UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION	*	Docket No.: 16-MD-2740
	*	Section "H(5)"
	*	January 18, 2019
This Document Relates To Durden v. Sanofi S.A., et al, 16-16635	*	New Orleans, Louisiana

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TRANSCRIPT OF ORAL ARGUMENT PROCEEDINGS
HEARD BEFORE THE HONORABLE JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE

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PROCEEDINGS

(January 18, 2019)

(AFTERNOON SESSION)

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(COURT CALLED TO ORDER)

THE COURT: All right. I think we're going to take up the oral argument on the motion, and then we'll finish this.

MR. COFFIN: Are you ready for us to proceed, Your Honor?

THE COURT: Just give me two minutes to move binders.

(WHEREUPON, the Court took a recess.)

THE COURT: Okay. We're ready.

MR. COFFIN: Good afternoon, Your Honor. Chris Coffin on behalf of the plaintiff, Ms. Antoinette Durden, and the plaintiffs' steering committee.

As Your Honor is aware, we are here on the plaintiff's motion to enforce CMO 12A. The purpose of CMO 12, and then 12A, which has followed, is obviously to streamline this product ID/manufacturing ID process that the Court realized could be quite cumbersome in a case like this with multiple defendants. And CMO 12, as well as 12A, were negotiated amongst the parties, and the specific language that we're going to talk about today in this hearing is agreed upon language that you'll notice stay the same from 12 and 12A.

As the Court knows, both the plaintiffs and the defendants in this MDL have used NDC codes as the gold star, the gold standard, for proving product ID, establishing it in this case.

The defendants have used it in hundreds of situations where, for example, Sanofi wants to be able to illustrate that the product administered to a plaintiff was not theirs. So they produce an NDC and say, "See, here, here's an NDC code and billings records and insurance records that shows it's not us." And plaintiffs, on the other side, of course, have used this process for as long as CMO 12 has existed to show the defendants that a product, in fact, was administered to a specific plaintiff.

Then we get to Ms. Durden, who, as you know, is the first trial plaintiff in this MDL, and now the defense is working to muddy the waters in what CMO 12A says.

THE COURT: Does CMO 12 do anything beyond create a rebuttable presumption?

MR. COFFIN: No. It creates a rebuttal presumption, and that presumption then can be rebutted with contrary evidence. And I think the point that Your Honor's getting at is the issue as to whether or not CMO 12A is definitive, and whether or not we need to move to a motion for summary judgment on the evidence that we've presented. If the Court wants that, we're happy to do that, but we felt that the first step is:

Did we present undisputed information, or is there actual contrary evidence?

And I think what's very clear is the NDCs are the best evidence. You've heard the defense say this in chambers to you, months ago, say, "Well, we need NDCs. They haven't produced NDCs." Well, we produce the NDCs, and then we get what they call contrary evidence, which, in fact, is not really contrary evidence, and I'll go to that. I'm sorry, did you have another question, Your Honor?

THE COURT: No. No. I think that -- keep going.

MR. COFFIN: So we've -- Ms. Durden has clearly met the standard set in CMO 12A through production of NDCs that Ochsner provided. They billed Medicaid for the NDCs, which was a Sanofi product, and they were paid for the Sanofi product that was administered. And the law says if you are Ochsner and you are using an NDC for billing purposes, then you are making the claim that this is the drug administered to the patient. That's the gold standard, and that's what we have here. So we've met the presumption.

But the real question before Your Honor really isn't whether we've met the presumption because there's no dispute about whether these NDC codes actually exist. The question is: Did the defense present real contrary evidence?

THE COURT: Right.

MR. COFFIN: Now, they've put a lot of information

before the Court, but none of it is truly contrary to the fact that these NDC codes establish administration of a drug to Ms. Durden. So you don't see one affidavit or one piece of documentary evidence from Ochsner stating that the NDC codes that plaintiffs have produced are false. You don't see any affidavit or any information from Ochsner, documentary evidence, saying that this was an error. Where is that affidavit?

We know they produced an affidavit from Neil Hunter, the pharmacist, but where's the affidavit from the billing people who say, "Oh, this is an error. This isn't the drug that was actually administered to Ms. Durden"? That doesn't exist. If that existed, that would be contrary evidence. So there really doesn't exist contrary evidence with regard to Ochsner.

Now, let's go to Molina, which is Medicaid's third-party biller. There is an affidavit from Molina that we obtained -- the plaintiffs obtained to show that, in fact, Ochsner was paid for the NDC codes that it submitted as the medication administered to Ms. Durden.

What you do not see -- what you do not see -- is any person from Medicaid, from Molina, saying, "There is an error in the NDC codes that we paid for." There's no contrary evidence to say that what Molina has provided is somehow an error, "There was a mistake. We didn't actually submit payment

for these NDCs." None of that. That's contrary evidence, and it doesn't exist.

So what have you seen? What you've really seen is speculative evidence at best that, quite frankly, is the result of some creative lawyering that tries to manufacture something that's contrary when it's not, and it comes in the form primarily of two affidavits. One from this gentleman who's a pharmacist at Ochsner named Neil Hunter.

What Neil Hunter puts in his affidavit is a lot of information that says nothing about whether or not the NDC codes are accurate or not. What he does say and what he does focus on is the purchase history for Ochsner.

THE COURT: Right.

MR. COFFIN: Okay. The purchase history is a red herring. It is a red herring because --

THE COURT: Does anybody -- what's the shelf life?

MR. COFFIN: It is 18 months to 24 months, Your Honor. A very important question. Because this is what I'm getting at, let's take the 18 months for the 20-milligram dose, hospitals -- this is not in evidence, but I'm happy to get an affidavit from a pharmacist who will testify that it is the general practice of hospitals to use the oldest product first because they don't want it to expire and then have to throw it away.

So really what we should be asking ourselves is

not what is the purchase history, but what was the availability of a product. Something such as an affidavit with an attached inventory log because that would inform us, and that would be contrary in some way to show that these are the products with the NDC codes that we had available for Ms. Durden, and if these weren't available, we didn't administer it.

