disabilities. Post-marketing studies of several flouroquinolones have shown an incidence of adverse reactions much higher than were originally reported in pre-clinical studies. (1,2,3)

You are probably aware that the fluoroquinolones are eukaryotic DNA gyrase and topoisomerase inhibitors very similar to many antineoplastic agents. Because of their similar mechanisms of action, it's no surprise that fluoroquinolones and many antineoplastic agents share similar toxicity profiles. Studies have even been conducted using fluoroquinolones to inhibit neoplastic chondrocyte growth in chondrosarcoma. (4)

There are many patients who have a syndrome of associated symptoms that include, but are not limited to: CNS agitation, depression, insomnia, new-onset anxiety and panic attacks, and even elevated intracranial pressure and visual abnormalities. They may also present with peripheral neuropathy usually of the small fiber type with temperature and pain sensory aberrations, but also often involving larger sensory and motor nerves. Spontaneous muscle activity with fasciculations, myokymia and myoclonic jerks may also occur. Many have musculoskeletal damage with degeneration of cartilage and tendons often leading to tendon rupture and severe ongoing musculoskeletal pain long after therapy has been discontinued. (1,2,3,4,5,6,7,8)

This complex symptomatology does not usually resolve after discontinuation of the inducing fluoroquinolone and may in fact worsen. Many patients go on to have disability that may persist for years. (1) Unfortunately, such patients are often seen by many physicians from multiple specialties who, given the complex symptomatology, fail to recognize a unifying diagnosis.

The mechanism of injury is not fully apparent, but several studies have been conducted and researchers have implicated the following possible mechanisms:

1. Inhibition or disruption of the CNS GABA receptor. (9)

2. Depletion of magnesium and disruption of cellular enzymatic function. (10)

3. Disruption of mitochondrial function and energy production. (11,12)

4. Oxidative injury and cellular death. (14)

This seems to be a functional disorder and structural abnormalities are not usually seen on radiological studies. (13) Patients may have abnormal EMG/NCV studies, abnormal skin punch neurologic density and morphology, abnormal vasomotor and sudomotor function on autonomic testing, and abnormal degeneration of tendons and cartilage on MRI. (13)

There may be a large number of these patients with coexisting endocrine abnormalities including: antithyroid antibodies and abnormal thyroid function, abnormal adrenal function with either hyper

or hypocortisolism, hypogonadism, hypo or hyperglycemia and possibly impaired pituitary function. (13)

Most patients suffering from these side effects have a very clear onset of symptoms temporally related to a course of fluoroquinolone antibiotic. (13) They were often given the fluoroquinolone in conjunction with a corticosteroid or NSAID. Both of these classes of medications are associated with an increased incidence of adverse drug reaction from fluoroquinolones. (10,13)

As of yet no scientifically proven effective treatment is known, however patients will definitely benefit from your caring support and appropriate informed care. Of course, other diseases with similar symptoms need to be carefully ruled out.

There exists a large community of these patients who share information on the World Wide Web. Their numbers grow as the prescription of fluoroquinolones increases. Many of these patients are professionals like myself who have been affected by these drugs. Thank you for your time and consideration.

Todd R. Plumb MD

References:

1. Cohen JS; Peripheral Neuropathy Associated With Fluoroquinolones

Annals of Pharmacotherapy. 2001;35(12):1540-1547

2. Francesca Lunzer Kritz; New Cipro, Same Side Effects, Washington Post, December 24, 2002.

3. Shepard CW et al; Antimicrobial Postexposure Prophylaxis for Anthrax: Adverse Events and Adherence Emerging Infectious Diseases ¡E Vol. 8, No. 10, October 2002

4. Fox EJ et al; The effects of ciprofloxacin and paclitaxel on metastatic and recurrent chondrosarcoma COMMUNITY ONCOLOGY November/December 2005

5. Physisicans Desk Referfence 2006

6. de Bazignan DA etal; Psychiatric adverse effects of fluoroquinolone: review of cases from the French pharmacologic surveillance database[Article in French] Rev Med Interne. 2006 Jun;27(6):448-52. Epub 2006 Mar 9

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10. Stahlmann R. etal; Effects of magnesium deficiency on joint cartilage in immature Beagle dogsimmunohistochemistry, electron microscopy, and mineral concentrations, Archives of Toxicology. Jan. 2000 73(11,12)

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13. http://health.groups.yahoo.com/group/quinolones/

14. Simonin MA etal. Pefloxacin-Induced Achilles Tendon Toxicity in Rodents: Biochemical Changes in Proteoglycan Synthesis and Oxidative Damage to CollagenAntimicrobial Agents and Chemotherapy, April 2000, p. 867-872, Vol. 44, No. 4

From: PAUL *** SMA & OMB Memorandum M-07-16 ***
Sent: Tuesday, March 08, 2011 4:20 PM
To: shareholderproposals
Cc: dchia@its.jnj.com
Subject: Page 2 Reconsider Proxy
Attachments: Plumb_Dear_Doctor_Letter.doc; ManipulatedResearch0001.pdf

Please find attached additional documents that are part of the reconsideration request that are evidence and discussion of social significance of the Proxy and Ordinary Business/Chronic Company Risk. (this is second try for second page... delayed sending)

Dear Doctor,

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through a list of possibilities. One of them is a concern about restricting Tavanic, which was the European name for Levaquin, to in-hospital use. That gets you to the same contraindication problem that sparfloxacin got to. Labeling changes would follow, and least onerous would be letting the company continue its current campaign of alerting doctors to the situation, which of course they were not doing.

This is the doctor talking about how to minimize the warning label so that they don't have economic, adverse economic impact. Farther down on that document they start talking about the epidemiology study that Europe wanted, and I've highlighted the section that reads, Moreover, the study envisioned struck many as very insufficient in its present design.

That's Aventis's proposed study. It might actually generate more damaging material unless careful thought were given to other fluoroquinolone and nonfluoroquinolone experience in the same database. They're worried about an adverse result if they do the proper study. They had to manipulate the study.

Ultimately, they did manipulate the study in our view. That was the Ingenix study, and we will talk about what they did with that. Mr. Saul will go into more detail than I will. You can see the precursor of manipulation of

the Ingenix study right after the Kitano meeting. The proper remedy is not to fault the agent but to seek remedy in either changing medical practice or more thoroughly advising physicians of the identified risk factors.

It's not Levaquin's fault. It's the doctors' fault. We have got to make sure the doctors don't use this wrong. There is nothing wrong with Levaquin. Of course, blame others. Isn't that always the case, blame the victim in situations like this?

The sine qua non of our efforts should be making the case that the European picture is distorted by medical practices and in no way implicates levofloxacin as the lone culprit. It's the doctors' fault. We need to consider doing the correct epidemiological study ourselves. We have far more at stake than does Aventis, and there would be no ambivalence clouding our commitment to doing it right.

Far more at stake? Ortho-McNeil had one antibiotic. Aventis had a bunch. If Aventis lost Tavanic, Levaquin, their revenues would not suffer. If Johnson & Johnson, Ortho-McNeil, lost Levaquin, they would be losing their number one drug. They had far more at stake, and that's all for that document.

Their mindset, the entire franchise was riding on a single toss. That's what Jim Kahn said again in his deposition. The stakes have gone up, Larry Johnson wrote

this, when the Germans suggested there was a problem with Levaquin. There was some discussion about contraindication occurring with the British advisor, Dr. Steven Evans, and the writing was that a contraindication would be tantamount to a withdrawal. They were worried about that.

The MCA, that's the British authority, they were proposing a label change, and this could lead to a bad result, which we have already detailed. Now this document is the one that I was talking about that I don't believe was used in the deposition, but it also had the provision in it that said we cannot accept a label change that would show Levaquin having a greater potential for tendon toxicity than any other fluoroquinolone. The study could be a nightmare. That would be the Ingenix study, if it came out wrong.

And finally one of the marketing people talking to the scientists about how to manage the study said, you've got to do whatever it takes. This is the marketing people talking now about how to do science, just as the science people were talking about how to do marketing with ultimately one goal, profits over people.

We have four categories of claims of bad acts that we believe are germane to this motion. First, the defendant deliberately disregarded patient rights concerning the warnings. Second, they manipulated the

scientific literature for their own economic purposes. That's the Ingenix study.

Third, they deliberately disregarded existing scientific literature. There were, we count, 16 articles published by 2003 wherein either Floxin or Levaquin was shown to have a greater tendinopathic potential than other fluoroquinolones in the class. It was out there. It was not in JAMA. It was not in the Archives of Internal Medicine.

Dr. Beecher, our family practice physician in the Schedin case working in Edina, would not be seeing these. Some of them were internal documents, like the Aventis study that as given to the MCA. There were 16 articles that Johnson & Johnson had and should have known about that they disregarded.

Then on top of that what do they do is, they turn their sales force loose, and their sales force has one mantra: Tell everybody how safe Levaquin is, touting the high safety profile of this drug. They deliberately disregarded patient rights. They created a plan to maximize profits while avoiding safety issues.

Sitting around in board room 301 in the Kitano meeting, you didn't see anything in that James Kahn memo that said anything about safety issues and how do we fix the safety problems. It was how do we avoid the safety

problems in order to make sure we don't lose any money. They purposely sought to avoid label changes.

I had an e-mail from Dr. Noel, one of the medical people involved in this. That's attached to this, but I highlight back for you the notion that I mentioned before about how they refuse to incorporate anything in their label change about Levaquin being worse than the other fluoroquinolones.

They knowingly decided not to share the warnings information with the public. One of the documents that I have that the defendant has finally acknowledged is a set of handwritten notes from yet another doctor, Chuen Yee, from Johnson & Johnson, sitting at the Kitano meeting, and that documents says in her handwriting, Not share with public, and it's talking about the French agency reports. Don't tell anybody about it.

They ignored their own published literature and how best to communicate warnings to doctors. I mentioned Dr. Fife. He's one of the doctors involved with Johnson & Johnson. He's an epidemiologist. One of the epidemiology studies he published, and I'm not sure but what this article is marked confidential. Let me just take a quick look here.

No, they didn't mark this one confidential. What Dr. Fife says at the end of his article, if I have it

highlighted -- let's see if I can pull that up for you. He did an epidemiology study to determine what is the most effective way to communicate warnings to doctors, and what he finds in the last sentence is the most telling I think. The key characteristics of a successful drug warning appear to be specificity, prominence, brevity, no reliance on secondary information, publicity and in-person discussions.

You've got to do stuff other than bury it on the lower left corner of page 2,448 of the PDR when that book comes out every year and don't tell a doctor about it. Their own doctor says, their own epidemiology department tells how you should be doing that. They ignore their own published literature and how best to communicate with doctors.

They intentionally buried the warning, as I have described to you. They failed to send a dear doctor letter. There were dear doctors letters sent, if I get the countries right, in France, Italy, Belgium, Germany, Austria, and I'm missing one. There were six of them, all in 2001 and early 2002, about the corticosteroid elderly problem. Was there one sent in the United States? No.

Dr. Canabarro from Aventis was deposed, and what she said in her deposition was, she was asked, you know, why do you send out a dear doctor letter, and her response was, well, you know, we had it in the warnings. But why

did you send out the dear doctor letter? Because the warning wasn't enough, and we wanted to make sure to communicate with doctors. Aventis did it. Johnson & Johnson didn't.

They deliberately did not train their sales representatives to proactively call out label changes to doctors. I deposed Teresa Turano two weeks ago. She was the 30(b)(6) corporate representative on sales training. She didn't know much, but what was clear from her was that there was no policy to tell sales representatives that whenever there is a label change you have got to tell doctors.

What they did do is, they handed out a copy of the package insert every time they went there, theoretically, but that doesn't mean they said to the doctor, you know, take a look here. There is a label change. I want to make sure you're aware of this. They did not do that.

They did do that with the black box. The sales force was told proactively, tell doctors about the black box. Were they told proactively to tell doctors about the black box? Were they told proactively to tell doctors about that 2001 label change? According to the corporate representative, there was no such policy.

They deliberately didn't issue press releases

publicizing changes. I deposed Greg Panico last week, the corporate representative on press releases. He, too, didn't know a lot, but what he did say was there was no policy to initiate press releases about label changes. We went through a litany of documents. They kept track of every news article.

There were clear press releases issued about new indications that the FDA had approved, but was there any indication whatsoever that they issued a pretty release on any label changes? Not a one. They didn't undertake any seminars, public speaking engagements, lunch or learn trainings.

They didn't educate doctors in the manner that they otherwise do educate doctors about new indications. They didn't publish articles talking about the risk of tendon disorders, and I will come back to that in a little bit when I talk about the publication plan and the ghost writing.

They manipulated the Ingenix study for their own economic purposes. The Ingenix study started to appear in discussions in the late fall of 2001. Aventis made a proposal about the protocol. The idea was that they would respond to the French authorities. The French authorities wanted to know what was the comparative tendon toxicity between Levaquin and the other fluoroquinolones.

The Johnson & Johnson response was -- and Aventis was going to do a study that said that. Johnson & Johnson said we can't afford that study. If we end up with a bad result, we're in trouble. So they started taking control of the study from Aventis, and they slowly but surely turned the battleship around to change the focus of the study from a comparison between fluoroquinolones to talking about fluoroquinolones in general and the impact on the elderly and corticosteroids, because by that time they had already decided to include that warning in the label.

And so if they found that there was a negative impact, no big deal. It was already in the label. They already had a strategy for that. So they were going to figure out a way to manage the Ingenix study so that they would get the result that they wanted. So they manipulated the one study to achieve an outcome that was in their best economic interests.

They took it over from Aventis. They controlled the study with Ingenix. I will talk about that for a second. The protocol that was written, it was drafted by Dan Fife. It was discussed between Dan Fife and John Seeger at Ingenix.

There were meetings to talk about the protocol. There were exchanges of drafts on how to do the protocol, the type of study that it was was developed by Johnson &

Johnson in discussion with Ingenix. I mean, they did the whole protocol process.

To be sure, I mean, John Seeger was involved in this, but Johnson & Johnson really controlled the protocol process. Once the protocol was set, it was just a matter of filling in the numbers by mostly administrative mechanism, although we certainly have complaints about how John Seeger did that, and I will talk about that.

They avoided comparing Levaquin with other fluoroquinolones as was requested in Europe. All the items on the bottom are references to documents, and if the hyperlink works, you could pull up the documents. They changed the desired outcome. Europe wanted to know what was the problem related to tendonitis and tendinopathy.

Johnson & Johnson said we can't do that. It has got to be tendon rupture. Ostensibly the reason is because tendon rupture is better defined. It's easier to identify what constitutes a tendon rupture, but really what they're saying at that point in time is that doctors don't know how to diagnose a tendinopathy and they won't trust tendinopathy diagnoses.

Paul Van der Linden in the Netherlands whose four studies, including his PhD thesis, talked about how Floxin was worse than the rest, focused on tendinopathy and tendon rupture. He was able to distinguish between tendinopathy

and its relative risk compared to other drugs and to placebo and also tendon rupture compared to other drugs and placebo.

He could do it. It was academically acceptable to people accepting his PhD thesis, but that was not good enough for Johnson & Johnson. The reason? Because there were fewer tendon ruptures than tendinopathies, and as a result the relative risk was going to show lower, they would get a better number.

They manipulated the power estimates of the study. I don't know to what extent you're conversant with the notion of power, but power tells you the ability to make accurate predictions about epidemiology studies. If you start out with power that is wrong, it's too high. If the power is at four when you're going to find a relative risk of two, what you are going to end up with as a result of that is a confidence interval that is very wide.

In order for you to have statistically significant results, the narrower the confidence interval the better, and most importantly, if the lower bound of the confidence interval is over one, you know that at worst it's still more statistically significant than random. One is random.

So when you have got a wide confidence interval that results in a lower bound being below one, you can say

with honesty this is statistically not significant, but it all stems from where you started. If you start with the wrong power estimate, you end up with a wide confidence interval and no statistical significance.

If you take the trouble to go through the litany of testimony from John Seeger that is listed on that page, you will see he admits that that's true and that they knew it going in, that they picked the wrong power. It was a manipulated study.

They minimized the number of elderly contained in the study data. I know Mr. Saul will talk about that. They improperly included children in the study. Mr. Saul will talk about that. John Seeger admits that that's true. They incorrectly identified what constitutes a tendon rupture for the study by having a nonmedical doctor, Seeger, do the study.

In particular what you might pay attention to on that slide is the bullet point saying testimony of Seeger regarding Schedin. We happened to pull out Mr. Schedin's medical record where it talks about whether he has got a tendon rupture or not a tendon rupture. It says tendon tear.

We asked Dr. Seeger, Is this a tendon rupture that would be included as a positive finding in your study. He said, no, this would not be a tendon rupture in our

study. Our plaintiff here, who has clearly defined tendon ruptures and his doctors have all said so, his treating doctors have said so, was not a tendon rupture for purposes of John Seeger's study. That's how badly defined some of these tendon ruptures were.

Why? Keep them out of the study and keep the numbers low. There was a medical record review for evaluating tendon ruptures, but there was no such medical record review for tendonitis cases which was used as a covariate. It was an internally inconsistent study.

Seeger is not blinded during the study. He knew which cases had fluoroquinolone use and which were not. Dan Fife, Johnson & Johnson's own witness, says that as a result the study is invalid. They destroyed abstracts. We wanted to reproduce the study. In order to reproduce the study we needed the abstracts and the medical records that they used to determine what was a tendon rupture and what was not. They have been described.

They admit it. Seeger admits that in the fall of 2006, three months after the article was published, they destroyed these documents. That's contrary to the guidelines published by the International Society of Professional Epidemiologists, ISPE, which requires that such documents be held for five years.

Normally you wouldn't think that would be such a

big deal except the guidelines were written in part by Seeger's boss at Ingenix, Alec Walker. Walker said, I don't know the guidelines. Are there guidelines? These guidelines go back to 1996. Walker wrote them in 1996. They were revised in 2000, 2004 and 2007, if my memory serves me correctly.

Walker doesn't know them. Seeger doesn't know them. They destroyed the documents in contravention of guidelines that they wrote. Mind boggling. They ignored the existing scientific literature. I told you about the 16 articles. They lied to the FDA about comparative tendon toxicity of fluoroquinolones.

Finally, on the converse side, their marketing efforts. They touted Levaquin's excellent safety profile without disclosing its risk and trained its sales representatives in this manner. I have got a pile of documents that show that. The do and don't document that is on there do tout the excellent safety profile of Levaquin.

The quick tips guide that is on the bottom there, I worked with Teresa Turano and went through much of that verbatim. I said, does this paragraph have anything about safety in it? No. Does this have anything about tendon ruptures in it? No. Does this have anything about warnings on tendon ruptures? No. Does this have anything

about comparative tendon toxicity? No.

All over the place there is nothing about tendon warnings, and it's all about the excellent safety profile of Levaquin. They knowingly marketed to the elderly population. Again, the quick tips guide will tell you that. They marketed it as first line therapy. Levaquin is a good drug for certain circumstances. We don't dispute that.

For people who are seriously ill, it will do what it's supposed to, but if you're got a sinuitis or an acute bacterial exacerbation of chronic bronchitis, like John Schedin did, you don't use Levaquin. He had one trial on Zithromax. Could easily have gone back to another trial on Zithromax or another less potent antibiotic, but this was marketed like candy, samples left, right and sideways. They had millions of dollars in samples for first line therapy for these indications that were hardly severe enough to warrant them.

They did ghost writing. From 1994 to 2002, DesignWrite, their hired gun, caused to be authored two -- 144 papers on either Floxin or Levaquin, touting its benefits. Of those 144 papers, 13 of them had the word "safety" in the title, and only one of them had anything to do with tendons, and that was a published, published paper on children and tendon disorders. Nothing about the

You don't have to, you shouldn't listen to any contrary evidence or challenges or cross-examination by defendant because that's not what the law allows or requires. We think the motion should be granted. Thank you very much.

THE COURT. Thank you, Mr. Goldser.

Mr. Saul, did you have something?

MR. SAUL: Good morning, Your Honor.

THE COURT: Good morning.

MR. SAUL: Louis Saul on behalf of plaintiffs.

Mr. Goldser talked at some length about the Ingenix study, and I will fill in the gaps. I realize our time is limited here. Just to go back, Johnson & Johnson had nothing to do with the European situation. Aventis, their trading partner in Europe, was asked to do studies because of the signal in Europe that there were tendon problems, particularly among the elderly, emphasis added, and particularly with corticosteroids.

