No. SC88890

IN THE SUPREME COURT OF MISSOURI

CORTEZ STRONG,

Respondent,

v.

AMERICAN CYANAMID COMPANY,

Appellant.

On Appeal From The Circuit Court Of The 22nd Judicial Circuit, City Of St. Louis
Hon. Michael B. Calvin, Circuit Judge
Cause No. 9920880

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JURISDICTIONAL STATEMENT

In this products liability case alleging that Plaintiff Cortez Strong's polio vaccine was inadequately tested under FDA regulations, Defendant American Cyanamid Company ("Cyanamid") appeals from the entry of judgment on a jury verdict in favor of Strong in the amount of $8.5 million.

Cyanamid filed its notice of appeal on October 5, 2005, in the Court of Appeals for the Eastern District. LF XXIV:4213-14. Strong cross-appealed the denial of prejudgment interest. On August 28, 2007, the court, in a 2-1 decision, affirmed the jury's verdict and reversed the denial of interest. On September 12, 2007, Cyanamid filed a motion for rehearing and an application for transfer to this Court. The Court of Appeals denied both on October 9, 2007. On October 24, 2007, Cyanamid filed its application for transfer to this Court, which was granted on December 18, 2007.

The Court has jurisdiction under Art. V, § 10 of the Missouri Constitution and Supreme Court Rules 83.04 and 83.09.

STATEMENT OF FACTS

I. Polio and the Oral Polio Vaccine.

Poliomyelitis is a crippling and sometimes fatal disease caused by any of three distinct strains of poliovirus, referred to as types 1, 2, and 3. *See* Additional Standards for Viral Vaccine, Poliovirus Vaccine Live Oral, 56 Fed. Reg. 21,418, 21,418 (May 8, 1991); *Graham v. American Cyanamid Co*., 350 F.3d 496, 499-500 (6th Cir. 2003). In the United States in the early 1950s, the disease paralyzed more than 21,000 people annually. *See Graham*, 350 F.3d at 499. The country mounted a national campaign to combat this grave epidemic, and, in 1955, Dr. Jonas Salk developed an inactivated polio vaccine, known as IPV, made from killed poliovirus. Salk's vaccine significantly reduced the number of cases of polio, but because it could be administered only by injection and required regular booster doses to maintain immunity, crippling polio persisted. Between 1958 and 1961, nearly 19,000 cases were reported in the United States, and more than a thousand people died. *See id*.

Aiming to eradicate polio, scientists continued to work at developing a different type of vaccine made from strains of virus that were not killed but were purposefully weakened (or "attenuated") so that they would trigger immunity without causing polio. *See id*; Tr. 1592. Dr. Albert Sabin was a leader in this effort, and after clinical trials were conducted using the live-virus vaccine strains that he developed, the United States Public Health Service approved Sabin's strains in 1960 for use in making vaccine in this country. *See Graham*, 350 F.3d at 500; *see also* Tr. 1680-81.

Sabin's vaccine, known as live oral polio vaccine or OPV, is administered orally in small, liquid doses. Its ease of administration and its ability to confer life-long immunity caused it quickly to become the vaccine of choice for combating polio in the United States. After it came into use, the number of cases rapidly declined to an average of about ten per year. *See Graham*, 350 F.3d at 501. Ultimately, OPV eradicated polio in the Western Hemisphere. *See* Tr. 957-59.

Although OPV is one of the safest vaccines in history, it is made from live virus and thus inherently poses a small, irreducible risk of causing paralysis in some recipients. *See* Tr. 1594; *see also* Tr. 1381-82. This risk is most commonly associated with the first dose in a four- or five-dose vaccination regimen, after which only one in 1.2 million recipients may develop vaccine-associated paralysis. *See* Tr. 965-66. With subsequent doses, the risk drops to between one in 21 million and one in 116.5 million. *See* Tr. 966-68, 1258-59. The inherent and unavoidable risk of vaccine-associated paralysis is well-recognized and fully disclosed in the vaccine's labeling. *See* Tr. 1594; *see also* Tr. 1381-82.

II. The Manufacture and Testing of Cyanamid's OPV.

In 1963, Cyanamid was one of three pharmaceutical companies licensed by the federal government to make oral polio vaccine. By 1987, when Cortez Strong was vaccinated, Cyanamid had been the sole supplier of OPV for nearly a decade. Tr. 1584-85. Cyanamid's vaccine was called Orimune®, and hundreds of millions of doses of it were given in this country for nearly forty years.

Cyanamid (like all other manufacturers) was required to make vaccine using the original Sabin strains, the only strains that the federal government ever approved. Tr. 1600-01; *see also Graham*, 350 F.3d at 500. Originally, the company received very small volumes—less than 15 milliliters each—of the type 1, 2, and 3 vaccine strains. These strains, which were made at the facilities of the Merck pharmaceutical company, are sometimes referred to as SOM—"Sabin Original (Merck)"—Types 1, 2 and 3. Cyanamid's scientists grew larger volumes of each strain by inoculating tiny amounts of the original materials into batches of cell cultures extracted from the kidneys of monkeys. They repeated these "tissue culture passages" until they developed a large enough volume to constitute a "production seed" for each of the three types of poliovirus. Tr. 1601-03; *see Graham*, 350 F.3d at 500. The production seeds were then stored in a special freezer, and once or twice a year small volumes were withdrawn, thawed, and used to make much larger volumes called "monopools," again by passing small volumes of the production seed through additional monkey kidney cell cultures. Finally, monopools for all three virus strains were combined into a single, "trivalent" vaccine, which was dispensed in one-dose plastic vials that pediatricians used to inoculate their patients. Tr. 1601-05; *see Graham*, 350 F.3d at 500.

During the forty years that it produced OPV, Cyanamid created only two sets of production seeds, the first in the early 1960s and the second in the mid- to late-1970s. The vaccine that Strong received was produced from the second set of production seeds. Creation of those seeds began with small amounts of SOM Type 1, SOM Type 2, and a version of SOM Type 3—referred to as either "SOR," "45B164," or the "Pfizer

material"—that had been altered slightly by Pfizer, Ltd., another company that was licensed to make oral polio vaccine. *See* Def.'s Ex. 113A, C, E. For the type 1 and type 2 components, the SOM strains were first neutralized with an antiserum to a simian virus known as SV40, and the neutralized materials were designated 45B157 and 45B158. *See* Def.'s Ex. 113A, C. Small amounts of 45B157 and 45B158 were then passed through monkey kidney cell cultures to make intermediate materials known as 701S and 801S, and those intermediate materials in turn were passed through new cultures to make type 1 and type 2 production seeds, designated 45B160 and 45B162. *See* Def.'s Ex. 113A, C. For the type 3 component, the Pfizer material (45B164) was used directly to make the type 3 production seed, designated 45B165. *See* Def.'s Ex. 113E. These three production seeds—45B160 (type 1) , 45B162 (type 2), and 45B165 (type 3)—were then used over the years to make vaccine monopools, including the three monopools, designated 1-261, 2-281, and 3-504, that were combined to make the dose of Orimune that Plaintiff Strong received. *See* Tr. 1606.

