

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION
C/A No. 3:04-22306-10

David W. Bibeau, as Personal)
Representative of the Estate of)
Katherine Ann Kurtz-Bibeau,)
)
Plaintiff,)
)
v.)
)
James Michael Shortt, M.D.; Health)
Dimensions, LLC; Congaree Pharmacy,)
Inc.; George Dawn, R.Ph. and J.H.)
"Buster" Phillips, Jr., R.Ph.,)
)
Defendants.)
-----)

COPY

VIDEO DEPOSITION OF
JAMES H. PHILLIPS, JR., R. PH.

Friday, July 15, 2005
10:15 a.m. - 2:50 p.m.

The deposition of James H. Phillips, Jr., R. Ph., taken on behalf of the Plaintiff at the law offices of Gergel, Nickles & Solomon, P.A., 1519 Richland Street, Columbia, South Carolina, on the 15th day of July, 2005, before Margaret S. Smith, Court Reporter and Notary Public in and for the State of South Carolina, pursuant to Notice of Deposition.

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1 immediately reinstated it.

2 Q: hat year was that?

3 A: I don't remember.

4 Q: Approximately, what year was it?

5 A: I don't remember.

6 Q: Was it in the decade of the nineties?

7 A: I believe so.

8 Q: What was the nature of the records that were
9 not available?

10 A: Controlled drug invoices.

11 Q: How long have you been associated with Congaree
12 Pharmacy?

13 A: I believe it was 1986.

14 Q: Did you found Congaree Pharmacy?

15 A: No, sir. I bought it, purchased it.

16 Q: From whom?

17 A: Wayne Sturkie.

18 Q: And did you buy it by yourself or did you have
19 other people, other investors?

20 A: Wayne Sturkie and I jointly owned it for a
21 while and then I bought him out.

22 Q: Okay. Does anyone else own Congaree Pharmacy,
23 other than yourself?

24 A: It's owned by Congaree Pharmacy, Incorporated.

25 Q: And who owns the stock in Congaree Pharmacy,

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1 Incorporated?

2 A: Myself and my wife.

3 Q: Does Mr. Dawn have any ownership interest in
4 it?

5 A: No, sir.

6 Q: Are you the pharmacist in charge?

7 A: Yes, sir.

8 Q: Mr. Dawn is an employee?

9 A: Yes, sir.

10 Q: How long has he been an employee?

11 A: About ten years.

12 Q: To your knowledge, has he ever been disciplined
13 by any regulatory board concerning the
14 performance of his duties as pharmacist?

15 A: Not to my knowledge.

16 Q: Have you ever had any prior criminal charges,
17 either a misdemeanor or a felony?

18 A: No, sir.

19 Q: Have you been sued previously arising out of
20 your performance or duties as a pharmacist?

21 A: No, sir.

22 Q: Now, I see you have brought some documents here
23 with you and I think one of them is a statement
24 provided to you by your attorney; is that
25 correct?

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1 compound?

2 A: I'm not sure what you are ... I mean
3 specifically, what are you looking for?

4 Q: Well, for instance, do you have access to the
5 United States Pharmacopeia?

6 A: I have a copy of the USP, yes, sir.

7 Q: Okay. And for today, we'll refer to the United
8 States Pharmacopeia as USP. What is the USP?

9 A: It's a compendium of standards for medications.

10 Q: And are you supposed to follow those standards?

11 A: There's a very large book. Not all of it
12 applies to dispensing pharmacy.

13 Q: Yes, sir. But the part that applies to drugs
14 you dispense, you are supposed to follow the
15 USP, are you not?

16 A: You would have to be more specific.

17 Q: Well, for instance, if there is a requirement
18 ... in the USP, a requirement for a certain
19 type of labeling, are you required to following
20 the labeling, provide the cautions and the kind
21 of things required in the USP?

22 A: Not everything that's in the USP, no, sir.

23 Q: Okay. How about ... have you looked at the USP
24 on hydrogen peroxide?

25 A: I don't believe that it specifically has

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1 anything to do with what we produced.

2 Q: Well, different question. Have you looked at
3 the USP on hydrogen peroxide?

4 A: In what part of it, specifically?

5 Q: Anything to do with hydrogen peroxide, have you
6 looked at the USP?

7 A: Not this week.

8 Q: Have you ever looked at the USP on hydrogen
9 peroxide?

10 A: Not that I can remember specifically.

11 Q: Are there any resource books that you have
12 access to that address hydrogen peroxide and
13 the compounding of hydrogen peroxide? I'm
14 talking about pharmacy books, professional ...
15 things a pharmacist would use?

16 A: No, sir.

17 Q: When you compound, you obviously use materials
18 in combination with each other, do you not?

19 A: Yes, sir.

20 Q: Do those materials generally have labels and
21 materials related to them that are provided and
22 available to you?

23 A: Yes, sir.

24 Q: For instance, I believe you have told us in
25 response to discovery that you used hydrogen

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1 peroxide manufactured by a company called
2 Spectrum; is that correct?

3 A: Yes, sir.

4 Q: Now, when Spectrum delivered that produce to
5 you, did it have a label on the bottle or
6 container?

7 A: Yes, sir.

8 Q: Okay. Does that contain information about the
9 product?

10 A: Yes, sir.

11 Q: And does that container not also refer to a
12 material safety data sheet?

13 A: Yes, sir.

14 Q: Okay. And is that available to you?

15 A: It is available.

16 Q: Okay. And did you, prior to compounding
17 hydrogen peroxide, read the label on the
18 materials you received?

19 A: Yes, sir.

20 Q: Okay. And did you read the material safety
21 data sheet?

22 A: I have read it.

23 Q: When did you read it?

24 A: I can't tell you specifically.

25 Q: Do you have a specific recollection of reading

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1 it?

2 A: Yes, sir.

3 Q: Okay. And tell me specifically when you recall
4 reading it.

5 A: About two weeks ago.

6 Q: Prior to reading it two weeks ago, do you have
7 any recollection you ever looked at it?

8 A: Not specifically, no, sir.

9 Q: But if you had wanted to, that was the kind of
10 material available to you, is it not?

11 A: Yes, sir.

12 Q: And you are aware that the container from
13 Spectrum actually recommended that you look at
14 the material safety data sheet, did it not?