What the defendant was hoping to avoid and worked to avoid -- may I approach -- was to have this, this warning in the label. This is the warning that eventually got into the label. This is the black box warning that got into the label in November '08. Fluoroquinolones, including Levaquin, are associated with an increased risk of tendonitis and tendon rupture. The risk is increased on

When Public Citizen petitioned FDA FDA-2006-P-0390 (HRG petition)

those over 60 and those on concomitant therapies respiratory, heart and lung recipients.

They kept this warning from being placed in the PDR, in the package insert, for seven years. During that seven years, their sales were about 13 billion dollars. By keeping this warning out for seven years, this company earned themselves 13 million dollars, and we believe that that evidence in itself is enough to get us to the punitive damages claim.

However, how did they do it.

THE COURT: Is this the warning that is on right now?

MR. SAUL: This is the present day warning.

THE COURT: Go ahead. I will ask you a question about that later.

MR. SAUL: Sure. So what did they do? They had no interest in Europe. In fact, they told the Court during our motion practice that they had no relationship with the European authorities and they didn't want to give us documents related to that, that they actually went and took over this study. They took it away from Aventis because they said if we don't do this study and we don't get the proper results, essentially we're dead. Levaquin is off the market.

So what did they do? They hired this company

called Ingenix who had done numerous other studies for them. There was a young doctor there by the name of John Seeger who had just become an employee, and they had him conduct the studies. Mr. Goldser said they designed the protocol. What did they do in the study?

If I may give you another document, Your Honor. This was prepared by me, and this is how they intentionally manipulated the study. The first they wanted to do, the European authorities wanted to study -- the issue was among the elderly and corticosteroid use. What did Johnson & Johnson do? They intentionally left out elderly from the study.

This document that I just handed you was from the original protocol of this Ingenix study. If you will see here, table 1 talks about the UnitedHealthcare research database population. If you'll go down to the bottom, 60 to 64 and 65 plus, you will see that in their database, there was only 4.7 percent of, let's for lack of a better term, the aging population. I'm in there. Just leave it like that.

You will see in table number 2 in the census bureau, there were 16.2 percent of the population being over 60. So they chose a data -- Aetna was going to use a different database, but they took this away and used this particular database that underrepresented the elderly.

What else did they do? Levaquin was contraindicated for children, for pediatric use. Contraindicated, you can't use it for pediatric use.

You will see in the general population, there is 29 percent, and in their database there is 29 percent in approximate numbers. They included this 29 percent, the children, in the study. So what they did is, they kept the elderly out. They included children. Children can't even take Levaquin. The elderly, the focus was on the elderly. They cut that down. Okay.

So what did they do? So they intentionally excluded the elderly and included children. But then what happened? They did their study. Part of their study was to get this study published in certain journals. Those journals are the journals that most of us have heard about.

For instance, in New England -- I won't go through them all. Five journals, the New England Journal of Medicine and the first line journals. They could not get this study published anywhere. What did they do? They went to -- Johnson & Johnson and Ingenix, they were members of a society, and Ingenix was the head of the society. They got it published in that society's journal.

No one else would take it. The study was concluded in 2003. 2006 it got published. Lo and behold three or four months after it got published, they destroyed

the data. They went and they did medical review of a certain number of the patients in this study, and you have to keep this data because once you publish something, other researchers have to be able to duplicate the study.

What happened to the data? Dr. Seeger testified, we don't -- we didn't really know what happened. I'm not sure what happened, and he went on and on. Finally, we got him to admit, and I just want to read to you -- at any rate, Dr. Seeger admits, admits that under his tutelage or under his direction that he caused all the documentation to be destroyed regarding the study. This is, forms the basis also of our motion, our *Daubert* motion.

No one can duplicate this study. They also created an algorithm to define who was in the case. They can't find that algorithm. All the documentation is gone. That in itself, the intentional destruction of the data, they kept their product on the market for nine years or eight years, is enough to allow us to amend the, the complaint, and I believe it's enough for the jury to enter a substantial award.

I feel that our time is limited, but each of these dotted areas is covered in our brief extensively, and I would like to incorporate our motion in limine regarding Dr. Seeger into this because rather than me go on and on about the study, I think it's all well depicted in our

elderly taking corticosteroids.

That was in response to the events and the data that had been received in Europe about the experience and adverse reaction reports from the use of Tavanic, the -- Levaquin is marketed in Europe, and the company through a change is being effected, that is on its own initiative, incorporated the information that was coming from Europe to include that in the warning on its own.

The FDA approved it at the company's instigation. They approved that warning. It was that warning with a very slight amendment in 2004. That was the warning the prescribing physician for Mr. Schedin received.

Now, in Europe the reports, the adverse reaction reports that were received in Europe, showed variances within the different European countries. Germany had a much lower rate of reporting than did France. When those things were investigated, when the scientists and researchers looked at what were the reasons for divergence between the European countries, they determined that in France, Levaquin was prescribed and Tavanic was prescribed predominantly for upper respiratory tract infections, and there the French physicians used corticosteroids a significant percentage of the time when they used Levaquin.

Now, the debate has been, you know, what significance is that. When the meeting occurred at the

From:	PAUBMA & OMB Memorandum M-07-16 ***
Sent:	Tuesday, March 08, 2011 3:10 PM
To:	shareholderproposals
Cc:	dchia@its.jnj.com
Subject:	Reconsideration of Proxy Proposasl Rejection
Attachments:	SECTuesdayMar8b.wpd; TykenolBottleWarning0001.pdf; SafeMedPractices20110001.pdf; ER FQ Utilization Study.pdf; illiteracy statistics.txt

Dear Ladies and Gentlemen:
Please find attached a letter requesting that you reconsider your decision to allow Johnson & Johnson to withhold the Proxy on Levaquin from this 2011 Annual Meeting and proxy mailing.
Thank you for your reconsideration and for reviewing the attached letter and file attachments. There are nine attachments; due to computer limitations I have to send two emails.
Thank you.
Sincerely,
Paul W. Cahan
cc: E. Ising Gubson, Dunn & Crutcher

March 6, 2011

TO: Securities and Exchange Commission
FROM: Paul Cahan
RE: Johnson & Johnson Shareholder Proxy
Request to Appeal Proxy Decision with New Information

Dear Ladies and Gentlemen:

INTRODUCTION

Please find below, reasons why I request that you reconsider your decision about allowing the Shareholder Proxy about Levaquin to be denied access to a Shareholder Vote. Also for SEC and Johnson & Johnson consideration, is a revised Proxy that I hope the SEC will consider and suggest to Johnson & Johnson to use, and allow to go forth to shareholder vote.
The proposal was re-phrased with suggested change taken directly from the Company's own bottles of over-the-counter Tylenol, of course a much safer product than Levaquin. Another example of a common over-the-counter medication Excedrin adds: 'keep box for important information" which is a common phrase with OTC medicines.
(See photos attached)

UPDATED LEVAQUIN TOXICITY INFORMATION
QuarterWatch: 2010 Quarter 2
Monitoring MedWatch Reports
January 27, 2011
INSTITUTE FOR SAFE MEDICATION PRACTICES

http://www.ismp.org/QuarterWatch/2010Q2.pdf

The QuarterWatch report states not only was Levaquin suspect in more reports of serious injury than any other antibiotic, but substantially at much higher incidence levels then other drugs within the same class. The serious injuries not only involved tendon rupture but muscle, tendon, and joint/ ligament injuries. The current safety label also warns of potential for irreversible nerve damage that can impact the musculoskeletal system. The warnings fail to warn of the degenerative nature of such types of serious injury. While all drugs in this class carry a UNIFORM BLACK BOX Warning this does not disclose the higher frequency of which these serious adverse events are being reported with Levaquin.

2011 Quarterly Newsletter from the Institute for Safe Medication Practices supports the data of findings of regulatory agencies globally whose documents

were provided in the original proxy. Significantly higher incidence of serious safety report signals impact public health globally.

The proposal in essence asks the shareholders to vote for disclosure of the risks of Levaquin, which are now found to have a higher incidence of serious safety concerns. This significantly impacts Public Health Globally. The public and shareholders have the right to be informed, and vote that everything be done to encourage patients receiving Levaquin to read and understand all current and future disclosures; and thus help to limit legal liabilities of the Company.

Staff Legal Bulletin 14 July 2001
"We analyze the prior no-action letters that a company and a shareholder cite in support of their arguments and, where appropriate, any applicable case law. We may also conduct our own research to determine whether we have issued additional letters that support or do not support the company's and shareholder's positions.

The proxy relates to only ONE product, Levaquin. It is undisputably the most dangerous of any antibiotic on the market. (See latest article, January 2011)
From the 2011 Institute for Safe Medication Practices:
http://www.ismp.org?QuarterWatch/2010Q2.pdf

Re-worded Shareholder Proxy for SEC consideration to propose to Johnson & Johnson for inclusion in this years' Annual Meeting:

Vote FOR adding a phrase to all Levaquin tablet bottles and injection solutions that direct patients to pay close attention to all information (the "monogram" and the Patient Guide.)

Suggestion to add phrase to bottles of Levaquin:

CAREFULLY READ PRODUCT INFORMATION BEFORE USING AND DO NOT DISCARD

There is no information on Levaquin bottles of recent warnings, and no indication that small adverse reactions can build-up in the body and later start cellular events that can be painful and irreversible. If one has a MINOR reaction, sometimes it does NOT worsen while one completes the prescribed dose. It can stabilize or decrease giving the patient a false sense of security. This is what happened to me in 1998 after 10 days of Floxin; I am permanently disabled. If patients read the fine print and inserts they may know this, if they do not, many could be in danger. There have been over 159,000 adverse reactions reported to the FDA on Levaquin and Floxin, and over 37,000 individual safety reports. Complaints are "the tip of the iceberg." The delayed reaction mechanism is different than other medicines with black box warnings, and Levaquin has the highest tendon rupture rate within the floroquinolone "class". Everyone needs to see something on the bottle and "front line" pharmacy printing so they fully understand consequences of any minor initial reaction. Pharmacists cannot offer advise on medical issues. They only say: "Do you have any questions about this medicine?" Everyone has a right to know "up-front" the unique delayed reaction mechanism that can cause permanent pain. The 2008 Medication Guides are primarily not reaching the

majority of patients, they only get the fine print in the monogram.

To add one phrase this may take consulting with the FDA and companies that provide the computerized services when a prescription is filled. A possible decrease in sales would likely be offset by fewer lawsuits.

Information on the bottle of Levaquin 500 mg. Tablets:

"Medication should be taken with plenty of water.

Take this medication at least 2 hours before or 2 hours after magnesium or aluminum containing antacids, or other products containing calcium, iron, or zinc.

Avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication. May cause dizziness.

This medicine is dispensed as a(n) PEACH, OBLONG-SHAPED, FILM COATED TABLET with LEVAQUIN imprinted on one side and 500 imprinted on the other side. "

No mention of the dangers on the bottle, often the only information read by patients, especially those with lower reading abilities, difficulty seeing, or do not speak English.

There is no cure for permanent reactions that damage tendons, cartilage, nerves, etc. (Levaquin is deemed Floxin's "mirror" drug; Floxin was discontinued in 2009.) Help decrease shareholder liability, support health of the public, and decrease preventable government expenses for the disabled.

Sincerely,

Paul W. Cahan

VA & OMB Memorandum M-07-16 ***

Holding 51 Shares

The Numbers Updated: A Socially Significant Health Issue

Date Range: November 1, 1997 - Feb 2, 2010 (12+ years)

	Total Reactions	Deaths	Individual Safety Reports
Levaquin	130,578	1,600	30,735
Floxin	29,201	595	6,496
Total	159,779	2,195	37,231

Note: Statistics from Director of Statistics at FDA Mr. H. Stepper and include both Trade Name and all drugs that contain Levaquin or Floxin in the compound.

These numbers do not reflect the 'real' numbers, unknown.

Former FDA Commissioner Dr. David Kessler is cited as concluding that only about one percent (1%) of serious adverse reactions are ever reported to the FDA (8th paragraph,website)
http://occupational-therapy.advanceweb.com/Article/Is-Med-Watch-Looking-fo

r-You.aspx

It is important to note again, that the proposal does not seek a true 'label' change, but only that a phrase be added that calls attention to already provided information.

Details about Phrase that Proxy suggests to add:

It is quite ironic, that on the Tylenol bottle, an over the counter, commonly used medication, in fact a household name, a phrase that is prominently on the bottle says:

READ THE LABEL

there are arrows in both directions to the left and the right of these three words.

Also, on the Excedrin label it says:

"READ ALL PRODUCT INFORMATION BEFORE USING
KEEP BOX FOR IMPORTANT INFORMATION"

Is it still assumed that physicians, when they write a prescription, review adverse effects with patients?

Is it assumed that pharmacists tell people about the adverse effects of Levaquin, and tell them to carefully read everything?

Do patients read all the fine print when they are given a prescription medication?

NO to both of these, in this day and age.

So why are over the counter medications asking people to make sure they read all information, and it's not asked of patients who take the most dangerous medications? If only George Orwell were still alive.

This letter requesting the reconsideration of your decision will provide updated information that will prove the Shareholder Proxy transcends ordinary business; it will discuss a newly discovered example of a similar Shareholder Proxy about labels and how they are sold, which was allowed to go to a shareholder vote at Safeway Inc.. regarding disclosure of genetically engineered food products. The public needs far more awareness than is currently of general knowledge from people who are prescribed Levaquin in the US. It is indeed a significant social policy issue global in nature and the proposal seeks to only begin to remedy this serious education gap.

An important part of the proxy statement:

"... and **Levaquin has the highest tendon rupture rate** within the floroquinolone class of antibiotics." From the 2011 Institute for Safe Medication Practices:

http://www.ismp.org/QuarterWatch/2010Q2.pdf

The QuarterWatch report states not only was Levaquin suspect in more reports of serious injury **than any other antibiotic**, but substantially at much higher incidence levels then other drugs within the same class. The serious injuries not only involved tendon rupture but muscle, tendon, and joint ligament injuries. The current safety label also warns of potential for irreversible nerve damage that can impact the musculoskeletal system. The warnings fail to warn of the degenerative nature of such types of serious

injury. While all drugs in this class carry a UNIFORM BLACK BOX Warning, it **does not disclose the higher frequency** of which these serious adverse events are being reported with Levaquin.

2011 Quarterly Newsletter from the Institute for Safe Medication Practices supports the data of findings of regulatory agencies globally whose documents were provided in the original proxy. Significantly higher incidence of serious safety report signals impact public health globally.

The public and shareholders have the right to be informed, and vote on such disclosure, and in the long run protects shareholders from shareholder lawsuits against the company in cases where they were not told ahead of time what was happening to patients, non-disclosure of serious adverse events (ie: Merck's Viiox) can result in high legal costs that reduce shareholder value and lead to other lawsuits, lowering shareholder value even further. http://www.law.cornell.edu/supct/html/08-905.ZO.html

The SEC rules indicate that proposals are not excludable where the underlying subject matter of a proposal:

- transcends the day-to-day business matters of the company;
- raises policy issues so significant that it would be appropriate for a shareholder vote; and
- poses sufficient nexus between the nature of the proposal and the company

When a pharmaceutical company's ordinary business operations include suppressing important data for whatever reasons, consequences will inevitably follow, as evidenced historically with drugs that have posed significant serious
harm to public health globally. The public in general and shareholders in particular have the right to be informed. Investors seek disclosure of company practices in the belief that they impact shareholder value.

Black Boxed Tendon Rupture Warnings remain inadequate. They do not report the significantly higher reaction incidence for Levaquin. The higher serious incidence reports for Levaquin do not just pertain to tendon rupture, but tendons, muscle, joints, ligaments. While the black box warnings state that concomitant steroid use increases such risk, this does not convey to the public or prescribing physicians that utilizing corticosteroids to treat such reactions once they occur, may place patients at higher risk as ruptures are known to occur months after exposure. (With or without concomitant steroid use)

The Black Box warning for tendons **fails to disclose the degenerative nature of such events and/or the degenerative nature of serious events that impact both tendons, the musculoskeletal system, and peripheral nerves.** The Company's credo of patient safety falls short, when the higher incidence of such serious reactions are not disclosed to shareholders and the public.
Unless all patients are directed to **make sure that they read all the fine print information they possibly can, despite it's insufficiencies, then we**

are accessories to a possible serious assault on each and every patients health and well being.

(Please see attachments of the fine print information on the Patient "monographs" that they are given at the point of purchase.)

Since the elderly, those on corticosteroids, and those having received transplants are highlighted, it could lead many patients who even read the black box warning, to take the warning less seriously who are not in those medical or demographic groups. These people are less likely to question their physician on the need for the most risky antibiotic to treat their infection, since they do not know that it is such a risky product to begin with. If they do not read the material, they are less likely to even call their physician with a minor symptom. (which all antibiotics have to some extent.) People are used to taking antibiotics and having a mild stomach ache, but it went away when the course of antibiotics was over.

What else can account for the ongoing high rate of tendon ruptures? Please note also, there are likely MORE injuries that have multiple tendon tears and chronic tendinosis than actual tears, and unfortunately these people are not being chosen in current class-action suits; there are more people suffering than accountable for.

PROOF: A study from the Netherlands mentioned this point. This quote is from the Minnesota trial transcript from last year, when John Schedin sued J&J for his tendon ruptures:

"Paul Van der Linden in the Netherlands whose four studies, including his PhD thesis, talked about how Floxin (Levaquin's "mirror' drug) was worse than the rest, focused on tendinopathy and tendon rupture. **He was able to distinguish between tendinopathy and its relative risk compared to other drugs and to placebo and also tendon rupture compared to other drugs and placebo. He could do it. It was academically acceptable to people accepting his PhD thesis, but that was not good enough for Johnson & Johnson. The reason? Because there were fewer tendon ruptures than tendinopathies,** and as a result the relative risk was going to show lower, they would get a better number. They manipulated the power estimates of the study.

http://www.mnd.uscourts.gov/MDL-Levaquin/Transcripts/2010/092810.pdf

Also: see abbreviated transcript attached with most relevant information.

The current Black Box talks a lot about elderly, those on corticosteroids, and recent transplant patients' increased risk. This can be misleading to a lot of patients who read it.

The article below addresses the problem of floroquinolones among young athletes. Having young people affected, is certainly proof that this is a significant public policy/health issue and the Black Box Warning is not doing it's job. Studies point out that many people are given Levaquin, the most dangerous antibiotic, inappropriately. See this utilization study please:

http://www.archinte.ama_assn.org/cgi/reprint/163/5/601.pdf

Also in attachment format.

Staff Legal Bulletin 14 July 2001

"We analyze the prior no-action letters that a company and a shareholder cite in support of their arguments and, where appropriate, any applicable case law. We may also conduct our own research to determine whether we have issued additional letters that support or do not support the company's and shareholder's positions.

Similar Shareholder Proxy
that was successfully brought to a vote:

SAFEWAY INC 2007 SHAREHOLDER PROXY THAT WAS ACCEPTED BY SEC 2007

PROPOSAL 7
STOCKHOLDER PROPOSAL REGARDING LABELING PRODUCTS OF CLONING OR GENETIC ENGINEERING

The Company has been notified by the Adrian Dominican Sisters, 1257 East Sienna Heights Drive, Adrian, MI 49221-1793, which owns 150 shares of Common Stock, that it intends to present, jointly with ASC Investment Group, Bon Secours Health System, Inc., Boston Common Asset Management, LLC, the Dominican Sisters of Oxford, MI, the Dominican Sisters of Springfield

Illinois and the General Board of Pension and Health Benefits of the United Methodist Church, the following proposal for consideration at the Annual Meeting:

Label Products of Cloning or Genetic Engineering
2007 Safeway

RESOLVED: Shareholders request that the Board of Directors adopt a policy to identify and label all food products manufactured or sold by the company under the company's brand names or private labels that may contain genetically engineered (GE) ingredients or products of animal cloning.