Throughout the manufacturing process, Cyanamid conducted extensive testing, as required by the FDA's regulations. *See* 21 C.F.R. §§ 630.10-.17 (1987). One such test, the "monkey neurovirulence" test, was performed on live monkeys by injecting tiny amounts of material—taken either from a production seed or a monopool, depending on what materials were being tested at the time—into the brains and spinal cords of groups of monkeys. After a specified period, the monkeys' central nervous system tissue would be microscopically examined, and any lesions were compared to a reference standard. *See id.* § 630.10; Tr. 1638-39. The FDA also conducted its own tests—including monkey

neurovirulence tests—on samples that the company provided to the government along with its test results. *See id.* § 630.17(e); Additional Standards for Viral Vaccine Poliovirus Vaccine Live Oral, 56 Fed. Reg. at 21425; Tr. 1594-95. If the FDA concluded that all the test results were acceptable, it would issue an official "release," which authorized Cyanamid to package and distribute the vaccine. In this case, the FDA expressly approved the final vaccine that Strong received, as well as the production seeds and the monopools used to make the vaccine. *See* Def.'s Ex. 45-47, 54-56, 105H.

III. Strong's Vaccination and His Claims in This Case.

Plaintiff Strong received his second dose of Orimune in June, 1987. *See* Tr. 892-93. Shortly thereafter, he developed partial paralysis in his arms. *See* Tr. 891. The evidence also showed that Strong had been infected with Enterovirus 71, a virus causing symptoms that cannot be distinguished from polio. *See* Tr. 1193, 1197. Over the following years, his condition improved, but he has weakness in one arm and some weakness in his hands. *See* Tr. 873-74, 891.

In this case, Strong claims that he developed vaccine-associated polio from his second dose of Orimune. His claims against Cyanamid are based on two legal theories: that the vaccine he received was defective and that Cyanamid was negligent in manufacturing it.[1/] Both theories rest solely on an allegation that Cyanamid did not comply with FDA regulations governing vaccine production.

[1/] Strong's Second Amended Petition also asserted claims for breach of warranty, fraud, and punitive damages. Strong dropped the warranty and punitive damages claims,

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Cyanamid moved for summary judgment, arguing, among other things, that Strong could not raise a triable issue of fact either that his vaccine was made in violation of the FDA's regulations or that any alleged violation in fact increased the risk of vaccine-associated paralytic poliomyelitis over and above the risk inherent in all OPV. The trial court denied Cyanamid's motion, and the case was tried to a jury between May 10 and May 26, 2005.

In seeking to establish Cyanamid's liability, Strong first read and played videotape of lengthy excerpts from the depositions of five current and former Cyanamid employees. None testified that Cyanamid had done anything improper. *See* Tr. 561-63, 1071-85, 1150-61, 1303, 1309-21, 1459-84, LF XIX:3225-92, LF XIX:3305-LF XX:3663.

Strong then introduced the testimony of Thomas Bozzo, a former FDA compliance officer, whom he proffered as an expert on compliance with FDA regulations. Tr. 590-860. Bozzo acknowledged that each of the production seeds and monopools used to make Strong's vaccine was properly tested in compliance with the regulations, and he took no issue with the FDA's decision to release those materials. *See* Tr. 759; *see also* Tr. 764, 771, 774. He testified, however, that FDA regulations also required the company to perform certain additional tests at earlier stages of the manufacturing

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and they are thus waived. *See Elfrink v. Burlington N. R.R. Co.*, 845 S.W.2d 607, 611 (Mo. App. E.D. 1992). The fraud claim was dismissed before trial, and Strong never appealed that ruling.

process. *First*, he claimed that 21 C.F.R. § 630.10(b)(4) and (5) and 21 C.F.R § 630.16(b)(1) required that the company test the original strains (SOM Types 1 and 2 and the Pfizer material) and certain intermediate components (701S and 801S) for monkey neurovirulence.[2/] Tr. 689-91. This was the sole basis for the negligent manufacture claim that was submitted to the jury. *See* LF XXIII:4030.[3/] *Second*, he testified that 21 C.F.R. § 630.10(b)(3) required that the company test the original Sabin strains for extraneous microbial or adventitious agents. *See* Tr. 689-91. Bozzo thus disagreed with the FDA's own official determination that the final vaccine complied with the regulations.[4/] At trial, Strong never proffered Bozzo on the issue of causation.

[2/] The regulations are reprinted in the Appendix. (*See* A-11 to 20.)

[3/] The jury instruction on the negligent manufacturing claim also included (over Cyanamid's objection) references to 45B157 and 45B158—the SV40-neutralized versions of SOM Types 1 and 2—and to SOM Type 3 (the precursor to 45B164), but Bozzo never testified that testing should have been performed on any of those materials. In fact, he did not even know what 45B157 and 45B158 were. *See*, *e.g.*, Tr. 703-06, 732-33. There was no evidentiary basis for any finding with respect to those materials.

[4/] Bozzo initially suggested a third purported regulatory violation—that Cyanamid improperly used "experimental monkeys" to manufacture some components of the vaccine. Tr. 692. He based that assertion on a review of documents provided to him by Strong's counsel but never admitted at trial. On cross examination, Bozzo was shown another document, not provided to him by Strong's counsel, showing that certain

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The remainder of Strong's evidence related to the diagnosis of Strong's condition, his physician's liability for malpractice, and damages.

At the close of Strong's case-in-chief and again at the end of trial, Cyanamid moved for a directed verdict. Among other things, Cyanamid argued that Strong had adduced no evidence from which a jury could find that any alleged regulatory violation had any impact on the safety of the vaccine that Strong received. Cyanamid pointed out that, because all oral polio vaccines indisputably pose some risk of vaccine-associated paralysis, Strong must prove that his vaccine was *more likely* to cause polio than had the strains and intermediate materials undergone the additional tests that Bozzo claimed were mandated by FDA regulations. *See* Tr. 1548-66, 2025-27; LF XXIII:4015-18.

The trial judge voiced serious concerns that Strong had not connected Cyanamid's alleged regulatory violations with the injury in this manner, but he nevertheless denied

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monkeys used in experiments were not used to produce 701S or 45B160. Tr. 796-810. Strong thereafter abandoned this assertion entirely; he never mentioned it in his closing statement and never addressed it on appeal. *See* Tr. 2090-2101, 2134-50; Respondents/Cross-Appellant's Brief, *Strong v. American Cyanamid Co.*, No. ED 87045 (Mo. App. E.D. May 5, 2006). Indeed, the Court of Appeals brushed it aside by ruling that there was no evidence that the use of "experimental monkeys" had anything to do with vaccine safety in this case. *Strong v. American Cyanamid Co.*, No. ED87045, slip op., at 17 (Mo. App. E.D. Aug. 28, 2007) ("slip op.").

the motion and submitted the case to the jury. Tr. 2010-11, 2028. In a 9-3 vote, the jury returned a verdict for Strong and awarded the $8.5 million in damages he requested. LF XXIII:4037-38; Tr. 2093.

On June 27, 2005, Cyanamid moved for judgment notwithstanding the verdict and for a reduction in damages, which the trial court denied. LF XXIII:4196. In a 2-1 decision, the Court of Appeals affirmed. In rejecting Cyanamid's argument that there was no proof of causation, the majority relied (although Strong himself never had) on two brief exchanges from Bozzo's testimony:

> Q What happens if you don't do [safety tests required by regulations]?
>
> A Well, if you omit safety tests, then you *raise the possibility* of a product being unsafe. . . . [and "raising the possibility" means that] the general public is then exposed to product that is at higher risk or higher danger for an untoward effect. And if you're talking about a neurovirulence test, it's virulent polio virus being given to them.
>
> * * *
>
> Q Do you have an understanding of what causes [reversion of the attenuated polio virus used in vaccine to a more virulent form]?
>
> A Not from a virological standpoint, no.
>
> Q Do you have an understanding from some other standpoint?
>
> A Well, if the product was inadequately tested for neurovirulence, *then it's possible* that the product simply contained particles of neurovirulent virus[.]