15 A: I don't remember that.

16 Q: But it wouldn't surprise you, would it?

17 A: No, sir.

18 Q: What is a material safety data sheet?

19 A: It's a list of possible reactions of the drug
20 with other chemicals.

21 Q: And what does the materials ...

22 A: And it's ...

23 Q: I'm sorry. I interrupted you.

24 A: Well, that's fine. Go ahead.

25 Q: Well, I didn't want to interrupt you, sir, and

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1 Q: And does it at any strength indicate that it's
2 appropriate for direct human administration?

3 A: For direct human administration, yes, sir.

4 Q: For ingestion?

5 A: Putt on the skin, that's human administration.

6 Q: No, I'm talking about direct ... how about
7 internal use? Do you know anywhere where the
8 USP indicates that internal use is appropriate?

9 A: No, sir.

10 Q: Are you aware that the FDA has ever addressed
11 the issue where human ingestion is appropriate
12 for the ... for hydrogen peroxide at any
13 strength?

14 A: No, sir.

15 Q: Did you ever check to see what the FDA had done
16 prior to producing the hydrogen peroxide for
17 injection?

18 A: No, sir.

19 Q: Let's go in and talk about when you first
20 produced hydrogen peroxide for injection. When
21 did you first do that?

22 A: I don't specifically remember the date.

23 Q: Approximately, when?

24 A: It would have been after Dr. Short had
25 requested it.

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1 Q: I want to compound hydrogen peroxide and make
2 it for human injection, 3 percent, using 35
3 percent hydrogen peroxide as one of my
4 compounding materials, and I want to sell it.
5 Can I do that?

6 A: Well, I don't think it would be a good idea,
7 but it would be your option.

8 Q: Yes, sir. You think I have the right to sell
9 it under the laws of South Carolina?

10 A: You didn't mention the law.

11 Q: Yes, sir, that's what I meant.

12 A: I think it would be illegal.

13 Q: Why would it be illegal?

14 A: Well, you would have to have the order from a
15 physician first.

16 Q: Okay. And then would I have to have a pharmacy
17 license?

18 A: Yes, sir.

19 Q: And would I have to compound it under the laws
20 of the Board of Pharmacy?

21 A: Yes, sir.

22 Q: Okay. So you as a pharmacist, even though you
23 have a pharmacist's license, you still have to
24 obey the law about what you can compound and
25 what you can't compound, correct?

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- 1 A: Yes, sir.
- 2 Q: So you don't have a right to compound anything
3 a doctor asks you to compound, do you?
- 4 A: Yes, sir.
- 5 Q: Hold on a minute. Let me understand this. Is
6 it your testimony that anything a doctor asks
7 you to compound, you can, under the law of
8 South Carolina, compound that?
- 9 A: If it's reasonable.
- 10 Q: Well, who determines if it's reasonable?
- 11 A: The doctor.
- 12 Q: Okay. So again, let me ask the question. Any
13 doctor who asks you to compound anything, you
14 are telling me you have the right to do it
15 without any other consideration, other than you
16 received a request from the doctor?
- 17 A: As far as the law goes, yes, sir.
- 18 Q: Okay. There's no limitation whatsoever on what
19 you can compound; is that correct?
- 20 A: Well, it would have to be ordered by a doctor.
- 21 Q: But once it's ordered by the doctor, anything
22 the doctor orders you have a right to compound;
23 is that your testimony?
- 24 A: But again, the doctor is the one that's in
25 control here.

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1 associated.

2 Q: Okay. Well, tell me do you have a duty ...
3 upon getting that request, do you have any
4 duties, other than to follow exactly what the
5 doctor asked you to do?

6 A: Well, again, my own ... I mean I have my own
7 decisions to make, also.

8 Q: Okay. And what are those decisions?

9 A: Well, I can't specifically say, you know, what
10 they would be. It would depend on the
11 situation.

12 Q: Well, my question is you had mentioned to me
13 you had potential legal liability, correct?

14 A: Yes, sir.

15 Q: And what would that liability arise out of? I
16 mean what would be ... do you have to exercise
17 due care?

18 A: Yes, sir.

19 MR. COOKE: Richard, do these questions all pertain
20 to compounding?

21 MR. GERGEL: Yes.

22 Q: And you have a duty to consider the risks
23 associated with it, do you not?

24 A: Yes, sir.

25 Q: And you have the duty to consider the potential

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1 side effects, do you not?

2 A: Yes, sir.

3 Q: And you have a duty to consider the potential
4 benefit that may come from the product,
5 correct?

6 A: Yes, sir.

7 Q: All those are things that you have a duty to
8 consider to exercise due care as a pharmacist;
9 isn't that right?

10 A: Yes, sir.

11 Q: Okay. Tell me when you filled the request for
12 hydrogen peroxide on March 9, 2004, what risks
13 you considered.

14 A: If the physician used it in the manner he told
15 me he would use it, then there should be no
16 risk.

17 Q: Well, how did you know that?

18 A: Just from general knowledge.

19 Q: And where did you acquire that general
20 knowledge?

21 A: From reading over the past 20 years.

22 Q: Well, you told me before 1999, you had never
23 ... that you had never compounded hydrogen
24 peroxide; is that correct?

25 A: Not that I remember, no, sir.

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- 1 A: For a prescription it does, but not for office
2 use.
- 3 Q: Okay. Your understanding is is that you don't
4 need to have a practitioner/patient/pharmacist
5 relationship to compound?
- 6 A: There are two forms of compounding in the law.
7 There's another section that talks about making
8 it for a clinic or for institutional use, also,
9 and that doesn't require patient ...
- 10 Q: Well, do the doctors ... when you are doing it
11 for a clinic, do they have patients
- 12 A: Yes, sir.
- 13 Q: Okay. But you are asserting that it does not
14 have to be a practitioner/patient/pharmacist
15 relationship for you to compound, that's your
16 understanding?
- 17 A: If we do it for office use.
- 18 Q: Okay. And you acknowledge here that you
19 produced this hydrogen peroxide that was
20 provided to Ms. Bibeau, there was not any
21 practitioner/patient/pharmacist relationship;
22 is that your understanding?
- 23 A: That's exactly right.
- 24 Q: In fact, there wasn't a prescription, correct?
- 25 A: Right.

