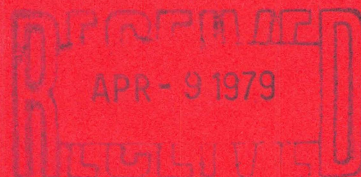


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CLERK
SUPREME COURT OF VIRGINIA



IN THE
SUPREME COURT OF VIRGINIA
AT RICHMOND

PFIZER, INC.,

Appellant,

v.

Record No. 781749

LOTTIE M. JONES,

Appellee.

JOINT APPENDIX

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5 April 1979

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AMENDED MOTION FOR JUDGMENT

Filed 26 May 1977

Comes now Lottie M. Jones, by counsel, and moves this Court for judgment against the defendant, Pfizer, Inc., (hereinafter referred to as Pfizer) on the grounds and in the amount as hereinafter set forth.

COUNT I

1. That at all times hereinafter mentioned, Lottie M. Jones was and continues to be a resident of Westmoreland County, Virginia.

2. That Pfizer, Inc., at all times hereinafter mentioned was and is a Delaware corporation with its principal place of business in New York City, New York, at the above captioned address.

3. That at all times hereinafter mentioned, Pfizer was doing business in Virginia and transacting affairs in Virginia on a regular, frequent and continuing basis by reason of the widespread marketing sales and distribution of its manufactured drugs and drug products including hydroxyzine hydrochloride, which is manufactured and marketed, sold and distributed under the brand name Vistaril.

4. That at the time of the commencement of this action, Pfizer has no registered office, registered agent, corporate officer, office or place of business, or corporate agent of any kind within the State of Virginia, and accordingly jurisdiction over Pfizer is invoked under Virginia Code Sections 13.1-111, 8-60, and 8-81.2.

5. That on or about August 16, 1975, Lottie M. Jones was admitted as a patient to Mary Washington Hospital in Fredericksburg, Virginia, for a scheduled surgical operation.

6. That on or about August 18, 1975, while a patient at Mary Washington Hospital aforesaid, the said Mrs. Jones was given a pre-operative injection of Vistaril which injection was administered by an employee of Mary Washington Hospital.

7. That prior to August 18, 1975, Pfizer manufactured, sold, distributed, and delivered a certain quantity of the drug, Vistaril, to Mary Washington Hospital, which drug, Vistaril, was subsequently administered to the said Lottie M. Jones as aforesaid.

8. That following the injection aforesaid, Lottie M. Jones experienced massive loss, infection, decay and destruction of tissue in her right hip and buttock area, necessitating numerous subsequent operations, extended hospitalization and extensive medical treatment, all of which has been extremely painful and mentally agonizing to said Mrs. Jones who has suffered and continues to suffer and in the future will suffer permanent disfigurement and disability, extreme pain and anxiety and the plaintiff has been and will be otherwise injured, all of which were a direct and proximate result of the use of the drug, Vistaril, by Mrs. Jones.

9. That Pfizer acting by and through its agents and employees negligently manufactured, marketed, distributed and sold the said drug, Vistaril, to Mary Washington Hospital in a

defective and impure condition without proper and adequate warning as to the use and administration of Vistaril, which Vistaril was administered to Lottie M. Jones as aforesaid.

10. That the aforesaid injuries of Lottie M. Jones are the direct proximate and sole result of the negligence of Pfizer as aforesaid.

11. That as a direct result and proximate cause of the negligence of Pfizer, as aforesaid, the plaintiff has incurred and will be compelled to incur in the future large expenses for medical doctors and nurses bills and other expenses.

COUNT II

The plaintiff repeats, re-alleges and repleads all the allegations of numbered paragraphs 1, 2, 3, 4, 5, 6, 7, and 8 of Count I with the same force and effect as though they were herein fully and specifically set forth in detail.

12. That the defendant, Pfizer, acting by and through its agents and employees impliedly warranted that the Vistaril administered to Lottie M. Jones as aforesaid was of merchantable quality and fit for its intended and ordinary uses and for the general purposes and uses for which it is manufactured, marketed, distributed and sold, was free from any defect being unadulterated and sterile, and that such Vistaril was fit for the particular purposes and uses of the plaintiff, and the plaintiff and her attending physician relied upon such implied warranties.

13. That as a direct, proximate and sole result of the breach of the implied warranties by the defendant, Pfizer, as aforesaid, Lottie M. Jones was caused to sustain such injuries and suffer such expenses as heretofore described.

COUNT III

The plaintiff repeats, re-alleges and repleads all of the allegations of numbered paragraphs 1, 2, 3, 4, 5, 6, 7, and 8 of Count I with the same force and effect as though they were herein fully and specifically set forth in detail.

14. That the defendant, Pfizer, acting by and through its agents and employees negligently failed to warn, inform, instruct and apprise the plaintiff and her attending and treating physicians and other medical personnel at Mary Washington Hospital of the dangers and risks involved in the use of the drug, Vistaril, of the proper methods of administering the same, and of the consequences and possible harmful effects of the drug, Vistaril.

15. That as a direct, proximate and sole result and proximate cause of the negligence of the defendant, Pfizer, as aforesaid Lottie M. Jones was caused to suffer grave injuries and the resulting expenses all of which is heretofore described.

COUNT IV

The plaintiff repeats, re-alleges and repleads all of the allegations of numbered paragraphs 1, 2, 3, 4, 5, 6, 7, and 8 of Count I with the same force and effect as though they were herein

fully and specifically set forth in detail.

16. That the defendant, Pfizer, acting by and through its employees and agents did negligently fail to warn, inform, instruct and apprise the plaintiff and her attending physicians and other medical personnel employed by Mary Washington Hospital of the proper methods of administering Vistaril and the dangers and risks involved in administering Vistaril and that such failure on the part of Pfizer constitutes violations of statutes of both the United States of America and the Commonwealth of Virginia pertaining to misbranding and mislabeling of drugs and further that such failure is thereby negligence per se.

17. That the plaintiff, Lottie M. Jones, is among the class of those persons intended to be protected and benefited by the statutes aforesaid.

18. That as a direct result and proximate cause of the negligence per se of the defendant as aforesaid the plaintiff was caused to suffer serious and grave injuries and attendant medical expenses all of which is heretofore described.

WHEREFORE, the plaintiff, Lottie M. Jones, demands judgment against the defendant, Pfizer, Inc., in the amount of \$500,000 plus costs.

LOTTIE M. JONES

By /s/ Russell H. Roberts
Of Counsel

JUDGMENT ORDER

Dated 28 February 1978

This day came the parties in person and by counsel, and the defendant having heretofore filed its grounds of defense herein, issue is joined.

WHEREUPON, came a jury, to-wit: Elliott Jett Berry, Nancy Bennett Bird, Anne Mills Brooks, Evelyn Sale Duffey, Barbara Hand Gabbert, Constance Jacobs Lane and Mildred Evans Marlowe, who were sworn to well and truly try the issue joined and a true verdict give according to the evidence and the law.

The evidence of the plaintiff was presented and at the conclusion thereof, the defendant by counsel moved to strike the evidence of the plaintiff on grounds stated in the record, which motion was overruled and to which ruling of the Court counsel for the defendant excepted.

Thereupon, the evidence of the defendant was presented and at the conclusion of all of the evidence, the defendant by counsel renewed its motion to strike the plaintiff's evidence, on the same grounds, which motion was overruled and to which ruling of the Court counsel for the defendant excepted.

After receiving instructions from the Court and hearing arguments of counsel, the jury retired to their room to consult of their verdict and after some time returned into Court with the following verdict:

"We, the jury, on the issue joined, find in favor of the plaintiff, Lottie M. Jones and against Pfizer, Inc., and we fix her damages at \$225,000.00.

Elliott J. Berry
Foreman".

The defendant, by counsel, moved to set aside the verdict on the ground that it is excessive and on the further ground that it is contrary to the law and the evidence.

The Court withholds entering any order on its ruling on the motions made by the defendant, Pfizer, Inc., pending the filing of written memoranda by counsel for all parties and this case is continued until April 10, 1978 at 2:30 o'clock P.M.

MEMORANDUM OF OPINION

Dated 1 August 1978

I have read carefully the two helpful briefs of counsel on the question of whether or not the Plaintiff's evidence should have been struck, and the jury verdict for the Plaintiff in the above styled case in the amount of \$225,000.00 should now be set aside, and finally, on whether the verdict was so excessive as to warrant a remittitur or a new trial.

The first basis for setting aside the verdict is the position taken by Plaintiff's [sic] counsel that the court should have struck the Plaintiff's evidence and entered a judgment for Pfizer upon the claim that the package insert warning accompanying the vial of Vistaril was adequate as a matter of law.

I see this as a jury question. The test of whether or not the evidence presents a jury issue is the ancient one of whether or not reasonable men might disregard upon the question presented.

It is admitted that the package insert failed to warn that significant tissue damage might result from a subcutaneous injection. The insert also failed to provide any special warning in the event the patient was obese. It is true, and there is no dispute, that the insert did make it clear that the injection was to be intramuscular, and not subcutaneous. The most important evidence, which in my opinion required the question to be presented to the jury, was Dr. Peter R. Smith's

testimony. He stated in effect that the insert warning was subject to two deficiencies. He said, "I think there is a need for more information * * * my feeling is that there is not sufficient [warning] regarding the potential danger * * * in terms of what kind of reaction could follow if the drug is not injected into the muscle, if the drug should come into contact with subcutaneous tissue, either by way of leak-back or otherwise. There is mention that it should be given intramuscularly, no mention as to why. Secondly, I think there should be a special warning regarding obese patients. It is virtually impossible in many cases to get intramuscular medication into the muscle in certain patients. They made no mention that that precaution be taken in the use of this drug for obese patients."

There, of course, was other expert testimony tending to show that the warning was sufficient. However, since Dr. Smith was equally assertive in his opinion that the warning was not sufficient, we have here a case posing the age-old dilemma of what to do "when doctors disagree". What better reason is there for submitting this question to a jury than this one where "reasonable men might disagree". Certainly it cannot be said by trial judge as a matter of law that the jury could not disagree on this very question. The expert testimony was clouded by disagreement, leaving the court no alternative but to submit that question to the jury and not strike the evidence.

The next basis on which the Defendant claims the evidence

should have been struck was its position that the attending physician, Dr. Thompson, was "fully aware" of the precise damage which Plaintiff alleges the Defendant Pfizer failed to specify in its package insert warning.

This, too, was a doubtful question. The Plaintiff [sic] states categorically that Dr. Thompson was fully aware of such precise damage. That is not the case. The trial judge heard Dr. Thompson's testimony. The Plaintiff [sic] cites three cases, Mulder v. Parke, Davis & Co., 181 N.W.2d 882, Leibowitz v. Ortho Pharmaceutical Company, 307 Atlantic 2d 449 and Ball v. Mallinkrodt Chemical Works, 381 S.W.2d 563, the first a Minnesota case, the second a Pennsylvania case, and the third one a Tennessee case. In each of these, the court emphasized that the criterion is that the physician must have full information from other sources of all possible reactions to the use of a particular drug if the manufacturer is to be relieved of liability for inadequate warning on the package insert.

There is no evidence here that Dr. Thompson, the treating physician, was fully aware, or otherwise had full information regarding the great potential danger to his patient. The substance of his testimony is that at some time or other he had heard from some source, he could not recall, that tissue necrosis might result when Vistaril was subcutaneously administered. He said that his real understanding of the drug's side effect was that some pain or swelling might be caused but that it definitely would be for a short duration only. His words were, "occasionally a patient will complain in a localized area, the site of the

injection, of pain and a swelling feeling of a lump that developed there. * * * Generally, the swelling is limited. It only lasts for a limited period of time. A short period of time. Only a short period of time is involved. Days, perhaps a week." He further stated in response to a later question that he had no personal or first-hand knowledge of a reaction such as Mrs. Jones (Plaintiff) sustained.

It is worth mentioning here too that in response to a question as to the adequacy of the warning on the package insert that he too did not feel that the warning contained on the insert was sufficient. (Tr. 108)

To have granted the Defendant's motion to strike the evidence would therefore, for those reasons, have plainly been in error.

The verdict, once rendered, was assailed by the Defendant and a motion made to set it aside for four reasons.

First, did the court err when it refused Instruction No. 9? This would have told the jury that even though it believed that the Defendant was negligent in failing to give adequate warning on its package insert, if it further believed that Dr. Thompson, the treating physician, was aware, knew, or was fully aware that subcutaneous injection could cause tissue necrosis, then any failure on the part of Pfizer to give adequate warning would not have been a proximate cause of Plaintiff's injuries and the verdict should be found in favor of the Defendant.

In my opinion, the record plainly shows that there was no evidence that Dr. Thompson was fully aware or had any direct knowledge that tissue necrosis in such severe form as that suffered by the Plaintiff could result. Such instruction would have suggested to the jury a fact that was not adequately developed from the evidence, namely, that Dr. Thompson did possess such knowledge when his testimony was to the effect that he did not in fact possess such knowledge. In other words, there was no evidentiary basis for this instruction. Very clear case law, emphasized in both briefs, requires that the physician be "fully aware" of the danger of tissue necrosis from a subcutaneous injection. Full awareness being the real test, nowhere in the evidence was it shown that Dr. Thompson was fully aware of such danger. Because such an instruction must be based on evidence, and no evidence of full awareness was presented, the instruction was properly refused. I agree with the Plaintiff's statement in her brief, "If Pfizer was not entitled to a strike as a matter of law on the adequacy of the warning and to proximate cause, then it was not entitled to finding Instruction No. 9, which the court refused."

The other three bases for setting aside the verdict and ordering a new trial were the exclusion of proof of Pfizer's compliance with regulations of the Food and Drug Administration, the admission of color photographs showing Plaintiff's wound and permitting two patients of Plaintiff's expert witness to sit as jurors.

Regarding the proof of Pfizer's compliance with regulations of the FDA, this would have been permitted under somewhat different circumstances from those obtaining when its introduction was sought. At the time Dr. Walmsley was first questioned on this point, no foundation for its introduction which would have linked it with this case was laid. The court did offer to permit its introduction following the laying of a proper foundation and otherwise showing its relevancy to the issue being tried. No further attempt was made by the Defendant to lay such foundation or to again introduce such FDA evidence.

The other two bases for Defendant's motion to set aside the verdict were the introduction of color photographs showing Plaintiff's wound and permitting two patients of Plaintiff's expert witness, Dr. Peter R. Smith, to remain as jurors, after full questioning of them by the court and no bias being shown. It is felt that both of these rulings were within the sound discretion of the court and I do not feel that any error was committed in overruling Defendant's objections.

The final question for consideration was that of whether or not the verdict of \$225,000.00 was so excessive as to justify a remittitur or a new trial.

As stated in Plaintiff's brief in citing Smithey v. Sinclair Refining Co., 203 Va. 142, as to excessiveness, " * * * but if it appears that the verdict is so excessive as to shock the conscience of the court and to create the impression that the jury has been influenced by passion, corruption or prejudice, or has

misconceived or misunderstood the facts or the law, or if the award is so out of proportion to the injury suffered as to suggest that it is not the product of a fair and impartial decision, than it becomes the duty of the judge acting within his legal authority, to correct the injustice." (Citing numerous other cases)

The verdict is clearly excessive. It does not bear any relationship to the evidence, which supports the Defendant's statement that Plaintiff's total medical expenses were less than \$8,000.00. She lost no income and has no disability other than the "large hole" in her hip. Although this is covered by clothing, it is indeed a deformity which should result in adequate compensation. It is permanent and disfiguring when it can be seen. If the scar were on any visible part of her body, it might be difficult to say that the verdict was excessive. Mrs. Jones is unemployed by choice, still performs the greater portion of her housework, though she apparently suffers some limitation in stooping, but this may be due in part as much to her obesity and early advancing years, as from any other cause. She is able to perform most any other activity, although she testified that as of the time of the trial, her sexual relations were sometimes affected.

Yet, the fact that she suffered no loss of income, not being gainfully employed, she now does all of the housework she ever did, has not been crippled in any way, has no continuing

financial loss, no probability of future expenditures to be cured of any existing ailment, does not contemplate any future surgery and except for the clothes-covered scar has no residual effect from the injury, and suffers no constant pain or real disability. Having said that the verdict was excessive and intending to require a remittitur, it becomes necessary to decide what would be adequate compensation.

There is no question but that her experience in the hospital was an agonizing one. The Plaintiff has summarized accurately her hospital experience on Page 14 of her brief which is more than confirmed by her attending physician. They state that the hip turned blue and her cramps became so severe, together with a burning sensation, that she could hardly bear the pain. The hip later turned black and developed painful blisters. The pain was so excruciating that even the slightest touch caused her even greater agony. Later on, the hip flesh over an area about the size of a man's hand became necrose. It was necessary that she be isolated and had great difficulty in this stage of treatment. She could not have visits from the Gray Ladies, and she underwent four painful surgical procedures of debridement to have the dead tissue removed. She testified that the odor from her wound was overwhelming, that the pain was constant and her mental anguish was almost beyond bearing. She still suffers muscle cramps which contribute to the interruption of sexual intercourse with her husband and has pain in her hip when she

reclines. She must wear loose clothing because tight clothing still irritates the site of the skin graft. The jury viewed the "scooped out" indenture in her hip and found that it was a deep one, although no longer disabling. Her graphic account of her pain and suffering and its intensity were certainly corroborated by Dr. Thompson, who found it necessary to perform the graft by taking skin from the side of her thigh.

One factor by which a trial judge should be controlled in deciding whether or not the remittitur is in order is the cost of future medical expenses. Here none are anticipated. There are no expected "after-care" costs here. This extremely large verdict is so far out of proportion to the Plaintiff's injuries, medical expenses, lack of future medical expenses, the fact that no wages were lost, that no great pain or mental anguish now exist, that the conscience of the court is truly shocked by its size which clearly places upon it the badge of unfairness.

The figure of \$225,000.00 being excessive, it must be held that the Plaintiff shall remit to the Defendant the sum of \$125,000 of the verdict. Final judgment will be rendered for the Plaintiff in the amount of \$100,000.00 with interest from date of verdict. While perhaps still high, this figure would be in line with the jury's desire to see that the Plaintiff was well-compensated for her pain, suffering, mental anguish and disfigurement. If the Plaintiff be no amenable to this remittitur, she will be required to accept a new trial of the issues.

Counsel for the Plaintiff is requested to prepare an order effectuating the terms of this opinion, with brief appropriate recitals of the findings of the court, and to present the same, appropriately endorsed by counsel for Defendant, for entry by the court.

/s/ J. A. Jamison
Judge

Date: August 1, 1978

App. 18

NOTICE

Dated 13 September 1978

Pursuant to the provisions of Section 8.01-383.1,
the Plaintiff accepts judgment in this matter for the sum
of One Hundred Thousand Dollars (\$100,000.00) with interest
from February 28, 1978 together with costs under protest.

Respectfully,

LOTTIE M. JONES

By /s/ Russell H. Roberts
Of Counsel

FINAL ORDER

Entered 13 September 1978

This day came plaintiff and defendant, by counsel, upon the jury verdict rendered for the plaintiff in the above-styled case in the amount of \$225,000.00 and upon the motions of defendant to set aside the verdict and enter judgment for defendant, to set aside the verdict and order a new trial and to remit a portion of the verdict or order a new trial.

Having considered the memoranda submitted by counsel, the argument of counsel and for the reasons set forth in the courts' Memorandum of Opinion, it is hereby

ADJUDGED AND ORDERED that the motions of the defendant to set aside the verdict and enter judgment for the defendant, to set aside the verdict and order a new trial be and the same hereby are denied. The motion of the defendant for a remittitur on the ground that the verdict is excessive is hereby granted.

The court being advised that plaintiff, by counsel, has filed her notice to remit and accept judgment of the court thereon for the reduced sum under protest, as set forth in its Memorandum of Opinion, it is further ORDERED that final judgment be and the same hereby is entered for the plaintiff against the defendant in the amount of \$100,000.00 with interest from 28 February 1978, the date of the verdict, together with her taxable costs expended.

