

**EXHIBIT**  
**9**

**A203**

1 UNITED STATES DISTRICT COURT  
2 SOUTHERN DISTRICT OF FLORIDA

3  
4 UNITED STATES OF AMERICA, )

5 PLAINTIFF, )

6 vs. )

7 DR. CHAD LIVDAHL, etc., )

8 DEFENDANT. )  
9

CASE NUMBER  
04-61717-Civ-Cohn

THIS VOLUME:  
PAGES 1-96

10  
11 TRANSCRIPT of PRELIMINARY INJUNCTION HEARING had  
12 before THE HONORABLE JAMES I. COHN, in Fort Lauderdale, Broward  
13 County, Florida, on Monday, January 10, 2005, in the  
14 above-styled matter.

15 APPEARANCES:


16 FOR THE GOVERNMENT:

RUSSELL KOONIN,  
ROBIN ROSENBAUM,  
GEORGE KERAVATSISS,  
Assistant U.S. Attorneys

17  
18 FOR THE DEFENDANT:

ROBERT F. GEHRKE, ESQ.

19  
20  
21 ANITA LaROCCA  
22 OFFICIAL COURT REPORTER  
23 U. S. COURTHOUSE  
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25 FORT LAUDERDALE, FLORIDA 33301  
954 769-5568



A204

THE COURT: All right.

MR. MOONIN: The defendants' labeling is Botulinum Neurotoxin Type A from clostridium botulinum, and highlighted for research purposes only, not for human use. On its face, therefore, it's not under FDA regulations. For research purposes only, not for human use.

However, Your Honor, as I discussed, the word drugs contain intention for use. And under 21 CFR 201.128, we see a definition of what it is that intended for use entails. If I could just approach again, Your Honor?

THE COURT: Yes, sir.

MR. MOONIN: The words intended uses are similar or import refer to the objective intent of the persons legally responsible for the labeling of drugs. The intent is determined by such person's expressions, or may be shown by the circumstances surrounding the distribution of the article.

This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives.

Your Honor, the United States submits to this Court that it is without question that the defendants' intended use of Botulinum Toxin Type A was for use on human beings. If we look at -- this is a flyer for a seminar that the defendants held, and I'll focus in on it.

Physician's approach to compounding for aesthetic

enhancement hands on workshop and demonstration, Saturday, July 19th, 2003. And as we scroll down, Sunday, July 20th, 2003, 10:45 to 12:45. Botulinum Toxin Type A tutorial. Also previously on Saturday, July 19th, 3:00 p.m. to 4:00 p.m., Botulinum Toxin Type A.

The presenters at the seminar include the Defendants, Zahra Karim and Doctor Chad Livdahl. Another presenter at this seminar is Bach McComb D.O., M.D., Ph.D. Turning our attention away from this for a moment, I'd like to turn the Court's attention to an email of March 18th, 2003, from Doctor Bach McComb.

Tuesday, March 18th, 2003, to Chad at Powderz dot com, subject, regarding compounding workshop July 19th, 20th. Dear Chad, thanks for the email. I hope all is going great with you guys. I do a fair amount of Botox and Restylane and I am quite proficient with a needle from my years of prolow. I would be delighted to participate with you in providing a hands on training on the two techniques.

Just let me know any further details, and I'll help put things together, et cetera. Doctor Bach McComb is writing that he knows about Botox' intended use. Turning our attention back to the seminar, as we stated, Doctor Bach McComb was one of the presenters. Now, the United States is not --

The defendants' product is not the cause of, as we know, Doctor Bach McComb and his three patients are infected

with botulism, and the United States does not submit to this Court that it was the defendants' product that caused the botulism of these four individuals.

However, it is without question that Advanced Integrated Medical Center in Oakland Park, Florida, where Doctor Bach McComb was employed, received four shipments of TRI's Botulinum Toxin Type A in March, April, August, and October of 2004.

Again, going back to the seminar brochure that we have here, we have testimony from Doctor William Steven Martin and Doctor Santos Soboron, M.D., both private physicians. Doctor Steven Martin, Board certified in plastic surgery; and Doctor Santos Soboron, Board certified in internal medicine.

At this seminar, as attached to Agent Leeds' declaration in support of the United States' temporary restraining order, individuals signed handwritten consent forms consenting to be injected with Botulinum Toxin Type A. As the declarations of Doctor Santos and Soboron state, on the second day they witnessed injections by the fourth presenter here, or the fourth presenter I should say, Doctor Robert S. Baker.