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1 Q: Okay. And there is no claim here that what you
2 produced here was not pursuant to a
3 prescription, correct? There was no
4 prescription from Dr. Shortt for this product
5 you compounded?

6 A: No, there was no prescription.

7 Q: Okay. Now, you understand that in Dr. Shortt's
8 office, this product you were compounding was
9 going to be used by individual patients,
10 correct?

11 A: I knew he would use it in his office as he saw
12 fit.

13 Q: And you knew he was going to be giving it to
14 patients, correct?

15 A: That was my understanding.

16 Q: And he was going to inject it into his
17 patients, correct?

18 A: Well, I wasn't exactly sure how he would use
19 it, but that seems reasonable.

20 Q: I believe it says on the label that it was
21 injectable, correct?

22 A: Yes, sir.

23 Q: You knew it was going to be injected, didn't
24 you?

25 A: We knew that it would be used to make a product

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1 to be given to the patients.

2 Q: Injected into the patient, correct?

3 A: Not in its raw stage.

4 Q: But in some state, you knew it was going to be
5 injected into the patient, correct?

6 A: That was my understanding.

7 Q: Yes, sir. And you also understood that he did
8 it intravenously, did you not?

9 A: Yes, sir.

10 Q: You knew he was going to give this product by
11 some mixing he would do? He would give it
12 intravenously to his patients, correct?

13 A: That was my understanding.

14 Q: And you supplied it to him with that
15 understanding, correct?

16 A: Yes, sir.

17 (PLAINTIFF'S EXHIBIT NUMBER TWO WAS MARKED FOR
18 IDENTIFICATION PURPOSES.)

19 Q: I want to hand you Exhibit Two, which is 40-43-
20 86 of the State Pharmacy Act, and I believe if
21 you will go back to page 20 of Exhibit Two, I
22 believe you will get back to the section of the
23 law that relates to compounding. Am I correct
24 about that (CC)?

25 A: Which part of (CC) are we looking for?

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1 A: Not now.

2 Q: And your understanding in 2004, it was not
3 available, correct?

4 A: The 3 percent hydrogen peroxide is commercially
5 available, so that's available in the
6 marketplace.

7 Q: Is your ... the way you did it for human
8 injection, available in the marketplace?

9 A: Three percent hydrogen peroxide is commercially
10 available.

11 Q: Is it available ...

12 A: And I would say that would meet the
13 requirements here.

14 Q: So you think that even though you produced it
15 for human injection and went through ... we
16 will go through the way you sterilized it and
17 diluted it. In that form, is it commercially
18 available in the marketplace?

19 A: Three percent is commercially available.

20 Q: Is it in the manner in which you compounded it
21 commercially available?

22 A: I think my product was better quality, if
23 that's what you mean.

24 Q: Is the product you compounded commercially
25 available in the marketplace in the form you

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1 compounded it?

2 A: Not in the form I compounded it, no.

3 Q: At any amount, is hydrogen peroxide
4 commercially available for human injection?

5 A: You mean with the labeling on it ...

6 Q: Yes, sir.

7 A: ... available? Well, that's not what this says
8 though.

9 Q: Let me finish, sir. Is it labeled available
10 for human injection at any amount of hydrogen
11 peroxide, to your knowledge?

12 A: Not currently, no, sir.

13 Q: And it was not available in 2004, when you
14 compounded Ms. Bibeau's medication, correct?

15 A: Not that specific strength labeled for
16 intravenous ...

17 Q: Yes, sir.

18 A: ... injection, but 3 percent hydrogen peroxide
19 was commercially available.

20 Q: Yes, sir. And that 3 percent says not for
21 human ingestion, correct, that's what the label
22 says?

23 A: Well, there are lots of different products out
24 there.

25 Q: Have you ever seen hydrogen peroxide, 3 percent

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1 pharmacist would do, correct?

2 A: Yes, sir.

3 Q: Okay. And would it require you to read the
4 manufacturer's information about the drugs?

5 A: Not if there's not a manufacturer's
6 information.

7 Q: Well, obviously, when you ... there are ...
8 certain chemicals can have an effect on the
9 body at different concentrations, it can still
10 have an adverse effect at any level, there are
11 certain drugs; isn't that correct?

12 A: Well, all drugs can have adverse effects.

13 Q: Yes, sir.

14 A: And if they are not used properly, there are
15 potential risks. But there's a risk to benefit
16 that has to be determined.

17 Q: But what you are telling me is before you
18 filled the prescription on March 9, 2004, you
19 did not look at the material safety data sheet
20 ...

21 A: I didn't fill a prescription.

22 Q: Let me finish. When you compounded or you
23 produced the medication, when you produced the
24 medication, you did not look at the material
25 safety data sheet from Spectrum at any level

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1 Q: But no ... you never had seen a label by a
2 manufacturer of an approved label that said it
3 was for human injection, did you?

4 A: Not that I remember.

5 Q: So your interpretation, going back to Exhibit
6 Two, page 21, that this language, your
7 interpretation is as long as it's in an
8 institution or an office setting, there's no
9 limitation by law, other than what you and the
10 doctor might agree to be a limit voluntarily;
11 is that your understanding?

12 A: That sounds reasonable.

13 Q: Okay. If you would, look at (f) below that.
14 You see it refers, it says ... it defines
15 things that will be manufacturing. Now, I
16 understanding you are not a ... you do not have
17 a license to manufacture, do you?

18 A: Where are you looking at now? Page 21?

19 Q: Page 21, right below (e) is (f). Do you see
20 that?

21 A: Okay.

22 Q: Now, you are not a licensed manufacturer, are
23 you?

24 A: No, sir.

25 Q: You would have to have licenses from the state

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1 and federal government to manufacture drugs,
2 would you not?