Slip op. at 17-18 (emphasis added); Tr. 686, 853.

In a motion for rehearing and application for transfer, Cyanamid argued that the Court of Appeals was wrong to rely on anything Bozzo said about causation, because Strong had not proffered or relied on him as an expert on this issue and because Bozzo had expressly stated that (a) he was *not* an expert on the "scientific aspects" of any of the tests he testified about, Tr. 623; (b) he was not a virologist or an epidemiologist, Tr. 605; and (c) while he thought that there was "certainly a potential association between what [he] cite[d] as deviations or noncompliance with regulations and the case, the polio case of the plaintiff," he was "*not in a position to say that that's what occurred*," Tr. 849 (emphasis added). The Court of Appeals denied rehearing and transfer. On December 18, 2007, this Court granted Cyanamid's transfer application.[5/]

[5/] Because the Court accepted transfer of this case, the decision of the Court of Appeals, including its ruling on Strong's demand for pre-judgment interest, is effectively vacated, and the $8.5 million judgment, without prejudgment interest, is the judgment that Cyanamid is appealing to this Court. Sup. Ct. R. 83.09; *Buchweiser v. Estate of Laberer*, 695 S.W.2d 125 (Mo. banc 1985). Should Strong decide to pursue in this Court the cross-appeal that he filed in the Court of Appeals, Cyanamid will address any issues so cross-appealed in its cross-respondent's/appellant's reply brief.

POINTS RELIED ON

I. The trial court erred in denying Cyanamid's motion for judgment notwithstanding the verdict because Strong failed to show any violation of FDA regulations, in that the meaning of those regulations (a) was a question of law for the court and not the jury and (b) should have been resolved by deferring to the FDA's own interpretation.

Wulfing v. Kansas City S. Indus., Inc., 842 S.W.2d 133 (Mo. App. W.D. 1992)

State ex rel. Webster v. Missouri Resource Recovery, Inc., 825 S.W.2d 916 (Mo. App. S.D. 1992)

Vittengl v. Fox, 967 S.W.2d 269 (Mo. App. W.D. 1998)

Additional Standards for Viral Vaccine, Poliovirus Vaccine Live Oral, 56 Fed. Reg. 21418 (May 8, 1991)

II. The trial court erred in denying Cyanamid's motion for judgment notwithstanding the verdict because Strong failed to present a submissible case on causation, in that (a) the evidence cannot support a finding that any alleged regulatory violation affected the safety of the vaccine Strong received, and (b) Strong's only expert expressly disavowed any ability to draw the requisite causal connection between the alleged violations and Strong's injury.

American Cyanamid Co. v. St. Louis Univ., 336 F.3d 307 (4th Cir. 2003)

Graham v. American Cyanamid Co., 350 F.3d 496 (6th Cir. 2003)

Kinealy v. Southwestern Bell Tel. Co., 368 S.W.2d 400 (Mo. 1963)

Heacox v. Robbins Educ. Tours, Inc., 829 S.W.2d 600 (Mo. App. E.D. 1992)

III. The trial court erred in denying Cyanamid's motion for remittitur or a new trial, because the $8.5 million verdict was excessive, out of line with other awards, not supported by the evidence, and can be explained only by the trial court's erroneous introduction of irrelevant and prejudicial evidence.

Vincent by Vincent v. Johnson, 833 S.W.2d 859 (Mo. banc 1992)

McCormack v. Capital Elec. Constr. Co., 159 S.W.3d 387 (Mo. App. W.D. 2004)

King v. Unidynamics Corp., 943 S.W.2d 262 (Mo. App. E.D. 1997)

LaRose v. Washington Univ., 154 S.W.3d 365 (Mo. App. E.D. 2004)

STANDARD OF REVIEW

Points I-II: This Court reviews denial of judgment notwithstanding the verdict *de novo* when the decision was based on an issue of law. *Jungerman v. City of Raytown*, 925 S.W.2d 202, 204 (Mo. banc 1996). Whether a party presented a submissible case, whether the evidence is substantial, and whether the jury drew reasonable inferences are questions of law and are thus reviewed *de novo* on appeal. *See Savory v. Hensick*, 143 S.W.3d 712, 716 (Mo. App. E.D. 2004).

If the plaintiff has failed to make a submissible case, then the denial of a defendant's motion for judgment notwithstanding the verdict should be reversed and judgment should be entered for the defendant. *See Giddens v. Kansas City S. Ry. Co.*, 29 S.W.3d 813, 818 (Mo. banc 2000). A case is submissible only if "each and every fact essential to liability is predicated upon legal and substantial evidence." *Id.* at 818; *Wilkerson v. Williams*, 141 S.W.3d 530, 533 (Mo. App. S.D. 2004); *see also* Mo. Sup.

Ct. R. 72.01 (1999). "Substantial evidence is that which, if true, has probative force upon the issues, and from which the trier of fact can reasonably decide a case." *Moore ex rel. Moore v. Bi-State Dev. Agency*, 87 S.W.3d 279, 286 (Mo. App. E.D. 2002). When evaluating whether the evidence can support the jury's verdict, "the evidence is viewed in the light most favorable to the result reached by the jury, giving the plaintiff the benefit of all reasonable inferences and disregarding evidence and inferences that conflict with that verdict." *Giddens*, 29 S.W.3d at 818 (internal citations omitted).

Point III: This Court reviews the denial of a motion for remittitur for abuse of discretion. *See LaRose v. Washington Univ.*, 154 S.W.3d 365, 370 (Mo. App. E.D. 2004). "Remittitur is appropriate when the court finds that the jury's award is excessive because the amount of the verdict exceeds fair and reasonable compensation for plaintiff's injuries and damages." *Lay v. P & G Health Care, Inc.*, 37 S.W.3d 310, 332-33 (Mo. App. W.D. 2000). Additionally, "when a jury's bias and prejudice result in an excessive verdict a new trial is required." *Id.* at 333.

ARGUMENT

While an understanding of the science of polioviruses and vaccines is necessary in this case, the issue on appeal is far more basic and routine to lawyers and judges: whether the essential rules of tort liability were followed here. They decidedly were not, and with respect to the core elements of products liability law—product defect, breach of duty, and causation—the plaintiff's evidence was insufficient as a matter of law to support the jury's verdict.

First, Strong failed to establish that his vaccine was defective or that Cyanamid breached any duty in tort. His claims turned entirely on alleged violations of the FDA's testing regulations, but his evidence—the testimony of Thomas Bozzo—never should have been presented to the jury. According to the FDA's own interpretation of its regulatory standards, the testing that Bozzo claimed was missing was not in fact required by any regulation. More fundamentally, the meaning of these federal regulations was a matter of law for the court alone, and if there was a dispute about what those regulations required, it was the court's obligation to resolve that dispute and to instruct the jury accordingly. In resolving that legal dispute, moreover, the trial court should have given deference to the FDA's interpretation of its own regulations. *See* Point I, *infra*.