They witnessed injections by Doctor Baker of a substance that he termed experimental and its purpose being to treat wrinkles. After Doctor Baker injected these seminar attendees with the wrinkle -- with this experimental wrinkle treatment, Defendant Chad Livdahl addressed the seminar

attendees.

Doctor Livdahl addressed the attendees and stated that TRI's product was available in more units and was cheaper priced than Allergan's Botox. And Doctor Livdahl stated, according to Doctor Soboron and Santos, that although their label said for investigational use only, it had the equivalent affect on human beings.

Further, Doctor Livdahl represented that TRI's product would last longer than Allergan's product. In fact, Doctor Baker echoed these sentiments. Further testimony, as attached Agent Leeds' declaration, is from Doctor Helen Donstelli of Sunny Isles, Florida, of the Skin, Vein, Laser, and Anti-Aging Clinic, who stated that Doctor Baker said TRI's product is more potent than Allergan's.

Again, intended use, Your Honor. Let's focus the Court's attention on the fact that defendants' solicitation to non-research physicians is again evidence of their intended use. I have here a cold call script recovered pursuant to search warrant. Cold call script. Good morning, afternoon, evening. This is Doctor Blank for Doctor Blank, is he or she available. No. Is the nurse that does the derma filling available.

This is Doctor Blank from Powderz Medical Compounding calling about our future cosmetic compounding workshop coming up in July. The same cosmetic workshop where we saw that

1 right hand.

2 SUSAN LEEDS, DEFENDANT'S WITNESS, SWORN.

3 THE COURT: Please be seated.

4 State your name.

5 THE WITNESS: Susan Leeds, L-e-e-d-s.

6 THE COURT: All right. Mr. Gehrke.

7 DIRECT EXAMINATION

8 BY MR. GEHRKE:

9 Q. Susan, I first talked to you on December 4th, do you

10 remember that?

11 A. I do, sir.

12 Q. And you called me from Tucson, Arizona -- or I called you

13 when you were in Tucson, Arizona?

14 A. Another agent called you, and then you and I got on the

15 phone.

16 Q. And at that time, you had a search warrant for a company

17 called TRI?

18 A. That's correct.

19 Q. And nobody else, just TRI; is that right?

20 A. That's correct.

21 Q. And you were in the offices of Fowders, the Cosmetic

22 Company, and TRI?

23 A. We were in the suite that is used by all of those

24 companies, that's correct.

25 Q. Well, they're separate suites; aren't they?

1 A. It didn't appear that way, no, sir.

2 Q. Anyway, you asked me -- you said that you were having some

3 problems with the computers, and could I get a computer person

4 over there to help you out, because it would help out your

5 people. Do you remember that?

6 A. I don't remember saying we had a problem with the

7 computers. I know that Todd Livdahl did come over. I think we

8 were looking for a representative of the company. One of the

9 things we were concerned about was securing the location when

10 the warrant was completed.

11 Q. But the TI person from TRI came over to assist you in the

12 computers?

13 A. Yes, sir, he did.

14 Q. And then they informed you of the backup computers?

15 A. They didn't -- Mr. Livdahl did not talk to me, he talked to

16 Special Agent Scheurer.

17 Q. Okay. And then subsequent to that time, you talked to some

18 of the attendees of the Fowders' workshop?

19 A. Actually there were agents in my office who spoke with

20 those doctors, who then relayed the information to me, and I

21 put it in the affidavit.

22 Q. Okay. So you didn't personally talk to them?

23 A. No, sir, I did not speak to the people in the affidavit,

24 no.

25 Q. All right. So you have no idea, for example, how much

1 press they've been reading lately about the botulism case?

2 A. No, sir, I don't know that.

3 Q. Maybe you have some information, or the FDA does that you

4 know, how did you eliminate TRI from the botulism case that

5 happened here in Fort Lauderdale?

6 A. When we returned from the search warrant -- you're

7 referring to the four people who are in the hospital due to

8 their injections at the Advanced --

9 Q. Correct.

10 A. -- Integrated Medical Center?

11 Q. Correct.

12 A. With respect to that case, after we returned from the

13 search warrant in Arizona, I interviewed a gentleman named

14 Thomas Toya (phonetic). We got back on Sunday, I believe that

15 was December 5th, and on the evening of December 6th, I

16 interviewed Mr. Toya, who told me that Mr. McComb had asked him

17 to go to the List Laboratories website and to see if he could

18 order a y Botulinum Toxin.

19 Q. And how could that eliminate TRI?

20 A. Actually it didn't eliminate them, other than after that we

21 found out that he had ordered one hundred micrograms.