3 A: I'm not sure.

4 Q: But you know you are not licensed to
5 manufacture, don't you?

6 A: Yes, sir.

7 Q: And you know you can't manufacture a drug in
8 America if you don't have the FDA approval of
9 that drug? You know that, don't you?

10 A: Sir?

11 Q: You cannot manufacture a drug without FDA
12 approval. You are aware of that, are you not?

13 A: Well, it sounds reasonable.

14 Q: Yes, sir.

15 A: Now, let's look at (f). It says, the
16 compounding of drugs in anticipation of
17 receiving prescriptions without a historical
18 basis or the distribution of compounded
19 p r o d u c t s w i t h o u t a
20 patient/practitioner/pharmacist relationship is
21 considered manufacturing.

22 Q: Yes, sir.

23 Q: You do not ... you did not have, according to
24 you, a patient/practitioner/pharmacist
25 relationship, did you?

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1 A: We had a pharmacist/practitioner relationship
2 and the section above it allows us to do it for
3 physician's office use.

4 Q: I'm asking you, sir, the question ... first of
5 all, did you distribute compounded products?

6 A: I'm not sure what you mean by distribute.

7 Q: Well, let's look back at Exhibit One and look
8 at number (15). Distribute means the delivery
9 of a drug or device other than by administering
10 or dispensing. Did you administer the drug
11 yourself?

12 A: No, sir.

13 Q: Did you dispense?

14 A: No, sir.

15 Q: So did you deliver the drug?

16 A: I took it to the ... well, I took it to the
17 doctor's office.

18 Q: Okay. So distribute means the ... so you did
19 distribute it, did you not?

20 A: I suppose I did, yes, sir.

21 Q: Okay. The distribution of compounded products,
22 and was yours a compounded product?

23 A: Yes, sir.

24 Q: Without a patient/practitioner/pharmacist
25 relationship ... you admit that didn't exist,

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1 correct?

2 A: Yes, sir.

3 Q: Is considered what?

4 A: In this line here, it's considered
5 manufacturing. Again, the one above it allows
6 us to compound for office use.

7 Q: Well, if you compound it for office use, you
8 can do it for the patients in the office, can't
9 you? You can compound it for office use and
10 provide it to individual patients, can you not,
11 in the office?

12 A: We don't give it to individual patients. In
13 that condition, we would just ... the patient
14 would come down, pick up their own
15 prescription, and it would be labeled and we
16 would discuss the medicine with them. But if
17 we give it to the doctor to use in the office,
18 then he would use it in the office.

19 Q: Well, he can do ... he can get it for his
20 individual patients in the office, can he not?

21 A: I'm not sure I understand what you are talking
22 about now.

23 Q: Well ...

24 A: I mean we will provide it to his office and
25 then he can use it as he sees fit.

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- 1 A: No, sir. We used this for office use ...
- 2 Q: Yes, sir.
- 3 A: ... products, also.
- 4 Q: Did Dr. Shortt ever write you a prescription
5 for hydrogen peroxide?
- 6 A: No, sir.
- 7 Q: Did he ever give you anything in writing
8 relating to the compounding of hydrogen
9 peroxide?
- 10 A: I don't know. We don't keep that sort of
11 thing.
- 12 Q: You have no record of any prescription or other
13 written document requesting the compounding of
14 hydrogen peroxide; is that correct?
- 15 A: No, sir.
- 16 Q: You just did it on an oral request from him?
- 17 A: Yes, sir.
- 18 Q: And you are telling me that was not a
19 prescription?
- 20 A: No, sir.
- 21 Q: Okay. He just said, I want you to produce this
22 product, and you agreed to do it, correct?
- 23 A: Yes, sir.
- 24 Q: And even though it says original prescription,
25 that wasn't really true because it wasn't a

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1 A: Again, it's not a prescription.

2 Q: Yes, sir. But I'm asking a different question.
3 It's labeled that way, isn't it?

4 A: The label is a form label that we used for our
5 own internal tracking.

6 Q: But the label does also leave the office, does
7 it not?

8 A: Yes, sir.

9 Q: Okay.

10 (OFF THE RECORD.)

11 Q: Mr. Phillips, are you aware of requirements for
12 labeling under the Food, Drug and Cosmetic Act
13 of 1937, for materials that are compounded that
14 are not pursuant to a prescription? Are you
15 aware of any of those federal requirements?

16 A: 1936?

17 Q: 1937. The federal act. Are you aware there's
18 a Food, Drug and Cosmetic Act provides for
19 certain labeling requirements for medications
20 that are produced that are not pursuant to a
21 prescription? Are you aware of that?

22 A: There's a ten point labeling, if that's what
23 you are talking about.

24 Q: Well, you have told me that there's no
25 prescription, correct?

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1 A: Yes, sir.

2 Q: Okay. Are you aware of federal law regarding
3 the labeling of products that are not
4 prescription drugs? Are you aware of those
5 requirements?

6 A: I'm sure they ... there's what's called a ten
7 point label, I believe, if that's what you
8 mean.

9 Q: And what are the elements of the ten point
10 label?

11 A: The medication ... and this is for over-the-
12 counter use. Is that what you are talking
13 about? Are you talking about the ...

14 Q: I'm talking about any medication.

15 A: The ten point labeling refers to over-the-
16 counter medications.

17 Q: Okay.

18 A: That are used without the ... without a
19 physician.

20 Q: Okay. And what are those, as you understand?

21 A: The name of the medication, lot number,
22 expiration date, instructions for use,
23 precautions, need, the name of the ... the name
24 of the manufacturer, I believe, the ... maybe
25 it's a six point label.

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1 It was for him to use in his office.

2 Q: Okay. And are there any federal labeling
3 requirements you understand for drugs sold in
4 that manner?

5 A: Not for me to sell to a physician to use in his
6 office, no, sir.

7 Q: You're not aware of any?

8 A: No, sir.

9 Q: And if there were some, such requirements, you
10 did not know about them at the time you sold
11 this product for use for Ms. Bibeau on March 9,
12 2004, correct?

13 A: Yes, sir.

14 Q: Now, when you delivered they hydrogen peroxide
15 on March 9, 2004, you were delivering it to the
16 physician for use by the patient, correct?

