

**PUBLISHED**

**UNITED STATES COURT OF APPEALS  
FOR THE FOURTH CIRCUIT**

UNITED STATES OF AMERICA,  
*Plaintiff-Appellant,*

v.

ST. LOUIS UNIVERSITY, a corporation,  
*Defendant-Appellee.*

No. 02-1351

Appeal from the United States District Court  
for the District of Maryland, at Baltimore.  
J. Frederick Motz, District Judge.  
(CA-95-3639-JFM)

Argued: January 22, 2003

Decided: July 16, 2003

Before NIEMEYER, LUTTIG, and TRAXLER, Circuit Judges.

---

Reversed and remanded by published opinion. Judge Traxler wrote the majority opinion, in which Judge Niemeyer joined. Judge Luttig wrote a dissenting opinion.

---

**COUNSEL**

**ARGUED:** Mary McElroy Leach, Senior Trial Counsel, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellant. Marc Simon Moller, KREINDLER & KREINDLER, New York, New York, for Appellee. **ON BRIEF:** Robert D. McCallum, Jr., Assistant Attorney General, Thomas M. DiBiagio, United States Attorney, Jeffrey Axelrad, Director, Torts Branch, Civil Division,

UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C.; Daniel E. Troy, Chief Counsel, Eric M. Blumberg, Deputy Chief Counsel for Litigation, Michael N. Druckman, Associate Chief Counsel for Biologics, U.S. FOOD & DRUG ADMINISTRATION, Rockville, Maryland; Alex M. Azar, II, General Counsel, DEPARTMENT OF HEALTH AND HUMAN SERVICES, Washington, D.C., for Appellant. Mark R. Dunn, HERZOG, CREBS & MCGHEE, L.L.P., St. Louis, Missouri; Stanley P. Kops, Bala Cynwyd, Pennsylvania; Rex Carr, CARR, KOREIN, TILLERY, KUNIN, MONTROY & GLASS, East St. Louis, Missouri, for Appellee.

---

### OPINION

TRAXLER, Circuit Judge:

St. Louis University ("SLU") paid a \$16 million Missouri state-court judgment to the family of a boy who became paralyzed after receiving Orimune, an oral polio vaccine. SLU sought contribution from American Cyanamid, the parent company of the vaccine manufacturer, and United States government, which tested and approved the vaccine. The district court granted summary judgment in favor of Cyanamid and the government, concluding that SLU's contribution claims were barred by principles of collateral estoppel. We reversed and remanded. *See St. Louis Univ. v. United States*, No. 99-2227 (4th Cir. March 1, 2001); *American Cyanamid v. St. Louis Univ.*, No. 99-2224 (4th Cir. March 1, 2001). After remand, on motions and cross-motions for summary judgment, the district court concluded that the government, but not Cyanamid, was liable in contribution to SLU. The government appeals the district court's conclusion that it can be required to contribute to the state-court judgment entered against SLU.<sup>1</sup> We reverse and remand.

---

<sup>1</sup>In *American Cyanamid Co. v. St. Louis University*, No. 02-1235, SLU appeals the district court's rejection of its contribution claim asserted against Cyanamid. We address that appeal in a separate opinion.

---

## I. BACKGROUND

### A. The Vaccine

There are three types of poliomyelitis; "Type I can be contracted only from a Type I virus, Type II only from a Type II virus and Type III only from a Type III virus." *In re Sabin Oral Polio Vaccine Prods. Liab. Litig.*, 743 F. Supp. 410, 412 (D. Md. 1990). In the 1950s, an oral polio vaccine ("OPV") was developed that used a live but attenuated or weakened polio virus. "Like all vaccines cultivated from live viruses, OPV creates immunity by inducing a mild infection in the recipient." *Stuart v. American Cyanamid Co.*, 158 F.3d 622, 625 (2d Cir. 1998). However, OPV also carries with it a risk that a recipient (or someone in close contact with the recipient) will contract the disease through the vaccine.

OPV is produced by passing wild virus of each type through an animal host to develop a "strain" of attenuated virus. The vaccine manufacturer uses the strain to grow a "seed" of each type of virus, the seeds are used to produce monopools of each type of virus, and "lots" of that virus type are derived from the monopools. Lots from each type of virus are then combined into a single "trivalent" pool, from which a trivalent vaccine can be produced to protect against all three types of polio. See *Berkovitz v. United States*, 486 U.S. 531, 541 (1988).

The United States government approved OPV in 1960 and in 1961 adopted regulations governing the manufacture of the vaccine. The regulations required OPV to satisfy certain "neurovirulence" tests.