Purchase history, that doesn't tell you anything, especially going back only eight months. Eight months prior to the administration when you have a shelf life of a year and a half is really not helpful information at all, quite frankly.

The other piece of evidence that Ochsner -- excuse me, that the defense really relies on is this affidavit from Medicaid, Molina Medicaid Solutions.

The affidavit from Molina Medicaid Solutions first says that it was prepared at the request of Sanofi's counsel, and then it goes on to state that Molina is not involved in the creation of the product, it is not involved in the administration of the product, and that representatives from Molina aren't standing at the bedside when the patient is administered the product. It's very, quite frankly, just obvious information in this affidavit.

What Sanofi seems to be arguing is that if the chemotherapy nurse who actually hung the bag, and inserted the IV, and watched the drip, if that particular nurse isn't

providing testimony that, this is what the patient got, then we can't trust the NDC evidence. That's not contrary evidence either, and I'm confident that's not what the Court contemplated when it stated that the defense could present contrary evidence.

Let me go back to one other point that I failed to discuss with regard to the Neil Hunter affidavit. So the purchase history, as I said, it's really a red herring. We need to really talk about what's available. And the defense to that says -- Sanofi says, well, Ms. Durden is this unique situation, something got screwed up, and Ochsner doesn't know what's going on, and everything got screwed up because this is the only situation in which we find the plaintiff saying these NDC codes are valid to show that Ms. Durden was administered the drug during this time period.

Well, in our supplemental memo that we just submitted to Your Honor yesterday, I believe it was, lo and behold, we found another plaintiff during the same time period that Ms. Durden was administered a Sanofi drug with a Sanofi NDC. Finally, Ochsner produced to the plaintiff's counsel in that case a screenshot showing that -- apparently, they have a database of this information, which we didn't know, but a screenshot showing the same NDC code indicating administration to a different plaintiff other than Ms. Durden during the same time period with the same drug.

So this idea that there's an anomaly here and that somehow Ms. Durden is some strange situation because Ochsner is all screwed up, it just doesn't hold water.

The other thing that I didn't mention -- I think I mentioned at the top of the discussion here is the most compelling -- I think probably the most compelling piece for Ms. Durden and the plaintiffs here is the law that we cited that states that when Ochsner bills and provides an NDC code for a specific drug, by law, they are affirming that that is the drug that was administered to the patient.

Now, if Ochsner -- if Sanofi wants to provide an affidavit that says that was false, there was some kind of fraudulent billing, well, then we're talking about contrary evidence.

The bottom line with the, quote/unquote, contrary evidence that has been argued by the defense is it is very artful lawyering. It's not really contrary evidence in the way that it needs to be in order to show that those NDC codes are false or fraudulent or somehow submitted in error.

The whole purpose of CMO 12A was to really avoid what's happening in the Durden case, and what we fear, quite frankly, Judge, will happen in any case that comes up for trial that the defense wants to argue is not a proper case.

The idea was to streamline this process and to save resources, and Durden has become the poster child for what

can really happen if we don't rely on evidence such as an NDC code that's submitted and paid for to a governmental agency.

The Court shouldn't permit this because we are concerned that this is going to allow the defense an opportunity to frustrate what the whole purpose of CMO 12 and 12A was, and I think we see that here in Durden because she's the first trial plaintiff. But I have no doubt, such as in Earnest, which Your Honor already looked at a summary judgment on, this is going to happen over and over in cases where the plaintiffs have made the pick of the trial plaintiff, and that's not the purpose of what CMO 12A was.

THE COURT: What precipitated this?

MR. COFFIN: What precipitated the --

THE COURT: I know that there was a time when we had difficulty with NDC codes, finding the NDC codes, because I remember talking about it during conferences, and at some point I said I think what you should do is -- then there was -- I don't know who said it, but we should look at this from Medicaid billing, Medicare billing, whoever it did. Was she -- and I know there's been some -- I read, and it's late in the day, she was selected, but at the time of the selection was there no evidence that she had been administered the Sanofi product?

MR. COFFIN: There was.

THE COURT: Okay.

MR. COFFIN: What happened with Ms. Durden in particular is that -- and it's like this with basically every plaintiff, Ochsner didn't cooperate real well in providing us with the information that we needed.

THE COURT: Right. I know that's been an ongoing issue for everybody.

MR. COFFIN: My office was very diligent in trying to get this information. There was a young lady in the billing department who finally wrote back to us on -- you know, we had sent over -- I believe we sent over the actual form -- no, it was before that. Before there was an actual form that existed where you checked off the information that existed -- that was administered to the patient. There was some back and forth between my office and Ochsner saying, "Hey, we need proof of this, and if you have an NDC code, please give it to us."

She wrote an NDC code, Ms. Canty did, I think it was on an actual -- the printout, perhaps it was the form or a printout from the Internet, and sent it back to us. We later followed up and said, "Wait. Wait. Thank you for providing this. We understand that you're representing that this is the NDC administered to Ms. Durden, but what we need is we need you to complete this form here that we've agreed upon with the Court." Okay. She eventually did that.

THE COURT: Okay.

MR. COFFIN: And it was difficult to obtain because

she didn't want to do it. But this representation -- I mean, there's been a lot of representations about what my office did to strongarm Ms. Canty. It just doesn't exist, Your Honor.

The reality is we just were trying to make sure that we had the proper documentation. But this woman had said to us, "Yes, this is the NDC," and then Sanofi went and talked to Ochsner's counsel, Ms. Canty, whoever they talked to and got a -- what do I want to say -- she withdrew her affidavit, recanted her affidavit.