17 A: No, sir. The physician uses it.

18 Q: Right. But you knew that it was being
19 delivered to the physician so he could
20 administer it to the patient?

21 A: That would be my assumption.

22 Q: Yes, sir. And you knew that you weren't
23 delivering it to him for his own personal use,
24 were you?

25 A: He may have used it personally. I don't know.

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1 of dispensing, the dispenser shall before the
2 actual physical possession ... I'm sorry,
3 actual physical transfer, interpret and assess
4 the prescription order for potential adverse
5 reactions or side effects, interactions,
6 allergies, dosage, and regimen. Do you see
7 that?

8 A: Yes, sir.

9 Q: Now, I believe you told me earlier that one of
10 your duties as a pharmacist was to consider the
11 side effects and potential reactions of any
12 medication, correct?

13 MR. COOKE: Objection to the form of the question.

14 Q: Go ahead and answer.

15 A: Can you repeat that again?

16 Q: Yes, sir. You told me earlier when I was
17 asking you what were your duties as a
18 pharmacist, you explained to me that because
19 there was potential liability you had to
20 exercise judgment yourself and that one of the
21 things that you had to consider were side
22 effects and reactions to anything you
23 compounded. Do you recall talking to me about
24 that?

25 MR. COOKE: Objection to the form of the question.

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1 A: Potential side effects ...

2 Q: Yes, sir.

3 A: ... and reactions.

4 Q: Yes, sir. And ...

5 A: Not all side effects and reactions occur.

6 Q: Yes, sir. But potential adverse reactions you
7 had to consider, correct?

8 A: Yes, sir.

9 Q: So you recognized as the first part of this
10 thing, as an element of dispensing, you need to
11 consider the potential adverse reactions and
12 side effects, correct?

13 A: Yes, sir.

14 Q: And that's for anything that you compound for
15 human use, correct?

16 A: Well, yes, sir.

17 Q: In this case, what investigation did you
18 undertake to determine the potential adverse
19 side effects or reactions of hydrogen peroxide
20 to be injected into the bloodstream of the
21 patient?

22 A: I think we've answered this earlier. You know,
23 I had done some reading and I had read that
24 hydrogen peroxide was used as a treatment for
25 many years in a .03 percent solution.

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1 than what you produced?

2 A: The bottle that was in that doctor's office,
3 but I don't specifically remember all the
4 labeling on it.

5 Q: Okay. You understood that bottle in Dr. Ghen's
6 office was for human injection?

7 A: Uh-huh.

8 Q: You understand that, correct?

9 A: Yes, sir.

10 Q: But you don't know if it, in fact, was labeled
11 that way, do you?

12 A: No, sir.

13 Q: And you don't know how produced it, do you?

14 A: No, sir.

15 Q: Other than that one vial, have you ever seen
16 hydrogen peroxide in any shape or form labeled
17 for human injection, other than what you
18 produced?

19 A: No, sir.

20 Q: And was your understanding at the time that the
21 FDA had not approved the use of hydrogen
22 peroxide for human injection; isn't that
23 correct?

24 A: Yes, sir.

25 Q: Did you provide any caution, in writing, on the

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1 label, orally to Dr. Shortt, about the
2 potential risks or side effects of the human
3 injection of hydrogen peroxide?

4 A: No, sir.

5 Q: And you did not provide that to Ms. Bibeau?

6 A: I didn't meet Ms. Bibeau, that I remember.

7 Q: We looked earlier at the label. The label did
8 not contain any caution or warning, did it?

9 A: No, sir.

10 Q: That was Exhibit Three.

11 (PLAINTIFF'S EXHIBIT NUMBER FIVE WAS MARKED FOR
12 IDENTIFICATION PURPOSES.)

13 Q: I hand you Exhibit Number Five. Could you
14 identify what Exhibit Five is?

15 A: That's a label from a bottom of hydrogen
16 peroxide 3 percent preservative-free injection.

17 Q: And this is the bottle that was compounded on
18 or about March 9, 2004?

19 A: The date on this is July the 7th, 2004.

20 Q: Well, it just says expires July 7, 2004. Do
21 you see that?

22 A: Yeah, you're right. I believe that one was
23 made January the 9th of 2004.

24 Q: Why do you think that?

25 A: Because of the lot number on it. Where did

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1 that come from?

2 Q: My understanding is that was provided by Dr.
3 Shortt to SLED as the bottle utilized by Ms.
4 Bibeau. That came from SLED.

5 A: Okay.

6 Q: So you really don't know ... you indicated ...
7 show me the indication that you think it was
8 January.

9 A: The lot number we use is the date that it was
10 made and then two digits after that.

11 Q: Okay. But whether this was done in January or
12 March, you don't really know?

13 A: Yes, I do know.

14 Q: Okay.

15 A: That was done in January.

16 Q: Okay. But is it possible that what was
17 provided to Ms. Bibeau in March was actually
18 ... came from a lot done in January or
19 February?

20 A: I mean again, this would have come from his
21 office, so I don't know what occurred down
22 there.

23 Q: Okay. Would the one that was compounded ...
24 the one that was reflected on Exhibit Number
25 Three, when was that ... can we tell from that

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1 Q: Okay. You did not communicate with the
2 manufacturer of the hydrogen peroxide,
3 Spectrum, about its potential use in the manner
4 you were proposing or Dr. Shortt was proposing
5 to use it for, did you?

6 A: No, sir.

7 Q: You could have called Spectrum and asked them,
8 could you not have?

9 A: I could have, yes, sir.

10 Q: You could have requested or sought out material
11 safety data sheets for different strengths of
12 hydrogen peroxide, couldn't you?

13 A: I could have.

14 Q: Were you aware that the 3 percent hydrogen
15 peroxide was actually manufactured by Spectrum?
16 Are you aware of that? Were you aware that 3
17 percent hydrogen peroxide was manufactured by
18 Spectrum?

19 A: Yes, sir.

20 Q: Okay. Did you check the material safety data
21 sheets since at least the strength of hydrogen
22 peroxide was the same, for the 3 percent?