Supporting Statement

- The right to know is a fundamental principle of democratic societies and market economics.
- The Food and Drug Administration is expected to make a decision regarding the sale of milk and meat from cloned animals by the end of 2006
- Safeway products contain corn, rice and soy, all of which potentially could be the genetically engineered variety.
- Safeway's O Organic line could be impacted by contamination from genetically engineered ingredients.
- Labeling is an indicator of due diligence of product ingredients.
- The global alliance Action by Churches Together took a stand supporting the "right to know" whether there are genetically engineered ingredients in the food purchased or in the seeds sown. (ReliefWeb 6/28/06)
- 132 countries, parties to the Cartagena Protocol, have agreed to documentation requirements for the export and import of genetically engineered organisms. (Financial Times 3/29/06)
- As of May 19, 2005, Alaska law requires that genetically engineered salmon be labeled as such.

Indicators that genetically engineered organisms can be difficult to control,and may be harmful to financial markets as well as to humans, animals and the environment include:

- Illegal unapproved Liberty Link long-grain rice, planted in field trials no later than 2001, was discovered to have contaminated U.S. rice supplies. (Reuters 8/28/06) This prompted Japan to suspend imports of US Rice, and the European Commission to require that rice imports be certified as free of unauthorized grain, greatly disrupting the US rice export market.
- Between 2001-2004, approximately 15,000 hectares (150 square kilometers) in four US states were planted with unapproved Bt10 corn. (New Scientist 3/23/2005)
- December 2006, U.N. Secretary General Annan cautioned that the international community lacks safeguards to prevent bioterrorism and accidental harm from biotechnology advances.
- The report Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects (National Academy of Sciences] 7/2004) states: ..."there remain sizable gaps in our ability to identify

compositional changes that result from genetic modification of organisms intended for food.

• Federal District Court ruled (8/10/06) that USDA's permitting of drug-producing genetically engineered crops in Hawaii violated the Endangered Species Act and the National Environmental Policy Act.

• Genetically engineered creeping bentgrass, not yet approved commercially, escaped into wild as far as three miles from the test plot.

• Five major US agricultural weeds have developed resistance to glyphosate, the herbicide used with genetically engineered Roundup Resistant crops. Addressing this problem includes use of additional herbicides.

• Research (Environmental Health Perspectives 6/2005) has shown that Roundup, increasingly needed on Roundup Ready crops, is toxic to human placental cells at concentrations lower than agricultural use.

The SEC recommend that the above Proxy be voted on by the shareholders of Safeway Inc. in 2007.

The supporting statement of this Proxy on "Label Products of Cloning or Genetic Engineering" was concerned with:

- the right to know
- FDA information:

  Johnson & Johnson did not voluntarily warn doctors and patients about tendon ruptures, see Exhibit E Rebuttal and

(Public citizen v. FDA,DDC No. 08-cv-005). The Attorney General of Illinois also submitted a citizen's petition to the FDA seeking action on the same issue.

"Labeling is an indicator of due diligence of product ingredients"

- This issue with Safeway Inc. Proxy is completely parallel to Levaquin regarding other countries taking measures that the US has not. Other countries have implemented more stringent safety requirements. (See attachment (EuropeanLimitedUse)

To quote from J. Schedin trial in Minnesota 2010:
(attachment pdf file)
Page 21 line 15 of trial transcript Sept. 28, 2010:
Ronald Goldser, Esq:
"They intentionally buried the warning, as I have described to you. They failed to send a dear doctor letter. There were dear doctor letters sent, if I get the countries right, in France, Italy, Belgium Germany, Austria, and I'm missing one. There were six of them, all in 2001 and early 2002, ... Was there one sent in the United States? No."

What the Safeway Proxy was afraid of was how consuming genetic engineered food was going to affect humans; and that consumers in Europe WERE being warned and made aware of genetic engineered food they were purchasing.

The entire concept of Safeway Proposal 7 that was accepted by the SEC in 2007, was that consumers have the right to know what they are purchasing, especially if, in the future, there is any evidence of negative effects of genetically engineered food products.

Socially Significant Policy Issue additional information:

There isn't a definition of what constitutes a socially significant policy issue, however, I think that the new data stated earlier on the First Quarter Report from Medwatch showing Levaquin leads in adverse reactions would be sufficient.

Updated statistics on reported adverse events to the FDA are below:
Date Range: November 1, 1997 - Feb 2, 2010 (12+ years)

	Total Reactions	Deaths	Individual Safety Reports
Levaquin	130,578	1,600	30,735
Floxin	29,201	595	6,496
Total	159,779	2,195	37,231

Note: Statistics from Director of Statistics at FDA Mr. H. Stepper and include both Trade Name and all drugs that contain Levaquin or Floxin in the compound.

Also of note regarding Social Significance:

There are endless websites in the US and abroad that where patients worldwide are reporting and discussing their reactions on-line seeking help. The same stories being reported to Medwatch are the same stories patients around the world are posting to a wide variety of forums and websites. The anecdotal reports by patients on-line, are the same as reports shown in regulatory databases. They convey that their physicians fail to warn them, fail to recognize their reactions, pain, and don't know how to treat them and cure them. The patients themselves, many come to the sites quite desperate, wanting to know how to get better, and ask why the possibility of these devastating disabling outcomes that impact multiple systems was never disclosed to them in the first place.
These websites have grown over the years, and only reflect a very small percent of the true victims of adverse effects.
It's logical to hypothesize that most victims do not find these support sites... Age, socio-economic statistics, medical condition, and long-term victims 'give up'.

A physician, Dr. Todd Plumb of Utah, experienced an adverse reaction to Levaquin. He composed a letter that patients could bring to their physicians. This letter has been used countless times, is a public document, and helps bridge the gap of knowledge, but it is used unfortunately after it's too late by patients who are experiencing great problems after taking Levaquin. When patients have to seek outside medical advise and are forced to give their own doctors information about a new malady that was caused by a medicine, that is a very significant indication of a most serious societal health problem.

IMPORTANT ADDITIONAL INFORMATION
THAT IS A SOCIALLY SIGNIFICANT ISSUE
BEYOND NORMAL BUSINESS OPERATIONS:

It is an extraordinary situation where hundreds, perhaps thousands of patients become ill, do not heal, and need to bring their own information to their physicians. Dr. Plumb wrote this letter in response to the request from people on the floroquinolone social websites, whose physicians are unaware of the adverse effects of Levaquin or do not know how to deal with it.

LETTER WRITTEN BY DR. TODD PLUMB
ST. GEORGE, UTAH
TO HELP PATIENTS EXPLAIN TO THEIR DOCTORS THE ADVERSE REACTIONS CAUSED BY
FLOROQUINOLONE ANTIBIOTICS

Dear Doctor,

As you are probably aware, the fluoroquinolone class of antibiotics is useful for certain serious infections. Unfortunately, fluoroquinolones also have a long history of serious adverse drug reactions, many of them long term. (1) As a consequence of these reactions, several of these drugshave been removed from clinical practice or their use severely restricted. Besides the severe life threatening immediate reactions, those of a more chronic nature may occur.

The spectrum of these adverse reactions is extremely broad. Patients suffering from these reactions are often misdiagnosed, referred for a psychiatric consult or even unfairly labeled as "difficult patients."

Many physicians have not been properly educated about the severe nature of these chronic adverse reactions, some of which result in life-long disabilities. Post-marketing studies of several flouroquinolones have shown an incidence of adverse reactions much higher than were originally reported in pre-clinical studies. (1,2,3)

You are probably aware that the fluoroquinolones are eukaryotic DNA gyrase and topoisomerase inhibitors very similar to many antineoplastic agents. Because of their similar mechanisms of action, it's no surprise that fluoroquinolones and many antineoplastic agents share similar toxicity profiles. Studies have even been conducted using fluoroquinolones to inhibit neoplastic chondrocyte growth in chondrosarcoma. (4)

There are many patients who have a syndrome of associated symptoms that include, but are not limited to: CNS agitation, depression, insomnia, new-onset anxiety and panic attacks, and even elevated intracranial pressure and visual abnormalities. They may also present with peripheral neuropathy usually of the small fiber type with temperature and pain sensory aberrations, but also often involving larger sensory and motor nerves. Spontaneous muscle activity with fasciculations, myokymia and myoclonic jerks may also occur. Many have musculoskeletal damage with degeneration of cartilage and tendons often leading to tendon rupture and severe ongoing musculoskeletal pain long after therapy has been discontinued. (1,2,3,4,5,6, 7,8)

This complex symptomatology does not usually resolve after discontinuation of the inducing fluoroquinolone and may in fact worsen. Many patients go on to have disability that may persist for years. (1) Unfortunately, such patients are

often seen by many physicians from multiple specialties who, given the complex symptomatology, fail to recognize a unifying diagnosis.

The mechanism of injury is not fully apparent, but several studies have been conducted and researchers have implicated the following possible mechanisms:

1. Inhibition or disruption of the CNS GABA receptor. (9)
2. Depletion of magnesium and disruption of cellular enzymatic function. (10)
3. Disruption of mitochondrial function and energy production. (11,12)
4. Oxidative injury and cellular death. (14)

This seems to be a functional disorder and structural abnormalities are not usually seen on radiological studies. (13) Patients may have abnormal EMG/NCV studies, abnormal skin punch neurologic density and morphology,

abnormal vasomotor and sudomotor function on autonomic testing, and abnormal
degeneration of tendons and cartilage on MRI. (13) There may be a large number of these patients with coexisting endocrine abnormalities including: antithyroid antibodies and abnormal thyroid function, abnormal adrenal function with either hyper or hypocortisolism, hypogonadism, hypo or hyperglycemia and possibly impaired pituitary function. (13)

Most patients suffering from these side effects have a very clear onset of symptoms temporally related to a course of fluoroquinolone antibiotic. (13) They were often given the fluoroquinolone in conjunction with a corticosteroid or NSAID. Both of these classes of medications are associated with an increased incidence of adverse drug reaction from fluoroquinolones. (10,13)

As of yet no scientifically proven effective treatment is known, however patients will definitely benefit from your caring support and appropriate informed care. Of course, other diseases with similar symptoms need to be carefully ruled out.

There exists a large community of these patients who share information on the World Wide Web. Their numbers grow as the prescription of fluoroquinolones increases. Many of these patients are professionals like myself who have been affected by these drugs.

Thank you for your time and consideration.

Todd R. Plumb MD

References:

Please see attachment for copy of article, and full list of scientific references.

]----------

ALSO OF SOCIAL SIGNIFICANCE IS THE EXTENT OF PAINFUL SMALL NERVE DAMAGE THAT IS NOT DISCLOSED OR DIAGNOSED BUT IS OFTEN A PAINFULLY CHRONIC MALADY

Dr. Plumb's letter discusses peripheral neuropathy being typically of small nerve fiber type.Typically patients being evaluated for PN often only have EMG and Nerve Conduction studies that do not detect small fiber neuropathies that are noted in the current warning where it says (small fiber nerves).

Many patients' painful nerve damage to small fiber nerves goes undiagnosed and not disclosed in their medical records There are tests (small fiber Skin Punch Biopsy) which detects small fiber nerve density

loss but unfortunately this test is only done at a few facilities in the USA, therefore many patients nerve damage is not documented. It can be done at Johns Hopkins, Massachusettes General Hospital, and a few others.

Social Significant Issue Continued:

VICTIMS SEEK MEDICAL HELP
FROM THOUSANDS OF MILES AWAY

In addition, many victims of Levaquin toxicity have gone to great lengths to try and get help. Many have flown to see an expert in Dr. Flockhart, in Indianna. Many have gone to the Mayo Clinic. No-one has walked away with a cure, I can safely say that nearly all have walked away from these appointments with great disappointment.

Note: All the bottles of floroquinolones have the same label and phrases in terms of no added indicators regarding the importance of reading the fine print information that is given to them by the pharmacies. If Levaquin helps the situation, other companies may follow suit. A ripple effect can follow globally. (Cipro information below)

Date Range: November 1, 1997 - Feb 2, 2010 (12+ years)

	Total Reactions	Deaths	Individual Safety Reports
Levaquin	130,578	1,600	30,735
Floxin	29,201	595	6,496
Total	159,779	2,195	37,231
Cipro	136,388	2,461	30,647

(Cipro not manufactured by Johnson & Johnson)

Hopefully any improvement in the education process of patients who are given Levaquin will spread to other floroquinolone antibiotics, such as Cipro and Avelox. (See Attachments: Monogram Other Floroquinolones)

Note: Statistics from FDA Representative Mr. H. Stepper and include both Trade Name and all drugs that contain Levaquin or Floxin in the compound. The numbers in reality, are much higher, and unknown. Former FDA Commissioner Dr. David Kessler is cited as concluding that only "about one percent (1%) of serious adverse reactions are ever reported to the FDA " (8th paragraph,website)

http://occupational-therapy.advanceweb.com/Article/Is-Med-Watch-Looking-for-You.aspx

World Health Organization Alert:
http://www.who.int/medicines/publications/newsletter/en/news2002_1.pdf

Discussion of RISK and ORDINARY BUSINESS

Staff Legal Bulletin No 14E (CF)
Oct. 27, 2009

B) "To the extent that a proposal and supporting statement have focused on a company minimizing or eliminating operations that may adversely affect the environment or the public's health, we have not permitted companies to exclude these proposals under Rule 14a-8 (I) (7)

" On a going-forward basis, rather than focusing on whether a proposal and supporting statement relate to the company engaging in an evaluation of risk, we will instead focus on the subject matter to which the risk pertains or that gives rise to the risk."

In particular relative to the issue at hand, the "ordinary business" definition, there is ample proof of a long-standing trend of Johnson & Johnson hiding the risk of Levaquin from doctors and patients, they have acted most probably irresponsibly and put profits above their Corporate Credo. This is likely reprehensible behavior influencing decision models throughout the executive level of the company, and has likely increased shareholder risk by illegal recalls, high litigation fees, altering research results on Levaquin in Europe (attachment) and defective manufacturing practices that temporarily closed more than one plant, etc. What is most despicable, is what they did NOT say about this drug, and it's predecessor for so long, when at the same time the people of Europe were being warned. They have taken a risky path indeed; and shareholders share the burden of that risk as well as patients.

I hope that the SEC acknowledges the relevance of the context in which Levaquin was a part of the corporate culture of high risk at the company, and is thus of the highest Social Concern. Information that has been left out for years has injured countless patients, and has been fully or partially responsible for many deaths.

I am not asking for the drug to be totally banned; but that eventually it be used much more conservatively; our goal should be patient safety, Levaquin should be used after safer antibiotics are found to be ineffective against a particularly difficult medical situation. (See attachment:Ireland Medical Paper.

In fact;

In 2007, the Chairman of Pharmaceuticals , Christine Poon personally said to me, after a shareholder meeting I attended,'These medications should not be used for common infections."Ms. Poon is now Dean of Ohio Business School. (Transcript of my speech was in first Rebuttal)

At this stage, I am humbly requesting that people simply be reminded how important full disclosure is with this medicine, as soon as they get the medicine, and every time they open the top of the bottle and take out a pill. Hopefully this might make a small dent in decreasing the great tragedy that bestows thousands who are prescribed Levaquin, impacting the lives of patients, their friends, employers, and families.

One last note to ponder "Normally the quinolone class of drugs is used in patients who have failed at least one prior therapy. The patients tend to be fairly ill and require relatively acute care that often may be the last step before they are admitted into the hospital. ...By the time the physicians get to this classification, they tend to have a good idea of what bacteria is involved, what antibiotic is the most potent for the bacteria and which penetrates that particular body side the best. ...These drugs are often the last step before admission into the hospital..." Jim Hoover, for Bayer Corporation, Alaska Pharmacy and Therapeutics Committee March 19, 2004

http://www.hss.state.ak.us/dhcs/PDL/minutes_meetings_pdl/minutes_031904_pdl.pdf

TYLENOL
EXTRA
STRENGTH
Acetaminophen
EZ-TABS

From: PAUL *** FISMA & OMB Memorandum M-07-16 ***
Sent: Monday, March 07, 2011 6:17 PM
To: shareholderproposals
Subject: Re: request for reconsideration question/ Attn Charles Kwon
Attachments: LEVAQUINNEWPHRASEBOTTLE.wpd; SafeMedPractices20110001.pdf; TykenolBottleWarning0001.pdf

Dear Ladies and Gentlemen:
Attn: Charles Kwon
Please excuse this revision, attached and below.
If I am not allowed to suggest this re-worded proxy,along with a request for reconsideration, please let me know.
My forthcoming request for reconsideration letter will have new information in it, examples: attachment 2 and 3 below
Sincerely,
Paul Cahan

*** FISMA & OMB Memorandum M-07-16 ***

Paul Cahan

*** FISMA & OMB Memorandum M-07-16 ***

Vote FOR adding a phrase to all Levaquin tablet bottles and injection solutions that direct patients to pay close attention to all information (the "monogram" and the Patient Guide.)

Suggestion to add phrase to bottles of Levaquin:

CAREFULLY READ INSERTS BEFORE USING

DO NOT DISCARD ALL PRODUCT INFORMATION

There is no information on Levaquin bottles of recent warnings, and no indication that small adverse reactions can build-up in the body and later start cellular events that can be painful and irreversible. If one has a MINOR reaction, sometimes it does NOT worsen while one completes the prescribed dose. It can stabilize or decrease giving the patient a false sense of security. This is what happened to me in 1998 after 10 days of Floxin; I am permanently disabled. If patients read the fine print and inserts they may know this, if they do not, many could be in danger. There have been over 159,000 adverse reactions reported to the FDA on Levaquin and Floxin, and over 37,000 individual safety reports. Complaints are "the tip of the iceberg." The delayed reaction mechanism is different than other medicines with black box warnings, and Levaquin has the highest tendon rupture rate within the floroquinolone "class". Everyone needs to see something on the bottle and "front line" pharmacy printing so they fully understand consequences of any minor initial reaction. Pharmacists cannot offer advise on

medical issues. They only say: "Do you have any questions about this medicine?" Everyone has a right to know "up-front" the unique delayed reaction mechanism that can cause permanent pain. THE 2008 MEDICATION GUIDES ARE NOT REACHING ALL PATIENTS. Patients only get the fine print.

To add one phrase, this may take working with the FDA and companies that already provide the computerized services when a prescription is filled. A possible decrease in sales would likely be offset by fewer lawsuits.

Information on the bottle of Levaquin 500 mg. Tablets:

"Medication should be taken with plenty of water.

Take this medication at least 2 hours before or 2 hours after magnesium or aluminum containing antacids, or other products containing calcium, iron, or zinc.

Avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication. May cause dizziness.

This medicine is dispensed as a(n) PEACH, OBLONG-SHAPED, FILM COATED TABLET with LEVAQUIN imprinted on one side and 500 imprinted on the other side. "

No mention of the dangers on the bottle, often the only information read by patients, especially those with lower reading abilities, difficulty seeing, or do not speak English.

There is no cure for permanent reactions that damage tendons, cartilage, nerves, etc. (Levaquin is deemed Floxin's "mirror" drug; Floxin was discontinued in 2009.) Help preserve the health of shareholders, the public, and decrease government expenses supporting the disabled.

Sincerely,

Paul W. Cahan

FISMA & OMB Memorandum M-07-16 ***

Holding 51 Shares

Vote FOR adding a phrase to all Levaquin tablet bottles and injection solutions that direct patients to pay close attention to all information (the "monogram" and the Patient Guide.)

Suggestion to add phrase to bottles of Levaquin:

CAREFULLY READ INSERTS BEFORE USING
DO NOT DISCARD PRODUCT INFORMATION

There is no information on Levaquin bottles of recent warnings, and no indication that small adverse reactions can build-up in the body and later start cellular events that can be painful and irreversible. If one has a MINOR reaction, sometimes it does NOT worsen while one completes the prescribed dose. It can stabilize or decrease giving the patient a false sense of security. This is what happened to me in 1998 after 10 days of Floxin; I am permanently disabled. If patients read the fine print and inserts they may know this, if they do not, many could be in danger. There have been over 159,000 adverse reactions reported to the FDA on Levaquin and Floxin, and over 37,000 individual safety reports. Complaints are "the tip of the iceberg." The delayed reaction mechanism is different than other medicines with black box warnings, and Levaquin has the highest tendon rupture rate within the floroquinolone "class". Everyone needs to see something on the bottle and "front line" pharmacy printing so they fully understand consequences of any minor initial reaction. Pharmacists cannot offer advise on medical issues. They only say: "Do you have any questions about this medicine?" Everyone has a right to know "up-front" the unique delayed reaction mechanism that can cause permanent pain. THE 2008 MEDICATION GUIDES ARE NOT REACHING ALL PATIENTS. Patients only get the fine print.