Neurovirulence is the capacity of an infectious agent to produce pathologic effects on the central nervous system. In this context, it refers to the vaccine's ability to cause paralytic poliomyelitis. The neurovirulence of a vaccine product is tested by injecting the product into monkeys. The product meets the neurovirulence criterion only if a specified number of the animals survive and a comparative analysis demonstrates that the neurovirulence of the vaccine product does not exceed the neurovirulence of a reference product previously selected by the agency.

*Berkovitz*, 486 U.S. at 545 n.9 (internal quotation marks omitted). Under the original OPV regulations, a given monopool could be used to produce vaccine only if its neurovirulence did not exceed that of the reference vaccine and the monopool was one of five consecutively made monopools that all satisfied the monkey neurovirulence test.

The government substantially amended the monkey neurovirulence regulations in 1991, in part because studies did not show a correlation between higher neurovirulence scores in monkeys and the incidence of vaccine-associated polio in humans. *See Additional Standards for Viral Vaccines*, 56 Fed. Reg. 21418, 21420 (May 8, 1991) ("No single vaccine lot has been associated with an increased incidence of poliomyelitis. The lots that have been identified as associated with a case of paralytic poliomyelitis have had typically low scores when tested by FDA and the manufacturer for neurovirulence in monkeys."). In 1996, the FDA repealed a number of regulations, including the oral polio vaccine regulations. *See Revocation of Certain Regulations*, 61 Fed. Reg. 40153, 40155 (August 1, 1996).

#### B. The State Court Action

The state-court judgment paid by SLU arose from SLU's actions in treating 3-month old Danny Callahan. Approximately one month after receiving a dose of Orimune, Danny developed a fever and a perirectal abscess. He was treated at Cardinal Glennon Hospital by hospital and SLU employees. Although the abscess improved, Danny's legs and left arm were permanently paralyzed. Type III polio virus was isolated in Danny's stool, and doctors ultimately concluded that Danny suffered from vaccine-associated polio.

The plaintiffs' theory of the case was that SLU improperly treated Danny's abscess by giving him the wrong kind of antibiotic. The improper treatment allowed the release of endotoxins, which suppressed Danny's immune system during a time when the polio virus from the vaccine was still replicating in Danny's gastrointestinal tract. Because Danny's immune system was compromised, the attenuated polio virus in the vaccine was able to replicate fast enough to overcome his suppressed immune system, resulting in poliomyelitis. The plaintiffs' experts testified that if the abscess had immediately been incised and drained as required by the standard of care, and if Danny

had been treated with an appropriate antibiotic, the endotoxins would not have been released and his immune system would not have been suppressed. Thus, the expert witnesses testified that if Danny had been treated properly, he would not have been paralyzed by the polio vaccine. The jury's \$16 million verdict in favor of the plaintiffs was affirmed by the Missouri Supreme Court. *See Callahan v. Cardinal Glennon Hosp.*, 863 S.W.2d 852 (1993) (en banc).

### C. *In re Sabin*

While *Callahan v. Cardinal Glennon Hospital* was proceeding through the Missouri state courts, multi-district Orimune cases filed against the United States government under the Federal Tort Claims Act were transferred to the District of Maryland for resolution of the common legal and factual questions. *See In re Sabin Oral Polio Vaccine Prods. Liab. Litig.*, 743 F. Supp. 410 (D. Md. 1990); *In re Sabin Oral Polio Vaccine Prods. Liab. Litig.*, 763 F. Supp. 811 (D. Md. 1991); *In re Sabin Oral Polio Vaccine Prods. Liab. Litig.*, 774 F. Supp. 952 (D. Md. 1991) ("*Sabin III*").<sup>2</sup> The *Sabin* plaintiffs contracted polio after receiving the Orimune vaccine or after coming into contact with a recipient of the vaccine. They sued the government, alleging, *inter alia*, that the government negligently approved for release the vaccine lots which contained the doses given to the plaintiffs, even though the vaccine seeds from which the lots were derived did not meet the neurovirulence standards set forth in the governing regulations.

The district court ultimately concluded that the government could be held liable for approving vaccine lots that did not comply with the regulatory requirements for neurovirulence. Applying the "Good Samaritan" principles of the *Restatement (Second) of Torts*, the district court determined that the government, by violating its own regulatory standards and approving for release vaccine derived from seeds that exceeded the neurovirulence standards, had increased the risk of harm for those receiving the vaccine, which proximately caused the plaintiffs' injuries. *Sabin III*, 774 F. Supp. at 958. This court affirmed the district court's causation and liability determination. *See In re*

---

<sup>2</sup>The district judge presiding over the cases currently before us also presided over the *In re Sabin* cases.