So that's how we got here. And we said, "Wow. Wait a second. Recanting her affidavit." And then we got into this whole idea that it doesn't exist. Quite frankly, we've gone -- we have gone down a lot of paths to try to make sure that we can prove that Ms. Durden was administered Sanofi's Docetaxel. And, lo and behold, one day finally, after pushing and pushing for about a year and a half, Ochsner's outside counsel produced -- or, no, we got it from Medicaid first. I apologize. It was Medicaid. We got this idea to go to Medicaid, and Medicaid said, "Oh, yeah, sure. Here you go." And then we went back to Ochsner.

And it just takes pushing and pushing and pushing and subpoenas and 30(b)(6)s, and, oh, my goodness, in December, Ochsner produces the super billing that has the exact code, which is in the evidence here. And so now we have the gold standard.

So Your Honor often asks, "Where are we now?" Where we are now, Judge, is we have the gold standard to meet the presumption, and there is nothing that contradicts that in the form of an affidavit or written documentary evidence that says there was an error, this isn't the right NDC.

Now, my last point, Your Honor, it's very apparent that what the defendant is arguing in their briefing is it's a bit of a different position than we've ever encountered until Ms. Durden's case, but the position is now the defense is entitled to present evidence defending or trying to defeat product ID in front of the jury, and that this Court, through a CMO, i.e., 12A, cannot make a determination and pull that ability, that defense, away from Sanofi.

If that's the argument, and if the Court believes that is accurate, then we need the opportunity to go forward on a motion for summary judgment. But what that also means is that the whole purpose of CMO 12A is out the door. Because the idea was that we would have a streamlined process, and now the defense is arguing that CMO 12 and 12A can't be used because the law says that that's not valid for purposes of what you -- what you can and can't do in front of a jury, and that they should have the right to present their evidence in front of a jury, which, quite frankly, if that's where it goes, we're fine with that.

The only reason we went through the 12A process

is because that's what the Court asked us to do. So it would be very unfair to the plaintiffs to now change the rules of the game to say, "Oh, yeah, CMO 12A is out the door and it's okay for the defense to present this." If that's the case, fine. We'll keep Durden as the first pick, and we'll present that evidence to the jury, and I'm quite sure that they're going to determine it's a Sanofi product. But I don't think that's the road that we intended when we first started down.

Now it sounds like, no matter who the plaintiffs pick, if it's not prior to March of 2011, when the drug went off patent -- because they'll say, "Oh, prior to March of 2011 is fine." You know why? Because the second pick is a defense pick, and that's the situation with that pick. So, look, the bottom line, Your Honor, is this is the rules we've been playing by all along with regard to CMO 12A.

THE COURT: I got that.

MR. COFFIN: If Your Honor thinks we need a motion for summary judgment, we can do that.

Thank you, Your Honor.

THE COURT: Thank you.

Mr. Moore.

MR. MOORE: Your Honor, if I could just have a minute to plug my machine in. I have pictures I might show you of some of the exhibits.

THE COURT: If we're going to have pictures, I need

to get my other pair of glasses.

MR. MOORE: Okay.

(WHEREUPON, the Court took a recess.)

MR. MOORE: Your Honor, first, I know that it's been a long day --

THE COURT: It really has.

MR. MOORE: -- and everyone in this courtroom, and everyone that was here this morning, greatly appreciates your efforts to push through what is undeniably a very tedious agenda on a status conference day with a show cause docket, and the last thing that I want to do is do anything that might be trying your patience, but I'm going to ask you to bear with me a little bit because it is sort of dense, the material, that I need to get through.

I want to start off, though, because there was some emphasis in the discussion about CMO 12 and what CMO 12 was created for. CMO 12 was drafted and negotiated by John Olinde and I, and Dawn and Palmer, principally, for the purpose of fixing a problem in this MDL. It wasn't a problem that related to a bellwether plaintiff or set of bellwether plaintiffs; it was a problem that existed with thousands of cases being filed without knowledge of the proper defendant.

Thousands of cases were filed in this MDL identifying seven different defendants without knowledge of who the actual defendant should be, whose medicine did the

plaintiff take. CMO 12 is, quite frankly, an unprecedented type of order in a pharmaceutical litigation because usually you have one or two defendants and the identification of the medication is understood and researched and determined before the lawsuit is filed. But what we ended up with in this MDL was the exact opposite, thousands and thousands of cases that we don't know whose case they are.

And so the purpose of CMO 12 was to give a mechanism, a procedure, by which defendants -- I'm sorry, by which plaintiffs can gather evidence that we agreed would constitute sufficient evidence of product ID. And then once they produce that evidence, those plaintiffs are obligated to dismiss the improperly named defendant or defendants. Sometimes they were administered medicine from two or three different manufacturers. That's very common during the generic time period.

But what the order -- and it was a consent order that we agreed upon and submitted for the Court's signature. We didn't change the Rules of Evidence in this order. We didn't change the Rules of Civil Procedure. We didn't instill in it a mechanism to begin adjudicating essential elements of the plaintiffs' cases when they get to the bellwether process.

We always knew that there would be some cases that could not produce product ID. We knew that. We knew that would happen. We knew that there would be some percentage of

cases that would produce the evidence that we agreed would be sufficient evidence of product ID that would be, nonetheless, contradicted by other evidence. We knew that. We didn't know how many cases that would be. We didn't know how diffuse the problem would be. But we knew that would happen, and we put mechanisms in CMO 12 to deal exactly with that.

If I could get my computer to work. There we go.

So CMO 12, Your Honor, specifically states in it that we have the opportunity to dispute product ID so long as we offer testimonial or documentary evidence. That evidence is obligated to be submitted in a bellwether case before the end of Phase I discovery; but for the first set of trials, it was before the end of Phase II discovery, which was November 7th, 2017.

We did that in the Durden case. We attached that as Exhibit 15 to our opposition. We identified the testimonial and documentary evidence that we believe is contrary evidence to the argument of product ID that they ultimately landed on in this case because it changed about three times during -- you know, once this issue arose.