/s/ John A. Jamison
Judge
September 13, 1978

ASSIGNMENTS OF ERROR

Dated 12 December 1978

I. The trial court should have struck Plaintiff's evidence since her prescribing physician's independent knowledge of the consequences of improper subcutaneous injection of Vistaril intramuscular solution breaks the chain of causation between Plaintiff's injury and the content of Pfizer's package insert warning.

II. In the alternative, the trial court should have instructed the jury on Pfizer's theory of the case, based on Dr. Thompson's admitted knowledge of the association between tissue necrosis and improper subcutaneous injection of Vistaril intramuscular solution.

III. The trial court erred by excluding proof of Pfizer's compliance with regulations of the U. S. Food and Drug Administration.

IV. The trial court erred by permitting two patients of Plaintiff's expert witness to sit as jurors.

V. The trial court erred by admitting three color photographs depicting Plaintiff's wound where adequate medical testimony was available to describe the tissue necrosis and where the only effect of admitting said pictures was to influence the passions of the jury.

VI. The trial court erred by failing to strike Plaintiff's evidence on the grounds that Pfizer's package insert warning was adequate as a matter of law.

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COPY

1 THE CLERK: The case of Lottie M. Jones
2 vs. Pfizer, Inc. Are you gentlemen ready?
3

4 MR. ROBERTS: The plaintiff is ready.

5 MR. BURKHOLDER: The defendant is ready,
6 sir.

7 THE COURT: Call the jury.

8 THE CLERK: Please answer to your name
9 as I call it.

10 NOTE: The Clerk of Court now
11 calls the names of the prospective jurors to which
12 the prospective jurors answer as their names are
13 called. After the Clerk of Court duly swears the
14 jury panel on vior dire.

15 THE COURT: Members of the panel, as most
16 of you know who have set on a jury before, the
17 jury is selected from amongst you after the
18 process of elimination. That will take place
19 shortly, and some of you will then be excused to
20 leave.

21 You will be needed on Thursday

1 of this week, which is March the 2nd, at ten
2 o'clock. After that, I think you have clear sailing
3 for possibly two or three weeks. The next case that
4 my calendar shows is March the 13th. Some times
5 these cases are settled, and we will let you know
6 as soon as possible.
7

8 This is a case today in which
9 Lottie M. Jones brought a civil suit against
10 Pfizer, Inc., a Delaware Corporation, a pharmaceu-
11 tical manufacturer. This is what is commonly known
12 as a product liability case. The allegation concerns
13 a product manufactured by Pfizer, Inc. You will
14 hear more about that in opening statements by the
15 attorneys. I will not go into details about this
16 case.

17 I will ask you if any of you
18 are related to Lottie M. Jones or if any of you
19 are employees or stockholders of Pfizer, Inc.?

20 NOTE: No response.

21 THE COURT: This cause of action is said

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1 to have arisen out of an occurrence -- out of
2 an occasion during which the plaintiff was
3 hospitalized, on or about August 16, 1975. Are
4 any of you familiar with Mrs. Jones's hospitalization
5 at that time or anything else concerning this
6 case?

7 NOTE: No response.

8 THE COURT: Have any of you heard anything
9 about it from any source?

10 NOTE: No response.

11 THE COURT: Is there anyone who feels
12 that he or she can't sit here today and hear the
13 evidence in this case and render a fair and impartial
14 verdict based only on the evidence that you will
15 hear and the instruction that I will give you later
16 on in the case. Is there anyone who feels that he
17 or she cannot do that?

18 NOTE: No response.

19 THE COURT: Do you have any questions,
20 Mr. Roberts?
21

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22.

1
2 MR. ROBERTS: We have no questions, Your
3 Honor.

4 THE COURT: Mr. Page?

5 MR. PAGE: Yes, Your Honor. I'm sorry,
6 I wonder if it would be possible to go back and
7 start giving me their names again? I want to
8 make sure that I have the proper identification.

9 NOTE: At this time the
10 jury panel repeat their names for Mr. Page.

11 MR. PAGE: Your Honor, I would like to
12 ask the members of the jury if they have ever been
13 clients of Mr. Roberts personally or Mr. Haley
14 personally or of their law firm.

15 NOTE: No response.

16 MR. PAGE: I would like to ask the jury
17 if any of them are socially acquainted with Mr.
18 Roberts or Mr. Haley or with any member of their
19 law firm.

20 NOTE: No response.

21 MR. PAGE: Can I assume from your silence

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23.

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1 that the answer to these questions are in the nega-
2 tive?

3 I would like to ask if any
4 member of the jury has ever been a patient of
5 Dr. Peter Smith?

6 NOTE: Prospective juror raises
7 hand.

8 MR. PAGE: What is your name?

9 PROSPECTIVE JUROR: Yvonne Lewis Dickinson.

10 MR. PAGE: And what is your name?

11 PROSPECTIVE JUROR: Barbara Gabbert.

12 MR. PAGE: I would like to ask the jury if
13 any member of the jury has ever been a patient
14 of Dr. Richard N. Thompson. I would like to ask
15 if any member of the jury is a social acquaintance
16 of either Dr. Peter Smith or Dr. Richard N.
17 Thompson.

18 NOTE: No response.

19 MR. PAGE: I would like to ask if any
20 member of the jury, other than those two ladies
21

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24.

1
2 who have already identified themselves as being
3 patients of Dr. Peter Smith, ever have been
4 patients at the Pratt Clinic here in Fredericksburg.

5 NOTE: Several prospective
6 jurors now raise their hand.

7 MR. PAGE: Thank you.

8 Your Honor, I have a motion
9 with respect to striking for cause. Should I
10 take that up right now?

11 THE COURT: Let me ask them some questions.

12 Now, some of you have answered
13 in the affirmative to the question of whether or
14 not you have been patients of Dr. Smith and the
15 Pratt Clinic. Would that fact cause you not to
16 be able to make a fair decision based on the
17 evidence that you will hear today?

18 Is there anyone who feels that
19 he or she is prejudiced or biased by his or her
20 acquaintance with these doctors or the Pratt Clinic?

21 NOTE: No response.

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25.

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1 THE COURT: Is there anyone who feels
2 that he or she cannot render a fair verdict, keeping
3 in mind all of the questions that I have asked you?

4 MR. ROBERTS: Perhaps we should have
5 mentioned this prior to the panel being questioned:
6 Dr. Smith will testify in the matter.

7 THE COURT: Would that fact --

8 MR. PAGE: I think, Your Honor, Dr. Smith,
9 at least as I understand the representation, is
10 not only going to be a factual witness, but he
11 will also --

12 THE COURT: All right, take the panel
13 out for just a moment.

14 NOTE: The jury panel now leaves
15 the Courtroom accompanied by the Sheriff.

16 THE COURT: All right.

17 MR. PAGE: I would like to strike for
18 cause jurors Goodman and Dickinson on the ground
19 that they have been patients of Dr. Peter Smith.

20 Dr. Smith, as I understand it,
21

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26.

1 will be called as an expert witness to testify,
2 among other things, that he believes that the
3 warnings given by the defendant in the case were
4 inadequate. He will give his personal opinion
5 as to how the warning should have been given, should
6 Your Honor allow that into evidence.
7

8 Our position is that if you
9 have a person who has enjoyed a doctor-patient
10 relationship, which the law recognizes as being
11 serious and one of confidentiality and a close
12 one, and the relationship must be of mutual trust
13 and reliance, that that person is not a proper
14 person to sit on the jury in which that physician
15 will offer an opinion on the very issue that these
16 jurors must decide. To do so would be to ask them
17 to disbelieve their doctor, and it is for those
18 two people that simple.

19 We think that that is a basis
20 to strike those two jurors for cause.

21 THE COURT: What do you have to say about
that?

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MR. ROBERTS: Your Honor, the Court submitted additional inquiry as to whether or not those people would be prejudiced by the fact that they are patients of Dr. Smith's. They did not respond in the affirmative.

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13
Dr. Smith is not a party to this suit. He is a totally independent witness whose judgment is based upon his experience and education and nothing more. I submit that striking these jurors for cause, would be erroneous. It would be like trying the case in a vacuum. Perhaps that is what Mr. Page would like to do.

14
15
16
MR. PAGE: Mr. Roberts has suggested that I would like to try this case in a vacuum. I don't want to do that.

17
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21
We have here a personal and professional relationship that exists between the two jurors and the expert witness in the case. We believe that it is not proper to allow a juror in that situation to sit in the case.

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28.

1 We don't know what testimony
2 is going to come in. If he says that yes he
3 saw Mrs. Jones on August the 21st or 22nd or the
4 25th, and yes she had this problem, I have no
5 problem with that. But, if he is going to be a
6 witness on which the plaintiff relies on her case,
7 then I think it is improper to try the case before
8 a jury panel -- before a jury whose panel is
9 made up of six people who are patients of Dr.
10 Smith's and the Pratt Clinic, and two of whom
11 have a personal relationship with him.
12

13 My second motion is that the
14 other four jurors that are patients of the Pratt
15 Clinic also be stricken for cause. They do not
16 enjoy the same kind of doctor-patient relationship
17 but they do go there for examinations and treatment,
18 and they do place their trust in the members of
19 the Pratt Clinic. I move that they also be stricken
20 for cause.
21

THE COURT: All right, sir.

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MR. ROBERTS: We could go to the extreme and ask the panel if any of them have ever used a Pfizer product, and, if so, were they satisfied with Pfizer.

I noticed that Mr. Page has no authority to submit.

THE COURT: A doctor-patient relationship is at times a rather personal one. I think that if the motion were made in a case where the doctor himself were a party, and I think of course that that would be a much stronger reason to strike them for cause. But, this is a small community and seventy-five to eighty percent of the doctors practice there -- practice medicine there. I don't have any knowledge of any personal type feeling for the Pratt Clinic. If anything, you could possibly find the opposite to be the case.

The Court asked these two ladies if they would be prejudices or biased by the fact that they were patients of Dr. Smith, and

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30.

1 they did not indicate that they did have those
2 feelings. I don't think --

3 MR. PAGE: Could I say one thing, Your
4 Honor, before you rule? I think and I knew that
5 this patient-doctor relationship that these two
6 ladies have, is recognized in law and --

7 THE COURT: If he were a party in this suit.
8 He is just a witness. I am overruling your motions.
9

10 MR. PAGE: Note our exception.

11 THE COURT: All right, sir.

12 Bring the panel back.
13
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* * *

PATRICIA ANN WALMSLEY, M.D.,

a witness, being called for examination by counsel
for the plaintiff, first being duly sworn, testified
as follows:

DIRECT EXAMINATION

BY MR. ROBERTS:

Q You are Dr. Patricia Ann Walmsley?
A Yes, I am.



direct - Walmsley

1 Q And, you are a medical doctor?

2 A Yes, I am.

3 Q And, you are trained as a pathologist,
4 is that correct?

5 A That is correct.

6 Q Dr. Walmsley, you were educated where?

7 A At the University of London, England.

8 Q Would it be possible for you to speak
9 up?

10 A At the University of London, England.

11 Q And, you had your internship and
12 residency in London?

13 A That is correct, yes.

14 Q And then you came to New York?

15 A Yes.

16 Q Did you have additional residency training
17 in New York?

18 A I had completed my residency when I
19 came to New York.

20 Q Where did you work as a pathologist?
21

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52.

direct - Walmsley

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2 A At the New York Hospital in New York,
3 and I was on the faculty of the Cornell University Medical
4 Center.

5 MR. PAGE: (interjecting) I will ask you
6 to do two things: First, speak loud enough so
7 that everyone on the Courtroom can hear you, this
8 is a very hard Courtroom to hear in, and, secondly,
9 be sure that you let him finish his question before
10 you give your answer so that the jury will have
11 the opportunity to hear your answer. Thank you.

12 BY MR. ROBERTS: (continuing)

13 Q Now, Dr. Walmsley, you are currently
14 employed by the Pfizer Company, is that correct?

15 A Yes, that is correct.

16 Q And, you are Assistant Medical Director?

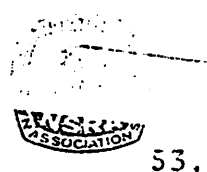
17 A I am Senior Associate Medical Director.

18 Q And, your responsibilities in that job
19 are directly related to the product Vistaril, is that right?
20

21 A That is correct.

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direct - Walmsley

1 Q What are your duties with regard to
2 the product Vistaril?

3 A I am what is referred as product physician.
4 I deal with all of the medical aspects of that drug. This
5 includes all of the studies made on the drug and the evaluating
6 results of such studies. I am also a liaison to the marketing
7 department to help produce promotional and educational
8 materials such as booklets, films, brochures. I also arrange
9 symposiums, and also would answer any questions that come
10 in physicians about Vistaril. That, essentially, is it.

11 Q Are you also responsible for educating
12 yourself with thr properties of the drug that your company
13 manufactures, and I am talking about Vistaril?

14 A Yes.

15 Q Are you also responsible with -- for
16 educating yourself with the properties of other drugs that
17 can be mixed with Vistaril?

18 A Yes.

19 Q So, that you are fully aware of this
20 interaction that might take place when another drug is mixed
21 with Vistaril?

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direct - Walmsley

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2 A Yes.

3 Q Your company recommends that Vistaril
4 and Demerol be mixed together, doesn't it?

5 A Yes.

6 Q And, the reason for that, I believe,
7 is that the Vistaril accelerates the effect of the Demerol,
8 is that right?

9 A It potentiates the effect.

10 Q What is the difference between "accelerates"
11 and "potentiates"?

12 A Accelerating, perhaps, means an effect
13 that is faster, where "potentiating" would indicate that
14 you get a greater effect. So, if you are giving the Demerol
15 to relieve pain, you get a greater pain reliever if you
16 give the Vistaril in addition to the Demerol.

17 Q As a result of this suit being brought,
18 you have had an opportunity to familiarize yourself with the
19 hospital and medical records of Mrs. Jones, have you not?

20 A I have.

21 Q And, you have reviewed the literature

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direct - Walmsley

1
2 that accompanied this drug or was published concerning
3 this drug prior to August 18th, 1975, is that correct?

4 A Yes.

5 Q And, you have likewise, have you not,
6 reviewed the records of the Pfizer Company with regard to
7 previous adverse reactions to Vistaril?

8 A Yes.

9 Q And, as a result of that study, I believe,
10 have you not, determined that as far back as 1964 necrotic
11 reactions to the drug Vistaril have been reported to Pfizer,
12 have they not?

13 A Yes.

14 Q Necrotic reaction is really that the
15 tissue is being killed by the drug Vistaril, is that right?

16 A Yes, it means that the tissue dies.

17 Q The tissue dies as a result of coming
18 in contact with the Vistaril, is that right?

19 A This is assumed. It is difficult to
20 determine in all cases. In some cases there were other
21 drugs in addition to the Vistaril. But to the best of my
knowledge, it relates to the drug Vistaril.

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56.

direct - Walmsley

1 Q The drug Demerol. You have reviewed
2 the literature on Demerol, have you not?

3 A Yes.

4 Q And, you are familiar with Demerol, are
5 you not?

6 A Yes.

7 Q Demerol can be injected either subcu-
8 taneously or intramuscularly, can it not?

9 A Yes.

10 Q Now, in this situation, as a result
11 of your reviewing the medical records, you would conclude,
12 would you not, that this reaction that Mrs. Jones had
13 was due to the Vistaril, have you not?

14 A I would, yes.

15 Q I want to show you a document that
16 bears the revision date of August 1970, and I ask you to
17 identify it, if you would, doctor.

18 A This is a package insert for the
19 drug Vistaril.

20 Q Did your company have that with the
21

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57.

direct - Walmsley

1 vial from which the injection that Mrs. Jones got?

2 A Yes.

3
4 MR. ROBERTS: I would tender this as
5 plaintiff's exhibit number one.

6 THE COURT: Any objections?

7 MR. BURKHOLDER: No objections.

8 THE COURT: It will be admitted as
9 plaintiff's exhibit number one.

10
11 NOTE: The package insert is
12 now being marked and filed by the Clerk of Court
13 as PLAINTIFF'S EXHIBIT NUMBER ONE.

14 BY MR. ROBERTS: (continuing)

15 Q Now, that package insert was something
16 that someone who was administering the drug would primarily
17 rely on in administering the drug, is that correct?

18 MR. BURKHOLDER: (interjecting) We object
19 to the form of the question. It is obviously
20 something that Pfizer wants physicians to read
21 before the administration of the drug. Pfizer

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58.

direct - Walmsley

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can't -- a physician relies on his medical training
and experience. That is something that Dr. Walmsley
would have to speculate on.

THE COURT: The objection is sustained
to the question in its present form.

BY MR. ROBERTS: (continuing)

Q Let me ask you this: Does anything else
accompany this vial of the drug?

A No. This is, essentially, the information
that is given out.

Q That is called the package insert?

A Yes.

Q That was available to anyone who opened
a new pack of Vistaril, is that correct?

A Yes.

Q Now, that package insert states, does
it not, that Vistaril is not to be injected subcutaneously?

A Yes, it states that under no circumstances
should Vistaril be given subcutaneously.

Q It likewise states that it should be
given intramuscularly?

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59.

direct - Walmsley

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2 A Yes.

3 Q Under section "Adverse reactions", on
4 that package insert, does it say anything at all about the
5 reaction that -- the type reaction that Mrs. Jones had
6 to the drug?

7 A No.

8 Q And, prior to that package insert being
9 put in the vial of Vistaril that was used to give Mrs. Jones
10 her injection, you had a history of necrosis as far back
11 as 1964, had you not?

12 A Perhaps I should explain adverse re-
13 actions. We are talking about reactions that occur if the
14 drug is given properly. The kind of reaction you are talking
15 about, that occurred in Mrs. Jones, only occurs if the
16 drug is injected subcutaneously. And we say in that package
17 insert that under no circumstances is the drug to be in-
18 jected subcutaneously.

19 Q You also don't see under "Precaution"
20 or "Adverse reaction" or "Contraindication" anything about
21 a necrotic reaction do you?

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direct - Walmsley

A No.

Q It doesn't say that the tissue can
be killed, does it?

A No.

MR. ROBERTS: Your Honor, I would like
for the jury to have the opportunity to see this.
It is quite long.

THE COURT: I think that it will distract
the jury from your case while they read this.
It will be presented to the jury at the proper
time.

MR. ROBERTS: Very well, Your Honor.

MR. BURKHOLDER: Mr. Roberts has been
kind enough to show me the next exhibit, which
raises some questions as to whether or not it is
proper evidence. Perhaps it would be appropriate
to discuss that out of the presence of the jury.

THE COURT: All right, take the jury out.

NOTE: The jury now leaves the
Courtroom in the company of the Sheriff.

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JURY OUT

MR. ROBERTS: We are seeking to introduce into evidence a package insert for another Pfizer drug called Permapin. A drug which has a reaction similar or not dissimilar to this particular reaction, to show what kind of warning was given for that drug. I think that the jury is entitled to see this evidence to see whether or not Pfizer gave adequate warning for the Vistaril.

This other drug, according to the package insert, causes irritation of the subcutaneous tissue. The package insert states that it causes that irritation and it further tells what to do about it.

I submit that in determining the adequacy of the warning, the jury is entitled to know what warnings Pfizer gave with respect to its other drugs.

MR. BURKHOLDER: Judge, --

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62.

JURY OUT

THE COURT: (interjecting) The problem that I have with that is in order for you to get what you think is the connection, you have to use a totally different drug. I have to wonder about the relationship.

MR. BURKHOLDER: I have a Physician's Desk Reference, which was in effect back in 1975. This shows all of the package inserts for all of the drugs, along with Vistaril. This other one is also listed. Judge, it lists a number of reactions which could occur if the drug is used in the wrong way or in the wrong spot or if it is improperly used. This is boundless, Judge. Physicians will tell you that even similar drugs consist of different components. There are different indications. These two drugs are not identical. I would be improper for the jury to compare these two drugs. That is like asking to compare Vistaril

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63.