*Sabin Oral Polio Vaccine Prods. Liab. Litig.*, 984 F.2d 124 (4th Cir. 1993) (per curiam) ("*Sabin IV*"). The Orimune vaccine received by Danny Callahan was derived from one of the vaccine seeds that the district court in the *Sabin* cases concluded were improperly approved by the government.

## II. THE CONTRIBUTION ACTION

After the Missouri Supreme Court affirmed the *Callahan* verdict, SLU filed a contribution action in Maryland against the United States, alleging that Danny Callahan's polio was caused by the governmental failings identified in the *Sabin* cases. The government moved for partial summary judgment, arguing that SLU was barred by collateral estoppel from relitigating the *Callahan* jury's conclusion that SLU's malpractice caused Danny's polio. The district court agreed, concluding that SLU was prohibited from relitigating the facts that the court believed the *Callahan* jury necessarily found in order to reach its verdict against SLU: (1) that SLU breached the applicable standard of care when treating Danny's abscess; (2) that Danny's immune system would not have been suppressed but for SLU's inadequate treatment of the abscess; (3) that, but for the suppressed state of Danny's immune system, the live polio virus contained in the vaccine would not have been able to replicate fast enough to cause polio; and (4) that, but for SLU's negligence, Danny would not be paralyzed. The district court's collateral estoppel order prevented SLU from arguing that it was not negligent at all or that any negligence on its part did not contribute to Danny's polio, but the ruling allowed SLU to proceed on any theory consistent with the *Callahan* verdict. Thus, after the collateral estoppel order, SLU could still prevail if it could establish that an immunosuppressed child would not have contracted polio from a vaccine that complied with all regulatory requirements.

After the collateral estoppel ruling, the parties engaged in eighteen months of discovery. The government then moved for summary judgment on the ground that SLU could not prove that the government's negligence caused Danny's polio. The district court reviewed the evidence submitted by SLU and concluded that it was insufficient, given the *Callahan* findings, to establish a causal connection between the government's negligence and Danny's injuries. The district court

therefore granted summary judgment to the government on SLU's contribution claim.

We reversed and remanded, concluding that the district court improperly applied Missouri law when it held that the *Callahan* jury verdict had collateral estoppel effect on SLU's contribution action against the government. We explained that Missouri law did not limit SLU to causation theories predicated on the *Callahan* jury's implicit conclusion that Danny would not have contracted polio but for SLU's negligence which resulted in the suppression of his immune system. However, the district court had limited SLU during discovery to causation theories consistent with its ruling as to the collateral estoppel effect of the *Callahan* judgment, and the district court premised its order granting summary judgment on SLU's failure to present evidence of causation consistent with its collateral estoppel ruling. Because of the district court's error with regard to the collateral estoppel issue, we reversed the district court's grant of summary judgment to allow SLU an opportunity to develop other appropriate theories of causation.

After remand, SLU offered no new evidence, deposed no new witnesses, and offered no new theory of causation. Instead, it relied almost exclusively on the fact that in the *Sabin* cases, the court determined that the government's regulatory violations caused the injuries at issue. SLU argued that Danny Callahan's polio vaccine came from one of the seeds that the district court in *Sabin* had concluded the government negligently approved in violation of its own regulatory standards. Since the *Sabin* court had concluded that the government's failings proximately caused the injuries of the *Sabin* plaintiffs, SLU suggested that those same regulatory violations must also be held to have proximately caused Danny's injuries.

The district court agreed with SLU. Applying the same analysis the court had used in *Sabin III*, the district court concluded that the government's negligence in approving vaccine that did not satisfy the neurovirulence standards caused Danny's polio. The district court therefore granted partial summary judgment to SLU, concluding that the government was liable in contribution to SLU, but reserving for

later the determination of the extent of the government's liability to SLU.<sup>3</sup>

### III. ANALYSIS

The government's liability in contribution, of course, is dependent on SLU's ability to establish that the government can be held liable on the tort claim in the underlying action. *See United States v. Yellow Cab Co.*, 340 U.S. 543, 546-50 (1951) (concluding that the waiver of sovereign immunity under the Federal Tort Claims Act encompasses claims for contribution if the law of the relevant state would hold a private individual liable for contribution in the same circumstances); *Gramex Corp. v. Green Supply, Inc.*, 89 S.W.3d 432, 442 (Mo. 2002) (en banc) ("To maintain an action for contribution, both the party seeking contribution and the defendant against whom contribution is sought must be tortfeasors, originally liable to the plaintiff-injured party." (alterations and internal quotation marks omitted)). The government contends that SLU presented no evidence showing that the government's violations of the original polio vaccine regulations proximately caused the injuries suffered by Danny Callahan. According to the government, the district court's approach to the case amounts to the imposition of absolute liability for the government, which is inconsistent with the requirements of the Federal Tort Claims Act and does not meet the causation requirements of Missouri law. Given the absence of any admissible proximate cause evidence, the government contends that the district court must have reached its decision by giving collateral estoppel effect to its decision in *Sabin III*, but that collateral estoppel cannot be applied against the government in this case.