But we specifically state in paragraph 9(d) -- let me move this over because I can't see it on my screen, but I can see it over here. Unless there is any confusion about what we were agreeing to in terms of our ability to dispute

product ID, we put in paragraph 9(d) of the order: "Plaintiffs acknowledge that defendants have not confirmed the sufficiency of any product identification obtained and agree that the defendants retain their right to timely dispute product identification."

All we have to do is submit our countervailing evidence at the time specified in paragraph 8, and then we have the right to dispute product ID in that case. And once that happens, product ID in the case is disputed, and the only way to remove a disputed factual issue in a legal case is either the jury does it or the judge does it under Rule 56. Those are the only two mechanisms to do that.

We did not put in CMO 12 a mechanism for the Court or for anyone else to test the sufficiency of the countervailing evidence that's submitted. That's not in the order. What's also not in the order is any sort of specification about what this contrary evidence needs to be. Like we defined what the evidence would be that would be satisfactory under CMO 12 for us not to dispute product ID so long as there was no other countervailing evidence. We put that in the order.

We could have defined in the order what countervailing evidence must be. We could have put a mechanism in it to have that countervailing evidence tested and adjudicated under the order. We didn't do any of that because

we didn't know what the evidence would be, we didn't know how many cases it would pertain to, and we wanted to preserve our rights to dispute product ID in any case so long as we complied with the deadline in the order, which is what we did in this case.

And we have heard in the chambers conferences and again in some of their submissions on this motion, "Well, what about all these other cases, the thousands of cases that have obtained NDC codes and they have gone and dismissed improperly named defendants?" We accounted for that in this order too.

In the same paragraph, we acknowledge that in the event we dispute product ID, the plaintiff retains the right to reinstate claims against any defendant. Any defendant that they dismiss on the grounds of NDC codes, if there is a dispute to the sufficiency of that evidence, then they have the right to reinstate those claims.

Ms. Durden sued Hospira. She sued Sandoz. Those medicines were being administered at Ochsner at the time she was there. We are disputing product ID. She has the right under the order to reinstate her claims against those defendants.

So the idea that CMO 12 is a mechanism by which we can adjudicate a disputed issue in this case, we disagree with that. We think that the only way to dispute product ID in

this case is to do it either through Rule 56 or in front of the jury. We do not think that based on the evidence that exists today that summary judgment could ever be granted in this case.

And the reason this issue has arisen is because we had an agreement, the parties did, and it was memorialized in CMO 14 that cases with disputed product ID, cases without uncontroverted product ID, would not be part of the bellwether process. That was their ask of us. They wanted us to give up a defense so that we could get better guidance on issues of liability, causation, and damages, and we were fine with that. Fine.

If it was a product ID defense, we'll just make sure that the case doesn't have a product ID defense in it. That's how this issue in Durden got raised. But what -- and Your Honor is the boss, and I heard Chris say during his argument that he wants to present product ID now to the jury in the Durden case. He would rather do that. We wouldn't be opposed to that either.

We think when you see some of what the evidence is, the concerns about doing that in front of the jury still remain. It would not be a good idea to add that defense in on the bellwether cases, but if that's what Your Honor wants to do -- if Your Honor wants to try the Durden case, we can go try the Durden case. That's fine.

But what we don't want to have happen is, for

the sake of trying the Durden case, have an essential element of their claim adjudicated against us under CMO 12 and not under Rule 56 or in front of the jury, which is where we think that issue should be raised.

The reason we think that, Your Honor, is because the issues in this case surrounding product ID have changed quite a bit.

I'm just going to grab my water.

So, this is sort of where the story begins. On June 30th, 2017, the parties made their nominations for bellwether picks for the bellwether discovery pool, and Antoinette Durden was included in that group. The very next day -- or the very next week, in front of Judge Engelhardt at the status conference, it was represented that on the plaintiffs' side, they only selected those cases with confirmed product use through an NDC code.

But what they actually had at that time for Ms. Durden was an Internet printout of a carton of the Taxotere product with the NDC code handwritten on it. You can see from the date that I circled, this document was downloaded on May 11th, 2017. That's the same day that it was faxed by Ochsner to Chris' office.

So we did not notice this, though, Your Honor, and we didn't discover that this was the product ID that had been uploaded for the Durden case. Of course, this happened

before there was a CMO 12. But, nonetheless, the first argument that we received on product ID in the Durden case was that this NDC code --

THE COURT: Let me ask a question: Has any other NDC code been identified for use by Ms. Durden?

MR. MOORE: Yes. I mean, this was the first one.

THE COURT: Okay.

MR. MOORE: That's not the code they say she took now.

THE COURT: Okay.

MR. MOORE: There were different codes for argument number two. And the argument that they settled on based on the Molina and the Ochsner billing records is the argument that they're advancing now.

THE COURT: Okay.

MR. MOORE: And so when this evidence came in, we didn't have a basis, when the case was identified, to understand that it was not valid evidence of product ID. As Chris mentioned, his office kept working to obtain the actual checklist that was provided to this employee -- her name is Ashley Canty -- from Ochsner's Revenue Cycling Billing Department.

But after August 7th, after the case is nominated, there were no further attempts that we can see in any of the e-mails that have been produced to obtain this

product ID code. But a paralegal at Shook, Hardy & Bacon, after the new year in the beginning of 2018, found this printout and brought it to us. And so we said, well, let's -- "That doesn't look right. That's not product ID" -- issue a request to Ochsner.

And what Ochsner sent us was this. They sent us a document that says, "Look, due to the age of the dates of service, we don't have NDC codes for this patient." This is not just a problem with Durden, I should mention. Because at this time, we were getting -- and I'll show you some of these in a few minutes -- we were getting lots of certifications from Ochsner saying, "We don't know. We don't have the NDC codes. All we can tell you is what medicine was on the shelf at the time. What medicine we were purchasing at the time. What medicines we purchased at" -- what they call -- "the pertinent time period." But they couldn't identify which medicine was actually administered to a patient.

So when this comes in, four days later, Judge Engelhardt nominates Durden as the primary trial plaintiff. And so the effort then is made to try and get the certification.

