United States Court of Appeals
For the First Circuit

No. 22-1547

VIRGINIA CORA WARD, as the administratrix of the estate of EDMUND EDWARD WARD,

Plaintiff, Appellant,

v.

ERNST J. SCHAEFER, MD,

Defendant, Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. F. Dennis Saylor, IV, U.S. District Judge]

Before

Rikelman, Selya, and Howard,
Circuit Judges.

Timothy Cornell, with whom Cornell Dolan, P.C. was on brief, for appellant.

Tory A. Weigand, with whom Morrison Mahoney, LLP was on brief, for appellee.

January 29, 2024

SELYA, Circuit Judge. Although this appeal arises out of an experimental protocol undertaken at a site famed for the development of new cures and treatments, the appeal itself hinges on familiar fare: the persuasiveness vel non of the appellant's claims of trial error. After careful consideration of a scumbled record, we conclude that the appellant's claims of error lack force. Accordingly, we affirm the judgment below as to the remaining appellee.[1]

I

We briefly rehearse the relevant facts and travel of the case. We take the facts in the light most congenial to the verdict, consistent with record support. See United States v. Kilmartin, 944 F.3d 315, 323 (1st Cir. 2019).

Edmund Edward Ward was born with a rare genetic deficiency that caused his body to refrain from producing a blood enzyme called lecithin-cholesterol acyltransferase (LCAT), which is critical to cholesterol production. The disease process

[1] Because the appellant's claims of error against this appellee (Ernst J. Schaefer, MD) raise a set of issues that are distinct from his claims of error regarding certain other appellees, we elected to resolve this appeal in two separate opinions. See, e.g., Alston v. Town of Brookline, 997 F.3d 23, 29 n.1 (1st Cir. 2021); United States v. Santiago-Rivera, 744 F.3d 229, 231 n.1 (1st Cir. 2014). The first of these opinions has already been issued. See Ward v. AlphaCore Pharma, LLC, 89 F.4th 203 (1st Cir. 2023). That opinion is based upon review of a prima facie record and, thus, does not contain many of the factual details that populate this opinion (which deals with claims of error arising in the context of a full trial record).

resulting from this enzyme deficiency — familial LCAT deficiency (FLD) — may cause kidney failure, which requires either regular dialysis or kidney transplantation. The doctor who initially treated Ward for his kidney damage believed that he had LCAT deficiency and referred him to a specialist practice. After consulting several physicians about his condition, Ward met Dr. Ernst J. Schaefer (who is the appellee here). Dr. Schaefer confirmed a diagnosis of FLD and developed a creative approach to Ward's medical care.

Bereft of any good treatment options, Dr. Schaefer enlisted the National Institutes of Health (NIH) and AlphaCore Pharma, LLC (ACP) to see if Ward might be a candidate for experimental enzyme therapy. Ward's condition at the time was deteriorating, and the prospect of dialysis loomed. Although Ward alleges that he was promised a potential cure, Dr. Schaefer insists that Ward was warned about the "unchart[ed] territory" that they would be exploring. If successful, the upshot would be delaying dialysis, not a cure.

An NIH researcher, Dr. Robert Shamburek, and ACP employees proceeded to write an expanded access protocol for ACP's recombinant enzyme known as ACP-501.[2] Dr. Schaefer testified that

[2] Expanded access, often referred to as "compassionate use," allows a person with a "serious or immediately life-threatening disease or condition" to access an investigational medical product (drug, biologic, or medical device) outside of the normal clinical

he was not involved in drafting the ACP-501 protocol, but he did lobby for approval of the protocol's expanded access use (which the United States Food and Drug Administration ultimately granted).

Dr. Shamburek testified that — before commencing the ACP-501 protocol — he twice reviewed with Ward (himself a lawyer) the detailed consent form that had been written specifically for this protocol. He also testified that he advised Ward to discuss the consent form with family and other doctors before signing it. The signed consent form was admitted into evidence at the trial. Ward testified, though, that he did not recognize the form, did not recall discussing it with Dr. Shamburek, and did not remember signing it.

Nevertheless, it is undisputed that Ward traveled periodically from his home in Massachusetts to the NIH facility in Bethesda, Maryland, so that he could receive infusions of the recombinant enzyme. And Dr. Schaefer continued to monitor Ward in Massachusetts.