But apart from the issues of duty, defect, and breach, another core issue lies at the heart of this dispute: whether Strong made a submissible case on the element of causation. Here, Bozzo, who was never even proffered on this critical issue, said nothing more than that the alleged regulatory violations "raise[d] the possibility" of injury. That is not enough to support a finding of proximate cause under basic principles of Missouri law. Strong was required to prove that any alleged regulatory non-compliance—here, the failure to conduct tests during the *initial* stages of vaccine production—made Strong's vaccine less safe than had the regulations been fully satisfied, assuming that Bozzo's view of the regulations somehow governed. Even the Court of Appeals agreed that this was the appropriate legal analysis. *See* slip op. at 13-16 (citing *American Cyanamid Co. v. St. Louis Univ. ("SLU")*, 336 F.3d 307 (4th Cir. 2003); *United States v. St. Louis Univ.*, 336 F.3d 294 (4th Cir. 2003); and *Graham v. American Cyanamid Co.*, 350 F.3d 496 (6th

Cir. 2003)). Bozzo, however, conceded that, notwithstanding a "potential association" between a regulatory violation and the injury in this case, he was "not in a position to say" that that association existed. That testimony defeats any effort to establish proximate causation here. The prerequisite causal link between a breach of duty and a plaintiff's injury cannot be found by a jury when the only witness to testify about the matter affirmatively states that he does not know whether a causal link even exists. Without testimony that a breach of duty in fact, and proximately, caused the injury (not that it "potentially" or "possibly" did), there was no evidentiary basis for the jury in this case to hold Cyanamid liable for *any* claimed violation of the FDA's regulations. This is particularly so in light of the undisputed evidence that the necessary tests were, in fact, successfully conducted during *subsequent* stages of the manufacturing process—including on the final vaccine that Strong received. The asserted failure to test thus could not have caused Strong's injury as a matter of fact or logic. Judgment notwithstanding the verdict should be entered in Cyanamid's favor. *See* Point II, *infra*.

Finally, should this Court not reverse the judgment here, it should order a substantial remittitur or a new trial. The verdict is far out of line with awards for much more serious injuries and was based on sympathy and irrelevant evidence that should never have been admitted. *See* Point III, *infra*.

POINT I

THE TRIAL COURT ERRED IN DENYING CYANAMID'S MOTION FOR JUDGMENT NOTWITHSTANDING THE VERDICT BECAUSE STRONG FAILED TO SHOW ANY VIOLATION OF FDA REGULATIONS, IN THAT THE MEANING OF THOSE REGULATIONS (A) WAS A QUESTION OF LAW FOR THE COURT AND (B) SHOULD HAVE BEEN RESOLVED BY DEFERRING TO THE FDA'S OWN INTERPRETATION.

Cyanamid is entitled to judgment because Strong failed to prove that there was any defect in the vaccine that he received or that Cyanamid breached any standard of care. Strong's only theory of defect or breach is his argument that the FDA's regulations required Cyanamid to perform certain tests earlier in the manufacturing process than it had done. Bozzo was Strong's only witness on this point, and his testimony was insufficient for two reasons. First, the trial court improperly allowed Bozzo to address, and the jury to decide, not some factual question about what tests Cyanamid did or did not do (as to which there was no significant dispute), but rather what tests the regulations required it to do. The meaning of regulations and what they require are legal issues within the province of the courts. *Wulfing v. Kansas City S. Indus., Inc.*, 842 S.W.2d 133, 153 (Mo. App. W.D. 1992), *overruled on other grounds by Exec. Bd. of the Mo. Baptist Conv. v. Carnahan*, 170 S.W.3d 437 (Mo. App. W.D. 2005). It was not the role of an expert to tell the jury what the regulations required. Second, Bozzo's interpretation of the regulations is legally wrong. It directly contradicts the FDA's own position, to which courts should give substantial deference. *See Willard v. Red Lobster*, 926 S.W.2d 550

(Mo. App. E.D. 1996); *see also Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 127 S. Ct. 2518 (2007).

There is no dispute that Cyanamid tested, and the FDA approved, the production seeds and monopools at issue in this case (as well as the final vaccine that Strong actually received). *See* Def.'s Ex. 45-47, 54-56, 105H. At trial, however, the court allowed Bozzo to offer opinions that the FDA's regulations also required Cyanamid to test both the original vaccine strains (SOM Types 1 and 2 and the Pfizer material) and certain intermediate components (701S and 801S) for monkey neurovirulence and the Sabin strains for extraneous microbial agents. Tr. 689-91. In both instances, Bozzo claimed that the original strains and the intermediate materials made from them were "seeds" that had to be tested within the meaning of the FDA's regulations governing seed testing. The FDA, on the other hand, had required that Cyanamid test only its *production* seeds (45B160, 45B162, and 45B165) and the vaccine monopools made directly from them, not the precursor strain and intermediate materials. Tr. 758-59, 762, 764; 56 Fed. Reg. at 21,422; 21 C.F.R. § 630.10(c) (1992). Because the production seeds and monopools were satisfactorily tested, the FDA approved and released the vaccine that Strong received. *See* Def.'s Ex. 45-47, 54-56, 105H.

Who was right about the meaning of the FDA's regulations—the FDA and Cyanamid, or Bozzo—is a question of law, which the trial court was required to resolve using the traditional interpretive tools that courts employ every day. *See, e.g.*, *Lumbermens Mut. Cas. Co. v. Thornton*, 92 S.W.3d 259, 266 (Mo. App. W.D. 2002) (meaning of regulations is a question of law "for the court alone"). It was error for the

court instead to allow an expert to testify before the jury about what the regulations meant. As this Court has made clear, "an expert's opinion cannot be received if it amounts to a conclusion of law." *Young v. Wheelock*, 64 S.W.2d 950, 1008 (Mo. 1933). (internal quotations omitted); *see also Wulfing*, 842 S.W.2d at 153 ("[T]he opinion of an expert on issues of law is not admissible.").

Moreover, the interpretation that Bozzo offered is legally untenable, not least because it conflicts directly with the FDA's construction and application of its own regulations. Cyanamid specifically described to the FDA each of the steps it undertook to prepare the production seeds at issue here (45B160, 45B162, and 45B165), including its use of intermediate materials 701S and 801S. *See* Def.'s Ex. 113A, 113C, and 113E. Indeed, Bozzo agreed that the FDA was fully aware of the production process. *See* Tr. 751-52, 754-58. Yet, the FDA never applied its "seed" testing regulations to require testing of the Sabin strains or intermediate materials used to make the production seeds. Rather, the FDA approved the production seeds for use based on the only testing that it believed was required. *See* Def.'s Ex. 45-47.

The FDA's position is not just a matter of inference. When the agency amended its polio vaccine regulations in 1991, it expressly rejected any argument that the term "seed" included precursor materials such as the original Sabin strain material:

> [T]he agency believes that SO [Sabin Original] (produced by Dr. Sabin), SOM (produced by Merck Sharp and Dohme), and SOR (produced by Pfizer, Ltd.) all constitute original Sabin strain material. Therefore, production of lots directly from any of these strain materials *should not*

require that SO, SOM, or SOR be tested in accordance with the criteria for qualification of the seed virus in 630.10(c).

56 Fed. Reg. at 21,422 (emphasis added).[6/] There is no question that, in the FDA's own long-held view, neurovirulence testing was required only for production seeds and monopools, the materials that are used directly in the production of distributed vaccine. *Id.*; 21 C.F.R. §§ 630.10, 630.16-.17.