#### A.

We first consider the government's arguments as to whether the decisions in the *Sabin* cases must be given controlling effect in this litigation. At the outset, we can dispense with the government's claim that the district court improperly gave collateral estoppel effect to the

---

<sup>3</sup>The district court certified the order as appropriate for immediate review, and this court granted the government permission to bring this interlocutory appeal. *See* 28 U.S.C.A. § 1292(b) (West 1993).

*Sabin* decisions, an action which might well have been error. See *United States v. Mendoza*, 464 U.S. 154, 162 (1984) (rejecting the use of offensive nonmutual collateral estoppel against the government). The district court expressly did not give the *Sabin* cases collateral estoppel effect. Instead, it appears that the court viewed the cases as establishing binding precedent on the question of proximate cause. See *St. Louis Univ. v. United States*, 182 F. Supp. 2d 494, 500 n.5 (D. Md. 2002) ("I am not relying upon the doctrine of collateral estoppel, which may not be invocable against the government. I am simply following my reasoning in *Sabin III* that was affirmed on appeal." (citation omitted)). The question, then, is whether *Sabin III* and our decision in *Sabin IV* serve as binding precedent in this case. We think the answer to that question is no.

Under the Federal Tort Claims Act, state law, not federal law, serves as "the source of substantive liability." *FDIC v. Meyer*, 510 U.S. 471, 478 (1994). The Act requires the government's liability to be determined "in accordance with the law of the place where the act or omission occurred." 28 U.S.C.A. § 1346(b)(1) (West Supp. 2003). The Supreme Court has concluded that the "law of the place" refers to the "whole law," including choice-of-law principles of the state where the negligent act or omission occurred. See *Richards v. United States*, 369 U.S. 1, 11 (1962).

Because the government's actions with regard to the polio vaccine took place in Maryland, see *Sabin III*, 774 F. Supp. at 953-54, Maryland law, including its choice-of-law principles, governs this case, just as it governed the *Sabin* cases. Under Maryland's choice-of-law principles, the law to be applied in tort cases is the law of the state where the injury was suffered, not where the negligent act occurred. See *Johnson v. Oroweat Foods, Inc.*, 785 F.2d 503, 511 (4th Cir. 1986). Danny Callahan was injured in Missouri, so Missouri law applies to SLU's claim against the government. But the plaintiffs in the *Sabin* cases were residents of Maryland and Florida and suffered their injuries in those states. Thus, the proximate cause determination in *Sabin III* was reached by applying Maryland and Florida law, while the proximate cause determination in this case must be made by applying Missouri law. Accordingly, notwithstanding the factual overlap of the

cases, the analyses of *Sabin III* and *Sabin IV* simply do not govern this case.<sup>4</sup>

B.

Under Missouri law, a plaintiff seeking to hold a defendant liable in tort must establish the existence of a duty on the part of the defendant to protect the plaintiff, a breach of that duty, and damages caused by the breach. *See, e.g., L.A.C. ex rel. D.C. v. Ward Parkway Shopping Ctr. Co.*, 75 S.W.3d 247, 257 (Mo. 2002) (en banc). In this case (and the *Sabin* cases), the district court concluded that the government's duty arose under the "Good Samaritan" doctrine, through which liability may be imposed for the negligent execution of voluntarily undertaken duties. *See Hoover's Dairy, Inc. v. Mid-America Dairymen*, 700 S.W.2d 426, 432-33 (Mo. 1985) (en banc) (following Good Samaritan standards set forth in *Restatement (Second) of Torts* §§ 323, 324A (1965)). For purposes of this litigation, the government has agreed to be bound by the findings in the *Sabin* cases that it breached its duty by violating the OPV regulations. *See St. Louis Univ.*, 182 F. Supp. 2d at 498. Thus, the only issue before the district court was whether SLU could establish that Danny Callahan's injuries were caused by the government's breach of duty.