JURY OUT

to Penicillin. That is another drug that shows
a potential reaction if used --

THE COURT: (interjecting) That bothers
me too.

If a doctor were a defendant
here and he had some choice between two drugs, and
he selected this rather than the other, I think
that that would be relevant. But this other drug
is all together different.

MR. ROBERTS: The drug Permapin is a
different drug. No question about it. However, in
dealing with the Pfizer Drug Company, doctors
become acostumed to Pfizer's warnings. And, I submit
the warnings that Pfizer gives to the other drug
for instance, Permapin , it tell of an irritation
that may occur, pain that may occur, and it tells
what to do in reference to the pain and irritation.
It tells how to treat the reaction.

Here, we have a severe reaction,

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64.

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JURY OUT

and no warning whatsoever of might occur. I think
that --

THE COURT: (interjecting) Let's see what
questions you plan to ask.

BY MR. ROBERTS: (continuing)

Q Dr. Walmsley, I tender to you what
I believe to be another package insert from the drug
Would you tell us whether or not that is such a package
insert?

A Yes.

Q That package insert states, does it not,
that the drug Permapin can cause mild irritation if injected
subcutaneously?

A Yes.

Q It does state that?

A Yes.

Q It furthers states, does it not, that --
what to do if such an irritation occurs?

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65.

JURY OUT

A Yes, however, the wording about the subcutaneous injection is not as strong as with the Vistaril. This package insert states that subcutaneous injection should be avoided. The Vistaril package insert states that under no circumstances should Vistaril be injected into subcutaneous tissue.

MR. BURKHOLDER: (interjecting) Judge, in the face of that --

THE COURT: (interjecting) You will have your chance. Go ahead with your questions.

BY MR. ROBERTS: (continuing)

Q I would ask the same questions with reference to the drug Tetracin. Dr. Walmsley, I show you what I believe to be a package insert for the drug Tetracin and ask you if you can identify it as such.

A Yes.

Q Tetracin creates a reaction similar to the reaction, doesn't it?

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JURY OUT

A Yes.

Q And, the Tetracin is not supposed to be injected subcutaneously, isn't that correct?

A I have not had the chance to read the entire package insert. I am not familiar with Tetracin.

Q Take your time.

MR. BURKHOLDER: (interjecting) May I say that one of the main indication is that it is used in the treatment of Rocky Mountain tick fever.

A I have not read the statement that it should not be given subcutaneously.

Q It states that mild pain may result and mild irritation may occur, doesn't it? It it also says what to do if that pain occurs, doesn't it?

A Yes.

Q Now, the Vistaril insert, does it say anything about necrotic reaction or what to do or how to treat the necrotic reaction?

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67.

JURY OUT

A No, it doesn't.

THE COURT: Do these two other drugs
say anything about a necrotic reaction?

MR. ROBERTS: The whole point is that
they are talking about reactions that are less
severe. The jury is entitled to know what Pfizer
had to say about less severe or mild reactions,
if you will, and what to do about a mild reaction,
to determine whether or not adequate warning was
given with a severe reaction.

MR. BURKHOLDER: Judge, Mr. Roberts is
now providing us with a medical opinion. These
are two separate drugs which create two different
problems. This last drug is designed to treat
Rocky Mountain spotted fever. Judge, the warnings
that Pfizer puts in these inserts is what the
Food and Drug Administration tells it to put in.

Judge, I am not familiar with

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68.

JURY OUT

this other drug. I don't have a judgment to make as to benefit or reaction. Mr. Roberts wants to take all of these package inserts and tell the jury what was done here and what wasn't done there.

THE COURT: I feel that these are different drugs. If you had drugs from competitive drug companies that are suppose to do the same thing as the Vistaril, and it showed what to do if such and such reaction occurred, I think that that would be proper to show that the other drug company did not give sufficient warning.

However, these drugs are designed for an entirely different purpose. That is what bothers me. You want to tell them about another drug all together. I will have to rule that you are not permitted to do that. I will sustain the objection.

MR. ROBERTS: I note my exception.

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69.

JURY OUT

Is it my understanding that
I am not permitted to ask this witness any questions
with regard to other drugs made by Pfizer?

THE COURT: I think that --

MR. BURKHOLDER: (interjecting) Judge,
let me interject something. Each one of these
drugs are manufactured under different specifications.
Each one has a file on reactions. Each one is
chemically different from the other. Pfizer
claims that it cannot be responsible for misuse.
We claim that that was clearly the case here.

We object to any questions
going in concerning any other drugs.

THE COURT: I will deny you questioning
about other drugs.

MR. ROBERTS: How are they to determine
if this warning was adequate?

THE COURT: The whole thing is that they

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1 JURY OUT, JURY IN

2
3 did give a warning. Common sense will tell the
4 jury that.

5 All right, bring the jury back.

6
7 NOTE: The jury returns to the
8 Courtroom. With everyone being present as before,
9 the matter continues as follows:

10 BY MR. ROBERTS: (continuing)

11 Q Dr. Walmsley, you received a call from
12 Dr. Smith, didn't you --

13 A (interjecting) Yes.

14 Q (continuing) Regarding the reaction that
15 Mrs. Jones had?

16 A Yes.

17 Q What was the date that that phone call
18 took place?

19 A I saw from my record that it was August
20 of 1975.
21

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71.

direct - Walmsley

1 Q August of 1975?

2 A Yes.

3 Q You had made a written memorandum of
4 that phone call, had you not?

5 A Yes.

6 Q Do you have that written memorandum with
7 you?

8 A Not on my person.

9 Q Do you have it in the Courtroom today?

10 A I have it in my bag.

11 Q Can you tell us what the substance of
12 that phone call was without referring to your note?

13 A Yes, I think so.

14 Q Tell us what Dr. Smith said and what you
15 said to Dr. Smith.

16 A I received a call from Dr. Smith who told
17 me that he had a patient who had received an injection of
18 Demerol and Vistaril together. That she had previously re-
19 ceived similar injections. I think that he said that she
20 had received two similar injections. The third time that she
21

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direct - Walmsley

1 received the drugs, she complained about pain in the site
2 of the injection. She had discoloration of the skin. I believe
3 he also stated that bullae had formed. That the skin was
4 kind of necrotic.
5

6 Q Did he asked you if you had seen this
7 before?

8 A He asked me if I had seen it before and
9 I told that I had in a few cases. That they had been re-
10 ported to us when the Vistaril was given subcutaneously.

11 Q You have had twenty to twenty-five reports
12 of that, had you not? Prior to then?

13 A Not prior to then. We have had twenty to
14 twenty-five prior to now.

15 Q Prior to today?

16 A Yes.

17 Q And they are all similar effects? The
18 effect in all of these cases is that the tissue is actually
19 killed, is that correct?

20 A Yes. They are varying in severity, the
21 degree of severity.

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73.

direct - Walmsley

1 Q And, they go back as far as 1964, don't
2 they?

3 A 1964 is the first report that we kept
4 a record of. The very first time that the drug was put on the
5 market was 1959.

6 Q It was put on the market in 1959?

7 A Yes.

8 Q And, the first report of any necrotic
9 reaction was in 1964?

10 A Yes.

11 Q And, then, you received -- regularly
12 received reports in the rate of one every three or four
13 months since then, didn't you?

14 A Not as frequently as that. It has been
15 on the market for nineteen years. We have received between
16 twenty to twenty-five reports since then.

17 Q You have no idea how many are unreported,
18 do you?

19 MR. BURKHOLDER: We object to that question.
20

21 She can only testify to what she knows.

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direct - Walmsley

THE COURT: She is an adverse witness.

The objection is overruled. Go ahead.

BY MR. ROBERTS: (continuing)

Q Do you have any idea how many are unreported? The statistics?

A No. There is no way I would know.

Q They could be reported to other sources and you would not know, is that correct?

A When you say "other sources", what do you mean?

Q Anybody could report it to the Food and Drug Administration and not advice you about it, couldn't they?

A I would doubt that. I think that I would find out of such report.

Q State, if you will, other drugs that you are familiar with that have the same properties and give the same effect as the Vistaril that potentiate narcotic type drug.

MR. BURKHOLDER: He is dealing with what

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75.

direct - Walmsley

1 I thought we already ruled on. I thought that you
2 had already ruled on that.

3 MR. ROBERTS: I want to know what the
4 competition for Vistaril is.

5 MR. BURKHOLDER: We object on the ground
6 of relevancy. We are dealing with Pfizer.

7 THE COURT: Ask her that.

8
9 BY MR. ROBERTS: (continuing)

10 Q Is there some other drug that you consider
11 to be in direct competition with Vistaril?

12 A Well, let me explain. There are several.
13 If you are talking about the specific effect to a narcotic,
14 there is only one drug which makes that claim, and that is
15 Panheprin.

16 Q How about Vallium?

17 A To my knowledge it has no evidence
18 substantiate that effect.

19 Q Is Vistrail used for other things?

20 A Certainly, it is used for other situations
21 other than to potentiate narcotic effect.

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direct - Walmsley

1
2 Q Now, Pfizer, in addition to making
3 prescription drugs, makes a number of product or items
4 that are not prescription drugs, don't they?

5 A I am not familiar with that side of the
6 company.

7 Q You don't know what they are?

8 A No.

9 Q You don't even know their names?

10 A That is not part of my job.

11 MR. ROBERTS: That is all we have, Your
12 Honor.

13 MR. BURKHOLDER: I would like to ask
14 Dr. Walmsley some question, Judge.

15 THE COURT: All right.

16 CROSS EXAMINATION

17 BY MR. BURKHOLDER:

18 Q Dr. Walmsley, Mr. Roberts only touched
19 upon your educational background. I believe you stated that
20 you were trained as a pathologist?
21

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77.

cross - Walmsley

1
2 A Yes.

3 MR. ROBERTS: (interjecting) He is leading
4 this witness. She was examined on direct examination
5 about that. This is cross examination.

6 MR. BURKHOLDER: I think that that is
7 a proper question.

8 THE COURT: Unless you are leading into
9 something, I do sustain the objection.

10 BY MR. BURKHOLDER: (continuing)

11 Q Dr. Walmsley, where did you take your
12 medical training?

13 A In England. At the University of London.

14 Q How many years did you attend the
15 University of London?

16 A Five years to get my medical degree. It
17 was a further six years before I attained my pathology
18 qualifications.

19 Q During the six years, what did you
20 concentrate on?
21

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78.

cross - Walmsley

1
2 A The first four years were spend doing
3 general pathology. Rotating between blood chemistry, surgical
4 pathology, looking at tissue, bacteriology. My last two
5 years were purely surgical pathology, the study of tissue.

6 Q What is the general study of pathology?

7 A It is really a study of diseased tissue.

8 Q Does it have anything to do with the
9 kind of reaction that Mr. Roberts has been discussing with
10 you?

11 A It is just among that kind of reaction.

12 Q You had a total of twelve years of
13 medical training?

14 A Eleven.

15 Q Could you tell me, please, Dr. Walmsley,
16 what sort of professional experience you have had after
17 your six year course of the specialty of pathology?

18 A I then came to this country and was on
19 the faculty of Cornell Medical Center, working as a pathologist.
20 I then came to New York, teaching undergraduates and residents.

21 Q How long did you stay in that capacity?

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79.

cross - Walmsley

1 A Two years.

2 Q How long have you been employed by
3 Pfizer?

4 A Four years.

5 Q And, during your stay with Pfizer in
6 this four year period, have you had occasion to review
7 medical records of cases similar to this?

8 A Yes, I have.

9 Q Dr. Walmsley, have you had occasion, in
10 this particular case, to review the medical records, copies
11 of which have been introduced into evidence? And, I might
12 ask you, before you answer, to look over those records.

13 A Yes, I have reviewed them in the past.

14 Q Dr. Walmsley, before we get into these
15 medical records, can you, generally, describe what Vistaril
16 was suppose to do?

17 A Primarily, it is used to treat anxiety.
18 Also, if it is used in conjunction with an analgesic, it
19 demonstrates a potential increase the amount of pain relieve
20 that these drugs give. It is used pro- and postoperatively
21

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80.

cross - Walmsley

1 in association with narcotics in the treatment of pain
2 and anxiety.

3 Q What is the advantage of being able
4 to use Vistaril with a narcotic?

5 A Well, the main advantage is that you
6 get a greater degree of pain relieve than if you just used
7 the narcotic. You can reduce the amount of the narcotic that
8 you give, and still get the pain relieve. It reduces the
9 side effect you get from a narcotic, such as nausea.

10 Q Dr. Walmsley, up until August of 1975,
11 approximately, how many doses of Vistaril Intramuscular
12 Solution have been sold by Pfizer?

13 A Over fifty million. I am not sure exactly
14 how many over fifty million.

15 Q Out of the fifty million doses that have
16 been sold, approximately how many reports have you received
17 concerning particular reactions?

18 A From the time that Vistaril was first
19 put on the market to the time that Mrs. Jones was injected,
20 we had twenty-one reports of similar reactions, adverse
21

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cross - Walmsley

1 reactions, in the file. In addition, there are two or three
2 that we have received that note adverse reactions, reports,
3 through our legal department.

4 Q As a result of reviewing the medical
5 records in this case, Dr. Walmsley, have you been able to
6 form an opinion, to a reasonable degree of medical certainty,
7 as to exactly what caused the tissue necrosis in Mrs. Jones?

8 A Yes, I have.

9 Q Please state your opinion.

10 A In my opinion, the reaction that Mrs.
11 Jones suffered was caused by injecting the Vistaril into
12 the subcutaneous tissue.

13 Q Now, I am going to make reference to
14 plaintiff's exhibit number one, the package insert for
15 Vistaril, would you please read to us, from the insert, the
16 part pertaining to subcutaneous injection?

17 A It says: "Hydroxyzine hydrochloride
18 intramuscular solution is intended only for intramuscular
19 administration and should not, under any circumstances, be
20 injected subcutaneously, intra-arterially or intravenously.
21

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82.

cross - Walmsley

1 Q Would you explain to us, Dr. Walmsley,
2 your testimony that you believe that this injection went
3 into the subcutaneous tissue and not into the muscle, would
4 you explain the basis for your opinion?

5 A Well, because, firstly, the description
6 of the reaction in the medical records is similar to the
7 descriptions that we have received when Vistaril was in-
8 jected into subcutaneous tissue. Secondly, because of the
9 description in the notes of the surgeon when he removed
10 the dead tissue. The fact that there was viable tissue
11 between the fascia and the muscle, the fascia was not
12 affected, indicates that the injection never reached the
13 muscle.

14 Q Do you recall what tract-type delivery
15 was made for the injection?

16 A It doesn't say in the notes. I can't
17 find that in the notes.

18 Q What type needle needs to be used for
19 an intramuscular solution of this type?
20

21 A Well, it depends on what kind of system

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83.

cross - Walmsley

1
2 you use. There are ready-made systems that are made for
3 injection. For instance, where the solution is already
4 prepared in a syringe, and the whole thing is sterile. Or,
5 you select your own needle and take it from the vial.

6 Q In injecting the Vistaril, would you
7 tell us, from your experience, what the drug has to pass
8 to get to the proper location?

9 A Well, you have to go through the skin
10 and then through the subcutaneous tissue, that is the fatty
11 tissue, through the fascia, which is over the muscle, and
12 then into the muscle.

13 Q What portion of the muscle is the
14 Vistaril supposed to be put in?

15 A It is supposed to put into the large --
16 into the body of a large muscle.

17 Q Does it say that anywhere in the insert?

18 A Under precaution, it says: "Vistaril,
19 Hydroxyzine hydrochloride intramuscular solution, should
20 be injected well within the body of a relatively large
21 muscle.

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cross - Walmsley

1
2 Q In your opinion, and again, within
3 a reasonable degree of medical certainty, how deep was this
4 injection made?

5 A Well, it was made above the fascia
6 tissue. It did not go into the muscle. It was not made deep
7 enough.

8 Q Is the reason for your opinion the
9 fact that there was still viable subcutaneous tissue?

10 A Yes.

11 Q What does that mean?

12 A In my opinion, the injection didn't go
13 into the fascia. There still was a layer of viable tissue.

14 Q Dr. Walmsley, as a product monitor at
15 Pfizer, are you familiar -- with respect to Vistaril, are
16 you familiar with the requirements that are imposed on
17 Pfizer by the Food and Drug Administration?

18 A Yes.

19 MR. ROBERTS: (interjecting) We object to
20 that, Your Honor. If he wants to put on evidence
21 of that later, that is fine. But, he ought to
discuss facts with this witness.

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App. 69

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85.

cross - Walmsley

1
2 MR. BURKHOLDER: The plaintiff is trying
3 to show that not sufficient warning was given
4 with this drug. I think that is it important
5 to show that this drug was approved by the Food
6 and Drug Administration and that it passed
7 the mustard.

8 MR. ROBERTS: We object to presenting
9 that to the jury.

10 THE COURT: The objection is sustained.

11 MR. BURKHOLDER: Please note my exception,
12 sir.

13 THE COURT: All right.

14 BY MR. ROBERTS: (continuing)

15
16 Q Dr. Walmsley, upon your review of these
17 medical records, would it have been possible for this
18 particular injection that Mrs. Jones received, to have gone
19 into the muscle?

20 A No, I don't think so.

21 Q If it had gone into the muscle, would
the Vistaril have created this reaction?

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cross - Walmsley

1
A No, I don't think so.

2
Q What is the basis of your opinion in
3 that regard?

4
A If the injection had gotten into the
5 muscle, you would not have seen this kind of a reaction.
6 You would not get that kind of reaction, in my opinion.

7
Q Dr. Walmsley, you stated in your
8 testimony that over fifty million doses of Vistaril have
9 been sold since it was put on the market, and that you have
10 received between twenty and twenty-five complaints similar
11 to this type. Dr. Walmsley, referring to the exhibit in front
12 of you, what has Pfizer done in its instructions concerning
13 this potential problem with the drug if the drug is not
14 used properly?

15
MR. ROBERTS: (interjecting) I object
16 to that question. The Court has already ruled on
17 that. The package insert speaks for itself.

18
MR. BURKHOLDER: Your Honor, --

19
THE COURT: (interjecting) The objection
20 is overruled.
21

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cross - Walmsley

MR. ROBERTS: Please not our exception.

THE COURT: All right.

BY MR. BURKHOLDER: (continuing)

Q What has Pfizer done, in this particular package insert, to alert physicians concerning the problem of misuse?

A Well, it states under contraindications that under no circumstances should the drug be given subcutaneously and that is to specifically avoid this kind of reaction.

MR. BURKHOLDER: Thank you, Dr. Walmsley.

REDIRECT EXAMINATION

BY MR. ROBERTS:

Q Dr. Walmsley, as far as the warning is concerned, it doesn't go and say what happens if the drug is injected subcutaneously, does it?

A No.

Q And, the other warnings that you have read, do say what happens if the drugs are misused, don't they?

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1 MR. BURKHOLDER: (interjecting) Judge,
2 we have been over this matter of other drugs.
3

4 THE COURT: The objection is sustained.

5 MR. ROBERTS: Your Honor, I tender this
6 exhibit that has been marked for identification
7 previously.
8

9 * * *
10
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direct - Thompson

* * *

RICHARD N. THOMPSON, M.D., a
witness, being called for examination by counsel
for the plaintiff, first being duly sworn, testified
as follows:

DIRECT EXAMINATION

BY MR. HALEY:

Q Dr. Thompson, would you please state
your full name and occupation?

A Richard Neal Thompson, I am a physician
in Fredericksburg.

Q Where do you practice your profession?

A At the Pratt Clinic.

Q How long have you been with the Pratt
Clinic?

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direct - Thompson

1
2 A Since April of 1974.

3 Q Do you have a particular medical
4 specialty?

5 A Yes, I do. I am a surgeon.

6 Q Would you tell the Court and the ladies
7 and gentleman of the jury something about your educational
8 background, particular as to your medical training?