22 Q. What is that -- twenty thousand times stronger?

23 A. I've been told by experts at the CDC and the FDA that that

24 amount is twenty thousand times the amount of toxin that you

25 would get for instance in Botox.

1 Q. And you took a hundred and thirty-four vials of TRI's

2 product, and I assume you tested it?

3 A. It is being tested, sir. We have not gotten the results

4 yet.

5 Q. In any event, this product that was twenty thousand times

6 stronger than Botox, and we've heard evidence that Botox and

7 TRI's product have a similar amount of Botulinum Toxin Type A,

8 then you eliminated not only my client, but you eliminated

9 Botox?

10 A. That's correct.

11 Q. Okay. So you're quite certain of those two things?

12 A. I am, as the lead agent on the case, I am fairly certain

13 and have no reason to believe that it was any toxin other than

14 the List toxin that caused the injury to those four people.

15 Q. Has there been some release by the FDA that the toxin found

16 was twenty thousand times stronger than either the TRI product

17 or the Botox product, or any other Botulinum Toxin Type A?

18 A. We generally do not issue press releases regarding ongoing

19 criminal investigations, which this is. But what we do

20 normally do is ask that our affidavits to our search warrants

21 be sealed.

22 In this case, so that the government could get that

23 information out, the FDA was asked to give permission that the

24 affidavit that was filed in support of the search warrant at

25 List Laboratories be unsealed, in effect not be sealed.

1 to research institutions and licensed physicians conducting  
 2 research only.

3 Again, for all the reasons previously stated, this was  
 4 clearly false.

5 THE COURT: I'm sorry, your time has expired.

6 MS. ROSENBAUM: Okay, Judge.

7 THE COURT: Thank you very much.

8 MR. ROSENBAUM: Thank you.

9 THE COURT: Mr. Gehrke.

10 MR. GEHRKE: Thank you, Your Honor. May it please the  
 11 Court.

12 THE COURT: Yes, sir.

13 MR. GEHRKE: Botulinum Toxin Type A is Botox. It is  
 14 also TRI. It is a scientific term. Botox just has a patent on  
 15 that name. There is no way that my client had his TRI product  
 16 injected by Doctor Baker into human beings at those Powderz'  
 17 conferences.

18 There's affidavits of doctors who they don't really  
 19 have a clear recollection. But all those recollections are  
 20 after there was a sensational botulism case, which we now know  
 21 involved twenty thousand times the amount of toxin that either  
 22 Botox or TRI's product had.

23 My client, Chad Livdahl, wants to have an FDA approved  
 24 product. He's going to great expense to build a laboratory in  
 25 Tucson, Arizona. He's wanting to do it right. He's selling

1 this product to only licensed physicians. They're all signing  
 2 forms. They all receive faxes. When they receive a fax --  
 3 When they call, they receive a fax that tells them  
 4 exactly what that product is, exactly what it does, and that it  
 5 is not for human use, that it is for research purposes only.  
 6 That is the only use that product has. And Doctor Livdahl has  
 7 a right to rely upon licensed physicians who sign documents  
 8 saying I understand this, I agree. They sign the order forms  
 9 that it's for research only.

10 He has subsequently found out, because of some of  
 11 these affidavits, that there are some doctors who do that.  
 12 He's willing to take additional steps to make sure that it's  
 13 used only for research. He has a product he wants to bring to  
 14 market. He has a product that he is not trying to sell to the  
 15 public. He's not trying to sell this product for doctors to  
 16 use on humans.

17 He's trying to sell it to doctors who do research.  
 18 Physicians are also researchers. Some physicians don't have  
 19 large research departments. Some physicians do things because  
 20 they have an interest in something, they want to buy quantities  
 21 they can work with. The ten thousand, hundred thousand  
 22 nanograms that can be purchased from List Laboratories is a  
 23 dangerous product.

24 You've got to take sophisticated steps to deal with  
 25 it. It's much easier using a product that has very few

1 nanograms, nanograms of one billionth of a gram. That's a  
 2 product that doctors who are in private practice can use.  
 3 Basically, my clients are here today. They're testifying,  
 4 they're telling their story.

5 And their story is that Chad Livdahl wants to get his  
 6 product out. He wants to sell it as a research product at this  
 7 time. He wants to get FDA approval. He wants to do it right.  
 8 He's making everybody sign forms. He's making everybody agree  
 9 this is only used for research. And that's what it is, it's  
 10 only used for research.

11 I do not believe the government has met their burden  
 12 that my client has sold this as a drug. And the more common  
 13 theory of preliminary injunction should be instituted here, and  
 14 that is that there should be a substantial likelihood of  
 15 success on the merits. There should be irreparable harm,  
 16 inadequacy of other remedies at law, and the public interest  
 17 for the issuance of a preliminary injunction.