The district court concluded that SLU had sufficiently established that the government's regulatory violations caused Callahan's injuries. The court explained that in *Sabin III*,

I held that proximate cause was established by the mere fact that if seeds 45 B 85 and 45 B 165 had not been in use, the vaccine giving rise to the injuries would not have been manufactured. The evidence clearly establishes that but for the United States's negligence, the seeds would not have been used. I went on to reject an ancillary contention made by the

---

<sup>4</sup>Even assuming that SLU is correct in its contention that the tort laws of Maryland and Missouri are similar, it makes little sense for this court to apply Missouri law by way of *Sabin III* and *Sabin IV*, cases that applied Maryland and Florida law. Instead, we will go directly to the source and consult Missouri cases to determine whether SLU has satisfied the requirements of Missouri law.

government that proximate cause was dispelled by the fact that the specific lots involved in the two cases under consideration had met the regulatory neurovirulence criteria, and I concluded that the causal connection between the regulatory violations and plaintiffs' injuries are logical, sensible and direct. The Fourth Circuit affirmed this holding on appeal.

My reasoning in *Sabin III* is equally applicable here. This can be most easily seen by hypothesizing that SLU is correct in contending that the immunosuppression allegedly caused by its malpractice played absolutely no role in making Callahan susceptible to contracting polio from OPV. If that is true, Callahan stands in exactly the same position as did the plaintiffs in other *Sabin* cases because in that event the sole cause of his polio was the vaccine. Likewise, even if the immunosuppression did play some role in the disease process, Callahan's exposure to the oral vaccine had to be a contributing cause to his paralysis. The isolation of Type III polio virus in Callahan's stool demonstrates he contracted polio, and no one suggests that the immunosuppression alone could have caused the disease. Accordingly, as I held in *Sabin III*, Callahan was exposed to the virus as a consequence of the government's violation of the OPV regulations. If the government had not wrongfully approved the seed from which the vaccine was derived, Callahan would never have been administered a dose of Orimune and would never have contracted polio even if he had been immunosuppressed. This "but for" relationship meets the standard of proximate cause under Missouri law just as it does under the law of Maryland and Florida applicable in *Sabin III*.

*St. Louis Univ.*, 182 F. Supp. 2d at 499-500 (footnotes, alterations, and internal quotation marks omitted)).

We assume, of course, that *Sabin III* and *Sabin IV* properly applied Maryland and Florida law.<sup>5</sup> Nonetheless, it is clear that the approach

---

<sup>5</sup>The government points out that when this court in *Sabin IV* affirmed the proximate cause analysis in *Sabin III*, we relied on *Waffen v. United*

taken in the *Sabin* cases is inconsistent with the requirements of Missouri law, which governs this case. Under Missouri law, a plaintiff must establish both causation-in-fact and proximate cause. *See Callahan*, 863 S.W.2d at 862, 865; *Robinson v. Missouri State Highway & Transp. Comm'n*, 24 S.W.3d 67, 77 (Mo. Ct. App. 2000) (per curiam).

A defendant's conduct is the cause in fact of a plaintiff's injuries where the injuries would not have occurred but for that conduct. Proximate cause is not causation in fact, but is a limitation the law imposes upon the right to recover for the consequences of a negligent act. The requirement of proving proximate cause absolves those actors whom it would be unfair to punish because of the attenuated relation which their conduct bears to the plaintiff's injury.

*Robinson*, 24 S.W.3d at 77 (citations and internal quotation marks omitted). The district court's conclusion that Danny Callahan would not have contracted polio "but for" the government's action thus goes only to the question of causation-in-fact, not proximate cause, because it does not answer the question of whether the particular result that occurred was a reasonable and probable consequence of the government's conduct. *See Callahan*, 863 S.W.2d at 865 (Missouri courts "have generally said that the injury must be a reasonable and probable consequence of the act or omission of the defendant.").

The district court's explanation of why different results were required as to the claims against the government and Cyanamid, the

---

*States Department of Health & Human Services*, 799 F.2d 911 (4th Cir. 1986), which considered causation requirements under Maryland law in the context of a claim for loss of chance of survival. Subsequent cases from this court and Maryland state courts have indicated that *Waffen* did not accurately articulate the contours of Maryland's proximate cause requirements. *See Hurley v. United States*, 923 F.2d 1091, 1096 (4th Cir. 1991) ("Our interpretation of Maryland law in *Waffen* is called into question because we were interpreting Maryland law as espoused in *Hetrick v. Weimer*, which was later reversed by the Maryland Court of Appeals." (footnote omitted)); *Cooper v. Hartman*, 533 A.2d 1294, 1297 & n.4 (Md. 1987) (placing *Waffen* among a group of decisions that improperly "relaxed the standards regarding causation").

vaccine manufacturer, suggests that the court believed the causation standard is different in cases where the duty arises under the Good Samaritan doctrine. The court stated:

I find that Cyanamid cannot be held liable for contribution to SLU and that it is therefore entitled to summary judgment. While I recognize that this holding may seem asymmetrical, paradoxical, or even perverse in light of my finding that the government is liable for contribution, the difference in result flows from the difference in the nature of the respective duties owed by the United States and Cyanamid to those who were exposed to the live virus contained in OPV.