9 A I went to college in Northfield,
10 Minnesota, then went to medical school --

11 Q (interjecting) Speak up a little bit.

12 A I went to medical school at the
13 University of Tennessee in Memphis. I received my medical
14 degree in 1965. I interned for one year back in Minnesota.
15 St. Paul, Minnesota at the Ramsey Medical Center. I stayed
16 there for the following four years and afterward to do
17 my residency training in general surgery. After that, I
18 spent two years in the Army Medical Corps as a surgeon before
19 coming to Fredericksburg.

20 Q Are you with anyone at the Pratt Clinic?

21 A Yes. I am the partner of Dr. Charles
V. Miller.

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94.

direct - Thompson

1
2 Q Do you have any particular honors or
3 belong to any medical societies?

4 A I belong to the local Fredericksburg
5 Medical Society and to the State of Virginia Medical Society.
6 I have also been accepted by the American Board of Surgeons
7 and I belong to the American College of Surgeons.

8 Q Do you regularly practice medicine at
9 Mary Washington Hospital?

10 A Yes, that is correct.

11 Q Are you on the staff there?

12 A That is correct.

13 Q How long have you been on the staff of
14 Mary Washington Hospital?

15 A I was a professional member of the staff
16 for about a year and ten months, and then have been an
17 active member since then, since that time.

18 Q You were on the staff in August of 1975?

19 A That's correct.

20 Q In August of 1975, did you have occasion
21 to treat Mrs. Lottie Jones?

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A Yes.

Q Would you describe the circumstances whereupon you came about treating her or were going to treat her?

A Mrs. Jones was referred to me by her family physician in Montross with abdominal pain and fever and other symptoms, which we felt represented cholecystitis or gallbladder attack.

She was admitted to the hospital on the 16th of August, 1975, under my care.

Q What treatment was prescribed or given to Mrs. Jones upon her admittance to Mary Washington Hospital on the 16th of August?

A She was placed on bed rest, given intravenous fluids to maintain her hydration, was given antibiotics, and because of the considerable amount of pain, was given pain medicine for that.

Q Did you prescribe any pain medicine for Mrs. Jones on the 18th of August of 1975?

A Yes.

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96.

direct - Thompson

A Yes.

Q Do you recall what it was that you prescribed for her pain?

A A combination of Demerol and Vistaril.

Q Had you used that combination before?

A Yes.

Q Were you present when this particular pain medication was injected?

A No.

Q Did there come a time when something unusual occurred with regard to Mrs. Jones's right buttock?

A Yes.

Q Would you tell us when you become aware of anything unusual and would you describe what that was?

A I was informed, I believe by one of the nurses on the nursing staff, that Mrs. Jones complained of discomfort in her hip. When I come to Mrs. Jones's room and started questioning her, she told me that she was in a lot of pain in her hip after she had received an injection for pain.

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direct - Thompson

1 Q Did she describe that pain that she
2 experienced at that time to you?
3

4 A Yes, she did.

5 Q What type of pain sensation?

6 A I remember her just as describing as
7 very bad pain. Very unusual pain that she was having.

8 Q When was the first time after that
9 particular injection that you saw her right buttock, the
10 area where the injection was administered?

11 A Pardon me?

12 Q After you learned of her problem, when
13 was the first time that you actually saw her right buttock?

14 A It was during that visit to her bedside.

15 Q Do you recall what day that was?

16 A I suppose that it was the morning of the
17 19th.

18 Q Do recall what you saw at that time?

19 A The area of her right bottuck was redish.
20 One area was somewhat hard underneath the skin, warm to the
21 touch. If I remember correctly, there was the beginning of

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98.

direct - Thompson

1 blisters in a small area, and it was tender to the touch.

2 Q What type of treatment, if any, did
3 prescribe?

4 A We prescribed ice packs for the area.

5 Q Could you describe how this injury
6 developed over the following days?

7 A Yes, raised blisters developed in the
8 area of the right buttock. The central area was redish at
9 first and then became purple, more of a purple hue, and
10 then quite dark in the center. This was the beginning area
11 of maybe two or three inches in diameter and it spread in
12 several days into an area the size of the palm of your hand.
13 Later it became quite large. It eventually ruptured and
14 it appeared as though the discoloration beneath the skin
15 was hemorrhaging within the skin. The center of the area
16 became anesthetic to touch. By that I mean that she could
17 not feel my hand examining her.
18

19 Eventually, after about a week
20 to ten days, the whole involved skin became quite dark. It
21 later ruptured.

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direct - Thompson

1
2 Q How would you describe this particular
3 wound in terms of tissue involvement?

4 A The first inkling that I had that this
5 was indeed a very serious injury to the tissue, was the
6 time that I examined the skin and she had no sensation.
7 This indicated that the skin was dead. At least in that
8 area. There was a good possibility that the injury went
9 further than just the skin because of the surrounding
10 swelling and redness and so forth.

11 Q After the ice pack applications or
12 warm compresses, did you perform any further procedure,
13 render any further treatment with regard to the wound, and
14 if so, describe what you did.

15 A It was rather obvious that there was
16 tissue death involved, and it was necessary to remove the
17 dead tissue, and in order for healing to commence, this
18 was done on the 4th of September of 1975. The amount of
19 tissue that was removed was quite large.

20 Q What kind of procedure is that?

21 A It is called "debridement". It simply

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100.

direct - Thompson

means to excise or remove the dead tissue from the living part.

Q Is that classified as an operation?

A Yes, it is.

Q Let me show you three photographs and ask you if these accurately represent Mrs. Jones's wound in the right buttock as you observed it.

A Yes, very accurately.

MR. BURKHOLDER: Your Honor, we have already reviewed the pictures. Please note our exception to them.

THE COURT: Do you want them marked as one exhibit or two, three and four?

MR. PAGE: I'm sorry. Are they going to be marked as one exhibit?

MR. HALEY: It doesn't matter.

THE COURT: They will be marked as two, three -- How many are there?

MR. HALEY: Three.

THE COURT: All right, they will be so

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101.

direct - Thompson

1
2 marked. You should refer to them by number so that
3 the Reporter can get the number.

4 MR. HALEY: I'll give them them to the
5 jury at this time.

6 NOTE: The previously referred
7 to picutures are now being marked and filed by
8 the Clerk of Court as PLAINTIFF'S EXHIBIT TWO.

9
10 BY MR. HALEY: (continuing)

11 Q Dr. Thompson, after the debridement
12 operation that you performed on the 4th of September, did
13 anything further occur with respect to treatment?

14 A There was still some dead tissue, dead
15 tissue in the wound which had to be removed, and this took
16 place on separate occasions after the initial debridement.

17 Q There were further debridements?

18 A Yes.

19 Q Go ahead.

20 A I believe one was on September the 10th.
21 And, on September the 10th, there was a large amount of

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102.

direct - Thompson

1 necrotic or dead tissue that had to be removed again. And,
2 on the 16th of September again. And, I believe on the
3 23rd of September.

4
5 In between these procedures,
6 the wound was cared for in a particular manner. It involved
7 washing the wound. Literally washing out the wound with
8 solutions. We used various packs on it and various ointments.
9 All of this was applied to the wound to prevent germs from
10 getting into the wound. To prevent germs to go into to
11 Mrs. Jones's body through the open wound.

12 Q You are talking about a total of how
13 many debridement operations?

14 A Four.

15 Q Four?

16 A Yes.

17 Q During this period of time, was there
18 any other treatment prescribed?

19 A Yes, about four times a day, I believe
20 three or four times a day, the wound was irrigated, washed
21 out and then packed with gauze. This was done by the nursing
staff who are trained to do this.

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direct - Thompson

1
2 Q The irrigation, the washing out, was
3 done around the clock?

4 A Yes.

5 Q And, for approximately how many days?

6 A Until October 9th.

7 Q Dr. Thompson, did any special precaution
8 have to be taken with regard to Mrs. Jones because of the
9 large wound, the area of the large wound?

10 A Yes. She was placed in Wound Isolation
11 Patient Category, which involves confinement in a private
12 room. She could not go out in the hall or have visitors
13 unless they were properly gowned. This is a routine procedure
14 to protect the patient either postoperatively or preoperatively
15 from hospital infections.

16 Q Did she have the operation that she
17 originally came into the hospital for, the gallbladder
18 trouble?

19 A No, that was done at a later time.

20 Q From the 18th of August, when she re-
21 ceived the injection, through the remainder of her hospital

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direct - Thompson

1 stay, did she have any further trouble with her gallbladder
2 problem?
3

4 A Actually not. To the best of my recollection
5 her gallbladder attacks were fairly well controlled with
6 the appropriate low fat diet. That settled the attacks.
7 This was after the acute attach that she came into the
8 hospital for.

9 Q Were there any other procedures after
10 the debridement procedures?

11 A Yes. On October 9th, 1975, we put a
12 skin graft on the large wound which was now healing and
13 was ready to accept that.

14 Q Was the skin graft done under general
15 anesthesia?

16 A Yes, it was.

17 Q She went to the operating room for that?

18 A That's correct.

19 Q Describe where the skin was taken from
20 and how large an area the skin was that was taken.

21 A The skin was taken from the side of her

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direct - Thompson

1 thigh, the same side as the wound, and it measured approximately
2 twenty by ten inches -- centimeters, something like that.
3 Something of that nature.
4

5 Q Did there come a time that Mrs. Jones
6 was discharged from Mary Washington Hospital?

7 A Yes.

8 Q Do you recall when she was discharged?

9 A I believe around --

10 Q (interjecting) We have the medical
11 records right here.

12 A I don't recollect the exact date.

13 Q We have the medical records here if you
14 want to look at those.

15 NOTE: The previously referred
16 to document is now being handed to the witness.

17 BY MR. HALEY: (continuing)

18 Q While you are looking for that let me
19 ask you another question: Did there come a time when Mrs.
20 Jones later returned to Mary Washington Hospital for the
21 gallbladder operation?

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A Yes.

Q Do you recall when that was?

A That was about the 19th of November of 1975.

Q During the time that she was sent home, after being discharged from the hospital, was she given any particular instructions with regard to the care of her wound?

A Yes. A great deal of care had to be taken. These instructions that were given to Mrs. Jones had to do with protecting the new skin from cuts or abrasions or bruises or any type of injury to the new skin. The new skin is very thin. She also had to be careful not to expose it to heat or direct sunlight for a long period of time. Also, it was necessary to keep the new skin well lubricated, so it wouldn't crack.

Q I don't want to go into the gallbladder operation in great detail. Was that a normal operation?

A That was routine. There was nothing complicated about the gallbladder surgery or the care after the surgery.

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direct - Thompson

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2 Q Did her prior wound, which came about
3 by this injection, did that have any effect on the gall-
4 bladder surgery?

5 A No.

6 Q She essentially had two operations instead
7 of one?

8 A That's correct.

9 Q Have you been able to make a determination
10 as to what caused this wound, this killing of tissue?

11 A I feel, I am sure that is was the result
12 of the injection of the combination of Demerol and Vistaril.
13 One or both.

14 Q Dr. Thompson, let me show you plaintiff's
15 exhibit one, which has been identified as the package insert
16 that came with the Vistaril and that has the revised date
17 of August 1970 on it, and ask you if you recognize that as
18 the package insert that came with the Vistaril?

19 A Yes.

20 Q Do you see any warning or precaution or
21 contraindications anywhere in that insert that describes the

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108.

direct - Thompson

1 risk or the potential risk of the Vistaril coming in contact
2 with subcutaneous tissue?

3 A No.

4 Q That insert only says that it should
5 be injected deep into the muscle or words to that effect, --

6 MR. BURKHOLDER: (interjecting) Counsel
7 is leading the witness.

8 THE COURT: Don't lead the witness.

9 BY MR. HALEY: (continuing)

10 Q Dr. Thompson, let me ask you this: Do
11 you feel, as a physician and a surgeon, that that insert
12 properly informed you as so you can make a determination
13 as to whether or not to use the Vistaril? Do you feel that
14 the warning contained in the package insert is sufficient?

15 A No.

16 Q Why not?

17 A Because I had no personal or first-hand
18 knowledge of a reaction such as Mrs. Jones sustained.

19 Q Mr. Burkholder, in his opening statement,
20 indicated that you have seen or had knowledge of this type
21 of reaction.

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direct - Thompson

1
A Well, I had --

2
Q (interjecting) Had you seen some sort
3 of local reaction if the Vistaril came into contact with
4 subcutaneous tissue?
5

6
A That's correct.

7
Q As of August 1975, what was your under-
8 standing as to the nature of any local reaction that might
9 occur?
10

11
A Occasionally, a patient will complain
12 in the localized area, the site of the injection, of pain
13 and a swelling feeling of a lump that developed there.

14
Q What was your understanding as to the
15 severity of this reaction?
16

17
A Generally, the swelling is limited. It
18 only last for a limited period of time. A short period of
19 time. Only a short period of time is involved. Days, perhaps
20 a week.
21

Q Did you have any idea that a severe
necrotic reaction or a killing of the tissue, as happened
to Mrs. Jones, did you think that something like that could

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110.

direct - Thompson

1
2 come about as a result of using the Vistaril?

3 MR. BURKHOLDER: (interjecting) He has
4 already asked that two or three times. He is
5 leading the witness again. We have already heard
6 the answer.

7 THE COURT: The objection is sustained.
8 Ask a question that requires a specific response.

9 BY MR. HALEY: (continuing)

10 Q Dr. Thompson, what was your understanding
11 as of August 18th -- what was your understanding on August
12 18th with respect to the severity of a possible reaction
13 of the Vistaril coming into contact with subcutaneous tissue?

14 MR. BURKHOLDER: (interjecting) He has
15 already asked that question and the witness has
16 already provided him with the answer.

17 THE COURT: Rephrase the question.

18 MR. HALEY: I don't think I need to go
19 into any further.

20 BY MR. HALEY: (continuing)

21 Q Dr. Thompson, is there any scarring as

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1 a result of Mrs. Jones's wound or any residual effect to
2 Mrs. Jones's wound?

3 A Yes.

4 Q Describe that, please.

5 A Well, after the dead tissue was removed,
6 there was a large scooped-out area which was the open wound.
7 This did not fill in. Something this large fills in to a
8 certain extend. But, after everything was completed, and
9 after she had the skin graft, and several months after that,
10 there is still a concave, a large hole in her right hip.
11 Her right buttock.

12 Q In your opinion, is that a permanent
13 disfigurement?

14 A Yes, it is.

15 Q Dr. Thompson, do you still use Vistaril
16 for your patients?

17 A No.

18 Q When was the last time that you did use
19 it?
20

21 A The 18th of August, 1975.

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112.

direct - Thompson

1 Q Do you use a substitute for Vistaril?

2 A Yes.

3 Q What do you use?

4 A Peragan, generally.

5
6 MR. HALEY: That's all I have.

7 THE COURT: All right, sir.

8
9 CROSS EXAMINATION

10 BY MR. BURKHOLDER:

11 Q Dr. Thompson, I think during one point
12 of your testimony you stated that Mrs. Jones was readmitted
13 for her gallbladder surgery, her wound on her right hip
14 didn't have any effect on that surgery, did it?

15 A It didn't have any effect as to what
16 was done during that surgery or the outcome of it.

17 Q The gallbladder surgery was uneventful?

18 A That's correct.

19 Q This type of surgery requires a certain
20 period of recuperation, does it not?
21

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cross - Thompson

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A Yes.

Q I believe the last time that you saw Mrs. Jones was in May of 1976, insofar as the wound to her right hip was concerned?

A That's correct.

Q At that time, did you determine that although this was permanent, it would not effect her ability to get around and perform her activities?

A That was my impression.

Q Dr. Thompson, you have the copy of the medical record in front of you, and I would like to ask you to refer to that and ask you to briefly go over that. First of all, I would ask you to refer to the table there, and I believe that that is the nurse's notes, are they not?

A Yes.

Q Are these notes that the nurses must record when they administer an injection to a patient?

A That's correct.

Q Do you recognize the entry of August 17th, 1975, indicating that Mrs. Jones received an injection

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114.

cross - Thompson

1 of Demerol and Vistaral intramuscularly?

2 A Yes.

3 Q It is true, is it not, sir, there is
4 no record, to your knowledge, of any unusual or any reaction
5 or ill effect as a result of this reaction?

6 A That's correct.

7 Q Looking to the next page, this would
8 be the nurses's record on the 18th of August.

9 A Yes?

10 Q The 18th of August, I beg your pardon,
11 do you not see that Mrs. Jones received two injections of
12 Demerol and Vistaril?

13 A Yes.

14 Q Now, the first injection that she re-
15 ceived, if I read this correctly, was given at 1:15 in the
16 morning?

17 A Yes.

18 Q Now, as far as you know, based on these
19 records, there was no unusual reaction, ill effect or anything
20 like that from this injection, was there?
21

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cross - Thompson

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A That's correct.

Q The injection that resulted in the complaint of pain, immediately at the time of injection, was given at 2:55 p.m., was it not?

A Yes.

Q Now, that injection was given by Elizabeth Pronovost, was it not?

A That's correct.

Q And, as I understand your conversation with Mrs. Jones, as soon as she received this injection, she felt an immediate sensation of pain?

A That's my understanding, yes. That's my recollection.

Q That is, in fact, reported?

A Yes.

Q There is one other entry, looking about three days later, on the 21st of August, 1975, three days after this combination was injected, Mrs. Jones was again injected with a combination of Demerol and Vistaril, was she not, sir?

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116.

cross - Thompson

1 A I'm sorry, I can't read the copy.

2 MR. BURKHOLDER: May I approach the
3 witness, Your Honor?

4 THE COURT: You may.

5 BY MR. BURKHOLDER: (continuing)

6 Q What does that refer to?

7 A Yes, it says: I.M. medicine given in
8 the arm.

9 Q This refers to an injection of Demerol
10 and Vistaril, does it not?

11 A Correct.

12 Q Based on your examination and your
13 knowledge of these medical records of this case, there was
14 no complaint of pain or any problem with this injection of
15 Demerol and Vistaril, was there?

16 A That's correct.

17 Q And, all of these injections, doctor,
18 were given according to your prescription?

19 A That's correct.

20 Q Let's look at one other entry, would you
21

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117.

cross - Thompson

1 please, referring to your debridement procedure on the
2 4th of September 1975, this is a result of your notes that
3 you dictated as a result of your operation on Mr. Jones?

4 A That's correct.

5 Q And in these notes you described how
6 you excised the dead tissue from the wound site?

7 A That's correct.

8 Q And, this is a note, doctor, in which
9 you state that after you excised all of the dead tissue,
10 you were able to observe what you thought was viable tissue
11 in the wound site?

12 A Yes.

13 Q Now, doctor, do you recall testifying
14 in your deposition, that after all of these debridement
15 rprocedures were completed and after you had excised the
16 necrotic or dead tissue, you were still able to see viable
17 subcutaneous tissue in the wound site?

18 A That's correct.

19 Q And that means, doctor, and, correct
20 me if I am wrong, during no time did this wound extend or
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118.

cross - Thompson

1 expose that line on top of the muscle called the fascia?

2 A That's correct also.

3 Q At no time did this wound extend down
4 deep enough that the muscle was involved?

5 A Correct.

6 Q Now, doctor, you had had as of the
7 18th of August, 1975, when you prescribed the Vistaril,
8 you had had a lot of experience with the drug, had you not?

9 A Yes.

10 Q And, you did not have any problems with
11 the drug up to the 18th of August, had you?

12 A That's correct.

13 Q And, this was, and I don't want to push
14 you too far, this was the only prescription drug that you
15 used as a surgeon to relieve pain and anxiety?

16 A That's correct.

17 Q There is no question, doctor, is there
18 that as of the 18th of August, 1975, that you were familiar
19 with the package insert which was right next to you?

20 A Yes.

21

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119.

cross - Thompson

1 Q And, you knew back on the 18th of August,
2 1975, that under no circumstances was an injection of
3 Vistaril to be put into sucutaneous tissue?