Under well-established Missouri law, the trial court was required to defer to the FDA's position on questions uniquely within the agency's expertise. Indeed, deference "is even more clearly in order when interpretation of [the agency's] own regulation is at issue." *State ex rel. Webster v. Missouri Res. Recovery, Inc.*, 825 S.W.2d 916, 931 (Mo. App. S.D. 1992); *see also Willard*, 926 S.W.2d at 550 ("When interpretation of an agency's own rule is at issue, we give deference to the agency's determination."). Federal courts, too, have uniformly held that an agency's interpretation of its own regulations is entitled to deference. *See, e.g., Nat'l Ass'n. of Home Builders*, 127 S. Ct. at 2518 ("An agency's interpretation of the meaning of its own regulations is entitled to deference unless plainly erroneous or inconsistent with the regulation."); *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994) ("Our task is not to decide which among several competing interpretations best serves the regulatory purpose. Rather, the

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[6/] In 1991, the regulations regarding production seed qualification were recodified at 21 C.F.R. § 630.10(c). *See* 56 Fed. Reg. at 21,432. The 1987 regulations, relied upon by Bozzo, had addressed this issue at 21 C.F.R. § 630.10(b).

agency's interpretation must be given 'controlling weight unless it is plainly erroneous or inconsistent with the regulation.'" (quoting *Udall v. Tallman*, 380 U.S. 1, 16 (1965), in turn quoting *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945)).[7/]

This is particularly true "when, as here, the regulation concerns a complex and highly technical regulatory program, in which the identification and classification of relevant criteria necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns." *Thomas Jefferson Univ.*, 512 U.S. at 512 (internal quotation marks omitted).

Fundamentally, both regulators and regulated parties need to be able to rely on the consistent interpretation of regulatory standards. Failing to give deference to an agency's interpretation of its own regulations, allowing experts to testify about them, and then asking lay juries to interpret them on a case-by-case basis makes consistency unattainable.[8/] Here, the trial court's failure to defer to the FDA's position was reversible

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[7/] *See also Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 317 (E.D. Pa. 2007) (deferring to FDA interpretation expressed in preamble to regulations); *Barr Labs., Inc. v. Thompson*, 238 F. Supp. 2d 236, 249-50 (D.D.C. 2002) (deferring to FDA view, expressed in preamble, that amendment to regulations "merely codified pre-existing policy"); *American Fed'n of Gov't Employees, AFL-CIO v. Gates*, 486 F.3d 1316, 1326-27 (D.C. Cir. 2007).

[8/] Because Strong's only theory of liability rests on the asserted violation of FDA regulations for which no private right of action exists—and thus for which there should

(continued…)

error. Because the only purported regulatory violations on which Strong relied related to tests that the FDA did not in fact require, the evidence showed neither a defect nor a breach of any duty, and Cyanamid is entitled to judgment as a matter of law or, at the very least, to a new trial.

(…continued)

be no tort claim in the first place, *cf. Vanderwerf v. SmithKlineBeecham Corp*., 414 F. Supp. 2d 1023, 1026-28 & n.2 (D. Kan. 2006)—the trial court's failure to give deference to the FDA's position raises even greater concerns. Under these circumstances, the threat and uncertainty of litigation will interfere with the discretion that Congress has committed exclusively to the FDA to define and enforce its regulations in a manner designed best to protect the public health.

POINT II

THE TRIAL COURT ERRED IN DENYING CYANAMID'S MOTION FOR JUDGMENT NOTWITHSTANDING THE VERDICT BECAUSE STRONG FAILED TO PRESENT A SUBMISSIBLE CASE ON CAUSATION, IN THAT (A) THE EVIDENCE CANNOT SUPPORT A FINDING THAT ANY ALLEGED REGULATORY VIOLATION AFFECTED THE SAFETY OF THE VACCINE THAT STRONG RECEIVED, AND (B) STRONG'S ONLY EXPERT EXPRESSLY DISAVOWED ANY ABILITY TO DRAW THE REQUISITE CAUSAL CONNECTION BETWEEN THE ALLEGED VIOLATIONS AND STRONG'S INJURY.

As described above, the case Strong submitted to the jury rested entirely on the proposition that Cyanamid violated the FDA's regulations by (i) failing to test original strain materials for extraneous agents and (ii) failing to do monkey neurovirulence tests on the original strains and on certain intermediate materials, both precursors to the production seeds and monopools actually used to make the vaccine that Strong received. But even if the FDA's testing regulations required what Bozzo claimed, Strong could not prevail without proving that the putative violations proximately caused his injury. That he could not and did not do.

The expert witness called by Strong was Bozzo, and he was proffered only to testify about regulatory violations. He was not qualified to testify on causation, and indeed specifically disclaimed any ability to do so. *See* Tr. 849. Nothing he said was sufficient. And, indeed, because the production seeds and monopools that gave rise to

Strong's vaccine *were* tested—*later* in the manufacturing process and with fully satisfactory results—any lack of testing of the strain and intermediate materials could not possibly have affected the safety of the final vaccine. This record simply cannot support the requisite finding of causation.

A. Missouri Law Requires Proof of Causation in Products Liability Cases.

First principles of Missouri products liability law require proof that a defective product or some breach of duty proximately caused the plaintiff's injury. *See, e.g.*, *Nesselrode v. Executive Beechcraft, Inc.*, 707 S.W.2d 371, 375-76 (Mo. banc 1986) (plaintiff must prove injury would not have occurred if product had been defect-free); *Lay v. P & G Health Care, Inc.*, 37 S.W.3d 310, 325 (Mo. App. W.D. 2000) (plaintiff must prove injury occurred "as a direct result of [product's] defective condition"); *Klein v. General Elec. Co.*, 714 S.W.2d 896, 900 (Mo. App. E.D. 1986) ("[T]he plaintiffs must prove that the product was defective and dangerous . . . [and] that the plaintiff sustained damage as a direct result of the defect."); *see also Chism v. W.R. Grace & Co.*, 158 F.3d 988, 991 (8th Cir. 1998).

Moreover, for more than 100 years, the rule has been the same even where the standard of care is defined by a statute or regulation. "[R]ecovery cannot be had upon mere proof of injury and defendant's breach of a statute or ordinance. The plaintiff must prove that the breach of regulation was the proximate cause of his injury." *Bluedorn v. Missouri Pac. Ry. Co.*, 25 S.W. 943, 947 (Mo. banc 1894); *see also Sill v. Burlington N. R.R.*, 87 S.W.3d 386, 392 (Mo. App. S.D. 2002); *Bauman v. Conrad*, 342 S.W.2d 284, 287-88 (Mo. App. 1961).

And when causation is complex, Missouri law requires expert testimony to establish it. *See Mueller v. Bauer*, 54 S.W.3d 652, 656 (Mo. App. E.D. 2001) ("Expert testimony is required to establish causation in a medical malpractice case *where proof of causation requires a certain degree of expertise*." (emphasis added)); *see also Missouri Farmers Ass'n v. Kempker*, 726 S.W.2d 723, 727 (Mo. banc 1987); *Kinealy v. Sw. Bell Telephone Co.*, 368 S.W.2d 400, 404 (Mo. 1963); *Super v. White*, 18 S.W.3d 511, 516 (Mo. App. W.D. 2000); *Sanders v. Hartville Milling Co.*, 14 S.W.3d 188, 204 (Mo. App. S.D. 2000); *Jones v. Trittler*, 983 S.W.2d 165, 168 (Mo. App. E.D. 1998); *Biggerstaff v. Nance*, 769 S.W.2d 470, 473 (Mo. App. S.D. 1989); *Lifritz v. Sears, Roebuck and Co.*, 472 S.W.2d 28, 32 (Mo. App. 1971).