The experiment produced underwhelming results: the drug failed to ameliorate Ward's condition, and his suffering allegedly worsened because he was compelled to delay more effective dialysis

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trial constraints when "no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition" is available. 21 C.F.R. § 312.305; see id. § 812.36.

treatments. Thus, Ward began regular dialysis, departed from the ACP-501 protocol, and concluded that the only conceivable outcome was prolonged pain and suffering. With the protocol consigned to the scrap heap, Ward repaired to the courts. He sued Dr. Schaefer; Dr. Shamburek; Dr. Alan Remaley (an NIH physician who had worked closely with Dr. Shamburek); ACP and one of its principals, Dr. Bruce Auerbach; MedImmune, LLC (MedImmune), which had acquired ACP; and AstraZeneca Biopharmaceuticals, Inc. (AstraZeneca), MedImmune's parent, in a Massachusetts state court. Drs. Shamburek and Remaley removed the suit to the United States District Court for the District of Massachusetts. See 28 U.S.C. § 2679(d)(2). The United States later was substituted for Drs. Shamburek and Remaley as to certain claims. See id. The district court, in separate orders, dismissed the claims against ACP and Dr. Auerbach; the United States; and MedImmune and AstraZeneca. See Ward v. Schaefer, No. 16-12543, 2018 WL 1096829 (D. Mass. Feb. 27, 2018) (dismissing claims against Drs. Remaley and Shamburek and United States); Ward v. Auerbach, No. 16-12543, 2017 WL 2724938 (D. Mass. June 23, 2017) (dismissing claims against Dr. Auerbach and pharmaceutical companies).

The claims of fraud and failure to obtain informed consent against Dr. Schaefer went to trial. Ward's theory was that Dr. Schaefer fraudulently induced him to participate in the ACP-501 protocol and otherwise failed to obtain informed consent

for his participation in the protocol. The jury disagreed and returned a take-nothing verdict in favor of Dr. Schaefer on all claims. The district court denied Ward's motion for a new trial in a text order.

This timely appeal ensued. Ward died during its pendency, and Virginia Cora Ward, his sister and the administratrix of his estate, was substituted in his place and stead. See Fed. R. App. P. 43(a). We refer to her throughout as the appellant.

II

Before us, the appellant argues that Drs. Remaley and Shamburek represented that Ward's kidney function was improving materially while he was taking the drug, even though the data were ambiguous at best and he had switched to a lower dose of the drug due to a supply shortage. She also argues that Ward's nephrologist advised him that proceeding without dialysis was no longer medically acceptable.

The appellant's assignments of error, though, do not hinge on the substance of these arguments. Instead, her flagship contention as to the evidence is that the district court erred in excluding the ACP-501 patent.

We review a preserved objection to the district court's admission or exclusion of evidence for abuse of discretion. See Kilmartin, 944 F.3d at 335. A discretionary decision, however, "cannot be set aside by a reviewing court unless it has a definite

and firm conviction that the court below committed a clear error of judgment in the conclusion it reached upon a weighing of the relevant factors." Schubert v. Nissan Motor Corp., 148 F.3d 25, 30 (1st Cir. 1998) (quoting In re Josephson, 218 F.2d 174, 182 (1st Cir. 1954)). We add, moreover, that abuse of discretion is not a monolithic standard. See United States v. Padilla-Galarza, 990 F.3d 60, 73 (1st Cir. 2021). It "encompasses 'de novo review of abstract questions of law, clear error review of findings of fact, and deferential review of judgment calls.'" Id. (quoting United States v. Lewis, 517 F.3d 20, 24 (1st Cir. 2008)).

The district court refused to allow the introduction of the ACP-501 patent, concluding that the patent was inadmissible because it had been offered without any foundation and, in all events, had "nothing . . . to do with the medical issues" before the jury. The appellant contends that this ruling constituted an abuse of discretion because "the development, effects, and properties of [ACP-501] were the central issues in the trial." Inasmuch as claim one of the patent describes "a method for decreasing the amount of cholesterol in arteries of a human subject not suffering from [LCAT deficiency]," the appellant urges that the patent makes pellucid that the drug was not formulated to treat Ward's condition or the resulting kidney damage. She further urges that administering the drug to Ward was especially inappropriate

considering that none of his doctors had bothered to review the patent.