4 A That's correct.

5 Q And, you also understood, doctor, what
6 was supposed to be done when the Vistaril was used that
7 it should be injected, and we are talking about the buttock
8 area, that it should be injected deep enough to go through
9 the fascia, go all the way through the subcutaneous tissue,
10 go through the fascia and deep into the muscle, is that
11 correct?

12 A That's right.

13 Q Now, it is true, is it not, doctor,
14 that you testified when we had the opportunity to get to-
15 gether for your deposition, that after this occurred, you
16 formed an opinion, you had decided in your mind that the
17 cause of this problem was that the Vistaril and the Demerol
18 that was injected had been put completely into the subcutaneous
19 tissue?

20 A I had concluded that the Demerol and
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120.

cross - Thompson

1 the Vistaril, all or part of it, had caused the problem in
2 the subcutaneous tissue.

3 Q And, the reason this caused the problem,
4 Dr. Thompson, as reported in your deposition, that this
5 probably caused the problem was that this injection was
6 completely placed within the subcutaneous tissue and not
7 into the muscle?

8 A That's correct.

9 Q And, what you are basically saying
10 there, doctor, is that for whatever reason --

11 MR. ROBERTS: (interjecting) I don't
12 object to him using the deposition if he is going
13 to impeach the witness. The witness is agreeing
14 with his previous testimony.

15 MR. BURKHOLDER: I am trying to cross
16 examine this witness.

17 THE COURT: Just ask him without the
18 transcript unless you need to impeach him. Test
19 his memory.
20
21

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121.

cross - Thompson

1
BY MR. BURKHOLDER: (continuing)

2 Q And, what you have just told me, Dr.
3 Thompson, is that after your examination of Mrs. Jones you
4 decided that for whatever reason, that this combination
5 of Vistaril and Demerol had been injected by the nurse not
6 where it was supposed to have gone, but that it had been
7 injected into the subcutaneous tissue, is that correct?
8

9 A I concluded that the combination of
10 the drugs, all or part of it, had gotten into the subcutaneous
11 tissue, that's correct.

12 Q Thank you doctor. And, do you also
13 feel that if the drug had been injected into the muscle,
14 where it should have gone and where the other three injections
15 must have been, that she would not have had any problem?

16 A That's correct.

17 Q Dr. Thompson, would it be fair to say
18 that all drugs contain a potential for causing serious
19 and severe problems if they are not used in accordance with
20 the instruction contained in the package insert?

21 A Yes.

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cross - Thompson

1 Q Would it also be fair to say, doctor,
2 that you, as the prescribing physician, rely not only on
3 the package insert when prescribing drugs, but, obviously,
4 rely also on your medical experience obtained in medical
5 school and on the job?

6 A That's correct.

7 Q Now, you had not had any first-hand
8 experience with any reaction of any sort with Vistaril at
9 the time of the injection, had you, sir?

10 A Not specifically that I can recall per
11 patient name.

12 Q But, you had heard, had you not, Dr.
13 Thompson, and I don't mean from some other doctor that you
14 had spoken to at Mary Washington Hospital, but as a result
15 of either medical school or reading publications, by word of
16 mouth or otherwise, you had heard of reported irritations
17 to the subcutaneous tissue when the Vistaril was not put in
18 the right spot?

19 A That's true.

20 Q And, you knew when prescribing this drug,
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cross - Thompson

1 Dr. Thompson, that this one of the drugs, one of a number of
2 drugs, that could cause some sort of problem if it got into
3 subcutaneous tissue and didn't get into the muscle, didn't
4 you?

5 A That's correct.

6 Q Although you had not seen it, you didn't
7 have any direct experience with it, is it not also true
8 that you were aware; from any source whatsoever, that
9 tissue necrosis could result if the Vistaril inadvertently
10 was injected into the subcutaneous tissue?

11 A Yes.

12 MR. BURKHOLDER: Thank you very much,
13 doctor.

14 THE COURT: Do you have anything on
15 redirect?

16 MR. HALEY: We have no further questions.

17 THE COURT: Is there any reason to keep
18 the doctor?

19 MR. HALEY: No, Your Honor.

20 MR. BURKHOLDER: None.
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124.

direct - Smith

THE COURT: All right, sir, you may be
excused.

WITNESS STOOD ASIDE

THE COURT: All right, call your next
witness.

MR. HALEY: Dr. Peter Smith.

PETER R. SMITH, M.D., a
witness, being called for examination by counsel
for the plaintiff, first being duly sworn, testified
as follows:

DIRECT EXAMINATION

BY MR. HALEY:

Q Dr. Smith, please state your full name
and occupation, sir.

A Dr. Peter R. Smith, physician.

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125.

direct - Smith

Q Do you have a medical specialty?

A Yes, I am boarded in internal medicine and in Allergy immunology.

Q Where do you practice medicine?

A I practice medicine at the Pratt Clinic, Limited, in Fredericksburg, Virginia.

Q Are you also a member of the staff at Mary Washington Hospital?

A Yes, I am chief of the medical staff at Mary Washington Hospital.

Q Would you describe your educational background, and particularly with attention to your medical training?

A I was graduated from the University of Rochester, Rochester, New York in 1965. Following this, I went to Case Western University in Cleveland, where I spent five years with a straight medical internship. I had three years of internal medicine, residency at Case Western Reserve, and a year and a half of allergy immunology fellowship. Following this, I was head of the Allergy

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126.

direct - Smith

1 Department at the Bethesda Naval Hospital, serving there for
2 two years, and following that, in the summer of 1972, I
3 came to Fredericksburg and have been here since.

4 Q How long have you been on the staff of
5 Mary Washington Hospital?

6 A Since coming to Fredericksburg in June
7 or July of 1972.

8 Q Did you have occasion to see Mrs. Lottie
9 Jones in August or September of 1975?

10 A Yes, I did.

11 Q Could you tell us how you came to see
12 Mrs. Jones?

13 A I was asked to see Mrs. Jones on consultation
14 on August 22, 1975. I was asked by Dr. Thompson, who was
15 her attending physician and surgeon at that time.

16 Q Would you describe what you saw when you
17 examined Mrs. Jones?

18 A I was asked to see Mrs. Jones to give
19 my opinion regarding the cause or ideology of a lesion that
20 was present on her right buttuck or hip. Excuse me, do you
21

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direct - Smith

1 want me to describe the lesion or go into the history?

2 Q Describe the lesion.

3 A All right. I saw Mrs. Jones on, I believe
4 in the afternoon of August 22nd, and at that time the
5 lesion was approximately five to seven inches in size and
6 consisted of separate lesions, several of which were
7 hemorrhagic or blood filled with bullae or blisters. These
8 blisters varied in size from several centimeters to --
9 or one and a half inches to three or four inches. Several
10 of the blisters had ruptured, leaving an area of erythematous
11 basis, which means that there was redness and the area
12 was hard, indicating swelling beneath the skin, and indicating
13 that there was some inflammation extending beneath the skin.
14 There was no sign of secondary inflammation, no sign of pus.

15
16 The patient, at that time
17 was running a low grade fever since her admittance to the
18 hospital. There was no increase in her temperature.

19 Q In your investigation, did you reach
20 any conclusion as to the cause of this problem?

21 A There was no specific investigation

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128.

direct - Smith

1 conducted. It was a matter of examination, primarily, and
2 then determining from my examination and review of the
3 records, in terms of medication received, and then make
4 the determination how I felt the lesion came about.

5
6 There were no specific tests
7 that could be run in the lab that would help in making
8 a decision in this regard.

9 Q Do you recall calling the drug company,
10 Pfizer?

11 A Yes, I do. On seeing the patient and
12 taking the history and reviewing the record, it was apparent
13 that the patient, on the 18th of August, received an injection
14 of a combination of Demerol, 75 mg and Vistaril, 50 mg.
15 She had received injections of the same combination prior to
16 the injection in question, and had received an injection
17 since the injection in question. It was my feeling that the
18 lesion that I examined was related in some way to the
19 injection that she had received. I did not know in what way
20 it was related. I was not sure of a clear cause or ideology
21 or whether it represented toxic cause.

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129.

direct - Smith

1 I then contacted, that after-
2 noon, Pfizer Drug Company and talked to Dr. Walmsley on
3 their staff, who is their physician representative, and
4 discussed the case with her.

5 Q What was the substance of that conversation?

6 A As I recall, the history was presented,
7 the fact that the patient had received an injection of
8 a combination of Demerol and Vistaril, had received prior
9 ones and one since. That there was a lesion, and I described
10 that. At that time, she, Dr. Walmsley, asked as to the
11 technique of injection. Dr. Walmsley in fact asked whether
12 the Z-tract had been used. I was familiar with the Z-tract
13 technique. At that time, I told Dr. Walmsley that I was unsure
14 as to whether or not it had been used.

15 We then continued the conversation
16 and Dr. Walmsley added that she had, indeed, in her files,
17 several reports of toxic, necrotic reactions which occurred
18 when the Vistaril had inadvertently been injected into the
19 subcutaneous tissue. Whether this occurred by leak-back
20 or direct injection was not made clear. In the cases reported,
21

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direct - Smith

1
2 she mentioned to me that it was her feeling, her impression
3 that -- it was my impression --

4 MR. PAGE: (interjecting) I object to
5 him testifying about the impression that he got.
6 I don't think that he is entitled to testify about
7 his impression. He can tell what Dr. Walmsley said.

8 THE COURT: The objection is sustained.
9 Just testify as to what she told you.

10 THE WITNESS: As I recall, she told me
11 that the Vistaril was most likely the cause of
12 the reaction in question and it probably came
13 from inadvertently injection the material, Vistaril,
14 into the subcutaneous tissue. And that, in essence,
15 was the substance of the conversation at the time.

16
17 BY MR. HALEY: (continuing)

18 Q I show you a letter and ask you if this
19 is a copy of a letter that you received?

20 A Yes. This is a letter from the Pfizer
21 lab. New York, New York, dated August 29th, 1975.

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131.

direct - Smith

Q To whom is the letter addressed?

A The letter is addressed to me from
Dr. Walmsley.

Q Is this a copy of a letter that you
actually received?

A Yes, it is.

MR. HALEY: I tender this as plaintiff's
exhibit five.

NOTE: The previously referred
to document is now being marked and filed by the
Clerk of Court as PLAINTIFF'S EXHIBIT NUMBER FIVE.

BY MR. HALEY: (continuing)

Q Dr. Smith, let me show you plaintiff's
exhibit one which is a Pfizer package insert that accompanied
the pack of Vistaril that was used for this particular
injection in question of August 18th, 1975, and ask you to
review that for a moment, sir.

NOTE: The previously referred
to document is now being handed to the witness.

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Circle 344-3444

10-104-1011

1 BY MR. HALEY: (continuing)

2 Q Dr. Smith, what is your opinion as to
3 the sufficiency of the warning in the package insert?

4 A Regarding what? Just sufficient warning
5 or regarding any potential side effects or anything --

6 MR. PAGE: If he is able to rephrase
7 the question, maybe the doctor can respond to it.

8 THE COURT: Make your question more
9 specific.

10 BY MR. HALEY: (continuing)

11 Q Do you feel that the warning therein
12 contained is adequate or not so to enable you, the physician,
13 to make a determination as to whether you should use this
14 drug with a particular patient?

15 A I think that there is a need for more
16 information, and this particular revised sheet of August
17 1970, my feeling is that there is not sufficient regarding
18 the potential danger regarding -- in terms of what kind of
19 reaction could follow if the drug is not injected into the
20
21

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direct - Smith

1 muscle, if the drug should come into contact with subcutaneous
2 tissue, either by way of leak-back or otherwise. There is
3 mention that it should be given intramuscularly, no mention
4 as to why.

5
6 Secondly, I think that there
7 should be a special warning regarding obese patients. It
8 is virtually impossible, in many cases, to get intramuscular
9 medication into the muscle in certain patients. They made
10 no mention that that precaution be taken in use of this
11 drug for obese patients.

12 I guess that that is about
13 all the information that I feel is deficient.

14 Q Now, do you presently use the drug
15 Vistaril for your patients?

16 A I do.

17 Q Would you tell us under what circumstances
18 you do?

19 A I use Vistaril, primarily, by mouth in
20 using the antihistaminic properties, meaning antiallergic
21 to histamines, relieving itching due to hives, occasionally

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direct - Smith

1 for sedation for a patient who is sensitive to narcotic
2 type drugs. I use it primarily in that regard. I do not
3 use it by I.M. prescription, intramuscularly at this point
4 unless I feel that the patient can not use or take the
5 other drugs that I use. There are other drugs that can be
6 used.

7 MR. HALEY: Your witness.

8
9 CROSS EXAMINATION

10 BY MR. PAGE:

11 Q Now, Dr. Smith, I am particularly
12 interested in your last answer. Perhaps it would be best
13 to go over some material in the medical records. As I under-
14 stand it, there is some warning in the package insert, which
15 I believe is plaintiff's exhibit one, that would draw attention
16 to the person who is injecting Vistaril, but as I understand
17 your testimony, special care should be taken with obese
18 patients, is that correct?

19 A That is correct.

20 Q Now, you would conceive, would you not,
21 if the nurse who injected that Vistaril was already aware

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cross - Smith

1 of that fact and so testified, that wouldn't make any
2 difference, would it?

3 A Would you rephrase your question?

4 Q Yes, I will. You would concede, would
5 you not, that you wouldn't need the warning with a nurse
6 who has already used extra care in placing the injection
7 intramuscularly into an obese patient, that extra care
8 has to be taken in injecting Vistaril Intramuscular Solution
9 into an obese patient?

10 A I think that there should be something
11 in that circular as a reminder to anyone who injects the
12 drug. I think that that warning should be there.

13 Q Doctor, I take it that you are on the
14 staff at Mary Washington Hospital?

15 A Yes.

16 Q Do you know how familiar the nurse who
17 injected the Vistaril into Mrs. Jones on the 18th of August,
18 1975, was , how familiar she was with injecting drugs intra-
19 muscularly, not only Vistaril but also other intramuscular
20 drugs?
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136.

cross - Smith

1 A I do not know how familar she was, no.

2 Q But, you do know that a nurse who is
3 familar with that procedure does not read the insert each
4 time that she makes an injectiong, don't you?

5 A No, she does not.

6 Q My question is: Once the nurse understands
7 it, that extra care should be taken in injecting intra-
8 muscular solutions, including Vistaril, into obese patients,
9 putting it into the package insert is not going to make
10 any difference, will it?

11 A I think that it will help. The first
12 time that she gives the Vistaril, she wouldn't know.

13 Q Let us focus on this particular injection.
14 I would like for you to assume, first, that there is testimony
15 that she was familar with injecting Vistaril and other
16 intramuscular solutions, that she did in fact use extra care --
17 that she did in fact knew that extra care had to be taken
18 when injecting an obese patient, can you assume those facts?

19 A If she in fact said that, I can assume
20 it.
21

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cross - Smith

1
2 Q Given those circumstances, you would
3 agree, would you not, that it is not necessary to have
4 that warning in the package insert for that nurse with
5 respect to that injection, wouldn't you?

6 A If she is familiar with the technique
7 of given the injection, assuming that she understands
8 what the consequences are, with the full realization that
9 the kind of reaction that we are discussing could occur.
10 I am not so sure that the nurse in question could have
11 fully understood this. I don't know this.

12 Q But, you don't know that. And, if you
13 will assume for a minute with me that she did understand
14 that, understand that extra care or particular care had
15 to be taken when injecting an obese patient, you would agree,
16 would you not, that you did not have to say to that nurse
17 that particular care in injecting an obese patient had to
18 be taken?

19 A In working in a hospital ward, you are
20 absolutely correct. You cannot warn about every drug and
21 every possible complication.

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138.

cross - Smith

1 Q Thank you, doctor. Now, doctor, I would
2 like to, if I could, get into the record more about your
3 profession. As I understand your practice, your specialty
4 is allergies, is that correct?

5 A Yes, that is correct.

6 Q But, you practice general medicine?

7 A I am a general practitioner in internal
8 .medicine.

9 Q Do you do surgery?

10 A No, I do not.

11 Q And, as I also understand the testimony,
12 you saw the plaintiff on the 22nd of August of 1975, is
13 that correct?

14 A That is correct.

15 Q And, it is my understanding that that
16 is the only time that you saw the patient in that consultation
17 basis, is that correct?

18 A I did see the patient on an informal
19 follow-up. In terms of consultation, that was the only visit.

20 Q But, you saw her as a physician only
21 one time?

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cross - Smith

1 A That is correct.

2 Q And, at the time that you called Dr.
3 Walmsley, you had only seen the patient once, is that correct?
4

5 A That's correct.

6 Q And, at that time you could not be sure
7 that a necrosis had in fact occurred.

8 A No, I could not.

9 Q You didn't tell Dr. Walmsley that a
10 necrosis had occurred?

11 A I don't recall.

12 Q You don't recall that you did?

13 A I don't recall that I did.

14 Q I believe that you have already testified
15 that it was your opinion that Mrs. Jones's problem was re-
16 lated to an injection of a combination of Demerol and
17 Vistaril, is that right?

18 A That is right.

19 Q Now, do you recall, without reviewing
20 the records, the amount of these dosages?

21 A As I recall, it was 75 mg of Demerol and
50 mg of Vistaril.

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140.

cross - Smith

Q Demerol and then Vistaril?

A That is correct.

Q And, these two drugs are administered
or combined in one syringe?

A That is correct.

Q And, that was your understanding of
how is was given to this patient?

A That is my understanding.

Q I think that you have also testified
that you believe that Vistaril Intramuscular Solution is
a viable agent for preoperative medication to go along
with a narcotic because it allows you to reduce the amount
of the narcotic and for a number of other reasons?

A Yes.

Q You would agree with that, would you
not?

A Yes.

Q You are also aware, are you not, that over
fifty million doses of Vistaril have been injected into
patients all around the United States in the last eighteen
years?

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A I assume there has been.

Q Many, many doses of Vistaril have injected here in Fredericksburg at Mary Washington Hospital since you have been here, isn't that correct?

A That is correct.

Q Have you seen any other instances of tissue necrosis resulting from Vistaril since you have been here?

A No, I have not.

Q You also knew, did you not, that prior to the time that the Demerol and Vistaril was injected into Mrs. Jones on the 18th of August, 1975, at 2:55 p.m., that she had received two other injections of the combination of Demerol and Vistaril, 50 mg of Vistaril and 75 mg of Demerol, did you not?

A Yes, she had.

Q And, are you aware that there had been no adverse reaction or problem relating to those dosages?

A I am aware of that.

Q Are you also aware that subsequent to

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142.

cross - Smith

1 the injection that is the complaint in this case, Mrs. Jones
2 in fact received a fourty injection of Demerol and Vistaril
3 from which there was no reaction or ill effect, isn't that
4 correct?

5 A That is correct.

6 Q Now, I think that you have also previously
7 testified, and correct me if I'm wrong, that you believe
8 that it is impossible to give an opinion as to whether or
9 not Mrs. Jones's problem resulted from an injection into
10 the muscle and then leaked back or from an injection into
11 the subcutaneous tissue, which is in effect between the
12 skin and the muscle, is that correct?

13 A I have so testified.

14 Q That is your opinion today, is it not?

15 A That is my opinion today.

16 MR. PAGE: I wonder if I could have
17 exhibit one, please. May I approach the witness,
18 Your Honor?

19 THE COURT: You may.
20
21

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143.

cross - Smith

1 BY MR. PAGE: (continuing)

2 Q You will see on this package insert
3 that there are a number of notations that are called to
4 the doctor's attention. First of all, would you read the
5 top three lines beginning with Vistaril --

6 A (interjecting) Yes. It says that it
7 should be used intramuscularly.

8 Q What does it tell you about Vistaril
9 and where it is suppose to go?

10 A It implies that it is to used intra-
11 muscularly.

12 Q It says that it is to be used that way
13 under all circumstances, is that correct?

14 A That is correct.

15 Q And, that is in writing at the top in
16 big bold black print?

17 A Yes.

18 Q Now, something that has been bothering
19 me a little bit, I don't really know, doctor, I am not an
20 expert in how our body is layed out, and probably bothers
21

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144.

cross - Smith

1 the jury as well. I would like for you, if you could, walk
2 in front of the jury and on my yellow paper, sketch out
3 for them the hip area as though you look at it from a
4 cross section, and tell us what you mean by skin, subcutaneous
5 tissue, the fascia and the muscle. Would you do that for me?