23 A: Not Spectrum's, no, sir.

24 Q: Okay. Did you check out anybody's material
25 safety data sheet for 3 percent?

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1 A: No, sir.

2 Q: Okay. Would it surprise you that such a
3 material safety data sheet at 3 percent
4 indicates that it could be potential internal
5 damage, severe injury associated with the
6 ingestion of hydrogen peroxide? Would that
7 surprise you?

8 A: No, sir.

9 Q: Okay.

10 A: But that's not what we ... the way it was going
11 to be administered.

12 Q: Well, you had not gone to any ... the
13 manufacturer to determine whether it was safe
14 at .03 percent, had you?

15 A: No, sir.

16 Q: You had not gone to the FDA to determine if it
17 was safe at that level; is that correct?

18 A: No, sir.

19 Q: You had not gone to any independent source to
20 determine that it was safe at that amount?

21 A: What's your definition of an independent
22 source?

23 Q: You had not gone to, for instance, anybody who
24 had done studies at .03 percent, independent
25 studies?

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1 A: Well, a physician asked me to produce this so
2 he could use it in his office for his patients.

3 Q: And that for you was good enough?

4 A: Yes, sir.

5 Q: Okay. And did you ... why didn't you dilute it
6 to .03 percent?

7 A: The doctor didn't ask me to.

8 Q: And what actually happened when it left you and
9 how it got diluted, you don't really know?

10 A: No, sir.

11 Q: Whether they did it right or wrong, you don't
12 have a clue?

13 A: No, sir.

14 Q: Now, is there skill associated with diluting
15 medicines? I mean is that a skilled exercise
16 or can just anybody ... would you normally let
17 anybody do it, trained or untrained, to do
18 that?

19 A: No. I would prefer to have a pharmacist do it.

20 Q: Yes, sir. Was a pharmacist doing it in Dr.
21 Shortt's office?

22 A: No, sir, a physician was.

23 Q: Well, do you know that a physician was doing it
24 or was somebody else doing it?

25 A: My assumption is if it wasn't the physician,

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1 and other hormones for these patients. I know
2 Dr. Shortt does lab testing and evaluates each
3 patient for his or her individual status. I
4 have filled prescriptions and made a good faith
5 effort to be certain the medications used for
6 a legitimate medical condition of low hormone
7 levels, menopause for women and andropause for
8 men. I compound medications when the specific
9 dosage form is not available or the strength is
10 not available.

11 Q: You mentioned that Dr. Shortt had a unique
12 practice?

13 A: Yes.

14 Q: Your understanding was that Dr. Shortt
15 undertook methods that were not what your
16 ordinary, competent physician would undertake
17 for treating certain conditions; is that fair?

18 A: I'm not sure I understand the word competent
19 there.

20 Q: Well, let me ask you this. For the average
21 physician treating multiple sclerosis, your
22 understanding is that that average physician
23 would not ... would not administer intravenous
24 hydrogen peroxide; is that fair?

25 A: That sound reasonable.

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1 our own knowledge. In your own knowledge,
2 today, you know of no other pharmacy in the
3 Columbia area that has produced hydrogen
4 peroxide at the request of a physician?

5 A: Not to my knowledge.

6 Q: Okay. And I should add for human injection.
7 You are not aware of that, correct?

8 A: No, sir.

9 Q: Are you aware of any ... specifically aware of
10 any pharmacy in South Carolina who has produced
11 hydrogen peroxide for human injection?

12 A: Not specifically, no, sir.

13 Q: Are you specifically aware of any pharmacy
14 anywhere in America that has hydrogen peroxide
15 for human injection?

16 A: I have been told that it has been made in the
17 past and it's been used on patients, so I
18 assume that somebody made it.

19 Q: But you don't know whether that person who made
20 it was a pharmacist, do you?

21 A: No, sir.

22 Q: So my question specifically ... are you
23 specifically aware of any pharmacist who has
24 produced hydrogen peroxide for human injection
25 at anytime?

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1 A: No, sir.

2 Q: You knew at the time that one reason it might
3 not be produced anymore though was that the
4 government wouldn't allow it to be produced?
5 You understood that was one potential
6 explanation, didn't you?

7 A: Well, probably, it hadn't been through the
8 FDA's testing procedures.

9 Q: Yes, sir. So you thought that the reason it
10 may no longer be available is that the ... it
11 has not gone through the required testing
12 procedures for the FDA, correct?

13 A: Yes, sir.

14 Q: Okay. But did you call the FDA to ask the FDA
15 whether there were any problems with producing
16 this drug that clearly wasn't FDA approved?

17 A: No, sir.

18 Q: Is it hard to contact the FDA?

19 A: I don't know.

20 Q: You never tried?

21 A: I've sent them e-mails before, but not called
22 them on the telephone.

23 Q: And did you get a response from your e-mail?

24 A: Yes, sir.

25 Q: So prior to compounding hydrogen peroxide, you

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- 1 A: No.
- 2 Q: To your knowledge, you don't know what the
3 strength was, do you?
- 4 A: Huh-uh.
- 5 Q: If it's not in the article, you wouldn't have
6 a way of knowing it, would you?
- 7 A: We could call the author, if you would like.
- 8 Q: Yeah. But you didn't do that before March 9,
9 2004, did you?
- 10 A: No, sir.
- 11 Q: Are you familiar with the pharmacy book,
12 *Martindale*?
- 13 A: Yes, sir.
- 14 Q: Tell me about it. What is that?
- 15 A: It's a drug compendium that has short articles
16 about lots of different medicines.
- 17 Q: You have seen it before?
- 18 A: Yes, sir.
- 19 Q: Is it a reliable reference material?
- 20 A: It's reliable, yes, sir.
- 21 Q: All right. Is it used by professional
22 pharmacists and consulted with from time to
23 time?
- 24 A: From time to time, I'm sure it is.
- 25 Q: Yes, sir. And have you from time to time

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1 consulted it?

2 A: I don't have a copy of it of my own.

3 Q: Yes, sir. But have you ...

4 A: But I have looked at it.

5 Q: Yes, sir. And it's considered, in your view,
6 authoritative?

7 A: Yes, sir.

8 (PLAINTIFF'S EXHIBIT NUMBER SEVEN WAS MARKED FOR
9 IDENTIFICATION PURPOSES.)