If the evidence is not sufficient to link a breach of duty with a plaintiff's injury, it is error to allow a jury verdict to stand. In *Tompkins v. Kusama*, 822 S.W.2d 463 (Mo. App. E.D. 1991), for example, the Court of Appeals reversed denial of judgment notwithstanding the verdict where the plaintiff in a medical malpractice case offered no proof "of a causal connection between the act or omission and the injury sustained by the plaintiff." *Id.* at 464 (internal quotation marks omitted). Likewise, in *Heacox v. Robbins Educational Tours, Inc.*, 829 S.W.2d 600 (Mo. App. E.D. 1992), the same court affirmed entry of a directed verdict in favor of a tour operator where an elderly plaintiff sued for injuries she suffered after falling while walking up an incline. Even if the tour operator owed a duty to assist the plaintiff, and even if the incline posed an unreasonable risk, there was no evidence that "the degree of the incline caused her to fall." *Id.* at 603. Based on the evidence at trial, the cause of the plaintiff's fall was "nothing more than

speculation and conjecture, and speculation and conjecture do not constitute a prima facie showing of cause." *Id.* And in *Lindquist v. Scott Radiological Group, Inc.*, 168 S.W.3d 635, 654-55 (Mo. App. E.D. 2005), the Court of Appeals affirmed a grant of judgment notwithstanding the verdict where the plaintiff sought to hold a physician liable for failing to notice problems with the plaintiff's T-9 vertebrae on an MRI exam but could not prove that there was any connection between those problems and the paralysis for which he sought damages.

These fundamental principles of Missouri law were applied by the U.S. Court of Appeals for the Fourth Circuit in two companion cases nearly identical to this one. *See SLU*, 336 F.3d 307; *United States v. St. Louis Univ.*, 336 F.3d 294. There, the plaintiffs' experts could not establish that the regulatory violations about which they had testified had resulted in a vaccine that was any more likely to cause polio, or to cause a more severe case of polio, than a compliant polio vaccine. In the absence of such evidence, the plaintiff could not establish causation, and there was no liability under Missouri law. *See SLU*, 336 F.3d 307; *see also United States v. St. Louis Univ.*, 336 F.3d at 304 (presumption of increased risk based on regulatory violation would be "utterly inconsistent with Missouri law" because it would create automatic liability once plaintiff demonstrated violation).

Applying Ohio law, which is identical to Missouri law in this respect, the Sixth Circuit agreed:

> In the end, as in *St. Louis University*, plaintiffs have not met their burden of proximately linking their allegations of

> regulatory non-compliance with these undisputed and indisputably-severe injuries. That evidentiary gap is particularly significant in this medical setting. All vaccines produced from live viruses, as this one is, carry the paradoxical risk of inducing the very disease that the vaccine strives to prevent. *In the absence of expert testimony showing that these alleged regulatory violations made Orimune more unsafe than it otherwise would have been, a rational trier of fact could rule for plaintiffs only on the basis of conjecture, not a legitimate set of inferences drawn from admissible evidence*.

See Graham, 350 F.3d at 512 (emphasis added) (affirming entry of summary judgment in two cases, *Graham* and *Lundy v. American Cyanamid*).

These fundamental rules all apply here. Strong claims that Cyanamid is liable because it violated a duty under the FDA's regulations. To recover, he must do more than provide proof of a regulatory violation; he also must prove that the violation proximately caused his injury. And any attempt to connect a failure to perform monkey neurovirulence or adventitious agent testing at earlier stages of the vaccine manufacturing process with Strong's injury requires expert testimony, because it plainly does not fall within the "common knowledge and experience" of a jury. *Tillman by Tillman v. Elrod*, 897 S.W.2d 116, 118 (Mo. App. S.D. 1995). Without expert evidence to prove causation, the verdict cannot stand.

B. Strong Has No Evidence to Establish Causation.

Here, as in *Tompkins*, *Heacox*, *Lindquist*, *SLU*, *Graham*, and *Lundy*, Strong failed to adduce any expert testimony to show that Cyanamid's alleged regulatory violations caused the injury for which he seeks relief. There is no evidence from which the jury could have found that Strong's vaccine more likely than not posed any greater risk of causing polio than any other polio vaccine. That is fatal to his case.

Strong's expert, Bozzo, testified, albeit improperly, that Cyanamid violated the FDA's testing regulations in specific respects. But he could not, and did not, testify that any of those alleged violations had any impact on the safety of the vaccine Strong received—let alone that they proximately caused Strong's injury. He candidly admitted, for example, that he could offer no opinion about whether the presence or absence of adventitious agents (and, *a fortiori*, the failure to test for them) could affect the risk of vaccine-associated polio. Tr. 622-23; *see also* slip op. at 17.[9/]

[9/] The only witness who offered an opinion on this subject, Dr. Mary Ritchey, Cyanamid's Vice President for Vaccine Research and Development, Quality Assurance, testified that the presence of adventitious agents has nothing to do with the risk of vaccine-associated paralysis. *See* Tr. 1613. Bozzo likewise offered no opinion concerning any causal relation between Strong's injury and the supposed use of "experimental monkeys" in vaccine production. *See* note 4, *supra*; Tr. 813-14; slip op. at 17.

Likewise, although the Court of Appeals sought support for a causation finding in two snippets of Bozzo's testimony addressing Cyanamid's failure to test original strain and intermediate materials for monkey neurovirulence (*see* slip op. at 17-18), that testimony is insufficient as a matter of law.

First, Bozzo was never proffered to testify about causation. Strong's counsel made clear that Bozzo was called only to testify about Cyanamid's compliance with the FDA's regulations. *See, e.g.*, Tr. 622 ("I'm not tendering this witness—I'm tendering him for regulatory compliance."); Tr. 631 ("He's just going to say whether they did the tests, whether they complied."). Bozzo himself clearly understood his limited role. *See* Tr. 813-14 ("What I've been asked by [Plaintiff's counsel] to do is to take a look at these various documents and to see if there were deviations from regulations, so *I haven't gone past that point*." (emphasis added) (deposition testimony read at trial)); Tr. 627 (disclaiming intention to offer opinion regarding whether alleged regulatory non-compliance had any effect on risk associated with Strong's vaccine) (deposition testimony read at trial).

Bozzo's function was to identify regulatory infractions, not to testify about their consequences. Indeed, Bozzo was plainly unqualified to testify about how any supposed regulatory violation would increase the risk of vaccine-associated polio. Bozzo is a pharmacist who once served as an FDA compliance officer. He readily conceded that he was not an expert on "the technical aspects, the scientific aspects" of neurovirulence testing. Tr. 623. He had no involvement in the FDA's approval of any polio vaccine seed or monopool, he was not involved in drafting polio vaccine regulations, and he

could not identify any relevant experience that he had in interpreting those regulations. *See* Tr. 617-18, 723-26. He had, at best, a rudimentary knowledge of the manufacturing and testing of OPV, and was not aware of the nomenclature or lineage of the vaccine at issue in this case. *See* Tr. 701-06. He had no knowledge of how production seeds were used to produce monopools. *See* Tr. 708-09.