Dr. Schaefer offers a number of responses. First, he submits that Ward neither made an offer of proof nor provided any evidentiary basis for introducing the patent at trial. Second, he submits that the patent is of no relevance to claims of fraud and failure to obtain informed consent.

We start with the patent's relevance and with the application of Federal Rule of Evidence 403. Dr. Schaefer contends that the appellant's arguments for admissibility are meritless because the patent was offered without foundation and "any possible tangential relevancy was minimal and substantially outweighed by the . . . risk of confusion [due to] technical complexity." In our view, an analysis under Rule 403 disposes of the matter.[3] Accordingly, it would be superfluous to consider Dr. Schaefer's other arguments regarding the admission of this evidence.

Under Rule 403, a "court may exclude relevant evidence if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting

[3] Below, the district court did not articulate its exclusion of the patent as the product of a Rule 403 balancing. Even so, we "need not accept [the] district court's reasoning, but may affirm [a] judgment on any independently sufficient ground supported by the record." United States v. Nivica, 887 F.2d 1110, 1127 (1st Cir. 1989).

cumulative evidence." Fed. R. Evid. 403; see United States v. Leoner-Aguirre, 939 F.3d 310, 321 (1st Cir. 2019) ("A district court may exclude evidence when its probative value is substantially outweighed by the danger of unfair prejudice."). Applying this standard, we agree with the district court that the probative value of the patent is difficult to fathom. The requirements for obtaining patent protection are demanding, see 35 U.S.C. §§ 101-103 (requiring, inter alia, that invention be useful, novel, and non-obvious for patent protection), but completely different from the medical issues here, such as the efficacy and risks of a drug. What was distinct about ACP-501 for patent purposes is of absolutely no relevance to Dr. Schaefer's alleged failure to apprise Ward of the potential risks and rewards of taking the drug through expanded access. One sentence in a twenty-five-page patent noting that the patent does not cover LCAT deficiency reveals little about what risks the drug otherwise might carry. What is more, this limitation means only that the drug's efficacy was not shown sufficiently for patent purposes; it does not reveal what effect, if any, the drug might have when used experimentally for LCAT deficiency.

To be sure, Federal Rule of Evidence 401's standard for relevancy is low, and it permits the introduction of evidence that "has any tendency to make a fact more or less probable." Fed. R. Evid. 401. The patent's specific exclusion of LCAT deficiency

arguably offers some commentary — if minimal — on the biological nuances of the drug and, thus, what effects Ward reasonably could have expected. Yet, as the record plainly reflects, that tiny bit of relevant information would be grossly outweighed by the confusion created and time wasted by including the stockpile of other information that this dense document encompasses. In describing its relevance, Ward singles out a sentence from claim one of the patent while trying to introduce the entire twenty-five-page document, which is rife with irrelevant technicalities. Perhaps most strikingly, the document contains seven full pages that are filled with lines of letters that represent biologically important DNA sequences. We could not fault any reasonable factfinder for plunging into utter confusion as to what this alphabet soup adds to a fraud trial. An additional five full pages contain black-and-white figures that might seem like a Rorschach test to a lay jury. The remaining pages are littered with scientific jargon. Any relevance of the patent is sure to be lost in this sea of unrelated information.

Given the breadth of the patent and its marginal relevance, we cannot fault the district court for excluding it. After all, "[o]nly rarely — and in extraordinarily compelling circumstances — will we, from the vista of a cold appellate record, reverse a district court's on-the-spot judgment concerning the relative weighing of probative value and unfair effect." Freeman

v. Package Mach. Co., 865 F.2d 1331, 1340 (1st Cir. 1988). The district court reasonably concluded that the patent lacked any significant probative value, and the record reveals an ample potential for prejudice should the patent have been introduced. We hold, therefore, that the district court did not abuse its discretion in excluding the patent.

III

The appellant stakes out two claims of instructional error. First, she argues that the district court erred in not adopting Ward's proposed language for the jury instruction describing his professional relationship with Dr. Schaefer. Second, she argues that the district court erred in not instructing the jury on res ipsa loquitur. We start with the standard of review for jury instructions and then discuss each claim.