As indicated above, in *Sabin III* I ruled that the Good Samaritan doctrine and its parallel provision, *Restatement (Second) of Torts* § 323, imposed upon the government the duty not to approve vaccine seeds in violation of the OPV regulations. Cyanamid was under no such duty. Its duties and responsibilities to the members of the public, particularly to OPV recipients and their families, [are] defined by products liability law. In considering claims against Cyanamid, the focus must therefore be on the safety of its product, not the regulatory process for which the government bore responsibility. Likewise, in analyzing the element of proximate cause in claims against Cyanamid, the focus must be on whether the plaintiff can prove that it was a defect in the OPV that resulted in his injury, not simply—as in a case against the government—whether he had been exposed to OPV derived from a seed that had been improperly approved in violation of the regulatory process. Under Missouri law this element of causation is required whether a plaintiff sues for strict liability, negligence, or breach of warranty.

*St. Louis Univ.*, 182 F. Supp. 2d at 500. Missouri law, however, makes it quite clear that the Good Samaritan doctrine is relevant to the question of duty only; it has no effect on the general rules of causation. See *Wollen v. DePaul Health Center*, 828 S.W.2d 681, 683 (Mo. 1992) (en banc) ("[T]his Court has recognized that section 323

[of the *Restatement (Second) of Torts*] creates a duty of care. In creating this duty, this section of the Restatement defines a type of negligent behavior but does not alter the rules of causation." (citation omitted)). Thus, SLU's claim against the government requires evidence of proximate cause in addition to evidence of but-for causation.

As to proximate cause, we note that all OPV, including OPV that satisfied all regulatory requirements, carried the risk that the recipient would actually contract polio. Therefore, to show that Danny's polio was caused by the government's regulatory violations, we conclude that SLU was required to establish that Danny likely would not have contracted polio (or would have contracted a less severe case of polio) from a vaccine that satisfied the government's neurovirulence requirements. Any lesser standard would result in the government being held strictly liable for its regulatory violations, which would be inconsistent with Missouri law. *See Sill v. Burlington No. R.R.*, 87 S.W.3d 386, 392 (Mo. Ct. App. 2002) (explaining that the violation of a statute can, under certain circumstances, support a negligence *per se* claim, but that the plaintiff must prove that the statutory "violation was the proximate cause of the injury."). And this evidence, of course, must be in the form of expert testimony. *See, e.g., Wright v. Barr*, 62 S.W.3d 509, 524 (Mo. Ct. App. 2001) ("If there is a sophisticated injury, one that requires surgical intervention or other highly scientific techniques for diagnosis, expert medical testimony is required to prove causation.").

There is no such evidence in this record. At best, SLU's experts assumed that increased neurovirulence led to increased incidence of vaccine-associated polio, but SLU's experts did not offer that opinion. In fact, none of SLU's experts were even qualified to render such an opinion.<sup>6</sup> The district court recognized this absence of evidence, *see St. Louis Univ.*, 182 F. Supp. 2d at 502 ("Whether or not an oral polio

---

<sup>6</sup>In the first appeal, this court noted that there was some evidence that a more neurovirulent vaccine caused Danny to have a more severe case of polio. SLU, however, did not pursue this theory after remand and does not pursue it on appeal. Moreover, the district court concluded that the expert who provided this testimony was not qualified to render an opinion on causation, and SLU does not challenge that determination on appeal.

vaccine that complied with the OPV regulations would have caused Callahan and the plaintiffs in the other *Sabin* cases to contract polio ultimately is unknowable and unprovable."), as does SLU. SLU, however, insists that it is not required to present evidence of proximate cause.