If Bozzo had been proffered to provide opinions on causation, it would have been an abuse of discretion to accept him for that purpose. Disconnected bits of his testimony cannot, therefore, be retroactively mined (as the Court of Appeals did) in an effort to salvage an otherwise unsupported causation finding. *Cf., e.g., Brands v. St. Louis Car Co.*, 112 S.W. 511, 516 (Mo. 1908) (reversing in part on basis that plaintiff's experts were unqualified to testify about safety of product that caused plaintiff's injury); *Billings v. State*, 503 S.W.2d 57, 61 (Mo. App. 1973) ("'Where there is no evidence at all tending to prove that the witness is qualified to testify as an expert, it would seem that there is a palpable abuse of discretion, and the ruling of the trial court would be subject to review.'" (quoting *Robison v. Chicago Great W. R.R. Co.*, 66 S.W.2d 180, 185 (Mo. App. 1933))); *see also* § 490.065 RSMo. 2000 (setting forth the standard of admissibility in civil cases); *State Bd. of Registration for the Healing Arts v. McDonagh*, 123 S.W.3d 145 (Mo. banc 2004).

Second, even disregarding that Bozzo was not even proffered to testify about causation, the bits of Bozzo's testimony on which the Court of Appeals relied would be legally insufficient to support a causation finding:

Q What happens if you don't do [safety tests required by regulations]?

A Well, if you omit safety tests, then you *raise the possibility* of a product being unsafe. . . . [and "raising the possibility" means that] the general public is then exposed to product that is at higher risk or higher danger for an untoward effect. And if you're talking about a neurovirulence test, it's virulent polio virus being given to them.

* * *

Q Do you have an understanding of what causes [reversion of the attenuated polio virus used in vaccine to a more virulent form]?

A Not from a virological standpoint, no.

Q Do you have an understanding from some other standpoint?

A Well, if the product was inadequately tested for neurovirulence, *then it's possible* that the product simply contained particles of neurovirulent virus[.]

Slip op. at 17-18 (emphasis added); Tr. 686, 853.

Missouri cases uniformly hold that opinions like this that are couched in terms of "possibilities" do not make out a submissible case on proximate causation. The possibility that "a given action or failure to act 'might' or 'could have' yielded a given result" is insufficient to prove causation, and testimony that goes no further is "devoid of evidentiary value." *Baker v. Guzon*, 950 S.W.2d 635, 646 (Mo. App. E.D. 1997); *see also Abbott v. Haga*, 77 S.W.3d 728, 732 (Mo. App. S.D. 2002) (same); *Tompkins v. Cervantes*, 917 S.W.2d 186, 189 (Mo. App. E.D. 1996) (same)*; Shackelford v. W. Cent. Elec. Coop., Inc.*, 674 S.W.2d 58, 62 (Mo. App. W.D. 1984) ("That evidence is of no probative value and does not satisfy the purpose for which it is admitted if the opinion of

the expert is couched in terms of might or could. Evidence by the expert that the act or omission of the party charged was a possible factor or was extremely likely to have had a causal effect is not sufficient to make a submissible case." (citation and quotation marks omitted)).[10/]

Third, Bozzo's testimony about "possibilities" was wholly undercut by Bozzo himself when he specifically and expressly *disclaimed* any ability to offer the very evidence that was necessary here. In deposition testimony that was admitted at trial, Bozzo testified that he thought that there was "certainly a *potential* association between what I cite as deviations or noncompliance with regulations and the case, the polio case

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[10/] *See also Neiswonger v. Margulis*, 203 S.W.3d 754, 759 (Mo. App. E.D. 2006) (expert testimony regarding causation that was "sheer speculation" was "not sufficient to raise disputed issues of fact"); *Winkler v. Robinett*, 913 S.W.2d 817, 821 (Mo. App. W.D. 1995) ("Expert testimony that an act or omission of a defendant was a *possible* factor in causing a fire is not sufficient to make a submissible case." (emphasis added.)); *Mills v. Redington*, 736 S.W.2d 522, 524 (Mo. App. E.D. 1987) ("Proof of facts essential to submissibility of a case may not rest on speculation or conjecture. If the proof offered must depend on speculation or conjecture, then a verdict based on such proof cannot stand."); *Hills v. Ozark Border Elec. Coop.*, 710 S.W.2d 338, 341 (Mo. App. S.D. 1986) (testimony that injury could have been caused by certain things is not sufficient to establish causation).

of the plaintiff." Tr. 849. In the next breath, however, and without even an invitation from defense counsel, he continued, "*I am not in a position to say that that's what occurred*." Tr. 849 (emphasis added). That admission, by itself, is enough to preclude reliance on anything that Bozzo said regarding the issue of causation.

Fourth, and finally, what the record actually makes clear is that there *could not have been* causation in this case. As previously noted, Cyanamid (and the FDA) *did* conduct the necessary tests, successfully, on the production seeds from which Strong's vaccine was derived; on the relevant monopools made from those seeds; and, indeed, on the final vaccine that Strong actually received. *See* Def.'s Ex. 39-41, 45-50, 54-56, 105A-H; Tr. 1644-76. Bozzo specifically conceded the adequacy of that testing. Tr. 758-59, 764, 771, 774. Nothing in Strong's evidence suggests any possibility that Strong's dose of vaccine could have posed any greater risk because materials earlier in the production chain were not tested. To the contrary, the uncontradicted testimony was that, if anything, vaccine materials can only *lose* attenuation, thus becoming *more* virulent and *less* safe, through successive manufacturing stages. Thus, if the production seeds are satisfactorily attenuated, as demonstrated by the successful testing here, then the precursor materials—the original strains and intermediate materials—must have been sufficiently attenuated, too. Tr. 1611 (trial testimony of Dr. Mary Ritchey); *see also id.* at 1712-1715 (testing earlier components is not necessary to ensure safety when production seeds and monopools are tested).

That, of course, is why the FDA required that Cyanamid test only the final two stages of manufacture—the production seeds and the monopools used to make final doses

of vaccine. By demonstrating that *those* materials were attenuated in accordance with the regulations, Cyanamid necessarily demonstrated that the materials from which they were derived also were safe. As a matter of fact and irrefutable logic, performing the testing that Bozzo claimed was missing would have provided no additional information about the safety of the vaccine that Strong received. For the same reason, Bozzo could not say that "any live oral polio vaccine ever made *anywhere* in the world *ever* had a lower risk of vaccine associated polio than the vaccine given to Cortez Strong in 1987." Tr. 774-75 (emphasis added); *see also id.* at 859, 1382 (Dr. Shanske, another of Strong's experts, concurring in this opinion). And for the same reason, failure to perform the additional testing that Bozzo claimed was required *could not* have caused Strong's injury in this case.

The failure of proof on causation in this case closely parallels that in *SLU, Graham*, and *Lundy*, although here it is even more pronounced. In *SLU*, unlike here, experts testified that tests actually conducted on the monopools used to produce the vaccine in question indicated that the vaccine may have been more likely than normal to cause harm. After carefully evaluating that testimony, however, the federal court held that it failed "to establish a causal connection between a particular individual's contraction of polio, on the one hand, and the marginal difference in neurovirulence between vaccine derived from a seed compliant with the OPV regulations and vaccine developed from a non-compliant seed, on the other." *St. Louis Univ. v. United States*, 182 F. Supp. 2d 494, 501 (D. Md. 2002), *aff'd* as to defendant American Cyanamid Company, 336 F.3d 307, *rev'd on other grounds* as to defendant United States, *United*

States v. St. Louis Univ., 336 F.3d. 294. Even though the testimony was considerably more substantial than anything offered by Strong,[11/] the court concluded that there was scientifically nothing to back it up and held that the experts' conclusory opinions were legally insufficient to establish causation.