6 A You want the skin, the subcutaneous
7 tissue, the fascia and the muscle?

8 Q That's right.

9 NOTE: The witness now approaches
10 the jury and appears to be drawing.

11 BY MR. PAGE: (continuing)

12 Q Doctor, I note that you abbreviated
13 subcutaneous tissue, the fatty tissue, I would like for you
14 to write that out so that when people read this in the
15 future, they will know what we are talking about.

16 NOTE: The witness now appears
17 to be writing.

18 BY MR. PAGE: (continuing)

19 Q Before you explain this to the jury, I
20 would like for you to sign your name in the right hand corner,
21 if you would.

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145.

cross - Smith

NOTE: Witness now appears to
be writing.

MR. PAGE: I am going to introduce this
into evidence, Your Honor. If I could, I would
like to have this diagram that the doctor just
drew introduced into evidence. If I could, I would
like to have my pad back.

MR. ROBERTS: You can have your pad back.

THE COURT: Any objections?

MR. ROBERTS: No objections.

THE COURT: It will be so marked and
admitted.

NOTE: The previously referred
to document is now being marked and filed by the
Clerk of Court as DEFENDANT'S EXHIBIT NUMBER ONE.

BY MR. PAGE: (continuing)

Q Now, doctor, I would like for you, if
you would, take defendant's exhibit one and stand before
the jury and explain to them where the muscle is, where
the subcutaneous tissue is, and where the skin is that

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146.

cross - Smith

1 covers the subcutaneous tissue, and where the fascia is.

2
3 NOTE: Witness now approaches
4 the jury.

5 THE WITNESS: This is the hip as the
6 patient would be laying on the side. This elevation
7 is the skin. The skin being the first layer. Now,
8 if one were to give an intramuscular injection,
9 one has to go through the skin, right here, through
10 the subcutaneous tissue, right here, through the
11 fascia, right here, into the muscle, right here.
12 (witness indicating) The fascia is what covers
13 the muscle. The injection would have to go into
14 the body of the muscle, which is indicated by the
15 striped area.

16 BY MR. PAGE: (continuing)

17 Q Before you sit down, so that I am clear
18 as to where the needle would go in this diagram, you put
19 the needle first through the skin?

20 A That is correct.

21 Q Then through the subcutaneous or fatty

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147.

cross - Smith

1 tissue as you have labeled it here on this, then into and
2 through the fascia on into the muscle, is that correct?

3 A That is correct.

4 Q And, as I understand it, with Vistaril
5 Intramuscular Solution, you push the needle down into the
6 fatty tissue, down into the fascia and then deep into the
7 muscle as you inject the material, is that correct?

8 A That is correct.

9 Q I think that that takes care of my
10 exhibit number one. If you will pass that around to the jury?
11 Then I will resume my examination, doctor.

12 NOTE: The witness returns

13 to the witness stand. The exhibit is now being
14 passed to the jury.

15 BY MR. PAGE: (continuing)

16 Q Now, doctor, returning again to plaintiff's
17 exhibit number one, the package insert for Vistaril Intra-
18 muscular Solution, I would like for you to look down at the
19 third category, again in big bold black print, where it says
20 "Contraindications", and ask you what contraindications
21

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cross - Smith

1 means, what your understanding is as to what it means?

2 A To mean that these are indications
3 under which the drug should not be used.

4 Q Now, I would like for you to read to
5 the jury -- Do you understand, first of all, that Vistaril
6 is the tradename for hydroxyzine hydrochloride?

7 A I do.

8 Q Now, I would like for you to read the
9 first contraindication that you see on that package insert
10 which is plaintiff's exhibit number one, to the jury.

11 A "Hydroxizine hydrochloride intramuscular
12 solution is intended only for intramuscular administration
13 and should not, under any circumstances, be injected
14 subcutaneously, intra-arterially or intravenously."

15 Q What do you understand this to mean when
16 it says that it should not, under any circumstances be in-
17 jected subcutaneously?

18 A I understand it to mean that the drug
19 should not be injected subcutaneously.

20 Q And, that means that it should not be
21

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cross - Smith

1 injected into the area that you have described as subcutaneous
2 or fatty tissue?

3 A That is correct.

4 Q And, as I understand your testimony,
5 you have used Vistaril Intramuscular Solution from time to
6 time on your own patients?

7 A Yes, I have.

8 Q And, you are familiar with the package
9 insert?

10 A Yes.

11 Q You are familiar enough to know that it
12 says not to inject it or it should not be injected into
13 subcutaneous tissue.

14 A Yes.

15 Q And, you knew prior to August the 18th,
16 1975, that under no circumstances should the Vistaril be
17 injected subcutaneously, did you not?

18 A I did.

19 Q Now, the next large heading on this
20 package insert is entitled "Precautions". Would you read
21 that for the record?

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cross - Smith

1 A Are you speaking of this? (indicating)

2 Q I am talking about the large heading
3 after "Contraindications". What is the next large heading?

4 A "Precautions".

5 Q What does precaution mean to you as a
6 physician?

7 A To me it would mean that special care
8 should be given under certain circumstances, depending
9 on what is discussed beneath it.

10 Q And, as you continue on the second
11 page of -- or the back of plaintiff's exhibit number one,
12 the package insert for Vistaril Intramuscular Solution, and
13 you come down to the third paragraph, what do you see there
14 still headed under "Precautions"?

15 A "As with all intramuscular preparations,
16 Vistaril Intramuscular Solution should be injected well
17 within the body of a relatively large muscle."

18 Q That would mean to you that extra care
19 should be taken when given an injection of Vistaril to insure
20 that it gets directly into the body of a relatively large
21 muscle?

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151.

cross - Smith

1 A As with all I.M. solutions, yes.

2 Q And, as you said, I believe, to you
3 that means that extra care should be given?

4 A Yes.

5 MR. PAGE: Again, Your Honor, I would
6 be more than happy to pass this to the jury, but
7 perhaps it would be better to wait until the
8 jury goes to the juryroom.

9 THE COURT: It is too distracting now.

10 MR. PAGE: Very well; Your Honor.

11 I wonder if I could have the last exhibit that
12 was offered by the plaintiff, I believe that was
13 exhibit number five.

14 BY MR. PAGE: (continuing)

15 Q You have indicated to me, I think, that
16 it is impossible to form an opinion as to whether the
17 Vistaril that was injected into Mrs. Jones at 2:55 p.m. on
18 the 18th of August of 1975, was injected subcutaneously or
19 into the muscle, is that correct?

20 A That is correct.
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152.

cross - Smith

1 Q Directly into the muscle or into the
2 subcutaneous tissue?

3 A That is correct.

4 Q Would you be able to assume with me
5 for just a moment that if the Vistaril was injected directly
6 into the subcutaneous tissue, it would not have made any
7 difference whether or not the warning that you spoke about
8 would have been contained in the package insert, it would
9 not have made any difference?

10 A Would you rephrase the question?

11 Q If you would assume, please, that the
12 Vistaril and the Demerol that had been injected into Mrs.
13 Jones at 2:55 p.m. on the 18th of August of 1975, was in
14 fact injected subcutaneously, into the area of the fatty
15 tissue, it would not have made any difference whether you
16 used the Z-tract technique or not?

17 A Well, that is a different question.
18 Yes, if the Z-tract method had been used and the injection
19 was given into the subcutaneous tissue, you would get a
20 reaction.
21

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cross - Smith

1 Q Thank you. My question was that it would
2 not make any difference what technique is used if in fact
3 you put it into the subcutaneous tissue instead of into
4 the muscle, is that correct?

5 A That is correct.

6 Q Mr. Roberts has introduced this letter,
7 and I would like for you to read the third paragraph in
8 that letter, the letter from Dr. Walmsley to you, dated
9 August 29th, 1975, which is plaintiff's exhibit number
10 five.

11 A "Since we are required to obtain as
12 much information as possible concerning adverse reactions
13 associated with our product, if you could complete the
14 product experience form, and provide us with that information,
15 we will be able to record a detailed report of the reaction
16 to the Vistaril. That information, of course, is confident.
17 Please keep a copy for your file and provide us with a copy
18 for ours."

19 Q Did you in fact make such a report and
20 return it to Dr. Walmsley?
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154.

cross - Smith

1 A I could not recall.

2 Q You don't know whether you did or not?

3 A That is correct.

4 Q I would like, Dr. Smith --

5
6 MR. PAGE: Judge, I would like to tender
7 the medical records of Mrs. Jones into evidence.
8 The records that were stipulated to be the actual
9 medical records of Mrs. Jones. I would like to
10 tender these as defendant's exhibit number two.

11 MR. ROBERTS: I thought that they had
12 already been admitted.

13 THE COURT: Actually, not. They will
14 be marked and filed as defendant's exhibit number
15 two. They have been stipulated to.

16 MR. ROBERTS: The bill should be likewise.

17 MR. PAGE: These are our exhibits. You
18 can tender the bill yourself, if you want to.

19 MR. ROBERTS: All right.

20 THE COURT: They will be marked as
21 defendant's exhibit number two.

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155.

cross - Smith

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to documents are now being marked and filed by
the Clerk of Court as DEFENDANT'S EXHIBIT NUMBER
TWO.

BY MR. PAGE: (continuing)

Q Dr. Smith, I am going to offer to you
what has been marked as defendant's exhibit number two, and
ask you, if you would, Dr. Smith, turn to what has been
tabled as your consultation report on Lottie Jones.

NOTE: A documents is now
being handed to the witness.

BY MR. PAGE: (continuing)

Q Do you have that now?

A Yes.

Q Does this report reflect, doctor, what
in effect you wrote as a result of your professional con-
sultation with Mrs. Jones?

A It does.

Q And, I take it that when you said that

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cross - Smith

1 you went in to see her that you in fact were with her, is
2 that right?

3 A That is right.

4 Q What is the date of this report?

5 A August 22nd, 1975.

6 Q That is four days after the combination
7 of Demerol and Vistaril was injected that is the complaint
8 of this particular litigation, is that right?

9 A That is correct.

10 Q This is before you actually talk with
11 Dr. Walmsley, is that correct?

12 A I believe that I saw Mrs. Jones, called
13 Dr. Walmsley and came back and wrote the report.

14 Q You had seen Mrs. Jones before you
15 wrote this, and you talked with Dr. Walmsley, that being
16 your best recollection, before you wrote this?

17 A That is correct.

18 Q Looking at the secon sentence in the
19 report, you wrote that she experienced pain immediately
20 at the time of the injection. Is that what you wrote?
21

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157.

cross - Smith

1 A That is what I wrote.

2 Q To your best recollection, is that what
3 she told you when you came in to consult with her with
4 respect to the injury that she complained of?

5 A That is correct.

6 Q Did you write this as a quote from her?

7 A I don't recall. I used that as my under-
8 standing.

9 Q On the same day that you were called
10 to consult and examine her, there was another doctor who
11 went with you, wasn't there?

12 A Did not go with me. I think that Dr.
13 Schwartz, a dermatologist, was consulted regarding his
14 opinion.

15 Q Do you know whether or not he was?

16 A I believe he was, yes. |

17 Q And, finally, doctor, you have been called
18 today as an expert witness to give testimony regarding the
19 package insert, were you paid for your testimony?

20 A Yes.

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161.

direct - L. Jones

[LOTTIE MINOR JONES, the Plaintiff, being called for
examination by counsel for the plaintiff, first
being duly sworn, testified as follows:]

* * *

Q Where was the injection administered?

A In my right hip.

Q Did you make any complaint to the nurse
who gave you the injection?

A No. I did not know what to do, I began to
cry.

Q What transpired next?

A The nurse came around right at the end
of changing nurses, and asked me what in the world happened

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162.

direct - L. Jones

1 to my hip. I showed it to her. And it had begun to turn
2 blue or red. The muscle cramps were so severe, I could
3 hardly bear it, and the burning sensation.

4 Q When did this pain start?

5 A Soon after the shot.

6 Q What do you mean by "soon"?

7 A As soon as the shot was over. The nurse
8 left, and the paing began.

9 Q When did you next see a doctor with
10 regard to your right hip?

11 A The next morning. But, the nurse
12 contacted a doctor, and immediately, ice was put on my hip.

13 Q Now, I want you to look at these pictures
14 which have already been introduced as a plaintiff's exhibit,
15 do you know who took those pictures?

16 A My husband.

17 Q As you recall, it was the next morning
18 that you saw a doctor?

19 A Yes.

20 Q Was that Dr. Thompson?
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163

direct - L. Jones

1
2 A Yes.

3 Q How did your hip area feel then, and
4 what sort of treatment did you undergo, if any?

5 A Well, at that time I had ice packs to it,
6 and after he came, it was changed and some heat was added
7 to the area.

8 Q Did it get better or did it get worse?

9 A Worse, much worse.

10 Q In what way?

11 A Well, it began to get black. It began
12 to blister. It was painful. I could hardly bear for the
13 compresses. If they even touched in any way, it was just
14 unbearable.

15 Q Was anything unusual done with regard
16 to treating this wound or with regard to your reaction to
17 the injection that you had received?

18 A Well, Dr. Thompson finally told me that
19 my tissue had died. That it had to be removed.

20 Q What did Dr. Thompson do to treat this
21 wound?

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164

direct - L. Jones

1
2 A Well, after he found out what he had to
3 do, he had to go even further and remove more tissue.

4 Q Did you continue to have problems with
5 your gallbladder?

6 A No, I was put on a very strict diet, and
7 I didn't have any pain from the gallbladder.

8 Q Were you placed in a special room at
9 the hospital or anything like that?

10 A Yes, that was after my operation on
11 my hip.

12 Q Which operation are you talking about?

13 A I'm talking about when he removed the
14 tissue. The dead tissue.

15 Q The first time?

16 A Yes.

17 Q And, what was your experience in that
18 room like?

19 A Horrible.

20 Q Why?

21 A I didn't see anybody, only the nurses.

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165.

direct - L. Jones

I couldn't even have the nurse's aid get me to bring me
a drink of water --

* * *

* * *

BY MR. HALEY: (continuing)

Q Please go ahead.

A Well, the gray ladies that come around
and bring you drinks and little extras that you look forward
to, they had to pass my room each time, because the gray
ladies were not able to come into my room. The only way
that I would get something extra would be if my husband would
bring it to me. You know, whatever type of drink I was
allowed to have, and then the nurses would see to it that

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direct - L. Jones

1 I had a pitcher of ice and cups, and I would fix my own
2 drinks. I wasn't able to get any magazines of the carts
3 that come around, because I was not able to go out of my
4 room and they could not come into my room. My mail was
5 delivered, if a nurse was not available or around, they
6 would slide under the door in my room and I was a bed patient.
7 I couldn't get my mail. I would have to ring and wait for
8 a nurse to come and give me my mail.

9 Q Tell the members of the jury what this
10 debridement procedure was like.

11 A Yes, --

12 Q (interjecting) The first operation that
13 you told us about.

14 A You mean each time in my room?

15 Q Yes.

16 A Well, each time he came into my room
17 and Dr. Thompson had to trim the debris. Before he started,
18 there was a certain type of odor that you get when your
19 skin begins to die. It's an odor that comes from my body.
20 It really belonged to my body. It was long before I realized
21

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167.

direct - L. Jones

1 that it was my own body that that odor came from.

2 Q Describe that odor.

3 A Well, if you ever smelled anything that
4 is dead, that's all I can say. The odor was the worst part
5 of it. My body was warm, that kept the odor even stronger,
6 I guess. That was that way every time he had to trim. He
7 would give me something but not much. Because each time
8 he would trim I would tell him that it hurt so bad, and
9 then he would realize that he was getting down to the live
10 tissue. Then they would wash it all the time. I guess it
11 was hard to get all the dead tissue away. And, then, I was
12 put in a whirlpool bath, and that really did not do the
13 work, but that really cleaned the area, and then soon after
14 that I got my skin graft.

15 Q How many debridement procedures did you
16 have? How many times did he have to trim?

17 A It was four by the bedside.

18 Q You were awake during all of this?

19 A I was awake each time.

20 Q How long would the operation take?
21

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direct - L. Jones

1 A Sometimes an hour. Sometimes longer.

2 It was perfectly horrible. One time I got sick to my stomach.
3 The whole time, it was perfectly horrible.

4 Q When you got sick, did you get sick on
5 Dr. Thompson?

6 A No, I had a pan that they kept for that
7 purpose.

8 Q Was your wound bandaged or left open?

9 A It was an open wound at all times. Some-
10 times, just before the trimming, it would almost be green
11 looking. Sometimes I didn't know if they could save my
12 leg or not. Sometimes I got so afraid that nothing could
13 be done. Weeks on in I just wondered if something could be
14 done. My prayers were answered. The skin graft was performed.

15 Q There did come a time when a skin
16 graft was performed?

17 A Yes.

18 Q Where did they get the skin for the
19 skin graft?
20

21 A My leg.

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169

direct - L. Jones

1 Q Was that procedure done in your room?

2 A No, I went to the operating room and
3 was given an anesthetic.

4 Q Do you recal when you were finally
5 discharged from Mary Washington Hospital?

6 A I think it was October 22nd.

7 Q Now, --

8 A (interjecting and continuing) Dr.
9 Thompson had planned to keep me. He was afraid to sent me
10 home. Finally, I told him that if he just let me go home,
11 I'd do anything. He was afraid that I might have another
12 gallbladder attack. He gave me a special diet and I stuck
13 to that special diet, and I did not have any attacks. I
14 went back on the 19th of November. That is when he wanted
15 me back for my gallbladder operation.

16 Q You were in the hospital from August
17 16th, into September, and most of October, is that correct?

18 A Up to the 22nd of October when I went
19 home. I returned on the 19th of November, and was discharged
20 December 1st.
21

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direct - L. Jones

1 Q Would you describe the pain that you
2 initially had with the injection and during the hospitalization,
3 would you describe both degrees of pain that you experienced?

4 MR. PAGE: He should also ask if she
5 had any pain when she came to the hospital.
6

7 BY MR. HALEY: (continuing)

8 Q Did you suffer any pain during the time
9 that you were in the hospital, that is to say from August
10 the 16th to the 22nd of October, 1975?

11 A Yes, I suffered severely with my hip,
12 not from the gallbladder, it was my hip.

13 Q When, during this period, did you suffer?

14 A When the washed the wound. Each time
15 they cleaned it, it was very painful. Each time he trimmed
16 it, it was very painful.

17 Q During the time it was cleaned, each time,
18 and it was trimmed, each time, did it hurt?

19 A Oh, yes.

20 Q How bad?

21 A It just hurt. That's all I can say.

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171.

direct - L. Jones.

1 Q Let me ask you this: Did the pain ever
2 go away?

3 A At times it was less than other times.

4 Q When you went home on the 22nd of October,
5 did you have any -- Well, tell us about your experience while
6 convalescing and before you came back for your operation.

7 A Well, I went home, as I said, on a very,
8 very strict diet. I was to keep my wound clean. There was
9 a type of salve that he gave me to put on the wound every
10 day. I really couldn't do my work. My meals were prepared
11 by my neighbors or by the church members or by my family.
12 He told me to walk around, but he didn't want me to do
13 any work.

14 Q Mrs. Jones, how did your hip effect,
15 if at all, how did it affect you after your gallbladder
16 surgery?

17 A How do you mean "affect me"?

18 Q How did it affect you?

19 A How did it affect me?

20 Q Yes.
21

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172

direct - L. Jones

1 A I couldn't -- Do you mean what wasn't I
2 able to do?

3 Q Yes.

4 A Well, I wasn't able to do any stooping.
5 I wasn't able to sleep on that side. It affected my relation-
6 ship with my husband.