A

The standard of review for instructional error turns on the particular claim of error. See Shervin v. Partners Healthcare Sys., Inc., 804 F.3d 23, 47 (1st Cir. 2015). "We review de novo questions about whether a given instruction is, in substance, legally correct." Id. In doing so, we must remember that "[j]ury instructions are intended to furnish a set of directions composing, in the aggregate, the proper legal standards to be applied by lay jurors in determining the issues that they must resolve in a particular case." United States v. DeStefano, 59 F.3d 1, 2 (1st

Cir. 1995). "We review for abuse of discretion the particular wording chosen to convey a concept to the jury." Shervin, 804 F.3d at 47. The wording of the instruction must "adequately illuminate the law applicable to the controverted issues in the case without unduly complicating matters or misleading the jury." Testa v. Wal-Mart Stores, Inc., 144 F.3d 173, 175 (1st Cir. 1998).

If, however, the asserted error is failure to give a requested instruction, "the omitted instruction [must be] integral to an important part of the case and its content [must be legally correct and] not otherwise substantially covered by the instructions as given." Shervin, 804 F.3d at 47. "Like the district court, [w]e examine the evidence on the record and . . . draw those inferences as can reasonably be drawn therefrom, determining whether the proof, taken in the light most favorable to the [requesting party,] can plausibly support the theory of the [party]." United States v. Baird, 712 F.3d 623, 627 (1st Cir. 2013) (first and second alterations in original) (internal quotations omitted). In all events, "we examine the court's instructions as a whole, rather than reviewing fragments in isolation." Shervin, 804 F.3d at 47.

B

To begin, the appellant takes issue with the jury instruction about Dr. Schaefer's status and duties. She posits that Dr. Schaefer — who only monitored Ward from Massachusetts —

still had a "sufficiently close doctor-patient relationship" with Ward such that Dr. Schaefer had to obtain informed consent for Ward to participate in the ACP-501 protocol. At the charge conference, Ward lobbied for language to include the possibility that Dr. Schaefer, despite not administering the ACP-501 protocol himself, was acting as a principal investigator, co-investigator, or sub-investigator. And the appellant now explicitly asserts that a doctor-patient relationship can exist "without direct treatment of the patient."

The district court, though, considered that level of detail unnecessary, and Dr. Schaefer defends that decision on appeal. He suggests that any asserted difference between Ward's requested instruction and the district court's instruction is legally meaningless and that the court's instruction was legally correct.

We turn first to the legal standard for a claim of failure to obtain informed consent under Massachusetts law and then assess the jury instructions against the discerned standard.

1

In order to state a claim of failure to obtain informed consent under Massachusetts law, a doctor must have had a duty to disclose the relevant information to the patient, and the doctor's

breach of that duty must have caused the patient's injury.[4] See Halley v. Birbiglia, 458 N.E.2d 710, 715 (Mass. 1983). A doctor has a duty to disclose information if there was "a sufficiently close doctor-patient relationship"; the doctor knew, or reasonably should have known, the information; and the doctor reasonably should have recognized that the information would have been material to the patient's decision. Id.

The Massachusetts Supreme Judicial Court (SJC) considered this issue in two seminal cases. We take their measure.

In Harnish v. Children's Hospital Medical Center, the plaintiff alleged that surgeons failed to inform her of the potential for lost tongue function after a cosmetic procedure to remove a neck tumor. See 439 N.E.2d 240, 241 (Mass. 1982). The SJC held that a sufficient doctor-patient relationship existed not only between the plaintiff and the surgeon in charge but also between the plaintiff and one of two assistant surgeons. See id. at 245. That assistant surgeon had assured the plaintiff of the operation's success and mentioned potential consequences of the operation but omitted any mention of the risk of lost tongue function. See id. The second assistant surgeon — as far as the SJC could discern — had helped only with the performance of the

[4] The consent form that bears Ward's signature was introduced at trial, but for purposes of this appeal, we need not reach the question of whether that informed consent shelved any need for Dr. Schaefer to obtain his own informed consent.

surgery. See id. On these facts, the SJC held that the first assistant surgeon, along with the surgeon in charge, had established a doctor-patient relationship. See id. Given the absence of any comparable patient interaction, though, the second assistant surgeon had not established a doctor-patient relationship. See id.