To add one phrase, this may take working with the FDA and companies that already provide the computerized services when a prescription is filled. A possible decrease in sales would likely be offset by fewer lawsuits.

Information on the bottle of Levaquin 500 mg. Tablets:
"Medication should be taken with plenty of water.
Take this medication at least 2 hours before or 2 hours after magnesium or aluminum containing antacids, or other products containing calcium, iron, or zinc.
Avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication. May cause dizziness.
This medicine is dispensed as a(n) PEACH, OBLONG-SHAPED, FILM COATED TABLET with LEVAQUIN imprinted on one side and 500 imprinted on the other side. "

No mention of the dangers on the bottle, often the only information read by patients, especially those with lower reading abilities, difficulty seeing, or do not speak English.
There is no cure for permanent reactions that damage tendons, cartilage, nerves, etc. (Levaquin is deemed Floxin's "mirror" drug; Floxin was discontinued in 2009.) Help preserve the health of shareholders, the public, and decrease government expenses supporting the disabled.
Sincerely,
Paul W. Cahan

Holding 51 Shares

TYLENOL
EXTRA
EZ-OPEN

From:	PAUL *** FISMA & OMB Memorandum M-07-16 ***
Sent:	Monday, March 07, 2011 4:40 PM
To:	shareholderproposals
Subject:	request for reconsideration question
Attachments:	ProxyLevaquinMarch7.wpd

Dear Ladies and Gentlemen:

Is it within procedure that I may be allowed to include a reworded shareholder proxy as part of a request for reconsideration on the decision you recently made on the Johnson & Johnson Levaquin shareholder proxy?

I have a "request for reconsideration" letter with new information that I want to send to you shortly, but I'd like to also include the following as well, for you to review and suggest to the Company.

Please let me know if I can, or cannot include this reworded proxy in the letter I will send after I hear from you. If any alteration is not allowed unless you first initiate the request, then I will send the reconsider letter without this.

Sincerely,

Paul W. Cahan

PS I thought of it when I saw on the bottle of Tylenol, the phrase: "READ THIS" in bold on the bottle! with arrows on each end, and on Excedrin it says on the bottle in red capitals:

READ ALL PRODUCT INFORMATION BEFORE USING
KEEP BOX FOR IMPORTANT INFORMATION

Vote FOR adding a phrase to all Levaquin tablet bottles and injection solutions that direct patients to pay close attention to all information (the "monogram" and the Patient Guide.)

Suggestion to add phrase to bottles of Levaquin:

CAREFULLY READ PRODUCT INFORMATION BEFORE USING

AND DO NOT DISCARD

There is no information on Levaquin bottles of recent warnings, and no indication that small adverse reactions can build-up in the body and later start cellular events that can be painful and irreversible. If one has a MINOR reaction, sometimes it does NOT worsen while one completes the prescribed dose. It can stabilize or decrease giving the patient a false sense of security. This is what happened to me in 1998 after 10 days of Floxin; I am permanently disabled. If patients read the fine print and inserts they may know this, if they do not, many could be in danger. There have been over 159,000 adverse reactions reported to the FDA on Levaquin and Floxin, and over 37,000 individual safety reports. Complaints are "the tip of the iceberg." The delayed reaction mechanism is different than other medicines with black box warnings, and Levaquin has the highest tendon rupture rate within the floroquinolone "class". Everyone needs to see something on the bottle and "front line" pharmacy printing so they fully understand consequences of any minor initial reaction. Pharmacists cannot offer advise on medical issues. They only say: "Do you have any questions about this medicine?" Everyone has a right to know "up-front" the unique delayed reaction mechanism that can cause permanent pain. THE 2008 MEDICATION GUIDES ARE NOT REACHING ALL PATIENTS. Patients only get the fine print.

To add one phrase, this may take working with the FDA and companies that already provide the computerized services when a prescription is filled. A possible decrease in sales would likely be offset by fewer lawsuits.

Information on the bottle of Levaquin 500 mg. Tablets:

"Medication should be taken with plenty of water.

Take this medication at least 2 hours before or 2 hours after magnesium or aluminum containing antacids, or other products containing calcium, iron, or zinc.

Avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication. May cause dizziness.

This medicine is dispensed as a(n) PEACH, OBLONG-SHAPED, FILM COATED TABLET with LEVAQUIN imprinted on one side and 500 imprinted on the other side. "

No mention of the dangers on the bottle, often the only information read by patients, especially those with lower reading abilities, difficulty seeing, or do not speak English.

There is no cure for permanent reactions that damage tendons, cartilage, nerves, etc. (Levaquin is deemed Floxin's "mirror" drug; Floxin was discontinued in 2009.) Help preserve the health of shareholders, the public, and decrease government expenses supporting the disabled.

Sincerely,

Paul W. Cahan

FISMA & OMB Memorandum M-07-16 ***

Holding 51 Shares

Vote FOR adding a phrase to all Levaquin tablet bottles and injection solutions that direct patients to pay close attention to all information (the "monogram" and the Patient Guide.)

Suggestion to add phrase to bottles of Levaquin:
CAREFULLY READ PRODUCT INFORMATION BEFORE USING AND DO NOT DISCARD

There is no information on Levaquin bottles of recent warnings, and no indication that small adverse reactions can build-up in the body and later start cellular events that can be painful and irreversible. If one has a MINOR reaction, sometimes it does NOT worsen while one completes the prescribed dose. It can stabilize or decrease giving the patient a false sense of security. This is what happened to me in 1998 after 10 days of Floxin; I am permanently disabled. If patients read the fine print and inserts they may know this, if they do not, many could be in danger. There have been over 159,000 adverse reactions reported to the FDA on Levaquin and Floxin, and over 37,000 individual safety reports. Complaints are "the tip of the iceberg." The delayed reaction mechanism is different than other medicines with black box warnings, and Levaquin has the highest tendon rupture rate within the floroquinolone "class". Everyone needs to see something on the bottle and "front line" pharmacy printing so they fully understand consequences of any minor initial reaction. Pharmacists cannot offer advise on medical issues. They only say: "Do you have any questions about this medicine?" Everyone has a right to know "up-front" the unique delayed reaction mechanism that can cause permanent pain. THE 2008 MEDICATION GUIDES ARE NOT REACHING ALL PATIENTS. Patients only get the fine print.

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Sincerely,
Paul W. Cahan

Holding 51 Shares

From: PAUL *** FISMA & OMB Memorandum M-07-16 ***
Sent: Sunday, February 27, 2011 3:05 PM
To: shareholderproposals
Subject: False and Misleading Statement
Attachments: no vote statement0001.pdf; SafewayLabelProxy0001.pdf; labelonBottle0001.pdf; minnesotaLevCaseWon.pdf; Rebuttal[2].pdf

Paul Cahan

*** FISMA & OMB Memorandum M-07-16 ***

Office of Chief Counsel
Division of Corporation Finance
Securities and Exchange Commission
100 F. Street NE
Washington DC 20549

Ladies and Gentlemen:
Johnson & Johnson recently sent you a "Management's Statement in Opposition To Shareholder Proposal" (attachment: 'no vote statement0001.pdf)
It is full of false and misleading information, and I must, even prior to a decision being made, respond.

My Proxy merely wishes to add a few words to the bottles of a medicine; there is plenty of blank space still on the bottle to do so. Levaquin is proven to be extremely dangerous antibiotic compared with others. (Please refer to rebuttal to the 'no action' request)
The few words that I request to be added to the bottle are already stated in the FDA approved Patient Guide and the Black Box Warning that is a part of the Patient Guides.
I just think it's only fair for patients to be aware of what they are getting into when there is a broad spectrum of antibiotics to choose from in most medical situations. In fact, the shareholders in April 2008 gave me a loud round of applause when I suggested this same idea during the Q & A of the 2008 Shareholders Meeting.

The proxy is not asking ANYTHING NEW be said to patients. It just asks that important information be **REPEATED on the bottle label** that is in fact elsewhere.
(Bold: P. Cahan emphasis)
There is no need for "scientific, pre-clinical trial and safety reporting findings " etc to be involved. The companies' attorneys are trying to make this appear to be a complex issue, in order to simply protect their high profit margins from this "blockbuster' drug. The first paragraph is totally irrelevant, and MISLEADS shareholders to believe that the Proxy is about virtually a new medication or totally new usage of a current medication. That is what their statement implies. Just the contrary.

The issue of labeling a product has been brought to the attention of the Securities and Exchange Commission before; it has been allowed to be on a shareholder's ballot. In 2007, Safeway Stores had a Shareholder Proxy regarding "Label Products of Cloning or Genetic Engineering. (See attachment: Safeway Label Proxy 0001)

The second paragraph of their "NO VOTE" statement is also irrelevant, and was totally debunked in the rebuttal. In fact, their statement is a total waste of my time and time of the SEC's part.

There are only a handful of very large pharmacy service companies, such as First Data and Medispan, that take care of the labeling and computerized services at the point of purchase of a medication. Please refer to the already submitted rebuttal statement Page 5, below:

"While it is true that it is typically the job of a pharmacy worker to print and place the actual label on the bottle or packaging of a pharmaceutical product, this argument on the part of Gibson and Dunn is misleading. The Proposal does not ask Johnson & Johnson to micro-manage and oversee each and every prescription filled, but merely to facilitate the creation of labels regarding the existence of or referencing the contents of the aforementioned "Black Box Warning."

This is made clear in The Proposal itself, already quoted by Gibson and Dunn above, but repeated here: "This will take working with FDA and companies that provide computerized LABELING services when a prescription is filled." There is no wording in The Proposal that suggests that Johnson & Johnson work with any pharmacists or other retailers. Current bottles and packages of Levaquin® often already come with warning labels on them, stating such things as "Do not take antacids, iron, or vitamin/mineral supplements within two hours of this medication," "You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication," and "May cause dizziness. Do not drive or perform other potentially dangerous tasks until you know how this medicine will affect you." [Exhibit B of Rebuttal] These specific labels, while pertinent, do not represent the most significant risks associated with Levaquin®.

Labels placed on medication bottles and packaging are printed at the time a medication is dispensed. This is generally an automated process, accomplished by use of one of the various brands of software available to pharmacies and based on drug-specific information, interactions and warnings.

It is therefore not true that the creation of such labels would "Involve business negotiations between the Company and the countless number of third parties actually filling patient prescriptions of a specific medicine." It would merely involve the same process that prompted and created the warning labels already present on dispensed prescriptions of Levaquin®. "

I'm sure the SEC will concur with me that it is appalling that the most important information is NOT on Levaquin bottles, while **black box warning information is actually on so many other medicines. (see attachment "Labels on Bottles"**

Their 'scientists and medical professionals'in fact, have deliberately left out important information on the bottles for patients, that would lead to decrease sales of Levaquin, as stated

in the trail transcript as physicians would begin to prescribe less toxic antibiotics FIRST, and use Levaquin more as a "last resort" medication as they do in parts of Europe.

Pg. 12- 13 trail transcript:

"Dr.J.Kahn is acknowledging that both ofloxacin and levofloxacin have a greater tendon problem than the other fluoroquinolones..... back in 2001 they were admitting that problem... they specifically say they don't want to put that in the label, the greater potential. It would be a killer."

Less sales, is the one main reason why they are disputing this obviously compassionate and rational request. Patients care about patients, the company cares about profits first.

Johnson & Johnson's attitude of hiding the most important safety data from the public is sadly a long-standing strategy and has been clearly described in the Minnesota trail where John Schedin won a sizeable award from incurring tendon ruptures due to not having been properly warned. To quote directly their behavior to hide the truth as much as they could:

"starting in 2001 through 2009 we're talking about roughly 13 billion dollars, so what's at stake here for the company looking forward from 2001 when our story begins is the potential of 13 billion dollars of lost revenue. That's what they needed to protect. That was their motive. It was Ortho-McNeil's number one drug.

Pg. 29: Trial Transcript:

They lied to the FDA about comparative tendon toxicity of fluoroquinolones."

They want to continue to do this not only with patients who get Levaquin, but now to shareholders who, hopefully, will be asked to help overcome their deficiency and abuse of the prescription healthcare delivery system.

To continue quoting the trial transcript:

" Their actions were deliberate.

"This is the marketing people talking now about how to do science, just as the science people were talking about how to do marketing with ultimately one goal, profits over people.

We have four categories of claims of bad acts that we believe are germane to this motion. First, the defendant deliberately disregarded patient rights concerning the warnings. Second, they manipulated the scientific literature for their own economic purposes. That's the Ingenix study. Third, they deliberately disregarded existing scientific literature. There were, we count, 16 articles published by 2003 wherein either Floxin or Levaquin was shown to have a greater tendinopathic potential than other fluoroquinolones in the class. It was out there. It was not in JAMA. It was not in the Archives of Internal Medicine.

Dr. Beecher, our family practice physician in the

Schedin case working in Edina, would not be seeing these.
.....There were 16 articles
that Johnson & Johnson had and should have known about that
they disregarded.
Then on top of that what do they do is, they turn
their sales force loose, and their sales force has one
mantra: Tell everybody how safe Levaquin is, touting the
high safety profile of this drug. They deliberately
disregarded patient rights. They created a plan to
maximize profits while avoiding safety issues.
Sitting around in board room 301 in the Kitano
meeting, you didn't see anything in that James Kahn memo
that said anything about safety issues and how do we fix
the safety problems. It was how do we avoid the safety
problems in order to make sure we don't lose any money.
They purposely sought to avoid label changes."

Thus, paragraph three of their NO VOTE statement is false. They have in reality, worked AGAINST "the FDA and regulatory agencies around the world".

To further quote from the trial:
"What I want to
talk about is the mindset that the company had, and some of
the early documents that show the mindset I'm going to show
those here. They felt that an adverse regulatory decision
in Europe was going to be devastating. What was that? Let
me tell you the story."
PAGE 6: TRAIL TRANSCRIPT:
"It starts in April of 2001, as the brief shows
you, when the European, the French regulators went to
Johnson & Johnson's marketing partner Aventis and said
there is an increased reporting of tendon problems,
particularly with Levaquin. And they wanted to know what
that was about, and they wanted to know whether Levaquin
was experiencing a greater tendon disorder report than any
of the other drugs in the class of the fluoroquinolones.
So the report started coming to Aventis, and
Aventis immediately contacted Johnson & Johnson, and they
started talking to each other about what would be the
ultimate ramifications of this. So April of 2001 leads to
July 24, 2001.
The partners come together at the Kitano Hotel in
New York City...

They are talking not about safety. They are not talking about health concerns. What they're talking about is money. They're talking about the devastating potential of the adverse regulatory decision that might come out of Europe."

From the beginning of the trial in Minnesota: (see Rebuttal for reference, page 10)
"Now, who was there for Johnson & Johnson? One guy that was there was Dr. James Kahn. **Dr. Kahn was a medical affairs guy. He was not a marketer. He was not in sales. He was not in economics. He was the guy who gave birth to the molecule and gave birth to the science, but his whole mindset was about marketing and economics. (Bold: P. Cahan)** And so as you can see from this first document, which was used in Dr. Kahn's deposition which was not marked as confidential, he says, The repercussions from an adverse regulatory decision in France, who among us can forget what happened over there to sparfloxacin, would be immediate and devastating, so let's act promptly."

The case in Minnesota goes on to describe how they manipulated a study of Levaquin's in Europe. (called Tavanic)

I suggest to SEC regulators to read this document in full, if you have not had the time to do so already. (Minnesota case)

I will end by saying that there is nothing the company wrote in their opposition statement that is not misleading or in fact false in the context of shareholders voting on just adding a few words of warning to the bottle, which may save coutless lives from long term pain and misery and lost income, etc.. I suggest that the SEC block this statement and concur that the Proxy I submitted will help repair a broken system of communication that has been **intentionally implemented both here and throughout the world** with one goal in mind: to sell this product no matter what the consequences until they are forced to ban the drug completely, or have it severely limited to medical scenarios when it is the "last resort" for patients after safer antibiotics are used first. (please refer to rebuttal, charts Exhibit G that refer to studies showing that it is the most harmful of antibiotics in the class of 'floroquinolones'.

Thank you for your attention.
Sincerely,

Paul W. Cahan
attachments

MANAGEMENT'S STATEMENT IN OPPOSITION TO SHAREHOLDER PROPOSAL

The Board of Directors favors a vote AGAINST the adoption of this proposal for the following reasons:

Pharmaceutical product labeling is a complex and highly regulated area that necessitates a careful review by highly-trained professionals under strict regulatory supervision to consider all relevant scientific, pre-clinical, clinical trial and safety reporting findings regarding a pharmaceutical product. Decisions related to the labeling of pharmaceutical products, including patient safety information, can have profound consequences for human health, and thus, are necessarily delegated to highly trained and experienced science, medical and regulatory professionals, and are not suited to be put to a shareholder vote.

We believe that improving how prescription medicines are labeled by pharmacies when filling prescriptions, and the type of information that pharmacies should be providing their customers, are important matters that regulatory authorities are examining, however, the Company is not in a position to regulate or impose standards in that area. Nor would it be a prudent use of resources to attempt to negotiate with the numerous pharmacy chains and independent pharmacies nationwide on the type of literature each pharmacist must give to its customers with each of the prescription medicines manufactured or marketed by our pharmaceutical businesses.

Our pharmaceuticals businesses have worked in the past, and currently continue to work with the FDA and regulatory agencies around the world on developing appropriate labeling for the many branded pharmaceuticals that they manufacture and market, including LEVAQUIN. In doing so, all of our businesses are guided by Our Credo, which says that the safety and well being of patients must be first and foremost in everything that they do. Specifically, the current FDA-approved label for LEVAQUIN includes a "boxed warning" and a Medication Guide for patients, which address the risks associated with using LEVAQUIN.

The Board believes that having a vote on how a particular prescription medicine must be labeled delves too deeply into decisions best left to our science, medical and regulatory professionals working with the appropriate regulatory bodies, and would not be in the best interests of the patients who rely on these medicines.

It is, therefore, recommended that shareholders vote AGAINST this proposal.

PROPOSAL 7

STOCKHOLDER PROPOSAL REGARDING LABELING
PRODUCTS OF CLONING OR GENETIC ENGINEERING

The Company has been notified by the Adrian Dominican Sisters, 1257 East Sienna Heights Drive, Adrian, MI 49221-1793, which owns 150 shares of Common Stock, that it intends to present, jointly with ASC Investment Group, Bon Secours Health System, Inc., Boston Common Asset Management, LLC, the Dominican Sisters of Oxford, MI, the Dominican Sisters of Springfield Illinois and the General Board of Pension and Health Benefits of the United Methodist Church, the following proposal for consideration at the Annual Meeting:

Label Products of Cloning or Genetic Engineering
2007 Safeway

RESOLVED: Shareholders request that the Board of Directors adopt a policy to identify and label all food products manufactured or sold by the company under the company's brand names or private labels that may contain genetically engineered (GE) ingredients or products of animal cloning.

Supporting Statement

- The right to know is a fundamental principle of democratic societies and market economics.
- The Food and Drug Administration is expected to make a decision regarding the sale of milk and meat from cloned animals by the end of 2006 (WA Post 10/17/06).
- Safeway products contain corn, rice and soy, all of which potentially could be the genetically engineered variety.
- Safeway's O Organic line could be impacted by contamination from genetically engineered ingredients.
- Labeling is an indicator of due diligence of product ingredients.
- The global alliance Action by Churches Together took a stand supporting the "right to know" whether there are genetically engineered ingredients in the food purchased or in the seeds sown. (ReliefWeb 6/28/06)
- 132 countries, parties to the Cartagena Protocol, have agreed to documentation requirements for the export and import of genetically engineered organisms. (Financial Times 3/29/06)
- As of May 19, 2005, Alaska law requires that genetically engineered salmon be labeled as such.