7 Q How did it affect your relationship
8 with your husband? I am going to ask you to be specific.

9 A I couldn't resume intercourse, it was
10 August when I went into the hospital, and it was around
11 the first of April before we actually even tried. And what
12 happens at the time of intercourse, the spasms would go
13 into my hip every time I moved. Every time that I moved at
14 all that would make the muscles cramp. That would ruin it
15 for my husband, and we would have to quit.

16 Q What problems are you experiencing to
17 date?

18 A The same thing. I still have muscle
19 cramps. I still have pain in my hip in laying down. And
20 if it gets cold, I also have pain. When I try to stoop, it
21

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173.

direct - L. Jones

1 just folds in. If I walk for a certain length of time, it
2 doesn't bother me, but if I get tired, it starts to hurt
3 again, even when I sit down. I do my work at home according
4 how I feel. If I get overtired, it will act up.

5 Q How did the skin graft turn out?

6 A It was a ninety-five percent take.

7 Q How do you wear your clothes?

8 A I can't wear anything tight. It irritates
9 the area around the skin graft. There is a dent in there.

10 Q Would you stand up and come over in
11 front of the jury and show them the indenture through your
12 clothes?

13 NOTE: The witness now leaves
14 the witness stand and steps in front of the jury.

15 THE WITNESS: I am fortunate to be able
16 to buy the type of clothing that will hide it.
17 Everything I buy has jackets. I buy all jacket
18 dresses.

19 MR. HALEY: Your Honor, Mrs. Jones has
20 brought a robe or a housecoat with her, we would
21

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174

direct - L. Jones

1
2 like for her to slip into that and show the
3 jury how the wound actually appears today.

4 MR.PAGE: If it would suit the jury and
5 Mr. Haley, we have no objection to Mrs. Jones
6 and the jury to go to the juryroom and expose the
7 wound. It certainly would be more private. We
8 have been going a little over two hours. Perhaps
9 it would be appropriate to take a short recess.

10 THE COURT: All right, we will do that.
11 Let the jury take about five minutes to look at
12 that, and then we will take a short recess. We'll
13 take a total of ten minutes.

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175.

cross - L. Jones

CROSS EXAMINATION

BY MR. PAGE:

Q Mrs. Jones, I have to ask you some questions. Please bear with me. First of all, when you went on into the hospital in August of 1975, you were going there for a gallbladder attack?

A That's right.

Q And, that attack occurred some nine days before you went into the hospital, as I recall your prior testimony?

A It was on the third one that I was taken to the hospital.

Q In effect, once you got into the hospital and once this complaint in this particular trial occurred, the gallbladder problem went away didn't it?

A The pain went away.

Q As a result of that you were discharged from the hospital on October the 22nd of 1975, and you returned for the gallbladder surgery, didn't you?

A It came back.

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cross - L. Jones

1
2 Q You don't contend, do you, that the
3 shot of Demerol and Vistaril had anything to do with the
4 fact that you had to have the gallbladder operation, do you?
5 Before you came into contact with Demerol and Vistaril you
6 needed that operation, didn't you?

7 A It prolonged the operation.

8 Q I don't think it is in the record, it
9 might be in the medical records, how tall are you?

10 A About four foot four or six.

11 Q Would it be fair to say that the fair
12 average would be four five?

13 A I'll agree with that.

14 Q Could you tell us what your weight was
15 at the time that you went into the hospital in August of
16 1975?

17 A Approximately what it is now.

18 Q Which is?

19 A One hundred and eighty-seven pounds.

20 Q Now, I take it while you were in the
21 hospital, I take it that all the people that gave you

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177.

cross - L. Jones

1 all of your injections of Demerol and Vistaril and all of
2 the other drugs, were employees of the hospital, is that
3 correct?

4 A As far as I know.

5 Q You don't contend that there was any
6 employee of Pfizer's at the hospital that injected any shot
7 into you, do you?

8 A No.

9 Q Now, I believe that you testified pre-
10 viously that you received an injection for pain on the
11 17th of August of 1975, and on the morning, early morning
12 of the 18th of August, for pain, is that correct?

13 A That was in the evening.

14 Q The medical records reflect that you
15 got an injection of the same material on the 17th, and that
16 you got at 1:15 a.m., which is the early morning of August
17 18th another injection before you got the shot that you are
18 complaining of. Now, my question is: Did they in fact help
19 your pain from the gallbladder?
20

21 A I'm sure they did.

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178

cross - L. Jones

1 Q And, in fact, these prior injections
2 have not caused you any particular pain when they were
3 injected, have they?

4 A No.

5 Q Now, do you recall, Mrs. Jones, that
6 during the time that this suit was filed and the time
7 that we came here today, your lawyers sent you a set of
8 questions called interrogatories and helped you answer
9 them?
10

11 A Yes.

12 MR. PAGE: Your Honor, I would like, at
13 this time, approach Mrs. Jones, if I might, and
14 review with her one sentence in number eighteen
15 of the interrogatories and --

16 THE COURT: You may.

17 BY MR. PAGE: (continuing)

18 Q Do you recall receiving this question,
19 do you recall that?

20 A Would you repeat that?

21 Q Do you recall receiving a set of

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179.

cross - L. Jones

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interragatories that included this question here listed
in number eighteen, could you look at that please, ma'am?

NOTE: Witness is now looking
at the previously referred to document.

BY MR. PAGE: (continuing)

Q Do you recall that?

A Yes.

Q Am I correct in assuming that your
lawyers sat down with you and tried to work with you
to get the answers to these?

A No, he did not. I answered those.

Q You answered them yourself?

A Yes. I got them through the mail. I
answered them and then returned them.

Q Now, I am going to read your answer
out loud. "On August 18th, 1975, I was given an injection
of Vistaril and Demerol while at Mary Washington Hospital
in Fredericksburg, Virginia, and, which injection was given
in the area of the right hip. I experienced severe pain
symptoms with the injection." Was that your answer?

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189.

cross - L. Jones

1 A Yes.

2 Q Now, the record already reflects, and
3 you have heard the testimony of the doctors, you received
4 a shot of Demerol and Vistaril not only before the shot
5 you are complaining of, but also after the shot you complain
6 of, would you agree with that?

7 A Yes.

8 Q And, I take it that right up until
9 today nobody has represented to you that Vistaril I.M.
10 Solution not be used for intramuscular injections?

11 A No, they have not.

12 Q Now, you have indicated to us that you
13 were discharged from the hospital in November, I'm sorry
14 in October, that you went home and stayed there for a month
15 and I think you said previously that during the time that
16 you were home, you had occasion to ride up to Fredericksburg
17 to see Dr. Thompson on one occasion.

18 A I came whatever date he designated to
19 come back.

20 Q And, I think that you have also previously
21

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131

cross - L. Jones

1 testified that he wanted you to get your strenght back and
2 to get in shape for the operation.

3 A Yes,

4 Q You in fact did that?

5 A I did.

6 Q I think that you have also told us
7 in your previous testimony that you had, during this period
8 of time. a large number of visitors that came to see how
9 how you were getting on and that you entertained them in
10 the living room of your home?

11 A Yes, I did.

12 Q I think that you have also told us
13 in your previous testimony that when the people came that
14 you in fact would demonstrate the scar to them very much
15 like you did to the jury today? Is that correct?

16 A Well, when I was in the Hospital, a lot
17 of people knew what I had gone through, and when they visited
18 me, they asked if they could see the area. Well, I had
19 been through so much first, you know, being embarrassed, I
20 found that if I was going to look like that, that I better
21

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182

cross - L. Jones

1 stop being embarrassed. So, when my friends came and wanted
2 me to show it to them, I was happy to show them my hip.

3 Q And, you showed it to them, I believe
4 you have testified previously, without embarrassment?

5 A By that time I had been through so
6 much, I had been through the embarrassment stage.

7 Q In the motion for judgment that you
8 filed in answer to interrogatories, you indicated that
9 embarrassment was a problem subsequent to the operation,
10 and I believe that you told us now that you have put that
11 behind you? You have accepted this for what it is, is that
12 right?

13 A I'm trying to very hard.

14 Q When you got home on December the 1st,
15 you had undergone a gallbladder operation?

16 A Yes.

17 Q Without getting into the details of
18 the operation, would you explain to the ladies and gentleman
19 of the jury how large an incision was that was made for
20 that operation?
21

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183.

cross - L. Jones

1 A From here to here. (indicating) They
2 took my appendix out while they had me asleep.

3 Q Two for the price of one, is that right?

4 A I paid for both.

5 Q When you got back on December the 1st,
6 1975, you had undergone what in effect was another major
7 operation, had you not?

8 A Yes, I did.

9 Q When you went back on November the
10 19th, your doctor felt that you had recuperated sufficiently
11 to undergo this major surgery.

12 A May I hear that again?

13 Q When you went back on November the 19th,
14 Dr. Thompson advised you that you had recuperated from
15 your hip problem to undergo this major surgery?

16 A The day that he let me go, he made
17 reservations or reserve a room for the 19th, that is when
18 he wanted me back in the hospital. And I went back when
19 he wanted me back.

20 Q In fact, when you went home from the
21

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134.

cross - L. Jones

1
2 gallbladder operation, the incision of which you just
3 showed us as far as size is concerned, it was harder to
4 get around then before you had the gallbladder surgery,
5 wasn't it?

6 A I was recuperating from two operations
7 at that time.

8 Q And the recent one was in fact the
9 gallbladder operation the incision of which crossed completely
10 across the --

11 A (interjecting) That's right.

12 Q Now, it is my understanding that today
13 you are able to do a great majority of your housework, is
14 that correct?

15 A Yes, to a certain extend. Part of the
16 stooping I can't do.

17 Q You have problems stooping. Other than
18 that you can do most of what you have to do in your house,
19 is that right?

20 A I try.

21 Q In fact you get it done.

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185.

cross - L. Jones

1 A With the help of my husband.

2 Q It is also my understanding from
3 the testimony that Dr. Thompson has given previously, that
4 in his opinion there are no functional disabilities as
5 the result of this scar.

6 A At the time that I went back to Dr.
7 Thompson, I had not reviewed my relationship with my husband.
8 I did not know how it was going to affect me at that time.
9 But after that we did review my relationship with my
10 husband and the muscle cramps.

11 Q You could walk and bend over and stoop?

12 A I could bend over but I couldn't stoop.

13 Q At the time you went back to Dr.
14 Thompson to discuss this with him, did you know what your
15 functional disability was, did you discuss that with him?

16 A Well, he really did not get into that.
17 He told me -- I asked him if I was doing alright and he told
18 me that I was. He told me that he was sorry that my hip would
19 always have a hole in it, that he had tried, but it would
20 never fill out.
21

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186.

cross- L. Jones

1
2 Q And, you have been able to wear jacket
3 dresses and so forth that hide the indentation from the
4 general public, is that right?

5 A That's right.

6 Q And, I think that you also testified
7 that the pain that you now have is when there is cold
8 wheather or something like that?

9 A Cold wheather. Damp wheather. Whatever.

10 Q And you would also agree, would you not,
11 that the discomfort you have now is nothing compared to
12 what you had while you were actually going through the
13 actual recuperation. wouldn't you?

14 A No.

15 Q And that is the only discomfort that
16 you feel, the discomfort during cold or damp wheather?

17 A Yes.

18 * * *
19
20
21

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254.

1 THE COURT: Members of the jury, the
2 attorneys will now read certain parts of a
3 deposition taken of Elizabeth Pronovost, the
4 nurse who actually made the injection. Only
5 certain parts will be read to you. We will do
6 it with Mr. Haley taking the stand and Mr.
7 Roberts examining him.

8 MR. ROBERTS: Can Mr. Burkholder conduct
9 his own examination?
10

11 THE COURT: He may.

12 NOTE: Page thirty-one of
13 the previously referred to deposition is now
14 being read to the jury.

15 MR. PAGE: I would like to read from
16 page thirty, line seven.

17 NOTE: Page thirty, beginning
18 with line seven is now being read to the jury
19 from the previously referred to deposition.

20 MR. PAGE: I would like to start with
21 page four now, Your Honor.

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1 THE COURT: All right, start with page
2 four.

3 NOTE: Pages four through
4 fourteen are now being read to the jury from
5 the previously referred to deposition.

6 MR. PAGE: That's all, Your Honor.

7 THE COURT: All right, sir, you can
8 step down.
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Excerpt of deposition: direct-Pronovost

* * *

RE CROSS EXAMINATION

BY MR. HALEY:

10 BY π Q Mrs. Pronovost, when you say that with regard
11 to the injection you gave Mrs. Jones it is possible that
12 the injection could have been inadvertantly placed in
13 subcutaneous tissue, you certainly do not think it likely
14 or probable that you did that?

15 A I don't think I did; but, it is possible. The
16 possibility is there.

17 Q Because in medicine --

18 A (Interposing) Nothing is exact.

* * *

Excerpt of deposition: direct-Pronovost.

* * *

BY MR. BURKHOLDER:

Q Had you known back in August, 1975 on the 18th that vistaril if inadvertantly administered in the sub-cutaneous tissue could cause significant tissue damage or necrosis, would you have used the same injection technique?

A Yes, I probably would have.

* * *

Excerpt of deposition: direct-Pronovost

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18 DIRECT EXAMINATION

19 BY MR. BURKHOLDER:

20 Q You are Elizabeth Pronovost?

21 A Yes.

22 Q Mrs. Pronovost, could you tell me the inclusive
23 years when you lived down in Fredericksburg, Virginia?

24 A Okay. We moved there in November of 1973 and lived
25 there until February of 1977.

Excerpt of deposition: direct-Pronovost

1 Q Where did you work during that period of time?

2 A Mary Washington Hospital.

3 Q What type of position did you hold at Mary
4 Washington Hospital?

5 A I was an R.N.

6 Q That would be a registered nurse?

7 A Yes.

8 Q How old are you, Mrs. Pronovost?

9 A Twenty-six.

10 Q Could you just generally describe for me please
11 your educational background with specific reference to your
12 training as a registered nurse, of course?

13 A I went to St. Mary's Hospital School of Nursing.
14 I entered in 1969 and graduated in 1973.

15 Q Did you participate in what could be called a
16 degree program?

17 A No. It was a diploma program.

18 Q What sort of diploma did you receive, what did
19 that qualify you as?

20 A It qualified me to take the State Boards as a
21 registered nurse.

22 Q Did you take the Connecticut State Boards?

23 A Yes, I did.

24 Q You passed the State Boards?

25 A Yes.

App. 171

Q Were you required to take the Virginia State Boards or the equivalent thereof in order to practice in Virginia?

A They have reciprocity with Connecticut which would allow me to practice there.

Q Did you specialize while you were in school and while you were at Mary Washington in any specific aspect of the duties of a registered nurse?

A While I was working at Mary Washington I pretty much worked the emergency room full-time.

Q Yes.

A And, I was occasionally called upon to substitute when the floors were short of help.

Q Was there any additional or specialized training you received in working as an emergency room nurse?

A No.

Q Mrs. Pronovost, I am going to direct your attention to 16 February, pardon me, 16 August, 1975. Would you describe for me at that period of time your general duties during the August of 1975 at Mary Washington?

A Normally I was employed in the emergency room.

Q Now, did you have occasion to administer some injections to the Plaintiff in this case, Mrs. Lottie Jones, on 16 August, 1975?

MR. HALEY: Off the record.

App. 172

(Off the record discussion.)

BY MR. BURKHOLDER:

Q Did you have occasion on 18 August, 1975, Mrs. Pronovost, to administer some injections to the Plaintiff in this case, Mrs. Lottie Jones?

A Yes, sir.

Q Could you generally describe for me how you came to administer these injections and just what happened; go ahead and use your own words, if you would, please?

A I had been pulled to the unit she was on to cover because they didn't have enough help up there. I was put in charge of administering medications that day and in addition to Mrs. Jones, I had given injections and medication to a lot of other patients on that floor.

Q What unit or what floor was Mrs. Jones on?

A She was on the 3rd floor, but I don't recall the name of the unit offhand.

Q Do you recall specifically the injections which you gave Mrs. Jones on 18 August, 1975?

A She had received an injection of emetecon, demerol and also vistaril.

Q I am going to show you a document which reads at the top "Nurses Notes-Medication Record" and ask you if you can identify that?

A Yes.

App. 173

1 Q What is that particular document?

2 A This is a copy of the nurses notes on the day
3 that I did work on that floor.

4 Q Is there a date at the bottom?

5 A August 18, 1975.

6 Q What is the purpose of the Nurses Notes in
7 general and on this document in particular?

8 A Okay. At the top it has a medication record as
9 to what medications were given and the time and the route.
10 The bottom just gives a general overview of the day.

11 Q Which entries did you make on this particular
12 document?

13 A Okay. There is a note that I had given some
14 demerol and vistaril intramuscularly at 2:55. I had given
15 her a dose of emetecon at noontime and there was an
16 Ancefa I.V. that was given at 10:00 in the morning.

17 (Off the record.)

18 MR. BURKHOLDER: Could we have that marked,
19 please?

20 (PRONOVOST EXHIBIT I: One sheet entitled
21 "Nurses Notes-Medication Record" dated August 18,
22 1975 at the bottom.)

23 BY MR. BURKHOLDER:

24 Q Mrs. Pronovost, you have referred to 18 August,
25 1975 as the date you made the injection of demerol and

App. 174

vistaril?

A Yes.

Q Were there any other occasions besides this one date that you gave any injections to Mrs. Jones?

A Not that I recall, no.

Q Do you remember the shift that you were on that particular day; from what hour to what hour?

A I worked 7:00 a.m. to 3:00 p.m.

Q What time in the day did you give this particular injection?

A At 2:55.

Q That would be 5 minutes before the end of your shift?

Yes.

* * *

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* * *

17 *Began*
A Okay. When I had gone into her room, she had
18 turned over on her side. Her right hip was up which was
19 okay. She was a very obese woman, so when I had marked my
20 area which was the hip, you know, I just used the hip.
21 There aren't any nerves or major blood vessels there. I
22 depressed the skin and, you know, injected the medication.

23 Q Where were you supposed to make the injection
24 into?

25 A The muscle.

Excerpt of deposition: direct-Pronovost

1 Q Does a bottle of vistaril come with any type
2 of instructional literature?

3 A It just says for intramuscular use.

4 Q Is there a package insert which accompanies
5 drugs such as vistaril?

6 A Yes.

7 Q Were you very familiar with this type of drug
8 back in August of 1975?

9 A Yes, I had given many, many injections of it.

10 Q Could you provide a rough estimate, had you
11 given it more than 100 times in injections?

12 A Most positively up to that point. After working
13 in the emergency room -- it is a very common medication
14 that is used.

15 Q What, if any, information does the package insert
16 contain concerning where an injection of vistaril is
17 supposed to go?

18 A Even in the literature it says deep into the
19 muscle.

20 Q I am anything but an expert at anatomy but could
21 you describe just generally for me, referring back to Mrs.
22 Jones in particular back in August of 1975, what a needle
23 has to pass through that has demerol and vistaril on the
24 other end before it gets to deep within a muscle?

25 A Okay. First you would have your skin, you know,

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1 your skin thicknesses. Then you have your fatty tissue and
2 then it would be into the muscle.

3 Q Now, are certain drugs designed to be injected
4 in the fatty tissue?

5 A I don't know of any drug that would go into the
6 fatty tissue. The most common uses are intradermal,
7 intramuscular and subcutaneous.

8 Q Is a subcutaneous injection of a drug as deep
9 as or less than an intramuscular injection?

10 A Less deep. It only goes under the skin tissue.

11 Q Was there any question in your mind back on
12 18 August, 1975 where vistaril was supposed to be injected?

13 A No, it goes into the muscle.

14 Q Is there a special part of the muscle that it is
15 supposed to go into?

16 A Well, according to the thing it just says "i.m.
17 use only" and it would go into the muscle.

18 Q Would you want to inject it deep into the muscle
19 or just a short distance?

20 A Mostly goes deep into the muscle if it is "i.m.".

21 Q Well then, I'm sorry to repeat myself, did you
22 know from reading the package insert where vistaril was
23 supposed to be injected in terms of where in the muscle?