In Halley v. Birbiglia, parents alleged that doctors failed to inform them of the risks associated with an imaging technique performed on their one-year-old son, which caused blood clots that ultimately necessitated amputation of the child's foot. See 458 N.E.2d at 712. The SJC held that one of the physicians involved in the child's care had not established a doctor-patient relationship because he had served only as "a neurological consultant" who was not the admitting or attending doctor, "saw [the child] intermittently," did not order or perform the imaging, and did not assure the parents of the procedure's safety. Id. at 715-16. The SJC held that another doctor had established a doctor-patient relationship because he had performed the imaging and spoken to the parents right after the procedure's completion. See id. at 716.

2

Against this backdrop, the appellant first complains that the district court refused to instruct the jury consistent

with its framing of the same issue in the summary judgment order. This plaint lacks force.

The summary judgment order reasoned: "If [Dr. Schaefer] did not have [a sufficiently close doctor-patient] relationship, he stands in the position of the assistant surgeon in Harnish, or the consulting neurologist in Halley, and had no duty to obtain . . . consent. If he did have such a relationship, he had such a duty." Ward v. Schaefer, No. 16-12543, 2021 WL 1178291, at *13 (D. Mass. Mar. 29, 2021) (emphases in original). The jury instructions contained the "sufficiently close doctor-patient relationship" language that formed the centerpiece of the summary judgment order. And as our ensuing analysis reveals, the jury instructions otherwise fit seamlessly within the framework of the summary judgment order.

The essence of the appellant's complaint seems to focus on the appropriateness of the language employed in the jury instruction, which asked the jury to determine whether the doctor either "serve[d] a primary or lead role in treating the patient or discusse[d] with the patient a course of treatment in detail." This query was juxtaposed with language that asked, alternatively, whether "the doctor [was] only tangentially involved in the patient's treatment and care." In the former instance, a duty to obtain informed consent would arise, but not in the latter instance.

We discern no abuse of discretion in the phrasing of these instructions. The language about a doctor serving a "primary or lead role" in patient treatment and discussing "a course of treatment in detail" is quite similar to the language employed by the SJC discussions in Halley, 458 N.E.2d at 715-16, and Harnish, 439 N.E.2d at 244-45. Whether a doctor leads the treatment or is the primary treatment provider effectively encompasses the distinction between positions such as an attending or admitting physician (who must obtain informed consent) and a consultant (who need not obtain informed consent). So, too, a doctor who serves a primary or lead role in treatment invariably will have more extensive patient contact (and, thus, will be required to obtain informed consent) in contrast to one who only assists with treatment (and, thus, will not be required to obtain informed consent). By the same token, a doctor who is "only tangentially involved" in a patient's treatment cannot be the attending physician and, by definition, would not have significant direct patient contact. Indeed, this latter phrasing is the very language that the SJC elected to use in Halley. See 458 N.E.2d at 716 (recognizing absence of "support [for] the extension of the informed consent doctrine to an individual so tangentially involved in the performance of a medical procedure").

Any remaining quibbles with the particular wording of the court's instructions are inconsequential. A district court

retains broad discretion in choosing the specific language used to convey technical concepts to a lay jury. See, e.g., Febres v. Challenger Caribbean Corp., 214 F.3d 57, 62-63 (1st. Cir. 2000). "So long as the charge sufficiently conveys the [party]'s theory, it need not parrot the exact language that the [party] prefers." United States v. McGill, 953 F.2d 10, 12 (1st Cir. 1992). Here, the court appropriately exercised this discretion because its instructions explained the relevant Massachusetts law to the jury in an accurate and understandable manner. See Testa, 144 F.3d at 175 (constraining appellate review to whether jury instructions "adequately illuminate[d] the law applicable to the controverted issues in the case without unduly complicating matters or misleading the jury").

Contrary to the appellant's importunings, whether Dr. Schaefer was a principal investigator, co-investigator, or sub-investigator is not a meaningful legal distinction. A clinical investigator's duties may require direct patient interaction and treatment such that the investigator would be obligated to obtain informed consent under the SJC's analysis. See Halley, 458 N.E.2d at 715-16; Harnish, 439 N.E.2d at 244-45. The relevant inquiry, though, would focus on the doctor's interaction with patients, not on his formal title or status in a clinical study. And as we have explained, the court was permitted to prefer its explanation of

the law over Ward's even if both satisfactorily covered the subject.