10 Q: Okay. I'm going to hand you Exhibit Seven and
11 it is from *Martindale, The Complete Drug*
12 *Reference*; is that correct?

13 A: Yes, sir.

14 Q: Okay. And if you will look, hydrogen peroxide,
15 there's actually a section on hydrogen
16 peroxide; is that correct?

17 A: Yes, sir.

18 Q: And it refers to it, in the second column, that
19 using it in closed body cavities and then in
20 intravascular administration; is that correct?

21 A: Where would that be?

22 Q: Yes, sir. Thank you for ...

23 A: Adverse effects, closed body cavities, okay.

24 Q: Do you see that?

25 A: Yes, sir.

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1 Q: And then you see intravenous administration, a
2 little bit further down?

3 A: Yes, sir.

4 Q: Okay. Let's first look at intravascular
5 administration. That was what you understood
6 was going to occur, correct?

7 A: Yes, sir.

8 Q: Intravenous administration of hydrogen peroxide
9 solutions as unconventional therapy for AIDS or
10 cancer has resulted in severe haemolysis. Do
11 you see that?

12 A: Yes, sir.

13 Q: First of all, if you had wanted to investigate
14 when you prepared this product, Martindale was
15 a source you could have consulted; is that
16 correct?

17 A: Yes, sir.

18 Q: Okay. And had you received before March 9,
19 2004, the information that there had been
20 severe acute haemolysis as a result of
21 intravascular administration of hydrogen
22 peroxide?

23 A: Could you state the question again, please?

24 Q: Yes, sir.

25 A: Before March 9, 2004, were you aware that the

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1 or gas emboli would not be produced that could
2 be life threatening?

3 A: No, sir.

4 Q: So if you had wanted ... let's talk about the
5 things you could have done and did not do. You
6 could have gone and gotten the material safety
7 data sheet at 3 percent from Spectrum, that's
8 one thing you could have done, correct?

9 A: Yes, sir.

10 Q: You could have called Spectrum and asked,
11 correct?

12 A: Yes, sir.

13 Q: You could have consulted and contacted the FDA,
14 correct?

15 A: Yes, sir.

16 Q: You could have gone to *Martindale* and looked,
17 correct?

18 A: Yes, sir.

19 Q: You could have gone to other resources and
20 consulted on this question, correct?

21 A: Yes, sir.

22 Q: You did none of those, did you?

23 A: No, sir. I had general knowledge that it had
24 been used in the past as an effective treatment
25 and the physician that was going to do the

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1 Q: Have you gone and looked?

2 A: No, sir.

3 MR. GERGEL: Take a break for a moment here.

4 (OFF THE RECORD.)

5 (PLAINTIFF'S EXHIBIT NUMBER EIGHT WAS MARKED FOR
6 IDENTIFICATION PURPOSES.)

7 Q: Mr. Phillips, I'm going to hand you Exhibit
8 Number Eight, which is the Spectrum Material
9 Safety Data Sheet for hydrogen peroxide, 3
10 percent. Now, I take it before I put this in
11 your hands, to your recollection, you have
12 never seen this document, correct?

13 A: No, sir.

14 Q: But it would have been presumably available to
15 you had you sought it out, correct?

16 A: Yes, sir.

17 Q: And it indicates on the material safety data
18 sheet at the top that there's a potential
19 health hazard associated with this product; is
20 that correct? You see it says Health Hazard
21 number 2?

22 A: Health Hazard ... yes, sir.

23 Q: Okay. And if you would turn to the second page
24 of the document, under Potential Chronic health
25 Effects, it says at the bottom there, the

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1 could have provided you some information on the
2 potential effects of ingesting this product,
3 correct?

4 A: Yes, sir.

5 Q: But you did not consult such material?

6 A: No, sir.

7 Q: And until I handed it to you, you had never
8 seen the Spectrum 3 percent hydrogen peroxide
9 solution, correct?

10 A: No, sir.

11 Q: And is there anything on this document that you
12 saw that indicated that at some lower level
13 than 3 percent it was safe to ingest?

14 A: There was no indication that it's not either.

15 Q: A different question. Is there any indication
16 on this document that it's safe to ingest at
17 any level?

18 A: It's no indication that it's safe, no, sir.

19 Q: And when it says do not ingest, did it say do
20 not ingest at this level, but it's okay at a
21 lower level?

22 A: No, but it doesn't say that it's harmful at a
23 lower level either.

24 Q: It just simply says do not ingest, correct?

25 A: Yes, sir.

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1 supervision of a physician, is my thoughts.

2 Q: Why is that?

3 A: Because a physician is the one that is most
4 able to use it properly.

5 Q: Well, you recognize that the product could be
6 potentially dangerous, correct?

7 A: Yes, sir.

8 Q: But you didn't warn anybody on the label that
9 it was dangerous, did you?

10 A: No, sir. I gave it to a physician.

11 Q: And you feel like once you give this product to
12 a physician, you have washed your hands of any
13 responsibility?

14 A: Yes, sir.

15 Q: You don't need to warn or caution anybody,
16 correct?

17 A: No, sir.

18 Q: You don't need to label it in any way?

19 A: No, sir.

20 Q: And you are generally unfamiliar with the
21 necessity to label products under the federal
22 law that are not prescriptions? You are
23 generally unfamiliar with that, aren't you?

24 A: I believe those laws refer to over-the-counter
25 products that will be taken by consumers, not

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1 A: You are talking about for the intravenous?

2 Q: Intravenous hydrogen peroxide.

3 A: Yes, sir.

4 Q: Not one of them ever was accompanied or was
5 later documented by writing to you, correct?

6 A: No, sir.

7 Q: All oral?

8 A: Yes, sir.

9 Q: So, the only paper trail we really have of Dr.
10 Shortt requesting this product is your delivery
11 of it; is that fair?

12 A: That would be reasonable.

13 Q: So to the best of your recollection, for a
14 number of years every couple of months you
15 would prepare this hydrogen peroxide when he
16 orally would ask you for it and then you would
17 deliver it over there, delivering it with a
18 label, with the kind of labels we have looked
19 at today, correct?