And what happens is Ms. Canty ultimately signs a certification. She asks, when its sent to her, "Well, look, I'm not an -- I'm not the oncology department. I'm not with the infusion pharmacy. Am I allowed to sign this?" She's

told, "That's fine. Go ahead and cross that out and write in whatever department that you have." That's not fine. We had an agreement as to the content of this form under CMO 12 as to who could actually execute this form for it to be valid evidence of product ID.

But, anyway, long story short, Canty did not have authorization to do this. She had no idea what NDC codes were administered. It was that we took her deposition, my guess is she was trying to be helpful in providing information that was being requested of her, but, ultimately, she rescinded the certification.

But to answer Your Honor's question, this was the first argument. The argument was for each -- all six of these administrations, this was the NDC code for all six of them. But as we mentioned, we had conflicting evidence. There was some phone calls to Ochsner's legal department, and what ultimately happened was that Ms. Canty rescinded the certification.

She testified in her deposition that she didn't look up any documents, she didn't have any information about what medicine was administered to her, and ultimately argument number one failed.

So argument number two, and what happened next is so we didn't have any product ID evidence in Durden at this point. We're proceeding along Phase II of bellwether

discovery. She's the primary plaintiff. What we then say to plaintiffs' counsel is, "Look, we had agreement that we weren't going to have questionable product ID in the bellwether. Why don't we strike a line through Durden and just move on to the next case?"

We brought that up to them in September, and the reason we did was because we were looking ahead at the schedule and thinking that doing motion practice and experts and so forth in two cases would be better than three.

And so it was in conjunction with that status conference that we learned what the second argument for product ID for the plaintiffs for Ms. Durden was. And it was in their conference submission where they said, "Well, look, we know that she had 20-milligram Docetaxel, and Sanofi was the only one who had 20-milligram Docetaxel on the market at the time," and they based that on an FDA printout.

And the FDA printout showed that either Winthrop or Sanofi products were 20 milligrams per milliliter. And I'll spare Your Honor with all of the discussion of milligrams per milliliter because ultimately the problem with this argument was that there's no explanation in the medical records as to whether she was administered 20 milligrams per milliliter or 20 milligrams per vial, and there was multiple formulations of 20 milligrams per vial on the market at the time being purchased by Ochsner at the time.

So we were at this point debating this 20 milligram per milliliter versus 20 milligram per vial debate. The reason I'm pausing on this is because the evidence that was being advanced in support of this 20-milligram argument is evidence that still exists in the case. It's still there.

They're not arguing anymore that she received 20 milligrams per milliliter medicine. The NDC codes for Sanofi's medicines that are 20 milligrams per milliliter, they are no longer claiming that she took that medicine. They're claiming that she took 40 milligrams per milliliter medicine based on the NDC codes that were ultimately produced.

But what -- what happened after the chambers conference was that there was a deposition notice issued by Chris to Ochsner. It had 86 separate subject matters, 25 separate document requests, and there were two pieces of information that were produced and uploaded to MDL Centrality in response to -- in response to that request. The first was a declaration from Neil Hunter, and the second were a piece of evidence that they now rely on.

So the subpoena goes out October 18. Middle of October, we learn that Ochsner has responded to their subpoena with documents. We're asking when the deposition is going to take place. The discovery cutoff is November 7th. We don't know what position they're taking because what was produced

were purchasing records by Neil Hunter and billing screenshots, billing records, from someone else.

Neil Hunter is the pharmacy manager. And the purchasing records outline all of the medicine that was purchased from the seven-month period before Ms. Durden was administered the medicine. The NDC codes that are in the billing screenshots are not contained in the purchasing records.

So we said to the other side, "Wait a minute. You can't administer a medicine that you didn't purchase. You have to have it there. You have to have the medicine there and available to administer to the patient. So are you going forward with the deposition or not?" We couldn't get a clear answer, so what we did was we noticed the deposition of Ochsner, and we set the deposition for November 7th of both Mr. Hunter and Ochsner. We did a 30(b)(6) for Ochsner.

And so what we received in lieu of the deposition testimony from Neil Hunter was an affidavit. This is the affidavit that Mr. Hunter provided to us. He testifies in his affidavit that he's currently the manager of the inpatient pharmacy at Ochsner. He testifies that they were purchasing Hospira medicine beginning in March of 2011, that they were purchasing Sandoz medicine in August of 2011.

He takes the CMO 12 chart that was provided to him by the plaintiffs. I didn't give it to him. You can see

here, he refers to it as Plaintiff's Exhibit B. This was provided as the NDC code chart from CMO 12 to Mr. Hunter in response -- or in conjunction with the plaintiff's subpoena. He takes that and executes it in response to my subpoena.

And what he says is, "I've marked this to show the possible Docetaxel administered to this patient." These are the medicines that he says, as the pharmacy manager, could have possibly been administered to this patient. Two were made by Sanofi, two were made -- or marketed under Winthrop, that's also Sanofi. And then there are six medicines, three by Sandoz, and three by Hospira, that are not manufactured by Sanofi.

I put a red box around those two codes at the top. Those are the two codes that are in the billing records. Those are the two codes that the plaintiff says were administered to Antoinette Durden because they show up in the billing records. Those medicines had not been purchased in over a year. Those medicines were no longer manufactured by Sanofi.

In August of 2010, those NDC codes were removed from the product labeling. They were no longer purchased by Ochsner. I think the last purchase was in either October or November of 2010. And so we became concerned that the notation of that NDC code -- of those NDC codes were a default code.

It is not an unprecedented thing, especially

back in this time frame, for a default CPT or J code or NDC code at a medical billing department to be included in a Medicaid or health care claim for reimbursement.

It is supposed to be -- I agree with Chris. It is supposed to be the medicine that was actually administered to the patient. That's what they're required to do. It doesn't cost Medicaid any more money because Medicaid pays based on a different code, and they pay per milligram of the medicine regardless of who makes it. The reason the NDC code is in there is so that the payor, either the government or Blue Cross, or whomever, they can go back to the manufacturer and ask for a rebate.