To the extent that the appellant now argues for an instruction that a doctor-patient relationship can exist "without direct treatment of the patient," such a statement does not accurately reflect Massachusetts law on informed consent.[5] The requested instruction would contradict the SJC's teachings that a doctor who is only tangentially involved need not obtain informed consent. See Halley, 458 N.E.2d at 716. By definition, a doctor who is not directly treating the patient must be only tangentially involved in the patient's care. A doctor who does not directly treat the patient is akin to the assistant surgeon in Harnish and the consulting neurologist in Halley, both of whom the SJC absolved of responsibility for obtaining informed consent. See id.; Harnish, 439 N.E.2d at 245.

C

The appellant strikes her hammer one more time to chip away at the jury instructions. The district court refused to let

[5] Because Ward failed to request this instruction below, the argument is forfeited and our review is for plain error. See DeCaro v. Hasbro, Inc., 580 F.3d 55, 60 (1st Cir. 2009) (explaining that substantial failure to comply with Federal Rule of Civil Procedure 51(d)(1)(B)'s requirement that objecting party present desired instruction to the court "normally results in forfeiture of the objection to which the failure relates"). We need not delve into the plain error construct, though, because the appellant has failed to persuade us that any error has occurred.

Ward pursue damages for harm allegedly caused by a three-day atrial fibrillation episode at the NIH without presenting an expert witness to testify on causation. This expert witness requirement, the appellant says, creates an insurmountable hurdle because the experimental nature of Ward's use of ACP-501 meant that no expert could offer a credible opinion on whether ACP-501 caused any subsequent medical condition. In the absence of direct evidence showing a causal connection, the appellant says that the jury should have been allowed to consider a res ipsa loquitur theory. That is, the jury should have been instructed that it could infer negligence from the circumstances without identifying a specific cause. See Enrich v. Windmere Corp., 616 N.E.2d 1081, 1084-85 (Mass. 1993) (allowing "inference of negligence . . . [without showing] specific cause of the occurrence when an accident is of the kind that does not ordinarily happen unless the defendant was negligent . . . and other responsible causes . . . are sufficiently eliminated").

The appellant presents as supporting facts that Ward was susceptible to atrial fibrillation, that atrial fibrillation was a known risk of ACP-501, that the atrial fibrillation episode was unusually severe given Ward's medical history, and that the NIH directed all of Ward's medical care during the ACP-501 protocol. From this nucleus of operative facts, the appellant suggests that a jury should have been able to infer that — even without expert

testimony on causation — this is the kind of situation in which Ward's atrial fibrillation episode could have been attributed only to the ACP-501 protocol.

We resist this suggestion. The appellant's attempt to invoke res ipsa loquitur is an exercise in futility. To apply res ipsa loquitur, "(1) the instrumentality causing the accident [must be] in the sole and exclusive control and management of the defendant; and (2) the accident [must be] of the type or kind that would not happen in the ordinary course of things unless there was negligence by the defendant." Wilson v. Honeywell, Inc., 569 N.E.2d 1011, 1013 (Mass. 1991) (internal quotation marks omitted). This doctrine is plainly inapplicable here.

For a start, the appellant fails to show that Dr. Schaefer was negligent in any respect, let alone show negligence in any of Ward's medical care. In a contrived effort, the appellant struggles to reimagine this situationally specific doctrine used to show causation in negligence cases to excuse the paucity of evidence connecting Ward's maladies to Dr. Schaefer's alleged misrepresentations. The effort goes nowhere.

Even in the absence of negligence, there was no proof that atrial fibrillation episodes might not occur during the administration of the protocol. Critically, Ward presented no evidence at trial from which the jury could determine that the mere occurrence of an atrial fibrillation episode under these

circumstances implied that the ACP-501 protocol caused the episode. Cf. Enrich, 616 N.E.2d at 1085 ("The jury must be able to find . . . that the mere occurrence of the accident shows negligence as a cause."). What is more, the appellant's own facts undermine her argument. She admits that Ward had experienced episodes of atrial fibrillation before the ACP-501 protocol was implemented — and she provides no explanation as to why the very same phenomenon, occurring during the ACP-501 protocol, must have been caused by the protocol. Thus, the district court appropriately rejected the appellant's attempt to smuggle res ipsa loquitur into the case.

IV

We need go no further. For the reasons elucidated above, the judgment of the district court, in so far as it concerns the claims asserted against Dr. Schaefer, is

Affirmed.