According to SLU, the regulations establishing the neurovirulence standards created an "unrebuttable presumption" that any vaccine exceeding the standards posed an unacceptable risk that the recipient would contract polio. Brief of Appellee at 21. Thus, SLU contends that once it was established in the *Sabin* cases that the government violated its regulations and that the violations proximately caused the injuries, the government was automatically liable for the injuries suffered by anyone who received a vaccine derived from one of the vaccine seeds at issue in the *Sabin* cases. As noted above, such an approach is utterly inconsistent with Missouri law. See *Sill*, 87 S.W.3d at 392 ("If a submissible case is made under a negligence *per se* cause of action, a plaintiff could recover if a jury concluded that a statute was violated and the violation was the proximate cause of the injury."); *Friend v. Yokohama Tire Corp.*, 904 S.W.2d 575, 579 (Mo. Ct. App. 1995) ("One of the elements of a negligence *per se* action is that the violation of a statute was the proximate cause of the injury.").

Because there is no evidence that the government's regulatory violations proximately caused Danny's injury, SLU has failed to show that it is entitled to contribution from the government. We therefore reverse the district court's grant of partial summary judgment in favor of SLU and we remand for the entry of judgment in favor of the government. See *Monahan v. County of Chesterfield, Va.*, 95 F.3d 1263, 1265 (4th Cir. 1996) (explaining that where cross-motions for summary judgment have been filed, the appellate court can direct the entry of judgment in favor of the appellant).

*REVERSED AND REMANDED*

LUTTIG, Circuit Judge, dissenting:

I would affirm the district court's judgment in this case under the binding precedent of the circuit. In *In re Sabin Oral Polio Vaccine*

*Products Liability Litigation*, 984 F.2d 124 (4th Cir. 1993) ("*Sabin IV*"), we determined that under a tort regime, identical in all relevant respects to the one at issue here, an injury, identical to the one at issue here, was proximately caused by tortious conduct identical to that alleged here. On the basis of the *reasoning* which we adopted in that case, I must conclude that our application here of Missouri state law yields the conclusion that appellee SLU proffered sufficient evidence to establish the legally necessary causation for it to prevail.

The majority reaches the opposite conclusion. It reasons that "our decision in *Sabin IV* [does not] serve as binding precedent in this case," *ante* at 9, because "the proximate cause determination in *Sabin III* was reached by applying Maryland and Florida law, while the proximate cause determination in this case must be made by applying Missouri law." *Ante* at 9. This reasoning would be compelling if SLU proposed that we apply the *state law holdings* of *Sabin IV* to the facts of the case before us today. But, the majority is wrong to suggest that SLU, or by implication, I, argue that *Sabin IV* is binding as a matter of Missouri state law. All that SLU asks, and all that I contend is appropriate, is that we reach our judgment by applying the binding *reasoning* of *Sabin IV*.

While our decision in *Sabin IV* resulted in state law holdings, it also produced reasoning, by which we reached those state law holdings. This reasoning is uniquely the creature of this court, and, as it is binding upon us, we must apply it in other cases involving the same predicate facts (*i.e.*, functionally identical underlying tort regime, facts, and causation theories). In this manner, *Sabin IV* binds us as a matter of federal law, delimiting the open field that we would otherwise face in formulating our reasoning. Because the question before us is simply how we will reason to our application of Missouri's tort regime, which regime is functionally identical in the relevant regards to those from which we reasoned in *Sabin IV*, our conclusion as to how to reason to this application is governed by *Sabin IV*.

The majority, to its credit, does not attempt to deny the crucial point in this case, namely, that in *Sabin IV* we reasoned from two state tort law regimes, from injuries, and from asserted causation theories, that were functionally indistinguishable from those before us today. But, absent such a denial, it has no basis on which to reach the

conclusion it reaches today other than that it disagrees with the reasoning we adopted in *Sabin IV*. While I am somewhat sympathetic to the critique the majority implicitly levels at that reasoning, the majority, as am I, is bound to abide by it until this court *en banc* or the Supreme Court holds otherwise.

Having mistakenly rejected the authority of *Sabin IV*, the majority asserts that the district court erred here because it engaged in no proximate cause determination whatsoever. But *Sabin IV* quite clearly shows the majority to be in error on this point. There, we concluded that an identical causation theory, in the unique circumstance where the tortfeasor's function is that of a product-approver, suffices to establish proximate cause. We reasoned as follows:

The final point of appeal concerns the district court's determination that [the government's] *approval* of the lots was the *proximate cause* of [the plaintiff's] injuries. The test of probable [sic] cause is one of "reasonable probability or reasonable certainty." In other words, "the plaintiff has the burden of introducing evidence which affords a reasonable basis for the conclusion that it is more likely than not that the conduct of the defendant was a substantial factor in bringing about the result."