Indicators that genetically engineered organisms can be difficult to control, and may be harmful to financial markets as well as to humans, animals and the environment include:

- Illegal unapproved Liberty Link long-grain rice, planted in field trials no later than 2001, was discovered to have contaminated U.S. rice supplies. (Reuters 8/28/06) This prompted Japan to suspend imports of US Rice, and the European Commission to require that rice imports be certified as free of unauthorized grain, greatly disrupting the US rice export market.
- Between 2001-2004, approximately 15,000 hectares (150 square kilometers) in four US states were planted with unapproved Bt10 corn. (New Scientist 3/23/2005)
- December 2006, U.N. Secretary General Annan cautioned that the international community lacks safeguards to prevent bioterrorism and accidental harm from biotechnology advances.
- The report *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects (National Academy of Sciences] 7/2004)* states: ..."there remain sizable gaps in our ability to identify compositional changes that result from genetic modification of organisms intended for food... (p.15)
- Federal District Court ruled (8/10/06) that USDA's permitting of drug-producing genetically engineered crops in Hawaii violated the Endangered Species Act and the National Environmental Policy Act.
- Genetically engineered creeping bentgrass, not yet approved commercially, escaped into wild as far as three miles from the test plot. (8/9/06)
- Five major US agricultural weeds have developed resistance to glyphosate, the herbicide used with genetically engineered Roundup Resistant crops. Addressing this problem includes use of additional herbicides.
- Research (*Environmental Health Perspectives 6/2005*) has shown that Roundup, increasingly needed on Roundup Ready crops, is toxic to human placental cells at concentrations lower than agricultural use.

Board Recommendation

The Board of Directors recommends a vote "AGAINST" this proposal for the following reasons:

The Company shares and actively supports our customers' interest in food safety. The Company's policies regarding food products manufactured or sold under its own brand names and private labels that contain genetically modified ingredients are based on a number of factors, including the following:

To date, the Food and Drug Administration (FDA), the United States Department of Agriculture

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In Re: Levaquin Products Liability Litigation,	)	File No. 08-md-1943 (JRT/AJB)
	)	Minneapolis, Minnesota September 28, 2010 10:10 A.M.

BEFORE THE **HONORABLE JOHN R. TUNHEIM**
UNITED STATES DISTRICT COURT JUDGE
(MOTIONS HEARING)

APPEARANCES

For the Plaintiffs: **RONALD S. GOLDSER, ESQ.**
LEWIS J. SAUL, ESQ.
BRIAN McCORMICK, ESQ.

For the Defendants: **JOHN DAMES, ESQ.**
WILLIAM H. ROBINSON, JR., ESQ.
WILLIAM ESSIG, ESQ.
TRACY J. VAN STEENBURGH, ESQ.

Court Reporter: **KRISTINE MOUSSEAU, CRR-RPR**
1005 United States Courthouse
300 Fourth Street South
Minneapolis, Minnesota 55415
(612) 664-5106

Proceedings recorded by mechanical stenography; transcript produced by computer.

10:10 A.M.

(In open court.)

THE COURT: Good morning. You may be seated. This is civil case number 08-1943, In Re: Levaquin Products Liability Litigation. That's the MDL number. We have a number of motions this morning.

Let's see. Let's have counsel note appearances first.

MR. GOLDSER: Good morning, Your Honor. Ron Goldser for plaintiffs.

MR. SAUL: Good morning, Your Honor. Louis Saul for plaintiffs.

MR. MCCORMICK: Brian McCormick, Your Honor.

MR. DAMES: John Dames for the defendants.

MR. ESSIG: Bill Essig for the defendants.

MR. ROBINSON: William Robinson for the defendants.

MS. VAN STEENBURGH: Tracy Van Steenburgh for the defendants.

THE COURT: Good morning to all of you.

MR. GOLDSER: Your Honor, I thought what we would do is take the punitive damages motion first and then the judgment on the pleadings with your permission.

MR. DAMES: I don't have any disagreement, but I wanted to just raise an issue before we got started with the specifics on the oral argument. We have a reporter in

the gallery here, and there are going to be matters that are -- that have been to date confidential and are confidential, some documents embedded in the presentation, and my concern is that we don't wish to waive that. The motion hasn't yet been decided by the Court.

THE COURT: Okay. Very well.

MR. GOLDSER: We certainly oppose any action taken with regard to that. We think this is an open courtroom. The documents that we're going to be using have all been used in depositions, and none of the depositions have been marked as confidential ever, except minor parts dealing with individual personal finances, so the documents even though they may have a confidential stamp on them aren't even confidential anymore.

Presumption, strong presumption in favor of an open courtroom.

THE COURT: Let's address that when we get to it. Let's start with the punitive damages motion.

MR. GOLDSER: Okay. Thank you, Your Honor. The way we will divide up the punitive damages is, my presentation that is before you is designed to be a bullet point presentation. These are what we considered to be the bad acts, all of which have been substantiated by voluminous filings in the briefs.

I will highlight those bad acts for you. I will

call your attention to several documents. I am not going to be going through a lot of documents. The presentation has a lot of hyperlinks on them. Mr. Essig tells me that unfortunately the copy I gave to him, the hyperlinks weren't working. I don't know if that was true of the Court's copy or not. Obviously I hope they were working.

I'm on my laptop. I know they work. At least they did an hour ago. So we will see where that takes us. There are a few in particular that I want to call to the Court's attention. Mr. Saul will follow me on this and focus on the Ingenix study, although I will cover it fairly quickly.

The whole notion of the punitive damages motion, to start off with, there are a couple of preliminary legal issues that I want to address and get out of the way right away. First, the question of choice of law, that's been briefed extensively. We think there is little doubt that Minnesota law applies to this question. Even if it doesn't, we think we have met the New Jersey standard, and I'm quite perplexed by the defense posture.

To suggest that New Jersey law would apply, because as federal courts have rejected the *McDarby* decision out of the New Jersey appellate court, if you decide that New Jersey law applies and that *McDarby* is no longer good law in light of *Wyeth*, I think they have just

opened themselves up to a whole punitive damages claim in New Jersey in state court that they don't anticipate. So I don't think they really want to go there, and I don't think they're really serious about it.

Secondly, the law is quite clear to me that what you consider on this record is plaintiffs' prima facie proof that defendant doesn't have the right to cross-examine it. They don't have the right to challenge it. They don't have the right to present any of their own evidence, and so to the extent that the defense wants to present documents to you today, I don't think you consider them. I don't think they're part of the prima facie case at this point.

I mean, I'm glad to have had their brief because I now see what their closing argument is in front of the jury, and it's very nice, but they don't get to make that argument today. So for us what matters is what does the evidence show and what is this case all about, and as a starting point, the case is about money.

And this first slide will show you the history of the gross revenues that the company has earned over the years year by year on Levaquin. This is all public material. It comes from their annual report, so this is all out in the public domain.

So if our story for this motion begins in April

of 2001, you can see that starting in 2001 through 2009 we're talking about roughly 13 billion dollars, so what's at stake here for the company looking forward from 2001 when our story begins is the potential of 13 billion dollars of lost revenue. That's what they needed to protect. That was their motive. It was Ortho-McNeil's number one drug.

Their actions were deliberate. The Statute 549.20 says that in order to get punitive damages, plaintiff must show a deliberate disregard for the rights and safety of others. As the Court knows, that can be shown several different ways.

One of the ways is to talk about intentional acts. The other is to talk about deliberate disregard of knowledge and facts, and you'll see that there were both that occurred here, much disregard of information that was out and available.

But before I get to those acts, what I want to talk about is the mindset that the company had, and some of the early documents that show the mindset I'm going to show those here. They felt that an adverse regulatory decision in Europe was going to be devastating. What was that? Let me tell you the story.

It starts in April of 2001, as the brief shows you, when the European, the French regulators went to

Johnson & Johnson's marketing partner Aventis and said there is an increased reporting of tendon problems, particularly with Levaquin. And they wanted to know what that was about, and they wanted to know whether Levaquin was experiencing a greater tendon disorder report than any of the other drugs in the class of the fluoroquinolones.

So the report started coming to Aventis, and Aventis immediately contacted Johnson & Johnson, and they started talking to each other about what would be the ultimate ramifications of this. So April of 2001 leads to July 24, 2001.

The partners come together at the Kitano Hotel in New York City. It's a beautiful place. It is located on 37th and Park Avenue, and next time you're in New York you ought to run by. It's just a gorgeous hotel, and they meet in board room 301. What is it they're talking about in board room 301?

They are talking not about safety. They are not talking about health concerns. What they're talking about is money. They're talking about the devastating potential of the adverse regulatory decision that might come out of Europe.

Now, who was there for Johnson & Johnson? One guy that was there was Dr. James Kahn. Dr. Kahn was a medical affairs guy. He was not a marketer. He was not in

sales. He was not in economics. He was the guy who gave birth to the molecule and gave birth to the science, but his whole mindset was about marketing and economics.

And so as you can see from this first document, which was used in Dr. Kahn's deposition which was not marked as confidential, he says, The repercussions from an adverse regulatory decision in France, who among us can forget what happened over there to sparfloxacin, would be immediate and devastating, so let's act promptly.

MR. DAMES: I just wanted to object to something, Your Honor, and I'm sorry, Ron.

The document by its own at the bottom says protected document, document subject to protective order. However we want to handle this issue, I don't want to fall pit to his argument again, but we're going to run into this.

THE COURT: Mr. Goldser?

MR. GOLDSER: As I said, this is marked as Plaintiff's MDL Exhibit Number 38. That's also on the bottom. It's part of Dr. Kahn's deposition. It is part of Larry Johnson's deposition. Those depositions were not marked as sealed, and I think counsel will agree to that fact, and so this document is already in the public domain.

You never marked them as confidential, guys.

MR. DAMES: We marked the document as

confidential, Your Honor. The transcript portions were not marked confidential, the transcript itself, but the document itself has been consistently marked confidential. I just think that once that issue is decided by the Court as to the confidentiality of those documents, obviously this will be one way or another resolved, but we did protect that document.

The transcript portions, the testimony, I frankly don't remember if they were or not, but I will assume that they were not.

THE COURT: They were not made confidential?

MR. DAMES: The testimonial portion.

MR. ROBINSON: No, Your Honor. The transcripts were not marked protected or confidential, but under the protective order, we had the right to mark documents as confidential. I don't think there is any requirement that we go back each time a protected document is discussed in a deposition and seal that part of the deposition. It's not a public record.

MR. GOLDSER: One other item, Your Honor. I read this very sentence to Dr. Kahn in his deposition. It's part of the transcript. That's not confidential.

THE COURT: Do you have other documents as part of this presentation that raise this same issue?

MR. GOLDSER: Yes. There will be another

document, the next one, which is one of the most significant documents in the case, also authored by Dr. Kahn, I went through it in copious detail with him, and I read most of the parts I'm going to read to you in his deposition. They're part of the transcript.

THE COURT: Anything else then besides that?

MR. GOLDSER: There will be one or two others. There is one that I am pretty sure was not used in the deposition. I can tell you which one that is when I come to it.

THE COURT: Let's address that when we come to it. Since the language was read in the deposition, which is open and not marked confidential, I will allow at least these two documents to go forward.

Go ahead.

MR. GOLDSER: So let me explain the significance of that line. It's got two things of import. One is you can see that the repercussions of an adverse regulatory decision would be immediate and devastating, so let's act promptly. It tells you about the mindset of the company as of July 21, 2005, right after the Kitano meeting.

The other thing that it mentions, it says in parentheses, Who among us can forget what happened over there to sparfloxacin. Sparfloxacin was another fluoroquinolone. It had phototoxicity problems. There was

a contraindication given to sparfloxacin because of phototoxicity, and its use was severely restricted.

So the reference, and Dr. Kahn explains this in his deposition is, we can't afford to have a contraindication to Levaquin because the same thing would happen to us in Levaquin as what happened -- as happened to sparfloxacin. Our sales would go down. That 13 billion dollars I showed you in the first slide was in jeopardy.

That's the mindset. That's the deliberate disregard of patient rights. It was about money, and the statement comes from the doctor, the safety officer. It's not coming from the marketing people. What else did they say? It would have serious implications for marketing.

This is the second document that I just described to you. It is James Kahn's document. It is his long memorandum that, it is his long memorandum that describes what happened at the Kitano meeting, and I hope this is readable enough on your screen. I want to go through a number of these.

These are the quotations that I read to Dr. Kahn in his deposition. I don't know that I got all of the ones that I'm about to recite, but many of them, and this document was certainly included. It was MDL 98. It was noted that way in Dan Fife's deposition, as well as being used in Jim Kahn's.

Kahn writes that the regulatory situation in France was a very worrisome regulatory situation. It has clear and serious implications for our marketing of Levaquin and could have an impact in the U. S. as early as the coming respiratory season. I believe this matter to be urgent and to require our immediate attention.

That's the first paragraph. That certainly shows the mindset of Jim Kahn as he is conveying what happened at the Kitano meeting, but then if you go down to that third paragraph, the one that I just blocked off, this has some particular importance. These data should be considered against a prevailing background perception that both ofloxacin and levofloxacin might have greater tendinopathic potential than other fluoroquinolones.

Comparative animal data had previously suggested that the two agents were more prone to induce lesions than were many other members of the class. Reporting rates for ofloxacin, ofloxacin related tendinopathies have traditionally been higher than for other FQ fluoroquinolone agents. In our U. S. post marketing Levaquin experience, we see has a higher reporting rate for tendon disorders than for virtually any other AE, adverse event, commonly regarded as part of the fluoroquinolone profile.

There is a huge amount of stuff in that paragraph. First off, in July of '01, Kahn is

acknowledging that both ofloxacin and levofloxacin have a greater tendon problem than the other fluoroquinolones. They have denied that issue today. They will not say that there is a problem, but back in July of '01, they were admitting that problem.

As one of the documents that may still be subject to a confidentiality order says, and I will tell you about it without pulling it up, they specifically say they don't want to put that in the label, the greater potential. It would be a killer.

Next thing it says, there is comparative animal data that suggests that the two agents were prone to induce lesions than were many other members of the class. There is a huge argument the defense makes about you don't use animal studies to talk about whether it's predictive or not predictive. Jim Kahn says the animal studies will tell you it's predictive. It's a problem.

How can they with a straight face come here and say animal studies are not relevant? Their own doc says it's relevant. The next sentence says, Reporting rates for ofloxacin associated tendinopathies have traditionally been higher than other fluoroquinolone agents. Defense has been saying all along that Floxin is irrelevant, ofloxacin.

Kahn thinks it's perfectly relevant. He's worried that the higher reporting rates for Floxin tell you

something about Levaquin. He thinks it's relevant. The defense doesn't. In our U. S. post marketing Levaquin experience, we see has a higher reporting rate for tendon disorders.

What is it that they say there? They've looked at their owned SCEPTRE database. The SCEPTRE database is their database of adverse events that they maintain. Our expert Cheryl Blume has gone to a great length to evaluate the SCEPTRE database year by year, period by period to show where in the rankings tendon disorders fit.

THE COURT: What is the timing of the Kahn memo?

MR. GOLDSER: July 26th, 2001, the day after he comes back from the meetings with Aventis and Daichi.

THE COURT: Wasn't there a follow-up label change, though, right after this?

MR. GOLDSER: There was. There was a label change that occurred in October 2001. It was done by the CBE. The changes being effected procedure, so defense by that action acknowledges that CBEs are available. What they said in that label change was that there is a problem with the elderly in corticosteroids. Two problems there.

Number one, it ignores the question of Levaquin worse than the other fluoroquinolone, like this paragraph is talking about. It doesn't talk about the comparative tendon toxicity whatsoever. The other problem is the

adequacy of that warning, and I can talk about that somewhere along the line, but basically they put it in the PDR.

You have seen the PDR. It's an eight and a half by eleven book. The 2005 version has 3,558 pages in it. The Levaquin warning, the Levaquin part appears on page 2,445. The warning itself appears on page 2,448 in the lower left corner of three columns, and the only thing that defendant did in changing the label was to change one sentence in the middle of that paragraph on the lower left corner on page 2,448 of a 3,558 page document and say the doctor should have picked up that one sentence.

They never detailed it. They never did a dear doctor letter. They never did a seminar about it. They never did any published articles about it. They never did any of those things. So, yes, Judge, there was a label change after this.

But this point has to do with the analysis of the SCEPTRE database, which apparently the defendant did, never disclosed to us in discovery, which our expert Cheryl Blume did, reproduced, and found that tendon disorders were ranked as the number one disorder and were back to 1999 and consistently thereafter.

What else did Jim Kahn write on July 26th, 2001? He says, The agencies have several options, and he goes

through a list of possibilities. One of them is a concern about restricting Tavanic, which was the European name for Levaquin, to in-hospital use. That gets you to the same contraindication problem that sparfloxacin got to. Labeling changes would follow, and least onerous would be letting the company continue its current campaign of alerting doctors to the situation, which of course they were not doing.

This is the doctor talking about how to minimize the warning label so that they don't have economic, adverse economic impact. Farther down on that document they start talking about the epidemiology study that Europe wanted, and I've highlighted the section that reads, Moreover, the study envisioned struck many as very insufficient in its present design.

That's Aventis's proposed study. It might actually generate more damaging material unless careful thought were given to other fluoroquinolone and nonfluoroquinolone experience in the same database. They're worried about an adverse result if they do the proper study. They had to manipulate the study.

Ultimately, they did manipulate the study in our view. That was the Ingenix study, and we will talk about what they did with that. Mr. Saul will go into more detail than I will. You can see the precursor of manipulation of

the Ingenix study right after the Kitano meeting. The proper remedy is not to fault the agent but to seek remedy in either changing medical practice or more thoroughly advising physicians of the identified risk factors.

It's not Levaquin's fault. It's the doctors' fault. We have got to make sure the doctors don't use this wrong. There is nothing wrong with Levaquin. Of course, blame others. Isn't that always the case, blame the victim in situations like this?

The sine qua non of our efforts should be making the case that the European picture is distorted by medical practices and in no way implicates levofloxacin as the lone culprit. It's the doctors' fault. We need to consider doing the correct epidemiological study ourselves. We have far more at stake than does Aventis, and there would be no ambivalence clouding our commitment to doing it right.

Far more at stake? Ortho-McNeil had one antibiotic. Aventis had a bunch. If Aventis lost Tavanic, Levaquin, their revenues would not suffer. If Johnson & Johnson, Ortho-McNeil, lost Levaquin, they would be losing their number one drug. They had far more at stake, and that's all for that document.

Their mindset, the entire franchise was riding on a single toss. That's what Jim Kahn said again in his deposition. The stakes have gone up, Larry Johnson wrote

this, when the Germans suggested there was a problem with Levaquin. There was some discussion about contraindication occurring with the British advisor, Dr. Steven Evans, and the writing was that a contraindication would be tantamount to a withdrawal. They were worried about that.

The MCA, that's the British authority, they were proposing a label change, and this could lead to a bad result, which we have already detailed. Now this document is the one that I was talking about that I don't believe was used in the deposition, but it also had the provision in it that said we cannot accept a label change that would show Levaquin having a greater potential for tendon toxicity than any other fluoroquinolone. The study could be a nightmare. That would be the Ingenix study, if it came out wrong.

And finally one of the marketing people talking to the scientists about how to manage the study said, you've got to do whatever it takes. This is the marketing people talking now about how to do science, just as the science people were talking about how to do marketing with ultimately one goal, profits over people.

We have four categories of claims of bad acts that we believe are germane to this motion. First, the defendant deliberately disregarded patient rights concerning the warnings. Second, they manipulated the

scientific literature for their own economic purposes. That's the Ingenix study.

Third, they deliberately disregarded existing scientific literature. There were, we count, 16 articles published by 2003 wherein either Floxin or Levaquin was shown to have a greater tendinopathic potential than other fluoroquinolones in the class. It was out there. It was not in JAMA. It was not in the Archives of Internal Medicine.

Dr. Beecher, our family practice physician in the Schedin case working in Edina, would not be seeing these. Some of them were internal documents, like the Aventis study that as given to the MCA. There were 16 articles that Johnson & Johnson had and should have known about that they disregarded.

Then on top of that what do they do is, they turn their sales force loose, and their sales force has one mantra: Tell everybody how safe Levaquin is, touting the high safety profile of this drug. They deliberately disregarded patient rights. They created a plan to maximize profits while avoiding safety issues.

Sitting around in board room 301 in the Kitano meeting, you didn't see anything in that James Kahn memo that said anything about safety issues and how do we fix the safety problems. It was how do we avoid the safety

problems in order to make sure we don't lose any money. They purposely sought to avoid label changes.

I had an e-mail from Dr. Noel, one of the medical people involved in this. That's attached to this, but I highlight back for you the notion that I mentioned before about how they refuse to incorporate anything in their label change about Levaquin being worse than the other fluoroquinolones.

They knowingly decided not to share the warnings information with the public. One of the documents that I have that the defendant has finally acknowledged is a set of handwritten notes from yet another doctor, Chuen Yee, from Johnson & Johnson, sitting at the Kitano meeting, and that documents says in her handwriting, Not share with public, and it's talking about the French agency reports. Don't tell anybody about it.