So Ochsner's not getting any more money by not putting in the correct code, but we think that, and we're pretty confident, now having looked at the product ID information for Ochsner cases, Ochsner cases from the 2011 to 2014 time frame, that this is less of an Antoinette Durden problem than it is an Ochsner problem.

We have -- we've identified 29 cases in MDL Centrality who were treated at Ochsner, 2011 to 2014 time frame, and only three of them have produced NDC codes. These NDC codes are the same. They produced the same NDC code, even though at this time, based on the purchasing records that was provided by Neil Hunter in conjunction with his affidavit, that Sanofi had purchased 912 vials of other medicines, not those

NDC codes, at over half a million dollars of costs.

And all of those medicines were presumably not used, but instead put on the shelf in favor of a medicine that hadn't been made in a year, hadn't been purchased in a year, and that the pharmacy manager says couldn't have been administered to the patient.

What we're seeing in these patients are the certification. This is one that was contained in our supplemental submission last night. What this certification is, is it says, "We don't know what NDC code we administered to you." This was the type of certification we're getting across the board in Ochsner cases from this time period.

And so what they're saying is, "We can't tell you the exact medicine that was administered to you, but we can tell you for the pertinent portion of 2014, in this particular record, here are the medicines we had on the shelf at the time. These are the medicines that we purchased," and then he gives a little chart that shows who the medicine's NDC codes are and who manufactured them.

But you can see that this person was administered the medicine between January of '14 and March of '14, and the certification goes back about a month before the first administration and collects the purchasing data, and that's what Ochsner has been producing. So this tells us what they were purchasing at the time, but it doesn't tell us which

of these medicines was actually administered to the patient.

So this doesn't help us determine product ID. This was the same evidence that was produced by the same person in Antoinette Durden's case. But what he doesn't include in the certification is the medicines that are in the billing codes.

And it was -- we have, I think, one in 2014, and some others in 2015, where Ochsner begins issuing the certifications indicating that the NDC codes can be directly correlated to a particular patient. That information begins to come out. I think we saw one in '14, most of them are in '15.

And you can see that it's signed by a different person, an Epic analyst, who is a person who works in their systems administration in their pharmacy department. And the Epic system is a new system that Ochsner has that apparently requires bar scanning before you can administer a particular medicine.

But I wanted to talk a second about it because Your Honor brought up the shelf life issue of the NDC codes that are referenced in the billing records. The third patient that has this same NDC code, the NDC code that hadn't been purchased, the NDC code that the pharmacy manager said we couldn't have administered to the patient, this person was administered this medicine, at least according to this record, which is from Blue Cross and Blue Shield in 2012. And it

indicates that she was administered 200 milligrams. So that would be ten vials of that NDC code in 2012.

The shelf life for that NDC code, which is the 20-milligram version of the medicine because there's two in the Molina and the -- the Molina and the Medicaid -- or the Ochsner billing records, that is an 18-month shelf life. What the purchasing records tell us, that were provided by Neil Hunter, is they had not purchased ten vials of that medicine in the 18 months prior to this patient's administration.

So here's where we really are with the evidence. Their argument is that these NDC codes demonstrate that she was administered this medicine, and the rest is just smoke and mirrors by the defendant. But we have an affidavit, the pharmacy manager.

We think we should be able to put Neil Hunter on the stand at the trial of this case and ask him about those NDC codes, and ask him, "These are the NDC codes that Mr. Coffin says were administered to that patient. Is it possible, based on your knowledge as a pharmacy manager, for those medicines to have been administered to those patients?" In his affidavit, he says, "No."

There are ten medicines that could have been administered, and those two are not one of them. That medicine had not been purchased in over a year. It had not been manufactured by Sanofi anymore. It's a medicine that if -- at

least in Toneka Terry's case, would have been expired.

So we're supposed to believe that Ochsner is now administering medicine that they hadn't bought in a year, that we no longer manufacture, that the pharmacy manager says couldn't have been administered to the patient, and that in Toneka Terry's case would have been expired. We think that the most plausible explanation for the presence of these NDC codes is that they are a default code.

What is troubling to us with the procedural posture -- and this is the last comment I will make, Your Honor, because I know you have more show cause cases to get to. What is troubling to us about the procedural posture of this case is that we're seeking to adjudicate an essential element of their case under a case management order.

Ochsner responded to Chris' deposition notice that had the 86 requests in it. And there was some, I think in the last chambers conference, as you had indicated that you were very frustrated with Ochsner and its response, but Ochsner actually issued a response to Chris' subpoena. It was prepared by their outside counsel, which they have hired.

What they said was that they are unable -- this is in response to the most recent subpoena, the one that you said this deposition needs to go forward like yesterday. They issued a written response to it. They made their objections. They state in the objection that they are unable to identify a

person or witness who can testify as to the manufacturer of the medicines administered to this patient. They also state that there are four possible manufacturers of the Docetaxel products administered to Antoinette Durden.

It would be really easy -- it would be really easy -- for Ochsner to just go along with the idea that, "Well, the shelf life is 18 to 24 months for this product, maybe it was still on the shelf." If you look at the purchasing records, which is Exhibit B to Neil Hunter's affidavit, you can see that they are buying this medicine over and -- every couple of days. They're buying 15 units, 10 units, 12 units, 15 units.

Chemotherapy is not an emergency thing. Nobody comes in for chemotherapy the next day. Chemotherapy is a scheduled event. They know what medicines they need, when they need it, and they buy it when they need it.

And Neil Hunter's affidavit shows that medicines that they purchased a year ago are not medicines that could have possibly been administered to the patient. He's the pharmacy manager. It would have been really easy for him to just check those boxes and say, "Yeah, yeah, those too," because they're in the billing records, but he didn't. Because to do that would have been inconsistent with that witness' understanding of how they inventory their medicines in the pharmacy.