24 A I would assume it would have been deep into the
25 muscle.

Excerpt of deposition: direct-Pronovost

1 Q Let me talk about the equipment you had to
2 use for this injection with Mrs. Jones for a second.

3 A Um-hum.

4 Q Where did you get the demerol; that is to say,
5 what did it come in?

6 A It comes in a pre-packaged tubic syringe. It is
7 a cartridge that goes into a metal cylinder that is used.

8 Q Where did you get the needle?

9 A The needle is on the cartridge already.

10 Q So you don't have to get a needle from the
11 hospital supply itself?

12 A No, no.

13 Q Does the vistaril come in it's own syringe?

14 A No, vistaril is in a small ampule.

15 Q How did you combine the two drugs, then?

16 A The demerol is put into the cartridge and then
17 you draw the vistaril off of the ampule so it is a combined
18 injection.

19 Q How long is the needle that comes in this pre-
20 packaged affair?

21 A It is -- I believe it is an inch and a half.

22 Q Is there a standard size for a needle to be used
23 with an intramuscular injection?

24 A You can guage usually by the size of the person.
25 You would use an inch or an inch and a half needle.

Excerpt of deposition: direct-Pronovost

1 Q Is it necessary, Mrs. Pronovost, or let me
2 say, was it necessary for you back in August of 1975 and
3 before when you were working at Mary Washington Hospital as
4 a registered nurse to make some sort of judgment as to what
5 size needle you were going to use to make an intramuscular
6 injection?

7 A We just decided by the size of the person.

8 Q Well, you probably already answered this, but,
9 what do you take into consideration when you make a decision
10 as to the type of needle?

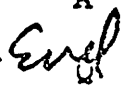
11 A Like I said, mostly the size of the person. She
12 was a very large woman so she would, you know, require a
13 much longer needle than someone who weighed half her size.

14 Q From your experience and training back in
15 August of 1975, was it easier or harder for you to get an
16 intramuscular injection deep within the muscle in the buttocks
17 area of a fairly obese woman?

18 A Yes, it is more difficult.

19 Q I believe you previously testified, and please
20 correct me if I am wrong, that you have got to as a
21 registered nurse make some sort of judgment as to the
22 actual location in the buttocks area where an intramuscular
23 injection is going to go, isn't that true?

24 A Yes.

25 

* * *

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1
2 IN CHAMBERS

3 THE COURT: Let's see the plaintiff's
4 instructions.

5 MR. PAGE: We would like to renew our
6 motion to strike the plaintiff's evidence on
7 the ground that there is no evidence, that's
8 number one, that Pfizer failed to give adequate
9 warning, when in fact the evidence is that Pfizer
10 warned that this should not be injected into sub-
11 cutaneous tissue under any circumstances. Now,
12 you can't give a more adequate warning. You can't
13 do it. Now, in addition to that, let's assume
14 for a minute that the warning wasn't proper.
15 The nurse said that she would not have done it
16 any other way. Secondly, the doctor said on
17 cross examination that he knew that it could
18 cause necrosis of the tissue. I don't think that
19 this case can go to the jury.
20
21

* * *

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259.

IN CHAMBERS

THE COURT: Some of the witnesses said that is was sufficient or they thought it was sufficient. Dr. Smith did not think that it was, and Dr. Thompson said, I believe, that it could cause necrosis. I believe that he said that he knew that it could cause, sometimes, some irritation. Maybe a lump or something that would go away in a few days. Dr. Smith did not think that the warning was adequate. There is a case of reasonable men disagreeing.

I think that there is still enough left to give it to the jury, and I am going to overrule the motion to strike.

MR. PAGE: Note our exception.

* * *

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IN CHAMBERS

THE COURT: That will be number seven.

Is this your first instruction?

MR. BURKHOLDER: Yes, sir.

MR. ROBERTS: We object to this. There
is not sufficient evidence.

MR. BURKHOLDER: I feel that that is --

THE COURT: I'll call this eight A.
I don't recall any evidence on that point.

MR. HALEY: What Federal regulation?

THE COURT: Eight A is refused.

MR. HALEY: Where did you get nine from?

MR. BURKHOLDER: That is an automobile
instruction and used the Vistaril. This is
basically taylored to this case.

MR. PAGE: It is our position that we
are not required to write a text book on medicine
and sent it out with each drug.

THE COURT: I will give it as nine.

MR. HALEY: Note our exception.

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IN CHAMBERS

THE COURT: All right, sir.

MR. BURKHOLDER: Judge, this has been referred to in our motion to strike. This basically raises the question of causation. If Dr. Thompson had independent knowledge, then this particular piece of information cannot be the proximate cause of this injury.

MR. HALEY: This was a severe destruction of tissue. He said that he knew of some local type reaction. This --

MR. BURKHOLDER: (interjecting) Well,--

MR. HALEY: (interjecting) Let me finish please. This is not a minor type reaction.

MR. BURKHOLDER: If he knew that it caused tissue necrosis, it does not matter what the size of the area is.

THE COURT: I understand you both.

MR. HALEY: He had no knowledge of the type of injury suffered by Mrs. Jones.

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IN CHAMBERS

MR. BURKHOLDER: I don't think that Mr. Haley should be allowed to argue that he only knew of a little bit of tissuenecrosis, and not a lot of tissue, and therefore the warning is not adequate.

THE COURT: I see the position that both of you are taking. This is a matter of argument. Dr. Thompson was somewhat vague on that. But, he did say that it would be some sort of lump that would last maybe a day or two. What this tells the jury is that if they believe from Dr. Thompson's testimony that he knew, then Pfizer had no duty. This is a decision for the jury.

MR. BURKHOLDER: Now if the jury becomes convinced that Dr. Thompson knew nothing about the tissue necrosis, that it was simply some mild irritation, the jury will follow his lead, if he is allowed to argue that. Dr. Thompson said something quite different.

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270.

IN CHAMBERS

THE COURT: The problem here is, that if they believe this, they have to find in favor of the defendant. I just don't see it.

MR. BURKHOLDER: I have a number of cases cited on the copies.

THE COURT: Yes, I can see that. But, you can only say that if the doctor was fully aware of it.

MR. BURKHOLDER: That is a matter for Mr. Haley to argue.

THE COURT: I feel that that is a matter of argument. I didn't understand from his testimony that he was fully aware of it.

I think it will have to be turned down. You can note your exception.

MR. PAGE: Ten has been refused?

THE COURT: Nine B has been refused.

MR. PAGE: Suppose we change it to read, and I don't know where I am going to get copies

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271.

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1
2 IN CHAMBERS:

3 of it, was potentially dangerous, strike was
4 aware of, which seemsto be Mr. Haley's argument,
5 I would like to offer the instruction with the
6 substitution knew with aware of.

7 MR. HALEY: Same diffrence, Your Honor.
8 Just leave all of causing tissue necrosis out,
9 and say potentially --

10 THE COURT: (interjecting) If you can
11 get together on it, fine, if not, fine.

12 MR. PAGE: All right.

13 THE COURT: Try. Something is better
14 than nothing.

15 MR. HALEY: Tissue destruction instead
16 of tissue necrosis.

17 MR. PAGE: We will go forward and
18 change it.

19 THE COURT: Since you are relying on
20 the Park Davis case, it is clear from the
21 holding that the physician was "fully aware".

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272.

IN CHAMBERS

In the case that we are trying today, there was merely a suggestion that instance it could cause necrosis.

MR. PAGE: I will read this in. If you believe from the evidence -- the preponderance of the evidence that the defendant was negligent in failing to adequately warn of the danger involved in the administration of Vistaril, and if you further believe from the evidence that Dr. Thompson was fully aware --

THE COURT: (interjecting) You are saying fully aware again. He did not say that.

MR. PAGE: On cross examination he told Mr. Burkholder that he knew that it could cause necrosis. He finally agreed after being asked on cross examination.

THE COURT: The instruction is refused. Both A and B are refused. You can note your exception.

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PRECAUTIONS (continued)

When hydroxyzine is used preoperatively or prepartum, narcotic requirements may be reduced as much as 50 per cent. Thus, when 50 mg. of VISTARIL (hydroxyzine hydrochloride) Intramuscular Solution is employed, meperidine dosage may be reduced from 160 mg. to 50 mg.

Since drowsiness may occur with use of this drug, patients should be warned of this possibility and cautioned against driving a car or operating dangerous machinery while taking this drug.

As with all intramuscular preparations, VISTARIL Intramuscular Solution should be injected well within the body of a relatively large muscle.

ADULTS: The preferred site is the upper outer quadrant of the buttock, (i.e., gluteus maximus), or the mid-lateral thigh.

CHILDREN: It is recommended that intramuscular injections be given preferably in the mid-lateral muscles of the thigh. In infants and small children the periphery of the upper outer quadrant of the gluteal region should be used only when necessary, such as in burn patients, in order to minimize the possibility of damage to the sciatic nerve.

The deltoid area should be used only if well developed such as in certain adults and older children, and then only with caution to avoid radial nerve injury. Intramuscular injections should not be made into the lower and mid-third of the upper arm. As with all intramuscular injections, aspiration is necessary to help avoid inadvertent injection into a blood vessel.

ADVERSE REACTIONS

Therapeutic doses of hydroxyzine seldom produce impairment of mental alertness. However, drowsiness may occur; if so, it is usually transitory and may disappear in a few days of continued therapy or upon reduction of the dose. Dryness of the mouth may be encountered at higher doses. Extensive clinical use has substantiated the absence of toxic effects on the liver or bone marrow when administered in the recommended doses for over four years of uninterrupted therapy. The absence of adverse effects has been further demonstrated in experimental studies in which excessively high doses were administered.

Involuntary motor activity, including rare instances of tremor and convulsions, has been reported, usually with doses considerably higher than those recommended. Continuous therapy with over one gram per day has been employed in some patients without these effects having been encountered.

DOSAGE AND ADMINISTRATION

The recommended dosages for VISTARIL (hydroxyzine hydrochloride) Intramuscular Solution are:

For adult psychiatric and emotional emergencies including acute alcoholism.	I.M.: 50-100 mg. Stat., and q. 4-6h., p.r.n.
Nausea and vomiting excluding nausea and vomiting of pregnancy.	Adults: 25-100 mg. I.M. Children: 0.5 mg./lb. body weight I.M.
Pre- and postoperative adjunctive medication.	Adults: 25-100 mg. I.M. Children: 0.5 mg./lb. body weight I.M.
Pre- and postpartum adjunctive therapy.	25-100 mg. I.M.

As with all potent medications, the dosage should be adjusted according to the patient's response to therapy.

FOR ADDITIONAL INFORMATION OF THE ADMINISTRATION AND SITE OF SELECTION SEE PRECAUTIONS SECTION. NOTE: VISTARIL (hydroxyzine hydrochloride) Intramuscular Solution may be administered without further dilution.

Patients may be started on intramuscular therapy when indicated. They should be maintained on oral therapy whenever this route is practicable.

SUPPLY

VISTARIL (hydroxyzine hydrochloride) Intramuscular Solution
 25 mg./cc.: 10 cc. vials
 50 mg./cc.: 2 cc. vials in packages of 10 vials; 10 cc. vials
 Isject
 25 mg./cc.—1 cc. fill: packages of 10 Isjects
 50 mg./cc.—1 cc. fill: packages of 10 Isjects
 100 mg.: 50 mg./cc.—2 cc. fill: packages of 10 Isjects.

FORMULA

Each cc. contains:	25 mg./cc.	50 mg./cc.
Hydroxyzine hydrochloride	25 mg.	50 mg.
Benzyl Alcohol	0.9%	0.9%
Sodium hydroxide	to adjust to optimum pH	

BIBLIOGRAPHY

Available upon request.

PFIZER LABORATORIES DIVISION
 PFIZER INC.
 NEW YORK, N.Y. 10017

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60-0843-00-9
 KARLTIFF'S EXHIBIT

Pfizer

Pfizer

Vistaril[®]

hydroxyzine hydrochloride Intramuscular Solution

For Intramuscular Use Only

CHEMISTRY

Hydroxyzine hydrochloride is designated chemically as 1-(p-chlorobenzhydryl)-4-[2-(2-hydroxyethoxy) ethyl] piperazine dihydrochloride.

ACTIONS

VISTARIL (hydroxyzine hydrochloride) is unrelated chemically to phenothiazine, reserpine, and meprobamate. Hydroxyzine has demonstrated its clinical effectiveness in the chemotherapeutic aspect of the total management of neuroses and emotional disturbances manifested by anxiety, tension, agitation, apprehension or confusion.

Hydroxyzine has been shown clinically to be a rapid-acting true anxiolytic with a wide margin of safety. It induces a calming effect in anxious, tense, psychoneurotic adults and also in anxious, hyperkinetic children without impairing mental alertness. It is not a cortical depressant, but its action may be due to a suppression of activity in certain key regions of the subcortical area of the central nervous system.

Primary skeletal muscle relaxation has been demonstrated experimentally.

Hydroxyzine has been shown experimentally to have antispasmodic properties, apparently mediated through interference with the mechanism that responds to spasmogenic agents such as serotonin, acetylcholine, and histamine.

Antihistaminic effects have been demonstrated experimentally and confirmed clinically. An antiemetic effect, both by the apomorphine test and the veritoid test, has been demonstrated. Pharmacological and clinical studies indicate that hydroxyzine in therapeutic dosage does not increase gastric secretion or acidity and in most cases provides mild antisecretory benefits.

INDICATIONS

The total management of anxiety, tension, and psychomotor agitation in conditions of emotional stress requires in most instances a combined approach of psychotherapy and chemotherapy. Hydroxyzine has been found to be particularly useful for this latter phase of therapy in its ability to render the disturbed patient more amenable to psychotherapy in long term treatment of the psychoneurotic and the psychotic, although it should not be used as the sole treatment of psychosis or of clearly demonstrated cases of depression.

Hydroxyzine is also useful in alleviating the manifestations of anxiety and tension as in the preparation for dental procedures and in acute emotional problems. It has also been recommended for the management of anxiety associated with organic disturbances and as adjunctive therapy in alcoholism and allergic conditions with strong emotional overlay, such as in asthma, chronic urticaria, and pruritus.

VISTARIL (hydroxyzine hydrochloride) Intramuscular Solution is useful in treating the following types of patients when intramuscular administration is indicated:

1. The acutely disturbed or hysterical patient.
2. The acute or chronic alcoholic with anxiety withdrawal symptoms or delirium tremens.
3. As pre- and postoperative and pre- and postpartum adjunctive medication to permit reduction of narcotic dosage, allay anxiety, and control emesis.

VISTARIL (hydroxyzine hydrochloride) has also demonstrated effectiveness in controlling nausea and vomiting, excluding nausea and vomiting of pregnancy. (See Contraindications.) In prepartum states, the reduction in narcotic requirement effected by hydroxyzine is of particular benefit to both mother and neonate.

Hydroxyzine benefits the cardiac patient by its ability to allay the associated anxiety and apprehension attendant to certain types of heart disease. Hydroxyzine is not known to interfere with the action of digitalis in any way and may be used concurrently with this agent.

Its effectiveness and safety make it an outstanding drug for long term use.

CONTRAINDICATIONS

Hydroxyzine hydrochloride intramuscular solution is intended only for intramuscular administration and should not, under any circumstances, be injected subcutaneously, intrarterially or intravenously.

This drug is contraindicated for patients who have shown a previous hypersensitivity to it. Hydroxyzine, when administered to the pregnant mouse, rat, and rabbit induced fetal abnormalities in the rat at doses substantially above the human therapeutic range. Clinical data in human beings are inadequate to establish safety in early pregnancy. Until such data are available, hydroxyzine is contraindicated in early pregnancy.

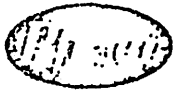
PRECAUTIONS

THE POTENTIATING ACTION OF HYDROXYZINE MUST BE CONSIDERED WHEN THE DRUG IS USED IN CONJUNCTION WITH CENTRAL NERVOUS SYSTEM DEPRESSANTS SUCH AS NARCOTICS AND BARBITURATES. Therefore when central nervous system depressants are administered concomitantly with hydroxyzine their dosage should be reduced up to 50 per cent. The efficacy of hydroxyzine as adjunctive pre- and postoperative sedative medication has also been well established, especially as regards its ability to allay anxiety, control emesis, and reduce the amount of narcotic required.

HYDROXYZINE MAY POTENTIATE NARCOTICS AND BARBITURATES, so their use in preanesthetic adjunctive therapy should be modified on an individual basis. Atropine and other belladonna alkaloids are not affected by the drug.

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PLAINTIFF'S EXHIBIT # 5



LABORATORIES DIVISION

PFIZER INC., 235 EAST 42nd STREET, NEW YORK, N.Y. 10017

Judge

MEDICAL DEPARTMENT

15-975

August 29, 1975

Dr. Peter R. Smith
17014 Fall Hill Avenue
Fredericksburg, Virginia 22401

Dear Dr. Smith:

Thank you for reporting the case of local reaction following an injection of Vistaril and Demerol to me. As I explained over the telephone, we have had a number of reports of similar reactions which in most cases seemed to be due to inadvertent subcutaneous injection. Vistaril is irritant to subcutaneous tissue.

We recommend that Vistaril be given by deep intramuscular injection using the Z-Track Technique to avoid possible back tracking into adjacent subcutaneous tissue, and have enclosed material concerning this method. Also enclosed is the booklet "What Nurses Need To Know About Vistaril" for your information, together with our Product Experience Report form.

Since we are required to obtain as much information as possible concerning any adverse reactions associated with our products for the FDA, I would appreciate your completing the Product Experience Report Form and mailing same to me in the enclosed return envelope provided. This information will enable us to have a more detailed record of reactions associated with Vistaril and, of course, your name and that of your patient will be kept confidential. The pink copy is for your files and information.

If I can be of any further assistance to you, please feel free to contact me at a/c 212-#573-2638.

Yours sincerely,

Patricia Walmsley
Patricia Walmsley, M.D.
Associate Medical Director *cdB*

PW/cdb
Enclosures

[Refused]

INSTRUCTION NO. 9(a)

Even though you may believe from a preponderance of the evidence that the defendant was negligent in failing to give an adequate warning of the danger involved in the administration of Vistaril, if you further believe from the evidence that Dr. Thompson knew that inadvertent subcutaneous injection of the drug Vistaril in violation of Pfizer's labelling was potentially dangerous or could cause tissue necrosis, then any such failure on the part of Pfizer to give an adequate warning of the dangers connected with the administration of Vistaril would not have been a proximate cause of plaintiff's injuries and you shall find your verdict in favor of the defendant.

[Refused]

INSTRUCTION NO. 9(b)

Even though you may believe from a preponderance of the evidence that the defendant was negligent in failing to give an adequate warning of the danger involved in the administration of Vistaril, if you further believe from the evidence that Dr. Thompson was aware that inadvertent subcutaneous injection of the drug Vistaril in violation of Pfizer's labelling was potentially dangerous or could cause tissue necrosis, then any such failure on the part of Pfizer to give an adequate warning of the dangers connected with the administration of Vistaril would not have been a proximate cause of plaintiff's injuries and you shall find your verdict in favor of the defendant.

[Refused]

INSTRUCTION NO. 9(c)

Even though you may believe from a preponderance of the evidence that the defendant was negligent in failing to give an adequate warning of the danger involved in the administration of Vistaril, if you further believe from the evidence that Dr. Thompson was fully aware that inadvertent subcutaneous injection of the drug Vistaril in violation of Pfizer's labelling was potentially dangerous or could cause tissue necrosis, then any such failure on the part of Pfizer to give an adequate warning of the dangers connected with the administration of Vistaril would not have been a proximate cause of plaintiff's injuries and you shall find your verdict in favor of the defendant.