They ignored their own published literature and how best to communicate warnings to doctors. I mentioned Dr. Fife. He's one of the doctors involved with Johnson & Johnson. He's an epidemiologist. One of the epidemiology studies he published, and I'm not sure but what this article is marked confidential. Let me just take a quick look here.

No, they didn't mark this one confidential. What Dr. Fife says at the end of his article, if I have it

highlighted -- let's see if I can pull that up for you. He did an epidemiology study to determine what is the most effective way to communicate warnings to doctors, and what he finds in the last sentence is the most telling I think. The key characteristics of a successful drug warning appear to be specificity, prominence, brevity, no reliance on secondary information, publicity and in-person discussions.

You've got to do stuff other than bury it on the lower left corner of page 2,448 of the PDR when that book comes out every year and don't tell a doctor about it. Their own doctor says, their own epidemiology department tells how you should be doing that. They ignore their own published literature and how best to communicate with doctors.

They intentionally buried the warning, as I have described to you. They failed to send a dear doctor letter. There were dear doctors letters sent, if I get the countries right, in France, Italy, Belgium, Germany, Austria, and I'm missing one. There were six of them, all in 2001 and early 2002, about the corticosteroid elderly problem. Was there one sent in the United States? No.

Dr. Canabarro from Aventis was deposed, and what she said in her deposition was, she was asked, you know, why do you send out a dear doctor letter, and her response was, well, you know, we had it in the warnings. But why

did you send out the dear doctor letter? Because the warning wasn't enough, and we wanted to make sure to communicate with doctors. Aventis did it. Johnson & Johnson didn't.

They deliberately did not train their sales representatives to proactively call out label changes to doctors. I deposed Teresa Turano two weeks ago. She was the 30(b)(6) corporate representative on sales training. She didn't know much, but what was clear from her was that there was no policy to tell sales representatives that whenever there is a label change you have got to tell doctors.

What they did do is, they handed out a copy of the package insert every time they went there, theoretically, but that doesn't mean they said to the doctor, you know, take a look here. There is a label change. I want to make sure you're aware of this. They did not do that.

They did do that with the black box. The sales force was told proactively, tell doctors about the black box. Were they told proactively to tell doctors about the black box? Were they told proactively to tell doctors about that 2001 label change? According to the corporate representative, there was no such policy.

They deliberately didn't issue press releases

publicizing changes. I deposed Greg Panico last week, the corporate representative on press releases. He, too, didn't know a lot, but what he did say was there was no policy to initiate press releases about label changes. We went through a litany of documents. They kept track of every news article.

There were clear press releases issued about new indications that the FDA had approved, but was there any indication whatsoever that they issued a pretty release on any label changes? Not a one. They didn't undertake any seminars, public speaking engagements, lunch or learn trainings.

They didn't educate doctors in the manner that they otherwise do educate doctors about new indications. They didn't publish articles talking about the risk of tendon disorders, and I will come back to that in a little bit when I talk about the publication plan and the ghost writing.

They manipulated the Ingenix study for their own economic purposes. The Ingenix study started to appear in discussions in the late fall of 2001. Aventis made a proposal about the protocol. The idea was that they would respond to the French authorities. The French authorities wanted to know what was the comparative tendon toxicity between Levaquin and the other fluoroquinolones.

The Johnson & Johnson response was -- and Aventis was going to do a study that said that. Johnson & Johnson said we can't afford that study. If we end up with a bad result, we're in trouble. So they started taking control of the study from Aventis, and they slowly but surely turned the battleship around to change the focus of the study from a comparison between fluoroquinolones to talking about fluoroquinolones in general and the impact on the elderly and corticosteroids, because by that time they had already decided to include that warning in the label.

And so if they found that there was a negative impact, no big deal. It was already in the label. They already had a strategy for that. So they were going to figure out a way to manage the Ingenix study so that they would get the result that they wanted. So they manipulated the one study to achieve an outcome that was in their best economic interests.

They took it over from Aventis. They controlled the study with Ingenix. I will talk about that for a second. The protocol that was written, it was drafted by Dan Fife. It was discussed between Dan Fife and John Seeger at Ingenix.

There were meetings to talk about the protocol. There were exchanges of drafts on how to do the protocol, the type of study that it was was developed by Johnson &

Johnson in discussion with Ingenix. I mean, they did the whole protocol process.

To be sure, I mean, John Seeger was involved in this, but Johnson & Johnson really controlled the protocol process. Once the protocol was set, it was just a matter of filling in the numbers by mostly administrative mechanism, although we certainly have complaints about how John Seeger did that, and I will talk about that.

They avoided comparing Levaquin with other fluoroquinolones as was requested in Europe. All the items on the bottom are references to documents, and if the hyperlink works, you could pull up the documents. They changed the desired outcome. Europe wanted to know what was the problem related to tendonitis and tendinopathy.

Johnson & Johnson said we can't do that. It has got to be tendon rupture. Ostensibly the reason is because tendon rupture is better defined. It's easier to identify what constitutes a tendon rupture, but really what they're saying at that point in time is that doctors don't know how to diagnose a tendinopathy and they won't trust tendinopathy diagnoses.

Paul Van der Linden in the Netherlands whose four studies, including his PhD thesis, talked about how Floxin was worse than the rest, focused on tendinopathy and tendon rupture. He was able to distinguish between tendinopathy

and its relative risk compared to other drugs and to placebo and also tendon rupture compared to other drugs and placebo.

He could do it. It was academically acceptable to people accepting his PhD thesis, but that was not good enough for Johnson & Johnson. The reason? Because there were fewer tendon ruptures than tendinopathies, and as a result the relative risk was going to show lower, they would get a better number.

They manipulated the power estimates of the study. I don't know to what extent you're conversant with the notion of power, but power tells you the ability to make accurate predictions about epidemiology studies. If you start out with power that is wrong, it's too high. If the power is at four when you're going to find a relative risk of two, what you are going to end up with as a result of that is a confidence interval that is very wide.

In order for you to have statistically significant results, the narrower the confidence interval the better, and most importantly, if the lower bound of the confidence interval is over one, you know that at worst it's still more statistically significant than random. One is random.

So when you have got a wide confidence interval that results in a lower bound being below one, you can say

with honesty this is statistically not significant, but it all stems from where you started. If you start with the wrong power estimate, you end up with a wide confidence interval and no statistical significance.

If you take the trouble to go through the litany of testimony from John Seeger that is listed on that page, you will see he admits that that's true and that they knew it going in, that they picked the wrong power. It was a manipulated study.

They minimized the number of elderly contained in the study data. I know Mr. Saul will talk about that. They improperly included children in the study. Mr. Saul will talk about that. John Seeger admits that that's true. They incorrectly identified what constitutes a tendon rupture for the study by having a nonmedical doctor, Seeger, do the study.

In particular what you might pay attention to on that slide is the bullet point saying testimony of Seeger regarding Schedin. We happened to pull out Mr. Schedin's medical record where it talks about whether he has got a tendon rupture or not a tendon rupture. It says tendon tear.

We asked Dr. Seeger, Is this a tendon rupture that would be included as a positive finding in your study. He said, no, this would not be a tendon rupture in our

study. Our plaintiff here, who has clearly defined tendon ruptures and his doctors have all said so, his treating doctors have said so, was not a tendon rupture for purposes of John Seeger's study. That's how badly defined some of these tendon ruptures were.

Why? Keep them out of the study and keep the numbers low. There was a medical record review for evaluating tendon ruptures, but there was no such medical record review for tendonitis cases which was used as a covariate. It was an internally inconsistent study.

Seeger is not blinded during the study. He knew which cases had fluoroquinolone use and which were not. Dan Fife, Johnson & Johnson's own witness, says that as a result the study is invalid. They destroyed abstracts. We wanted to reproduce the study. In order to reproduce the study we needed the abstracts and the medical records that they used to determine what was a tendon rupture and what was not. They have been described.

They admit it. Seeger admits that in the fall of 2006, three months after the article was published, they destroyed these documents. That's contrary to the guidelines published by the International Society of Professional Epidemiologists, ISPE, which requires that such documents be held for five years.

Normally you wouldn't think that would be such a

big deal except the guidelines were written in part by Seeger's boss at Ingenix, Alec Walker. Walker said, I don't know the guidelines. Are there guidelines? These guidelines go back to 1996. Walker wrote them in 1996. They were revised in 2000, 2004 and 2007, if my memory serves me correctly.

Walker doesn't know them. Seeger doesn't know them. They destroyed the documents in contravention of guidelines that they wrote. Mind boggling. They ignored the existing scientific literature. I told you about the 16 articles. They lied to the FDA about comparative tendon toxicity of fluoroquinolones.

Finally, on the converse side, their marketing efforts. They touted Levaquin's excellent safety profile without disclosing its risk and trained its sales representatives in this manner. I have got a pile of documents that show that. The do and don't document that is on there do tout the excellent safety profile of Levaquin.

The quick tips guide that is on the bottom there, I worked with Teresa Turano and went through much of that verbatim. I said, does this paragraph have anything about safety in it? No. Does this have anything about tendon ruptures in it? No. Does this have anything about warnings on tendon ruptures? No. Does this have anything

about comparative tendon toxicity? No.

All over the place there is nothing about tendon warnings, and it's all about the excellent safety profile of Levaquin. They knowingly marketed to the elderly population. Again, the quick tips guide will tell you that. They marketed it as first line therapy. Levaquin is a good drug for certain circumstances. We don't dispute that.

For people who are seriously ill, it will do what it's supposed to, but if you're got a sinuitis or an acute bacterial exacerbation of chronic bronchitis, like John Schedin did, you don't use Levaquin. He had one trial on Zithromax. Could easily have gone back to another trial on Zithromax or another less potent antibiotic, but this was marketed like candy, samples left, right and sideways. They had millions of dollars in samples for first line therapy for these indications that were hardly severe enough to warrant them.

They did ghost writing. From 1994 to 2002, DesignWrite, their hired gun, caused to be authored two -- 144 papers on either Floxin or Levaquin, touting its benefits. Of those 144 papers, 13 of them had the word "safety" in the title, and only one of them had anything to do with tendons, and that was a published, published paper on children and tendon disorders. Nothing about the

elderly. Nothing about corticosteroids. Nothing about any of the issues where Levaquin is worse than any other fluoroquinolone, and that's only through 2002.

In 2002 they spent a million dollars with DesignWrite on ghost writing alone. There was a lot more money spent with DesignWrite in that year. They used the Speakers Bureau as a promotional tool. Defendants' own expert John Segreti who is going to talk about Mr. Schedin's particular circumstances and case specific and also what you use Levaquin for.

I asked him -- he is on the Speakers Bureau, so they are bringing in a Speakers Bureau person as their expert witness, which is kind of curious. I asked him what he did when he was on the Speakers Bureau. He gave talks. I said, well, were they promotional. He said, of course they were promotional.

Well, why were they promotional? Because I was touting the use of Levaquin. It wasn't educational about disease. It was about how best to use Levaquin. They were promotional.

So at the end of the day, Judge, we have lots of good reasons why we believe defendant deliberately disregarded the rights of the plaintiffs, including John Schedin, intentionally, consciously, knowingly, willfully and with marked indifference. That's our evidence.

You don't have to, you shouldn't listen to any contrary evidence or challenges or cross-examination by defendant because that's not what the law allows or requires. We think the motion should be granted. Thank you very much.

THE COURT. Thank you, Mr. Goldser.

Mr. Saul, did you have something?

MR. SAUL: Good morning, Your Honor.

THE COURT: Good morning.

MR. SAUL: Louis Saul on behalf of plaintiffs.

Mr. Goldser talked at some length about the Ingenix study, and I will fill in the gaps. I realize our time is limited here. Just to go back, Johnson & Johnson had nothing to do with the European situation. Aventis, their trading partner in Europe, was asked to do studies because of the signal in Europe that there were tendon problems, particularly among the elderly, emphasis added, and particularly with corticosteroids.

What the defendant was hoping to avoid and worked to avoid -- may I approach -- was to have this, this warning in the label. This is the warning that eventually got into the label. This is the black box warning that got into the label in November '08. Fluoroquinolones, including Levaquin, are associated with an increased risk of tendonitis and tendon rupture. The risk is increased on

those over 60 and those on concomitant therapies respiratory, heart and lung recipients.

They kept this warning from being placed in the PDR, in the package insert, for seven years. During that seven years, their sales were about 13 billion dollars. By keeping this warning out for seven years, this company earned themselves 13 million dollars, and we believe that that evidence in itself is enough to get us to the punitive damages claim.

However, how did they do it.

THE COURT: Is this the warning that is on right now?

MR. SAUL: This is the present day warning.

THE COURT: Go ahead. I will ask you a question about that later.

MR. SAUL: Sure. So what did they do? They had no interest in Europe. In fact, they told the Court during our motion practice that they had no relationship with the European authorities and they didn't want to give us documents related to that, that they actually went and took over this study. They took it away from Aventis because they said if we don't do this study and we don't get the proper results, essentially we're dead. Levaquin is off the market.

So what did they do? They hired this company

called Ingenix who had done numerous other studies for them. There was a young doctor there by the name of John Seeger who had just become an employee, and they had him conduct the studies. Mr. Goldser said they designed the protocol. What did they do in the study?

If I may give you another document, Your Honor. This was prepared by me, and this is how they intentionally manipulated the study. The first they wanted to do, the European authorities wanted to study -- the issue was among the elderly and corticosteroid use. What did Johnson & Johnson do? They intentionally left out elderly from the study.

This document that I just handed you was from the original protocol of this Ingenix study. If you will see here, table 1 talks about the UnitedHealthcare research database population. If you'll go down to the bottom, 60 to 64 and 65 plus, you will see that in their database, there was only 4.7 percent of, let's for lack of a better term, the aging population. I'm in there. Just leave it like that.

You will see in table number 2 in the census bureau, there were 16.2 percent of the population being over 60. So they chose a data -- Aetna was going to use a different database, but they took this away and used this particular database that underrepresented the elderly.

What else did they do? Levaquin was contraindicated for children, for pediatric use. Contraindicated, you can't use it for pediatric use.

You will see in the general population, there is 29 percent, and in their database there is 29 percent in approximate numbers. They included this 29 percent, the children, in the study. So what they did is, they kept the elderly out. They included children. Children can't even take Levaquin. The elderly, the focus was on the elderly. They cut that down. Okay.

So what did they do? So they intentionally excluded the elderly and included children. But then what happened? They did their study. Part of their study was to get this study published in certain journals. Those journals are the journals that most of us have heard about.

For instance, in New England -- I won't go through them all. Five journals, the New England Journal of Medicine and the first line journals. They could not get this study published anywhere. What did they do? They went to -- Johnson & Johnson and Ingenix, they were members of a society, and Ingenix was the head of the society. They got it published in that society's journal.

No one else would take it. The study was concluded in 2003. 2006 it got published. Lo and behold three or four months after it got published, they destroyed

the data. They went and they did medical review of a certain number of the patients in this study, and you have to keep this data because once you publish something, other researchers have to be able to duplicate the study.

What happened to the data? Dr. Seeger testified, we don't -- we didn't really know what happened. I'm not sure what happened, and he went on and on. Finally, we got him to admit, and I just want to read to you -- at any rate, Dr. Seeger admits, admits that under his tutelage or under his direction that he caused all the documentation to be destroyed regarding the study. This is, forms the basis also of our motion, our *Daubert* motion.

No one can duplicate this study. They also created an algorithm to define who was in the case. They can't find that algorithm. All the documentation is gone. That in itself, the intentional destruction of the data, they kept their product on the market for nine years or eight years, is enough to allow us to amend the, the complaint, and I believe it's enough for the jury to enter a substantial award.

I feel that our time is limited, but each of these dotted areas is covered in our brief extensively, and I would like to incorporate our motion in limine regarding Dr. Seeger into this because rather than me go on and on about the study, I think it's all well depicted in our

brief.

THE COURT: Thank you, Mr. Saul.

MR. SAUL: Thank you, Your Honor. Did you have any questions about the black box?

THE COURT: No. That's fine. I may address it later in the hearing.

Mr. Dames?

MR. DAMES: Thank you, Your Honor. Your Honor, I just want to start from, actually maybe just the simplest of all is to start from the beginning, and that is when the drug was first marketed in 1997. There has much been made so far in the arguments concerning concealment, omissions, lack of warning, refusal to include things in the warning that I would like to refocus this as to what took place in the very beginning when the drug was first marketed.

From its inception, and the Court is well aware because we've said it many times, when it was first marketed, there has been a tendon rupture warning in the label. Not hidden, not in any way buried in a mass of language, prominently mentioned in the warnings.

At the time that Mr. Schedin received his prescription for Levaquin, the warnings had been updated as early as 2002 -- well, let me first go back to October of 2001. The warning was altered to include a reference to a heightened risk in the elderly, potential risk with the

elderly taking corticosteroids.

That was in response to the events and the data that had been received in Europe about the experience and adverse reaction reports from the use of Tavanic, the -- Levaquin is marketed in Europe, and the company through a change is being effected, that is on its own initiative, incorporated the information that was coming from Europe to include that in the warning on its own.

The FDA approved it at the company's instigation. They approved that warning. It was that warning with a very slight amendment in 2004. That was the warning the prescribing physician for Mr. Schedin received.

Now, in Europe the reports, the adverse reaction reports that were received in Europe, showed variances within the different European countries. Germany had a much lower rate of reporting than did France. When those things were investigated, when the scientists and researchers looked at what were the reasons for divergence between the European countries, they determined that in France, Levaquin was prescribed and Tavanic was prescribed predominantly for upper respiratory tract infections, and there the French physicians used corticosteroids a significant percentage of the time when they used Levaquin.

Now, the debate has been, you know, what significance is that. When the meeting occurred at the

Kitano Hotel, not quite as luxurious. I have actually stayed there. When the meeting was held at the Kitano Hotel to evaluate the situation and determine what should be done to investigate it, now remember already in place was J & J's CBE label change -- the label change occurred in October. I'm sorry. Already --

J & J incorporated that information in October that it learned, but in addition it wanted to do an investigation and a study, as did Aventis. Aventis does their own studies, a quick and dirty analysis, it was put, to look at the situation to respond to the French and European regulatory authorities. J & J decided it wanted to use the largest database then available, the UnitedHealthcare database.

Contrary to what you have heard so far, Your Honor, the Aetna database, an alternative, was not even available to be used. They couldn't use it. Why did they use UnitedHealthcare database? Well, it afforded J & J an opportunity to have access to medical records. Not all databases that were used would give you the access to the medical records.

And as I said, it was an exceptionally large database and would provide one of the best experiences to evaluate to see what was the frequency, what was the incidence of tendon rupture on Levaquin and what was the

incidence of tendon rupture on some other factors, for example, other fluoroquinolones and to evaluate --

I mean the study itself clearly was published by Dr. Seeger, included other factors besides Levaquin. It also evaluated corticosteroid use and some other predisposing factors. Now, why was tendon rupture used as a measure? Was it done to manipulate the data, to somehow hide something? No.

It was determined that the most objectively verifiable diagnosis that could be used in the study was a rupture. Not tendinopathy. Tendinopathy can be a wide variety of things. It is like 70 diagnostic codes are related to tendinopathies. So it could be confused with muscle tears. It could be confused with other kinds of diagnostic end products. So it was made, it was determined to use tendon rupture as the objectively verifiable point.

The diagnosis of tendon rupture by a physician was operative. Now what is wrong with that? Very, very little. Dr. Van der Linden used tendon rupture as the outcome in his own study.

Now, I want to remind the Court that J & J was very responsible in addressing the issue head on. It wanted to do the study on its own, not because it wanted to manipulate the results. Dr. Kahn testified quite clearly that what they wanted to do was the correct study. They

wanted to do it correctly. They wanted to make certain it was done right, and that's why they did the study the way they did, and that's why they did it rather than rely on any other company to do it on their behalf.

What was the outcome of their investigation? What was the outcome of their research? The French and European -- well, the European regulatory authorities evaluated not only the Johnson & Johnson sponsored study that was performed, and let's make this distinction clear. It was performed by Ingenix. J & J participated in the protocol. It helped plan the protocol of this study.

It did not conduct the study. That was done independently by Ingenix, and Dr. Seeger made the decisions concerning the development of the study together with other employees at Ingenix and the development of the algorithm which defined and decided which were cases and which were not.