18 Here there are adequate remedies that this Court could  
 19 impose on my client to sell this product. Having the  
 20 purchasers of such a product state in whatever detail is  
 21 appropriate what they're going to do with the product, so the  
 22 public is protected. My client has a business he's running.  
 23 He's trying to also to build his laboratory.

24 He should not be enjoined from running his business.  
 25 He's taken enormous precautionary steps when he's sold this

1 product. He's aware of FDA rules. He's an intelligent doctor.  
 2 He's not trying to sidestep the FDA and go around the laws, he  
 3 wants to work within the law. He wants to come back and get  
 4 FDA approval for his product when he can manufacture it at his  
 5 own facility.

6 He's willing to live with whatever safeguards are  
 7 appropriate for the public interest, and to insure that no  
 8 human will use his product.

9 Thank you.

10 THE COURT: Thank you, Mr. Gehrke.

11 Having considered the evidence presented in the  
 12 applicable federal statutes, the Court finds that the Court has  
 13 jurisdiction over both the subject matter and the parties to  
 14 this action.

15 The evidence clearly establishes that the defendants  
 16 knowingly and willfully violated and continue to violate the  
 17 Federal Food, Drug, and Cosmetic Act by introducing or causing  
 18 to be introduced into interstate commerce a misbranded drug;  
 19 have further perpetrated a fraud upon the United States; and  
 20 gave false statements to a federal agency.

21 The actions and practices of these defendants have  
 22 exposed the public to a great health risk. There is a  
 23 substantial likelihood that the United States will succeed on  
 24 the merits of its claim.

25 Although the defendants' products bore the label,

1 quote, for research purposes only, non-human use only, closed  
2 quote, or some derivation thereof, the marketing and  
3 promotional pitch of these defendants and their agents was  
4 clearly directed at non-research physicians and for patient  
5 use.

6 At a seminar the defendants represented their product  
7 was cheaper and more effective than Allergan's Botox Cosmetic.  
8 Botox had been FDA approved for human use. Botulinum Toxin  
9 Type A had not been FDA approved for human use.

10 The physicians, and ultimately the patients, were  
11 misled by this and other misrepresentations into thinking that  
12 the defendants' product was approved by the FDA and safe for  
13 human use.

14 The defendants made false and fraudulent statements or  
15 representations to agents of the Federal Drug Administration.  
16 Doctors Livdahl and Karim stated that they sold their Botulinum  
17 Toxin Type A only to research institutions and licensed  
18 physicians conducting research, and they had no specific  
19 knowledge of the uses TRI customers might find for Botulinum  
20 Toxin Type A.

21 A March 12, 2003 email from Doctor Livdahl clearly  
22 refutes this representation to government agents.

23 Other instances of fraud, misrepresentations, and  
24 misleading statements and omissions will be included in greater  
25 detail in a written order to follow.

1 In summary, these defendants have employed and  
2 continue to employ an intentionally misleading and deceptive  
3 practice that is likely to result in tragic consequences to the  
4 unsuspecting consumer.

5 This Court finds, without question, immediate and  
6 irreparable harm will likely result to the United States and to  
7 the public at large if a preliminary injunction is not granted.

8 Accordingly, the government's motion for preliminary  
9 injunction is hereby granted.

10 The defendants, their agents and assigns are hereby  
11 preliminarily restrained and enjoined from directly or  
12 indirectly doing or causing the sale, shipment, and/or  
13 distribution of Botulinum Toxin Type A.

14 The defendants shall institute a recall of any and all  
15 Botulinum Toxin Type A that they have distributed. Defendants'  
16 recall notice shall be distributed to every person or entity  
17 who may have received their Botulinum Toxin Type A from the  
18 defendants.

19 The defendants are further ordered to immediately turn  
20 over all Botulinum Toxin Type A in their possession or control  
21 to the custody of the Food and Drug Administration. The Food  
22 and Drug Administration shall be allowed to make inspections  
23 without prior notice, and to monitor and insure continued  
24 compliance with this order.

25 Additional proscriptions and directives will be .

1 provided in the Court's written order.

2 Is there anything further?  
3 This Court will stand in recess until 8:45 tomorrow  
4 morning.

5 [Hearing concluded at 4:25 p.m.]

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9  
10 **CERTIFICATE**

11 I hereby certify that the foregoing is an accurate  
12 transcription of proceedings in the above-entitled matter.

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14  
15  
16  
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