So we think we should be able to put that witness on. We think that the jury should be able to see this evidence and make a determination as to whether or not product ID, whether they carried their burden of proving that it was our product.

When they stand up in front of the jury and say, "These are the NDC codes," we get to say, "They didn't buy those NDC codes. They didn't have those NDC codes in a year. We didn't make those medicines anymore, and here's the pharmacy manager who says it's not possible for those medicines to have been administered to this patient."

We think that that is a defense we would raise in any case. And the only reason we're debating it now is because we raised it in the context of Ms. Durden's eligibility for bellwether treatment.

So if Your Honor thinks we should try the Durden case, we are fine trying the Durden case, but we think product ID is part of that case. We think there's going to be 29 other cases where NDC codes are produced by Ochsner that are not going to match the purchasing records, and we will dispute product ID in those cases.

But, by and large, the ultimate purpose of CMO 12, it is working. Cases are obtaining valid evidence of product ID, and those cases are being dismissed. He mentioned Ms. Earnest. He suggested that we would potentially raise an

issue of in fact in Ms. Earnest's case. We can't. We can't.

She wasn't treated at Ochsner. She was treated at East Jeff. She produced NDC codes for a Winthrop product that we were actually making at the time. There was no countervailing evidence in purchasing records. There was no countervailing evidence in medical records.

This is a picture of Barbara Earnest. This is the case that they want to try. This is their number one trial pick for the first trial. It's the number one trial pick in the second trial.

If I was just doing this to torpedo their cases, I would have torpedoed this one, but the evidence doesn't allow it, because the evidence doesn't exist. This is an Ochsner problem. There is an inventory of cases related to an Ochsner time period, and we think that creates an issue of fact on product ID in Ms. Durden's case that we should have the right to litigate.

If we try this case, we just want to be able to -- the ability to put on all of our defenses.

Thank you, Your Honor.

THE COURT: Thank you.

MR. COFFIN: Your Honor, it is accurate that as counsel for Ms. Durden, we made multiple attempts to obtain product ID in the case because that's our job, and that's what we do in every case. And the reality with Ochsner, as you've

seen not only with Ms. Durden, but you see with Ms. St. Ann who we submitted as well, is unless one of the plaintiffs' lawyers serves them with a subpoena or serves them with a 30(b)(6) notice, they don't have NDC codes.

So they represented that they didn't have those NDC codes from the time that Ms. Canty recanted what she originally told us, "Yes, we have these NDCs, and this is what it is". From that time, they kept telling us that there were no NDC codes.

And, in fact, as you heard Doug state, Sanofi actually learned that there were no NDC codes, so Ochsner said. They actually learned that on the same day that they, the defense, suggested Ms. Durden be one of the trial plaintiffs. They picked her as their, I think, their fourth -- their fourth pick. That was the same day they received the letter from Ochsner saying, "We don't have NDCs."

But the reality is that, of course, we tried many avenues.

THE COURT: Now, I'm not interested -- I think we need to get to is this something -- because I think what you've requested, and I have to tell you, I know there was supplemental briefing filed yesterday. I didn't see it.

MR. COFFIN: Understood.

THE COURT: So at the conclusion of this, as much as you all want to know what I'm thinking, I don't know. There's

apparently a great deal of information that I still have to sift through.

Two things, even if I should grant this motion and I enforce Case Management Order 12, does that put me in a position where they are precluded from raising the defense of product ID? Is that what you're saying? Or is this something that needs to be filed with rule for summary judgment, or are we really going to open up these bellwethers to product ID?

Because I think if I enforce CMO 12, that's the process that provides you a rebuttal presumption.

MR. COFFIN: Correct.

THE COURT: But that's not a finding or a judgment of product ID; right?

MR. COFFIN: Well --

THE COURT: That's what you're asking me to do.

MR. COFFIN: That is what we're asking you to do. But as I said in my initial remarks --

THE COURT: But can I do that through CMO 12, even if I wanted to?

MR. COFFIN: Well, I don't know whether you can or you can't --

THE COURT: Okay.

MR. COFFIN: -- but I think that the bottom line, Your Honor, is, sure, we'll move to a motion for summary judgment, but that's what you're going to get from us, and,

quite frankly, it's going to be in the same form of what you've seen. And like I said the first time I talked, sure, we're happy to do that. We just need to have that defined a little bit better. I guess it will be defined, if that's how you rule, in terms of what is CMO 12A doing.

Because like the Earnest case, they say, "We didn't try to torpedo the Earnest case." Well, yeah, they did. They filed a motion for -- we filed a motion for summary judgment, and they couldn't get over it. They fought it. They opposed it. Why didn't they just stipulate? We asked them, "Can you stipulate to product ID in Earnest?" They wouldn't stipulate. That's why we had to file a motion.

THE COURT: Okay. I don't want to -- I'm not -- I've got my plate full right here, so I don't want to talk about Earnest.

MR. MOORE: I wasn't going to talk about Earnest. I was just going to make the point that on Chris' point, that Ochsner did offer three witnesses when they objected to the subpoena.

THE COURT: Okay. I'm really trying to see what it is. And, Mr. Coffin, suppose -- I mean, we talked about suppose I agree with you, then I grant -- I enforce CMO 12, but really then we have to go through summary judgment. What if I disagree and I say, "You know what, this is just not clear to me." And I think it's -- I have to tell you, this has bothered

me about this case, and I have talked to other judges about this case.

This is not going to Walgreens where I have a receipt that tells me, you bought this product from Hunt or Sanofi or anybody. You know, I'm at an infusion center, and I'm at the mercy of these people because I don't know what's being administered to me. I don't know the manufacturer of the drug. So I don't need lectures on that.

My question is: Suppose I disagree with you and I say, this is just not very clear to me, and this is not the type of evidence upon which I would grant summary judgment. I would say, send it to the jury. Are we now -- I thought part of what we wanted to do from the bellwether process is remove that issue and just proceed with plaintiffs that didn't have a question about product ID.