Much reference has been made to destruction of medical records. Dr. Seeger in the course of an office move after the study was published, as plaintiffs state, lost the medical records involved in the study. It had nothing to do with Johnson & Johnson. Johnson & Johnson certainly had no relationship to any loss of the medical records, but it was inadvertent, and it was done during the course of his office move, as he testified.

There was a reference made to whether his study was blinded. Dr. Seeger pointed out, his study, he was blinded as to which fluoroquinolones were used by the people involved in the study. We could go on and on with how the study was designed. Were the elderly intentionally excluded? That's absolutely false. Here is a classic example of how the characterization by plaintiffs is so unfair.

The UnitedHealthcare database, of course, the basis of that database are the people covered under the UnitedHealthcare. That, there would be, because of Medicaid -- because of Medicare, there would be a possible underrepresentation of the elderly. That was recognized, and that's why the elderly and a Medicare database were added to the study.

So there wasn't any intentional exclusion. They were in fact included. Then it was contrasted with whether there was an intentional inclusion of children to also skew the results of the study. Children were not intentionally included. The database includes children. There were no Levaquin cases of tendon rupture involving children. There were no skewed results because of children, but you take a database as it comes, and it includes the span of ages in the database, so of course, the age range of children who would have been included.

The tears were excluded, according to Mr. Saul, in the study. If Levaquin, if there was a tendon rupture defined as having occurred with Levaquin by the prescribing doctor, it could be defined as a complete tear, it would be included. So we are really ending up talking about and debating the merits of a scientific protocol openly arrived at, submitted to the FDA, shown to the European regulatory authorities who in turn evaluated the published literature, Aventis's own studies and the Seeger study.

And they recognized the limitations of each, including the Seeger study, and what do they come out with after the purported suggestion -- it isn't purported. It was a suggestion by one of the assessors earlier on that the label be altered to include a statement concerning a greater use in the risk of Levaquin over the other fluoroquinolones.

That was rejected after all of the evidence was in by the European regulatory authorities, and the reason it was rejected was clearly stated that the data was insufficient to make any differentiation between fluoroquinolones and tendon rupture, and it is worthwhile to remind ourselves of exactly what the European health authorities after all of the data was in, up-to-date for them, in 2003.

And it says, and this is one of

Plaintiff's Exhibits, Exhibit 87. Under paragraph 8, and we mentioned it as well in our brief, Your Honor, the conclusions, it states, The morbidity and frequency of the suspected adverse reaction, that is, very rare and not fatal outcome which generally recovers, must be weighed against the nature of the benefits and indications for treatment with levofloxacin, reduction in morbidity and mortality of respiratory tract infections and other infections when considering the need for further studies and regulatory action.

They conclude, No further action -- this is on the next page -- given the rarity and nonlethality of adverse reactions, this is justified on the following grounds. Absolute risks of fluoroquinolone associated tendon rupture are very rare, and furthermore, the population attributable risk is very low.

Although we cannot exclude a slightly higher risk of tendon rupture with levofloxacin or ofloxacin, currently available data are inconclusive. Such estimates are likely to be rare or very rare. SPCs, that is a labeling, for levofloxacin products have been updated with adequate warnings. Further analysis of existing data are unlikely to be helpful.

There were several things in that conclusion that are important. Even considering all of the studies, even

considering the state of the animal data, considering all of the issues that plaintiff have put forth today about the adequacy of the studies, disagreeing with some, agreeing with others, the European regulatory authorities decided that the heightened risk label change was not necessary. There was no evidentiary basis for it.

They also, however, said something very important in this conclusion, and that is the benefits of Levaquin in the treatment of upper respiratory infection. There are benefits to this drug, and that is in part part of the passion that arises from Dr. Kahn. The benefits of Levaquin have been proved repetitively, and they are agreed to by everyone in this litigation.

At the trial of this case, you will hear from every expert witness, plaintiffs' and defendants' alike, that Levaquin is efficacious and is very valuable. It is a good drug. Quite simply, they have testified already that it is a good drug.

We have pointed out in the brief that Dr. Zizic, one of the plaintiffs' principal experts in this case, prescribes Levaquin, uses it to this day. Uses it, in fact, under the condition -- well, let me backtrack. Dr. Zizic took it himself. It actually cured his infection, a very severe infection which he had.

So he obtained the benefit of Levaquin himself.

He gives it to his patients from time to time, and there is no testimony from either Dr. Zizic or any other expert witness in this case that the use of Levaquin under the conditions of use in Mr. Schedin was somehow inadequate or inappropriate.

So in the midst of all of this characterization of how there was a clear disregard of the safety of patients, we have a unanimity of opinion as to the necessity and utility of the drug. We have a unanimity of an opinion that it should be used in the kinds of infections, upper respiratory tract infections, for which Mr. Schedin received the drug.

We have also heard about, it is not to be used as a first line of defense therapy for certain indications. Well, taking Mr. Schedin's case, for example, there will be no testimony, there is certainly none based on the expert reports of the depositions, that Mr. Schedin was not an appropriate candidate at the time he got Levaquin for Levaquin.

There are no indications in any label or any suggested indications in the label or contraindications which would minimize the use of Levaquin or have it as a second line of use. The published guidelines to this day, the Sanford Medical Guide, the Infectious Disease Society published guidelines, call for Levaquin to be used as a

first line therapy initially in upper respiratory tract infections.

So the current state of medical knowledge by neutral and expert physicians, by responsible and referenced medical guides all call for the use of Levaquin. Levaquin is in fact the most efficacious, the best antibiotic for upper respiratory tract infections.

So if I can mirror, even slightly, the belief that someone like Dr. Kahn and others brought to how important the drug was to be used in the current respiratory season in his memo and to push for the right study, the correct study, the properly done study, the mischaracterization of the memo and of Dr. Kahn in this is truly horrendous.

Dr. Kahn's attempts, J & J's attempts was to do a study using the largest healthcare database then available, to use it for a measure of outcome which was the most clearly and objectively verifiable, and they hired Ingenix to perform and conduct that study. None of the data that has been developed to this day shows that Levaquin has any greater risk of tendon rupture than any other fluoroquinolone.

The data referenced by plaintiffs in their brief, the information that can be gleaned from it is, you either have data on ofloxacin. You have no reference to Levaquin

and tendon rupture in those studies. You have suggestions on animal data as to comparative toxicities, but virtually none that any authority considered relevant and probative of the differential toxicities.

So how can anyone conclude that what shouldn't be in the label, what is not in the label anywhere today, was somehow the result of manipulation by J & J earlier? How can anyone conclude that something not required by any regulatory authority to this day is the by-product of a manipulation by J & J and a clear disregard of public safety by J & J earlier?

Added to that is, these attempts through marketing efforts to cloud and conceal and hide and ghost writing and detail people to call on physicians and not mention safety. Every visit that a sales representative makes upon a physician includes the prescribing information.

They don't just get it from the PDR, although that's a highly reputable source. They get it every time a sales rep calls on them. They get it prominently mentioned in the label. It's not hard to find, and the physicians, now we have taken enough prescribing physicians I've reminded the Court to this day. The physicians know about tendon rupture.

If there is one thing that we find consistently

is that the prescribing physicians are aware of tendon rupture, including Dr. Beecher. He testified he knew of tendon rupture at the time he prescribed the drug to plaintiff. Plaintiffs asked, were you aware of the fact of corticosteroid and the risk of elderly, and in all fairness, Dr. Beecher said he didn't remember that he was aware of that at the time.

I asked him, Did you have this label, and I read him that label, and he said, yes, I did have that prescribing information at the time. More importantly, in this case, the actual prescribing physician turned to the plaintiff who was there and said to him, I'm very sorry. This is all my fault. Not the drug company misled me, not based upon what you have told me to this day and what plaintiffs' attorneys have told me do I feel like the company consciously disregarded your safety, not that I felt I was manipulated by anyone, not that I looked at any other information from any other source and was misled, none of that.

It was, this was my fault. Am I blaming the doctor? Frankly, no. The doctor did the proper thing. Mr. Schedin was cured of his infection. He suffered an adverse reaction, but that is not the sign or the sole reason to hold any drug company culpable when it has adequately warned and the company did. Hardly a case for

punitive damages. Hardly a case showing an intentional disregard for the safety.

Now, I just want to summarize and conclude, Your Honor, that plaintiffs claim that there was a plan to conceal and failed to disclose the heightened risk. There was no plan documented anywhere here. There is no level of agreement or anything that can diagram an effort to conceal and disregard the public safety. They document no such plan.

Plaintiffs also failed to demonstrate evidence of a heightened risk. As I have said repetitively, no expert or regulatory agency has concluded there is a greater risk to this day. The only ones to offer that opinion, the only ones that will come to the Court and discuss heightened risk are plaintiffs' retained experts who actually learned of the information and read the literature available on the drug for the first time, by and large, when they were retained.

They didn't have the level of experience and knowledge that could have afforded them the opportunity to have that opinion before it. Regulatory agencies have specifically reviewed the data as I have suggested that plaintiffs claim and cannot establish and deny that there is a greater risk and have never suggested that J & J should have put that in its label.

Plaintiffs argue that simply -- they argue that what that really shows, and I've heard this before, is actually how well the plan worked. The fact that no one has taken any action to show them that our unidentified plan has actually had its intended purpose, met its intended purpose.

Any efforts made by the company to investigate the issue, submit the results to the regulatory agency and publish the results are claimed by plaintiffs to be part of this illicit and unidentified plan. The very act that J & J wished and did a study, sponsored a study by Ingenix and wanted to do the correct study is taken as an effort to conceal the truth.

It is almost a bit Orwellian that an effort by the company to find out what it believed to be would be the most reliable and correct answer to date is taken as conduct to justify the imposition of punitive damages, for a product which remains on the market and is to this day considered to be a premier antibiotic with an ample warning about tendon rupture.

So it is difficult to conceive of a less appropriate situation and a less appropriate drug to find that the defendant acted in intentional disregard of the public's safety. The public's safety has been benefitted by this drug. That is the final irony. The public safety

is what has benefitted and benefitted by the marketing of this drug, exactly as Dr. Kahn had hoped it would be.

Thank you, Your Honor.

THE COURT: Thank you, Mr. Dames.

Did you have anything else, Mr. Goldser?

MR. GOLDSER: Briefly, Your Honor. I once again thank Mr. Dames for a preview of his closing argument to the jury, but as I said in my opening remarks, what he says about the evidence in that fashion this Court must disregard.

In reaching a determination about punitive damages, the Court makes no credibility awards, does not consider any challenge by cross-examination or otherwise to plaintiffs' proof. So the spin that Mr. Dames puts on it has nothing to do with this Court's determination at this point in time. This Court has to decide whether from the plaintiffs' evidence there is a prima facie showing of deliberate disregard.

I could go on for a long time responding seriatim to each of the points that Mr. Dames makes. Let me pick up a couple of them. For example, he says, tendon ruptures were used as a measure because they were the most objectively verifiable test. Then why was it when the algorithm was completed that there were far more Levaquin tendon ruptures discarded as nonviable cases than Cipro

tendon ruptures?

Even when you get to the level of tendon rupture as they claim was the gold standard, their algorithm resulted in a manipulation that substantially threw out more Levaquin cases than Cipro cases. That was part of the manipulation that was involved.

Mr. Dames says, and the Medicare database was added. Indeed it was. There were three drafts of the study that were promulgated over time. The Medicare data was added in the second draft. The problem is, it was the first draft that was sent to the European agencies, and it was the first draft that caused the European agencies to back down.

That first draft did not have the Medicare data in it, and so the fact that the Medicare data was in the second draft did nothing to influence the European agencies to back down from their proposed warning. Mr. Dames says there are children in the database, and that was just normal and it doesn't matter, but you've got to think about what the impact of the children being in the database was.

They had no tendon ruptures because they weren't taking Levaquin. So if you have children in the database and you have got 100 people in the database as a result of the children being in the database and there is one tendon rupture in the adults, that's a 1 in 100 rate.

But if you throw out the children and let's say 90 percent of them were children, and obviously I'm using an extreme example, but you only have 10 adults in the database and one of those adults has a tendon rupture, you have a rate of 1 in 10. That's 10 percent. Children in the database mattered substantially because they skewed the numbers. It's not quite as easy as Mr. Dames would like to suggest.

I'm intrigued by the extensive argument that Mr. Dames makes about how no foreign regulatory authority took any legal action to change the label, and yet time after time after time in oral argument and in briefs in this court, defense has said you can't consider what the legal actions were that were taken by foreign agencies. We're not allowed to do that, they say, with Dr. Blume and her evidence.

There is a motion, the *Daubert* motions, their *Daubert* motion specifically addresses that. We can't do that, so well, why can they? Either those legal actions taken by the regulatory authorities are in or they're out. Not good for the goose, not good for the gander. It's our burden to show you based on our evidence and our spin of that evidence that a jury could find that punitive damages are warranted.

I understand Mr. Dames's spin. He has given us

that from the get-go. I hardly agree with it, but that doesn't matter for today. Mr. Saul had a comment he wanted to make.

THE COURT: Go ahead, Mr. Saul.

MR. SAUL: Very briefly, Your Honor, I must say I was somewhat disappointed in Mr. Dames and some of the things he said, particularly about the issue of destruction of the documents. He said that they were somehow destroyed in an office move.

It is just one minute of testimony of Dr. Seeger. I'm taking the examination. And who made the decision to destroy them? Mr. Saul.

I don't recall exactly, but it could have been one of a couple of scenarios. Either somebody asked me if I could, if these could be discarded and I said yes, or it's possible that the default was to get rid of things unless somebody stepped forward, and I did not step forward to not discard them.

Everything was discarded unless someone said save it?

That's right.

And it was your responsibility to determine in this particular project what was saved and what was thrown away?

That was a possible scenario.

What?

That was a possible scenario. Yes.

That was a question. Was it or was it not your decision as the project manager in this particular project to save or destroy documents?

It was my decision, and I followed one of those two scenarios that I laid out.

What Mr. Dames said was not what the testimony was. Thank you.

THE COURT: Mr. Robinson?

MR. ROBINSON: Thank you, Your Honor. Bill Robinson for the defendants. I will be brief. First with respect to Mr. Goldser's comments about the fact that the algorithm used in the Seeger study found more ciprofloxacin cases than levofloxacin cases, he did not tell you Dr. Seeger's answer when he was asked that at the deposition.

In fact, Dr. Seeger did a separate post hoc study of that issue, and it's very clear that doctors were misdiagnosing tendon ruptures in Levaquin patients, and that's in the published article. Basically that's why there were more ciprofloxacin cases. There was a diagnostic bias found in the study against levofloxacin and tendon ruptures.

Secondly, with respect to the Medicare database,

the testimony is pretty straightforward. The Medicare population was not available for the database when the initial protocols were done. As soon as it was available, it was added. The Medicare patients were included in the final study results and in the published paper results and in the results given to all the regulators.

The question of the children in the database, Dr. Seeger's comment to that was why would you exclude children from the database? You're looking at a study of the use of levofloxacin. Some doctors do use levofloxacin off label use for children. In fact, you're probably going to hear a lot about some of the studies done with children in the course of the trial.

As it turned out, there were no cases in the study of any children with an Achilles tendon rupture that were included in the data. That doesn't skew the data, the fact that they found no cases, because it's a case control study. You're comparing to controls. You're not looking at total numbers of cases in that sense.

In terms of the destruction of documents, Mr. Saul has referred to that on a couple of occasions here. Just for the record to be very clear what was destroyed, Dr. Seeger selected 328 random sample potential cases of Achilles tendon rupture, sent people out to get records, do abstraction forms. Those are the records that

were destroyed.

It's important to note Dr. Seeger was asked a question, well, could you reproduce this study without those records. He said, yes, you could. It would take some time and effort and money, but you could do that because they still have the code numbers for all those patients.

Those records have nothing to do with the final case selection process which was done by the algorithm, and I will just note, Your Honor, the algorithm was blinded to all fluoroquinolone exposure of any type, all antibiotic exposure. So the final computer program that picked the cases that were the cases included in the data analysis for the study was totally blinded to drug exposure, which fluoroquinolone, which antibiotic or whether any was used. It wasn't there.

Thank you.

THE COURT: Thank you, Mr. Robinson. Okay. Thank you, Counsel. The Court will take the motion under advisement and issue a written order quickly. Let's take a five-minute break before the other motions.

THE CLERK: All rise.

(Recess taken.)

(In open court.)

THE COURT: You may be seated. Okay. You may be seated. Okay. Let's take the other motions.

Ms. Van Steenburgh.

MS. VAN STEENBURGH: Your Honor. We're going to narrow the focus a little bit and look just at the complaint in the Schedin case, although we have included as our motion the other bellwether cases. Before I begin, Mr. McCormick informed me prior to my approaching the podium here that the plaintiffs are going to withdraw their claims on the Deceptive Trade Practices Act. That happens to be embedded in Count Number VI. There are two claims in there, but they will withdraw that one, so I will just restrict my comments.

MR. MCCORMICK: That's correct, Your Honor. We decided from the seven complaints that are at issue, six complaints that are at issue in this motion. Thank you, Your Honor.

THE COURT: Very well. Go ahead.

MS. VAN STEENBURGH: So we're moving today for motion on judgment on the pleadings in partial. There are three claims we're not moving on, strict liability, negligence and fraud. But there are seven causes of action that we believe are subject to dismissal, and they can be grouped into three areas: Consumer fraud, the warranty

claims and the unjust enrichment claim.

Each of those is deficient in terms of its pleading and are subject to dismissal. What I would like to do is turn to the consumer fraud claims initially. That would be Counts VI, VII, VIII and IX. I'm not going to spend really any time on Count VII, that's the handicapped and elderly provision, and that's derivative of the other consumer fraud statutes.

But as to the consumer fraud statutes in themselves, the basis of the motion is that the plaintiffs cannot show any public benefit. As the Court well knows, there is no private cause of action under those statutes, and in order to bring a claim, a plaintiff has to invoke Section 8.31 under the Minnesota Statutes, and the purpose of that is to allow a private litigant to stand in the shoes of the Attorney General.

And the purpose of the statute is to expand efforts to stop or prevent fraudulent business practices. Well, just as the Attorney General would have to do that for the benefit of the public, a private litigant has to show that in fact they are operating to benefit the public when they bring such a cause of action.

Now the plaintiffs have taken the position here that as long as their complaint alleges deceptive trade practices aimed at the public at large, they have satisfied

the public benefit requirement under the case law and the statutes. They rely on the *Collins versus Minnesota School of Business* case, and that case cannot be read so narrowly.

There was a narrow issue in that case involving District Court interpretation of a public benefit saying that maybe the number of plaintiffs was too small, and the Court said no, you need to focus more on what the representation was that it was a larger, it was made to the public.

But really the *Collins* case is consistent with the other case law having to do with the public benefit because the real issue is, what's the remedy and whether the lawsuit would change the behavior of defendant, whether you're going to stop deceptive trade practices or not. The *Collins* case, the minute the lawsuit was started, the television ads and the presentations that the Minnesota School of Business were presenting in order to attract students stopped immediately, and so the kind of behavior was immediately stopped by the lawsuit.

This case is very different. Mr. Schedin has brought an action. He brought an action three years after he took Levaquin. This is a classic products liability action. It involves products liability negligence, and the remedy is an individual remedy.

There are a series of cases, Judge Montgomery and

Magistrate Judge Erickson have rendered decisions in which they looked at that remedy, and when it's an exclusively individual remedy, they have held that that does not accrue to the public benefit. Mr. Schedin is seeking damages for himself, pain and suffering, past medical expenses, future expenses. Those are not for the public benefit.

If you also look at the representation, the issue in this case, and you look at the cases that look at that, for example, this case, the *Swenson* case, the horrible security case involving ADT Securities, and also Judge Magnuson on the *Tuttle* case, the issues there were, what are those representations?

What is happening? Are those still out there? Are they continuing? Is there something about this lawsuit that is going to change behavior? If you look at this case, this case involves the 2002 with the minor modification, the 2004 label. That label does not exist anymore. That label is not out in the public domain. There is nothing about that label.

We are litigating something in the past. It's like the childproof lighters in *Pecarina* that Judge Montgomery said they're not on the market. They're not going to change behavior. In *Tuttle* Judge Magnuson said that the plaintiff wanted to bring consumer fraud claims because she wanted to warn other consumers about smokeless

tobacco. The label had already been put on by the FDA.