The district court concluded:

Regardless of the acceptability of the specific lots from which were derived the vaccine . . . if [the government] had properly applied 42 C.F.R. § 73.114(b)(1)(iii) . . . the seed would not have been used. This is so because the manufacturer would have been unable to satisfy the consistency requirement found in 42 C.F.R § 73.116(c). Likewise, regardless of the acceptability of the lots from which the vaccine administered to [the plaintiff] were derived, the lots would never have been produced and released but for the approval of [the] seed. . . . Thus, the causal connections between the regulatory violations and plaintiffs' injuries are logical, sensible and direct.

The government's argument that the failure to amend the regulation was not the *proximate cause* of the plaintiff's injuries misconstrues the plaintiff's claims and the district court's opinion. [The government's] liability arose out of releasing vaccine in violation of the regulations, not in its failure to amend the regulations.

*Sabin IV*, 984 F.2d at 128 (emphasis added) (citations omitted).

By this passage, we clearly concluded that the district court's reasoning — what the majority here terms a merely but-for causation analysis — constituted a proper *proximate cause* analysis with respect to a tortfeasor who functions as a unilateral product approver. Under this binding precedent, we are required to conclude that the district court's identical reasoning here is likewise a proper proximate cause analysis.

The majority's underlying dissatisfaction with this analysis seems based on the belief that such an analysis "would result in the government being held strictly liable for its regulatory violations, which would be inconsistent with Missouri law." *Ante* at 14. As an initial matter, strict liability effects culpability standards (*e.g.*, negligence, recklessness, etc.), *not* causation standards. That every regulatory violation in the circumstance where the government is a product approver is the proximate cause of injuries sustained by the use of the defectively approved product simply does not create strict liability since under Missouri law it still must be proven that the violation was the result of negligence or recklessness.

And, while I am somewhat sympathetic to the majority's other apparent concern — that the government is treated differently than the manufacturer with regards to the causal effect of its action in Callahan's injury — we may not base our judgment on it, for it is quite clear that we have already concluded that the district court's analysis, distinguishing between the two parties' causal effects, was proper. And this determination binds us, regardless of whether our prior reasoning as to why it is so is persuasive.

The majority's concern on this score, however, is not even fully borne out. That the causal effect of the government's conduct is dif-

ferently understood than that of the manufacturer is the result of the fact that the government's role as tortfeasor here springs from its actions as a product-approver. As opposed to a manufacturer, who presumably sells a range of product, some with and some without defect, a product-approver's *only* role is to determine whether a particular product goes to market at all. In this unique role, failure, and breach of a duty of care, does not result in any easy comparison between what would have happened had the defective "product" not been defective, because, for such a tortfeasor, the defective "product" is the failure to withhold *completely* the distributed item from distribution. Thus, had the government's "product" been free of defect, none of the offending vaccine would have been distributed at all. This contrasts with the case of a manufacturer who, had its product been defect free, would have distributed a defect free product. The causation of injury by one's "defective" action is quite different from the other, since one's "defect-free" action keeps all product from the market while the other instead distributes defect-free product. Since Florida and Maryland law, just like Missouri law, require plaintiffs to prove proximate cause by demonstrating that, had the product been defect-free, the injury would not have occurred, and since the government's defect-free product would have been the complete withholding of the vaccine, it was not too great of a stretch, even if not wholly persuasive, for us to conclude in *Sabin IV* that the alleged conduct proximately caused the alleged injury.

The district court's notation that its causation analysis took into account that the government acted under a Good Samaritan duty articulates this aspect of the case. That the majority instead thinks this notation signals that the lower court mistakenly "believed the causation *standard* is different in cases where the duty arises under the Good Samaritan doctrine[.]" *ante* at 13 (emphasis added), illustrates the panel's failure to appreciate how a manufacturer's defect causes injury in one way, while defective product approval causes injury in another. That different causal relationships exist between different categories of conduct and the injury they cause bespeaks nothing as to what legal standard applies to those causal relationships in a tort action.

But even if there were any merit to the majority's concerns that our prior analysis effectively creates a strict liability culpability standard

or a but-for causation standard and treats the government differently from the manufacturer, those issues have already been fought over and decided — and not by today’s opinion. *Sabin IV* decided the matter and so provides binding reasoning, which, if we were to apply it today, would result in affirmance of the district court’s judgment. Indeed, the rule we face not only binds us, but also every district court within our circuit and every future panel of our court, and the dissent’s judgment only evades that reality temporarily. *See Booth v. Maryland*, 327 F.3d 377, 382-83 (4th Cir. 2003) (explaining that it is error to follow the more recent of two contradicting panels).

For these reasons, I respectfully dissent.