20 A: Yes, sir.

21 Q: And to the best of your recollection, each time
22 you did it, you used Spectrum?

23 A: I don't know specifically.

24 Q: Okay. That's the only one you can come up with
25 now in terms of the product?

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- 1 Q: Are you aware of any other physician in South
2 Carolina giving his patients hydrogen peroxide,
3 other than Dr. Shortt, and I believe you
4 thought you saw a bottle of it in Dr. Ghen's
5 office; is that correct?
- 6 A: Ghen.
- 7 Q: Ghen.
- 8 A: Yes, sir.
- 9 Q: Thank you, sir. Any other physician you ever
10 heard of that ...
- 11 A: Not that I know of, specifically.
- 12 Q: It would be fair to say it's a very
13 unconventional treatment; is that fair?
- 14 A: It's different.
- 15 Q: Yes, sir. Unconventional; is that fair?
- 16 A: Unconventional can mean lots of things.
- 17 Q: Non standard; is that a fair word?
- 18 A: Yes, sir.
- 19 Q: Unusual?
- 20 A: Unique.
- 21 Q: Rare?
- 22 A: Yes, sir.
- 23 Q: They are all fair terms, correct?
- 24 A: Uh-huh.
- 25 Q: And in your own personal knowledge, it is ...

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1 you are unique in having prepared it for human
2 injection as a pharmacist?

3 A: I mean I don't know the names of other people
4 that do it, other than what I've already told
5 you.

6 Q: Yes, sir. Did you ever discuss with Dr. Shortt
7 the risks associated with the intravenous use
8 of hydrogen peroxide?

9 A: No, sir.

10 Q: You never warned him in any way, correct?

11 A: No, sir.

12 Q: You never asked him about it, correct?

13 A: No, sir.

14 Q: Never asked him ... even though you knew that
15 it was not approved by the FDA for human
16 injection, you never asked him about the
17 potential risk; is that fair?

18 A: I don't remember discussing any potential risk.

19 Q: Now, when did you first meet James Michael
20 Shortt?

21 A: I think it was about 1997.

22 Q: And how did you meet him?

23 A: He went to work at Biogenesis Medical Center.

24 Q: What is that?

25 A: It's a physicians office near Lizard's Thicket

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1 Q: But as a professional pharmacist, you have an
2 independent duty yourself to assess the risks
3 and benefits to the patient of any medication,
4 right?

5 A: All medications have potential risks.

6 Q: But you have a duty as a pharmacist to exercise
7 your own professional knowledge and judgment
8 regarding risks and benefits, don't you?

9 A: I do. And there are risks and benefits to
10 everything. That doesn't mean they will happen
11 every time.

12 Q: And when you prepared that hydrogen peroxide
13 for Ms. Bibeau or for Dr. Shortt that was going
14 to be administered to Ms. Bibeau. You have the
15 duty to assess the potential risks to any
16 patient who might get this by IV injection,
17 correct?

18 A: Yes, sir.

19 MR. COOKE: Object to the form of the question.

20 Q: Has Dr. Shortt ever talked to you about what
21 happened to Ms. Bibeau?

22 A: Well, you mean like specifically what happened?

23 Q: Yes.

24 A: I mean we discussed it a few times, yes, sir.

25 Q: And did he tell you that she had bruising when

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1 A: No, sir.

2 Q: Okay. And you understand that the Coroner of
3 Richland County has issued an official death
4 certificate as to the death ... cause of death
5 of Ms. Bibeau?

6 A: I'm sure he has.

7 Q: Yes, sir. And are you aware that he indicated
8 the cause of death to be the use of hydrogen
9 peroxide?

10 A: Yes, sir.

11 Q: Okay. Are you in a position to question the
12 conclusions of the Coroner of Richland County
13 as to the cause of death?

14 A: No, sir.

15 Q: Today if someone ... a physician asks you to
16 prepare hydrogen peroxide, 3 percent, for human
17 injection, would you do that?

18 A: No, sir.

19 Q: Why is that?

20 A: Because this has been a very difficult time and
21 I don't want to repeat it.

22 Q: Well, what have you learned from this
23 experience?

24 MR. COOKE: Objection to the form.

25 Q: Go ahead and answer.

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1 was a result of the medication you provided,
2 correct?

3 A: Yes, sir.

4 Q: And you're not in a position to question that,
5 correct?

6 A: Yes, sir.

7 Q: As a pharmacist in charge, you are responsible
8 ultimately for policies and decisions made
9 about filling the prescriptions within your
10 pharmacy, correct?

11 A: Yes, sir.

12 Q: And you personally accept responsibility for
13 the preparation and delivery of the hydrogen
14 peroxide that went to Dr. Shortt on March 9,
15 2004; is that correct?

16 A: Yes, sir.

17 Q: And if there was a mistake and there is
18 liability, you share in that liability,
19 correct?

20 A: I'm not sure I understand the question.

21 MR. COOKE: Object to the form.

22 Q: If there was legal responsibility, negligence
23 associated with that preparation and delivery
24 of that medicine, you have ... you share some
25 of that responsibility, correct?

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1 MR. COOKE: Objection to the form.

2 A: If there was ...

3 Q: Go ahead and answer. If there was legal
4 liability for the pharmacist involved in the
5 preparation and delivery ...

6 A: There should be no legal liability for the
7 pharmacist because the physician is the one
8 that administered. We provided what he wanted
9 and we gave him exactly what he asked for, and
10 he gave it in his office.

11 Q: So it's his fault?

12 A: It's his responsibility if the treatment was
13 improper.

14 Q: And if the preparation of the material was
15 improper, that would be your responsibility,
16 correct?

17 A: If there was a problem with what we made, not
18 ... but what we made was exactly what was
19 requested.

20 Q: Independent of what a doctor's responsibility
21 might do to engage in safe medical practices,
22 a pharmacist has a duty to consider the safety
23 of the products he produces as well, correct?

24 A: Yes, sir.

25 Q: And to exercise do care and investigating those