The whole situation here is again, the claim is, was the label in 2004 adequate, and the plaintiff has lots of arguments as to why it wasn't. There wasn't sufficient information. We didn't send out dear doctor letters. It was confusing. In the end, if there is ever a verdict form, it's going to say was the label inadequate. It's not going to do anything about this label because that label doesn't exist anymore.

So the Consumer Fraud Act claims just do not apply because there is no public benefit by virtue of those claims in this lawsuit.

Turning now to the warranty claims, I'm going to just spend a brief moment, Your Honor, because I think those are pretty straightforward. They're in Count III. There is an implied breach of warranty claim. This Court has addressed that issue before. Strict liability in Minnesota preempts an implied warranty of merchantability, and so as long as there is a strict liability claim, there cannot be an implied warranty claim.

With respect to breach of express warranty, I'm amazed. There was lots of rhetoric in the plaintiffs' brief about how Minnesota recognizes an express warranty claim. Great. That's true. But the question is, what is that warranty that is the basis of the claim in this

lawsuit, and you look at page 19 of the plaintiffs' brief, they don't explain that at all.

They just fuss it up. They don't identify anything with respect to what that warranty is, and if you look at the complaint, paragraph 136 of their complaint where that warranty should be, all it says is that it wasn't safe. That's no different than an implied warranty, safe for its intended purpose.

So it's duplicative of the implied warranty. That one should also be dismissed. If it's an implied warranty, it's preempted under Minnesota law relative to strict liability. Finally, with respect to Count X, the unjust enrichment, I think that has been well briefed as well. As long as there is an adequate remedy at law, the equitable claims do not stand, and there are cases that have been, that so hold.

The plaintiffs do cite to a case by Judge Davis where he allowed an unjust enrichment claim, but if the Court notes those facts, there were lots of equitable claims in that set of facts. This was not in an alternative. Here there are plenty of adequate remedies at law under the strict liability, the negligence, the fraud claims.

The unjust enrichment claim is an equitable claim that should be dismissed. If there is nothing further?

THE COURT: Let me ask you one question, Ms. Van Steenburgh.

MS. VAN STEENBURGH: Yeah.

THE COURT: Back to the question about the public benefit.

MS. VAN STEENBURGH: Mm-hmm.

THE COURT: Do you think there is anything to an argument that although this is an action that is seeking damages that are personal to Mr. Schedin, and most of these cases do relate to that, is there an argument that because particularly his case is coming first as a bellwether trial in an MDL it affects a lot of potential future plaintiffs or current plaintiffs in other cases that that can somehow confer a public benefit by participating in the trial in that way?

MS. VAN STEENBURGH: I don't think so for a couple of reasons. Every single one of these cases really is an individual case. They just happen to be collected here for pretrial discovery as part of an MDL. All of these cases may involve different labels.

Mr. Schedin's case involves a 2004 label, so there may be one that involves a 2002. We have got a 2007. We have got a 2008, so you can't necessarily say that Mr. Schedin's case involving this particular label, which does not exist anymore, could somehow confer a public

benefit with respect to any of those others. The adequacy of any of those others in any of those cases has to be litigated separately.

THE COURT: Thank you.

MS. VAN STEENBURGH: Yes.

MR. MCCORMICK: Almost afternoon, Your Honor. Good morning. Still there.

THE COURT: You're close.

MR. MCCORMICK: Hopefully I will be done before afternoon, Your Honor. Your Honor, your last question I think goes to the heart of the public benefit issue, which is where does the public benefit begin to run or when does a public benefit stop running for an individual bringing a claim under these Minnesota statutes?

For every *Pecarina* case and every *Berczyk* case that Ms. Van Steenburgh can cite to you, I can cite your *ADT* case, which you know better than I do. I can cite to you the *Weigand versus Walser* case, which is a Minnesota state court case. I can cite to you the *Kinetic versus Medtronic*, all those cases where conduct may have stopped during the course of the lawsuit.

The public benefit still was seen, and there still was an enforceable case underneath the consumer fraud statutes using the Private Attorney General Act.

THE COURT: What about this argument that simply

bringing these claims now inside of an MDL with a potential impact on others? I mean is that a theory that would support a public benefit? Do you know of any cases that addressed the issue in that way?

MR. MCCORMICK: I do not, Your Honor, but I think if you go back and look -- I spent more time on Minnesota law in the past three months than I ever thought I would. If you go back and look at legislative reading and you go back and you look at the *Ly versus Nystrom* case and what led from that, I think that the way the defendants would have you read the public benefit is to basically shut down the consumer fraud statutes to almost any individual trying to bring, seek redress under those cases.

So I think that while there is not a case specifically on point, I think if you look at the line of cases that we have versus the line of cases that the defendants would rely on, I believe that this case is closer to the *Collins* line than it is to the other line of cases.

THE COURT: Recognizing that there is not injunctive relief sought and I think that the public benefit issue is more complicated than just injunctive relief versus personal damages, the current label, the November '08 label which I have a copy here in front of me, is that an adequate label?

MR. MCCORMICK: Your Honor, we would argue it's not an adequate label.

THE COURT: Does that affect the public benefit issue?

MR. MCCORMICK: I would believe it would. If, for example, in your *ADT* case if that is the issue, we should be able to amend the complaint to add the inadequacy of the November 2008 label, but looking back at the November 2004 label, Mr. Schedin's complaint was filed before the November 2008 label, but our argument all along and always will be, I believe, that the new label is not adequate, either.

THE COURT: Okay.

MR. MCCORMICK: Your Honor, I think I can be as brief with the implied warranty and the express warranty claims as defendant was. All of the cases that the defendants rely on for their citations to the express warranty -- well, let me stay with the breach of implied warranty.

At this point dismissing that claim on a motion for judgment on the pleadings is premature. We should be able to present that case to the jury. Then in a jury instruction if you decide at the end of the trial whether we're going to present it or if you say the jury instructions are going to be confusing, then we withdraw

that case.

Doing it right now before we get to the case, the actual trial, would be premature. All of the cases that they rely on are distributor cases. This is a case that involves a manufacturer. The express warranty claim is, again, I believe that their argument is misplaced here.

This is a motion for judgment on the pleading. If they felt like our express warranty does not expressly -- what we're complaining about is not in the complaint, they should have filed a motion for summary judgment and said your evidence isn't there.

At this point we have taken discovery for two and a half years. There is discovery that we could point to, express warranties over and over amongst the defendants' labels, the representations they have made to physicians, the detailing that they hand out. So --

THE COURT: But do we have evidence in these individual, what are we dealing with, five separate motions here?

MR. MCCORMICK: Six.

THE COURT: Six, that express warranties were made to patients or their doctors in these cases? Is there anything that has developed?

MR. MCCORMICK: Your Honor, I think under the Minnesota law, a general statement made by the company that

may have made it down to the physician or the patient is enough, but I don't know the specifics of these cases, but Mr. Goldser could better answer that question, Your Honor.

THE COURT: That's fine.

MR. MCCORMICK: As to the unjust enrichment claim, Your Honor, it is similar to our breach of implied warranty claim which is that this is a premature motion. While we have adequate theories of law, the unjust enrichment claim is not ready to be dismissed. We should be able to try a case like that.

If at the end of the trial we decide that there is no evidence or if you decide that the case then is unworthy, we should drop it out then before you give us your jury instruction.

THE COURT: On the implied warranty claim, when do you choose between that and strict liability?

MR. MCCORMICK: I would think when we have a charging conference, Your Honor, and you say what cases are you going to charge the jury on, and we say this or this.

THE COURT: We can probably make that clear to a jury at the end of the case, but it may get confusing during the trial.

MR. MCCORMICK: I would think that we would be able to provide evidence on both claims to the jury. To be honest, I think probably the same elements would go in, so

I don't know if the jury would understand until they receive two different instructions on the same elements.

Thank you, Your Honor.

THE COURT: Thank you.

MR. GOLDSER: May I, Your Honor?

THE COURT: Sure, Mr. Goldser.

MR. GOLDSER: I remember Professor Marshall from the University law school, dearly departed, I don't know if you had any experiences with him.

THE COURT: Oh, yes.

MR. GOLDSER: Wonderful man. When we were talking about the purpose, the public policy behind tort law, I hope this is going to work, that one of the public policies behind tort law was to change behavior of the defendant, and so I think you are exactly right when you say it's more complicated than simply whether or not there is injunctive relief.

Tort damages, tort cases for damages can get you there. I spent a long time earlier this morning talking about one of the theories of liability, and that is that Levaquin is worse than other fluoroquinolones in terms of comparative tendon toxicity. That is not in the warning. Never has been. Defendant denies it to this day. It's certainly not in the black box warning.

That, if we can convince a jury that there is

inadequate warning on that, is in fact a public benefit. Of course one would hope that defendant would learn from the tort decision on an individual remedy case that they need to change their warning to address the question of the comparative tendon toxicity of Levaquin versus other fluoroquinolones, which dovetails exactly into the express warranty issue.

And what I have up in front of you at the moment are the call notes that were provided to us by defendant where the defendants' sales representatives called on Dr. Beecher, and the one that you see right in front of you, and it actually scrolls up a little bit, this page, as you can see is July 2, 2002, it's Dr. Beecher.

Monica Sadar over here is the name of the sales representative, and when she is done with the call, she writes in this box down here what occurred in the call. And you can see that she described to Dr. Beecher on July 2, 2002, the safety of Levaquin versus other quinolones, versus Augmentin as well, and I don't understand what that last tag phrase is IN SIN, but she was there talking to Dr. Beecher that day about how Levaquin compares in safety to other fluoroquinolones.

I can promise you she didn't say to Dr. Beecher, well, you know, Levaquin is worse than other fluoroquinolones in terms of the tendon toxicity. Quite

the opposite. This call might suggest that it is in fact safer than other fluoroquinolones, which is a misrepresentation, and it's also an express warranty.

I can find for you several other references to descriptions of tolerability and safety. You can see that over on the right. This call note I believe was created on the top of the page July 12, 2002.

There were several others that look very similar that talked about safety as Monica Sadar or other sales reps referenced specifically to Dr. Beecher, the doctor in this case. We have not only an express warranty just generally out there, we have got a specific express warranty that was made to Dr. Beecher that we can see in the call notes.

Thank you.

MR. SAUL: Just one thing, Your Honor?

MS. VAN STEENBURGH: I'm getting triple teamed here. Seems unfair.

THE COURT: Go ahead, Mr. Saul.

MR. SAUL: 60 seconds.

THE COURT: We can give Mr. Dames and Mr. Robinson a chance.

Go ahead, Mr. Saul.

MR. SAUL: During depositions I specifically asked the defendants' experts as well as their employees,

did they agree or disagree with the black box warning, which is now in effect, and across the board, they either disagree with it in whole or in part.

So in terms of the public benefit, you have it there in testimony throughout the litigation.

THE COURT: Thank you.

Ms. Van Steenburgh?

MS. VAN STEENBURGH: Well, first, let me bring us back to the fact that we're here for a motion for judgment on the pleadings. Mr. Goldser has now just introduced a bunch of evidence that I wasn't aware that those were the express warranties. We looked at the complaint. The complaint says nothing. Paragraph 136 just says including plaintiff and physicians that Levaquin had been shown by scientific study to be safe for its intended use.

Their brief in response when we said there isn't an express warranty, as to express warranties, the various complaints make it clear with factual affirmations and product descriptions of Levaquin that form the basis of additional express warranties.

There is never any representation as to what warranty, where, who or what, other than it's safe, and even as Mr. Goldser said, the warranty that was given Dr. Beecher is, it was safe. That's an implied warranty. So there is nothing different about the express warranty

claim than there is the implied warranty claim.

Now, stepping back to that, what I'm hearing is, they don't want to make a decision about whether they're going to stick with their strict liability claim now or later. If they get rid of the strict liability claim, negligence merges in with the implied warranty, so that goes away anyway at trial.

So whether we get rid of it now or later it is not going to make any difference if they decide to drop their strict liability claims. Strict liability, and negligence is equal to the implied warranty, and under Minnesota law, you have to get rid of the implied warranty claim. So the decision is actually subject now. Strict liability as long as it stays in the complaint preempts implied warranty.

The final thing I wanted to say is, there seems to be some confusion about this issue of the public benefit. The question was, do the plaintiffs believe that the 2008 label is adequate? That isn't the subject of Mr. Schedin's lawsuit, nor any of the other bellwether plaintiffs.

The adequacy of the 2008 label is not at issue. The issue is the adequacy of the 2004 label, and that's what is going to be litigated in this case, and that label doesn't exist.

Now I hear Mr. Goldser saying, well, they still don't have two times endotoxic in the future label. Well, is that the only thing that is ever going to be litigated as part of the 2004 label? No. They have identified all kinds of deficiencies.

There is nothing that -- about the 2008 label that somehow can be brought back to the 2004 label, and if you look at *Pecarina*, you look at the *Tuttle* case, and it's distinguished from the *Swenson* case because in that case it was unclear whether there was national sales literature and installation literature still out there such that the impact of the lawsuit might impact the behavior. The 2004 label doesn't exist.

It is not going to have an effect. It is more like *Tuttle* where the label has changed, and now we're litigating something in the past. And whether Mr. Schedin is entitled to damages for past medical expenses, pain and suffering as a result of the alleged inadequacy of the label is the issue before the Court.

There is no public benefit with respect to that label, and thus there can be no consumer fraud claims. Thank you, Your Honor.

THE COURT: Thank you, Ms. Van Steenburgh. Do you want some backup?

MR. DAMES: She apparently doesn't need it.

MR. ROBINSON: We have our batting helmets.

THE COURT: Okay. Did you have anything else, Mr. McCormick?

MR. MCCORMICK: Your Honor, just one quick thing, and it brings me back to the express warranty, which is at this point in time a motion for judgment on the pleadings as opposed to a Rule 12 motion. If they felt like our express warranties were not there and not in the complaint, they should have brought a motion for summary judgment to have that opportunity, and they didn't do it.

As to the public benefit argument, I think my argument stands in that if you would read the public benefit as narrowly as defendants would have you do in an MDL setting, it would defeat the purpose of an MDL and setting law and following law and setting a group going forward for the rest of these cases.

Thank you, Your Honor.

MR. GOLDSER: So the records are clear, we move to amend the complaint to incorporate the express warranties set forth in the call notes that I described to you.

THE COURT: Speaking of the call notes, Mr. Goldser, where in the record is what you showed us there? Can you cite to the record so that we can look that up?

MR. GOLDSER: I don't believe it's in the record. Because this was a judgment on the pleadings, we didn't submit any evidence. I'm happy to send them to you if you would like.

THE COURT: I see. Okay. Anything else on the motions? Okay. Very well. Okay. Let's talk a little bit about scheduling. We have, I believe, I believe it's next week, Wednesday, the *Daubert* motions, the 6th? We have inquired about the advisability of splitting them up somehow. I am of a couple of minds about that. I thought I would raise that anyway.

I guess it depends in part on the length of arguments that you wish to do on the *Daubert* motions. If it's lengthy argument involving all of them, then -- I want to make sure. I've got a trial going on next week. I want to make sure I have enough time to prepare for all of them and to be able to prepare for arguments.

What's anticipated right now? Maybe each of you have thoughts on this.

MR. GOLDSER: I'm not sure that we have gone into a great deal of detail yet about what we want to argue and how we want to argue it. I have the concern about the longer we go before we get a ruling, the closer we are to trial, of course.

But I like to with, with due humility and

respect, suggest a possible solution. It may impose a greater burden on the Court, however. There is a procedure that is used in California courts, both state and federal, where the Court issues what is called a tentative ruling. I don't know if you're familiar with that.

I have experienced it a few times. It's pretty wonderful from a litigant's perspective. The Court actually issues a proposed order, and the litigants get it when they walk into court that morning.

THE COURT: Judge Renner did something like that on a regular basis. He would announce his tentative decision and ask lawyers to tell him where he was wrong. He was rarely wrong.

MR. GOLDSER: I find that to be true certainly as well when I have been in California, but from my perspective it's really wonderful. It cuts down the amount of time for the argument, and it focuses the argument. Of course, it puts a tremendous burden on the Court to have tentative rulings done.

One court, I wish I could recall who it was, handed out a list of questions, as opposed to what the tentative ruling would be, so that the arguments could be really focused. I went on at great length because I wanted to tell you the story. It was the first time I think we have had the chance. You have now seen it, and you have

read a lot about it in the *Daubert* briefs, so I don't know that we have that great need to go there.

I want to focus on what you need to know to make those decisions. If you can help us with that, I think we can get it done in one day.

MR. DAMES: We don't have an objection to having one day to hear all the motions. I think that really is going to be your calendar for the preparation time if you feel that you need to do --

THE COURT: What are you anticipating for the argument time?

MR. DAMES: You know, we haven't discussed it, Your Honor, but at some point the issues, I mean, clearly the first arguments are going to be longer than the later arguments, I suspect. The Seeger lay argument will probably be one of the longer arguments. The --

We have the Waymack/Blume arguments will probably be quite significant, and I should tell the Court that we're going to have John Winter, who is an attorney with Patterson Belknap, come and argue those motions.

THE COURT: Mm-hmm.

MR. DAMES: It's hard to say, but none of them will be particularly short.

MR. ROBINSON: Your Honor, if the Court will entertain possibilities here, we could do as much as we

could on the 6th and then perhaps have another date on the 13th if that's convenient for the Court as suggested to finish up if we need it.

THE COURT: Well, I mean, we will issue the order just as quickly as possible. It will be, obviously we know the trial is coming up, and it goes to the top of the list, so, you know, maybe that is the best way to proceed.

If I can give the parties some direction in advance, I will do so, but I'm not promising anything right now. I'm starting this other trial on Monday, and that will involve a lot of -- it's a bench trial, too. So -- but we can --

Go ahead.

MR. DAMES: I think that for some of the motions, I've had experience in California with the, with that procedure. It isn't a bad procedure to utilize if you think the oral argument isn't going to clarify things or if oral argument is going to have a substantial benefit.

I think on the *Daubert* motions, oral argument probably will have a substantial benefit so that, I mean, because a lot of arguments foreclose with that kind of a preliminary decision in practice, and I just think that it might be the least appropriate method, time to use that procedure if you do it with the *Daubert* motions.

THE COURT: Well, go ahead, Mr. Saul.

MR. SAUL: Your Honor, we suggest, plaintiffs suggest you do one plaintiff, one defendant, back and forth between the motions.

MR. ROBINSON: That's fine with us if the Court wants to set some kind of schedule.

THE COURT: We'll let you know. We'll try to get to that, you know, a day or two in advance so you know exactly how we are going to proceed, and I think the suggestion, we'll do what we can on the 6th, and if we can't get it all done, we'll just schedule another day shortly thereafter.

MR. ROBINSON: Your Honor, originally when we had talked about the schedule, we had reserved October 7th. I take it that is not going to happen now, and I just want to be clear about that.

THE COURT: Well, let's look here and see what we have got. I think we should probably continue to hold that for now, but I do have this other trial. It's just the other trial. That's all I have going on other than a sentencing.

I do have time available that day if we need to spill over. So I think let's hold it for now. Okay?

MR. ROBINSON: Yes, sir.

THE COURT: Okay. Anything else we need to discuss today?

MR. GOLDSER: I don't think so, Your Honor.

THE COURT: Okay. Very good.

MR. DAMES: Thank you, Your Honor.

MR. ROBINSON: Thank you, Your Honor.

THE COURT: The Court is in recess. Thanks for the arguments today.

THE CLERK: All rise.

(Court was adjourned.)

* * *

I, Kristine Mousseau, certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

Certified by: s/ Kristine Mousseau, CRR-RPR
Kristine Mousseau, CRR-RPR

From: PAUL[redacted] *** FOIA & OMB Memorandum M-07-16 ***
Sent: Saturday, February 26, 2011 2:22 PM
To: shareholderproposals
Cc: dchia@its.jnj.com
Subject: Proxy Proposal for JNJ

Dear Ladies and Gentelmen:
I noticed I left out one important word in my Proxy to Johnson & Johnson ... in **bold** below.
I hope prior to your making a decision, that you suggest, consistent with your authority and rules 14a-8 that I re-word the proposal and add the word **"bottle",** as below:

"add warning on labels to all Levaquin tablet **bottles** etc "

Thank you for caring about the health, welfare, and prosperity of the general public-at-large.
Sincerely,
Paul W. Cahan