MR. COFFIN: Right. The problem with -- so what happens if you do that? The problem is the presumption from the defense side is that you move to the next pick, and none of us --

THE COURT: Well, I guess what bothers me --

MR. COFFIN: Because you've decided that Ms. Earnest -- you've already ruled on that. So we are playing under different rules than we anticipated because now we have an NDC that we believe is clear that Ms. Durden was administered the drug. And so it's going to change the process

and the rules of how we thought we were choosing those plaintiffs who would be first at trial.

THE COURT: I guess what I'm thinking, and this is just -- and, of course, unfortunately, there's a great deal more that I have to look at that I didn't -- I'll be honest with you, I didn't know existed until -- I mean, when I walked in somebody said, "Do you know that there's a motion for you to," and I thought, "No, and I don't have time to look at it because I will be tied up with this."

Suppose I say this is not clear. I don't know. And this may ultimately be a question for the jury. Are you prepared to proceed with this as your one manufacturer you got? It seems to me that -- I mean, is that -- because if I said it's not clear and I don't know if it was Sanofi, it might have been any of these other manufacturers, and then you're waiving your right against any of those potential manufacturers and an opportunity to present that to a jury, tell me which manufacturer it was.

MR. COFFIN: Yes, we're prepared to do that. It is not another manufacturer other than Sanofi. If it was, we'd have an affidavit from Ochsner saying, "This is a mistake." This idea that it wasn't purchased within a year, it was purchased -- we have purchase records from February of 2011.

Yes, Your Honor, we'll put that in front of the jury and we'll take that one defendant, Sanofi. Yes, ma'am, we

will do that. Because these are the gold standard. And it's wonderful that they produced all this other stuff and the things -- but this, they got paid for it.

And I'll be happy to stand in front of a jury and say, "Ladies and gentlemen, this hospital got paid for this -- for administering this drug." And we'll have to put somebody from Ochsner on the stand and say, "Are you telling this jury that you got paid by the government" --

THE COURT: No, I know what your cross-examination is going to look like. And I think Sanofi's going to say, "Did we tell you to write that down?" So there is an -- that was a question I wanted to ask --

MR. COFFIN: So yes.

THE COURT: -- because I'm just in -- then I need to --

MR. COFFIN: Now, there --

THE COURT: -- dig through this.

MR. COFFIN: I would give you a different answer if we weren't able to obtain the NDCs. But if you -- and I think we're all in the same frame of mind in sitting in your chambers, I think what Your Honor -- I know what Your Honor said to all of us was -- to us was, "Look, if you don't get NDCs, if you don't get NDCs, I want summary judgment type evidence," and that's what the defense said too. We get the NDCs, and now we still have a problem. And it's just over and

over and over again.

THE COURT: Well, here we are. And this is, for all intents and purposes, while it's not fashioned as a summary judgment, a motion to enforce, but this is what we're doing.

MR. COFFIN: It is. And we just decided to do the CMO 12A route because that's the procedure this Court set up, and if you want us to go to the summary judgment, happy to do it.

THE COURT: Well, I don't think it's -- and I don't want to fight about that today. That perhaps will be an argument for another day. But what does this ruling mean? I'm not certain. Because I'm not sure this is --

MR. MOORE: Your Honor, I was going to --

THE COURT: Wait. Wait. You got to let him finish.

MR. MOORE: I'm sorry. I thought he was done.

MR. COFFIN: The only thing I'll say on whether this is the proper procedure is if you're -- I think -- I'm assuming Sanofi feels the same way. If Your Honor decides this isn't the proper procedure, no problem. Let us know. We'll turn it into a motion for summary judgment --

THE COURT: Oh, I know.

MR. COFFIN: -- and we'll talk about it then.

THE COURT: I got that. I got that. And you'll do a new heading.

MR. COFFIN: Thank you, Your Honor.

MR. MOORE: Just on that last point, Judge, the one -- the one comment I wanted to make is that as soon as Ochsner made its response to the subpoena, when you told us, "I want this deposition to happen yesterday," and we had to have some phone calls with them, they asked us to narrow the subject matters, Chris did that, I did that.

THE COURT: Sure.

MR. MOORE: They issued the response to the subpoena. They offered three witnesses, and then this motion was filed. If there is going to be -- if this is going to be considered on the question of whether or not there is sufficient evidence in the record for there to be no genuine issue of material fact on an issue that he has the burden of proof on, we think we should complete those depositions before proceeding on any Rule 56 type consideration.

MR. COFFIN: The issue that we had with the deposition, Your Honor, is we told Ochsner, "We need somebody who knows these billing -- the billing issues." They said, "We can't produce somebody like that." We said, "You have nobody who can testify about what you billed to Medicaid?" "No, we have nobody."

The pharmacist is talking about purchase history. Again, it's a red herring. I don't care about that. Because I want to talk to the person with the NDC knowledge, "What did you bill for, and what were you representing to the

government when you billed this?" They can't produce somebody. So I can ask them again, but they have this idea that we want them to produce --

THE COURT: But it's a bit like the doctors -- the doctor's deposition that we talked about this morning, which, for the record, is going to make no sense. We're not going to stop midstream of a deposition and then take it up in a summary judgment. So this may be --

MR. MOORE: It was --

THE COURT: There's a great deal for me to look at.

Is there anything else?

MR. MOORE: No, Your Honor.

MR. COFFIN: Not from us, Your Honor.

THE COURT: I think I got it. Thank you.

(WHEREUPON, the proceedings were concluded.)

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CERTIFICATE

I, Jodi Simcox, RMR, FCRR, Official Court Reporter for the United States District Court, Eastern District of Louisiana, do hereby certify that the foregoing is a true and correct transcript, to the best of my ability and understanding, from the record of the proceedings in the above-entitled and numbered matter.

s/*Jodi Simcox, RMR, FCRR*
Jodi Simcox, RMR, FCRR
Official Court Reporter