In *Graham*, the plaintiffs' experts also testified about actual neurovirulence test results that purportedly fell outside regulatory standards. One testified, for example, "that there is a scientific argument that you can make which would support such a conclusion [that a regulatory violation was linked to the safety of the vaccine] . . . [but] *I am not saying that is the right conclusion*." *Graham*, 350 F.3d at 510 (emphasis added). Indeed, this testimony is strikingly similar to Bozzo's testimony here that "I think there is certainly a *potential* association between what I cite as deviations or noncompliance with regulations and the case, the polio case of the plaintiff. . . [but] *I am not in a position to say that that's what occurred*." Tr. 849 (reading deposition) (emphasis added).[12/] The court in *Graham* noted that an expert's opinion "'must be supported by more than subjective belief and speculation,'" 350 F.3d at 510 (citation omitted), and concluded that the opinions offered were insufficient to create an issue of fact.

[11/] The plaintiff's experts' testimony in *SLU* is found at 1995 WL 17810633; 1999 WL 33996920; 1995 WL 17809992; and 1999 WL 33996920.

[12/] The court in *Graham* also held that this expert was unable to point to any study supporting his theory and that "[a]n admissible expert's opinion, it is clear, 'must be supported by more than subjective belief and speculation. . . .'" 350 F.3d at 510.

As in *SLU*, *Graham*, and *Lundy*, this case can be resolved on one point: Strong failed to introduce *any* evidence from which a reasonable jury could find any causal link between the regulatory violations alleged and the injury for which he seeks to recover. For that reason, Cyanamid is entitled to judgment as a matter of law.

POINT III

THE TRIAL COURT ERRED IN DENYING CYANAMID'S MOTION FOR REMITTITUR OR A NEW TRIAL, BECAUSE THE $8.5 MILLION VERDICT WAS EXCESSIVE, OUT OF LINE WITH OTHER AWARDS, NOT SUPPORTED BY THE EVIDENCE, AND CAN BE EXPLAINED ONLY BY THE TRIAL COURT'S ERRONEOUS INTRODUCTION OF IRRELEVANT AND PREJUDICIAL EVIDENCE.

If this Court sustains the jury's finding of liability, it should nevertheless reduce the $8.5 million damage award or order a new trial. The jury awarded exactly what Strong's counsel requested during closing argument, which was the first time it had heard any figure regarding damages. The size of the award—$1.5 million in past non-economic damages, $2 million for future economic damages, and $5 million for future non-economic damages—is grossly disproportionate to amounts awarded in other cases, and can be explained only by sympathy for Strong and prejudice against Cyanamid.

A. The Court Should Reduce What Is Clearly an Excessive Award.

This Court reviews the denial of a motion for remittitur for abuse of discretion. *See LaRose*, 154 S.W.3d at 370. "Remittitur is appropriate when the court finds that the jury's award is excessive because the amount of the verdict exceeds fair and reasonable

compensation for plaintiff's injuries and damages." *Lay*, 37 S.W.3d at 332-333; *see also* § 537.068 RSMo 2000. While "[t]here is no precise formula for determining whether a verdict is excessive," courts typically examine the reasonableness of compensatory damages using the following factors: "(1) loss of income, both present and future; (2) medical expenses; (3) plaintiff's age; (4) the nature and extent of plaintiff's injuries; (5) economic considerations; (6) awards approved in comparable cases; and (7) the superior opportunity for the jury and the trial court to evaluate plaintiff's injuries and other damage." *McCormack v. Capital Elec. Constr. Co.*, 159 S.W.3d 387, 395 (Mo. App. W.D. 2004).

1. Future economic damages.

Projections of future economic damages must be reasonably certain, not based on speculation, and supported by evidence that provides a jury with a basis for a reasonable estimate of the amount of loss. *See LaRose*, 154 S.W.3d at 371-72. Here, the jury was given *no* evidence on which to base any award for future economic damages.

Strong would be entitled to recover any difference between what he would have earned had he never been injured and what he will earn in light of his injury. *See Fairbanks v. Weitzman*, 13 S.W.3d 313, 320 (Mo. App. E.D. 2000). In many cases, a plaintiff will present an expert who can identify such an income differential and determine its present value. *See, e.g.*, *LaRose*, 154 S.W.3d at 372; *Williams v. Daus*, 114 S.W.3d 351, 362 (Mo. App. S.D. 2003) (en banc). Strong provided no such testimony. Instead, in closing argument, his counsel simply suggested, without explanation, that the jury should award $2 million for lost economic damages. That

figure assumes that, for example, Strong will work for 50 years and would have earned an additional $40,000 every year had he not been injured (50 x $40,000 = $2 million). It reflects no discount to present value. More importantly, Strong offered no evidence, expert or otherwise, to support any such computations.

Strong's only evidence of economic damages was the testimony of James England, a vocational expert. England testified that Strong's injury would preclude him from performing various jobs. *See* Tr. 1099-1102. He admitted, however, that if Strong graduated from either a two- or four-year college, he would be able to earn as much as he would have earned had he not been injured. *See* Tr. 1101-1102. Indeed, asked whether Strong "may not have suffered any loss whatsoever. . . economically," England responded, "It depends on how he does in school and things like that, *yes*." Tr. 1143-44 (emphasis added). That testimony would apply to virtually everyone, and provides no basis for any damage award.

Fundamentally, however, England provided no figures that would allow a jury to determine how much more money Strong would have made had he not been injured; the jury was left to guess.

This Court's decision in *Vincent by Vincent v. Johnson*, 833 S.W.2d 859 (Mo. banc 1992), presents a striking contrast to the situation here. There, the plaintiff suffered permanent brain damage and was unable to work. The Court upheld the jury's damage award of $1 million, which was supported by an economist's calculations that assumed a healthy woman would earn "'average female' wages" up to retirement at age 67. *Id.* at 865. Here, Strong was awarded twice that amount even though he is able to

work and presented *no* evidence of any economic loss. The award of lost future income is purely speculative and wholly unsupported.

2. Non-economic damages.

Factors relevant in assessing non-economic damages include the nature and extent of injuries sustained; the plaintiff's age; the compensation awarded in comparable cases; and intangible factors such as past and future pain, suffering, effect on lifestyle, embarrassment, and humiliation. *See Alcorn v. Union Pac. R.R. Co.*, 50 S.W.3d 226, 250 (Mo. banc 2001). Here, an award of $6.5 million cannot be sustained. Although Strong was injured at an early age, his injuries are limited to weakness in one arm and slight weakness in his hands. *See* Tr. 873-74. In addition, although Strong testified that he was embarrassed by his condition and had been teased about it, *see, e.g.*, Tr. 1496-97, he does not require any special care, he is able to work, his injury is only apparent when he wears a short-sleeved shirt, and he has an active social life, *see* Tr. 1498-99.

In considering whether the award here is excessive, it is appropriate to compare the facts here to those of other cases. *See, e.g.*, *Redfield v. Beverly Health & Rehab. Servs., Inc.*, 42 S.W.3d 703, 713 (Mo. App. E.D. 2001). In *McCormack*, for example, the plaintiff suffered from "chronic pain in his chest, hips and shoulders, as well as migraine headaches, impaired concentration, and confusion." 159 S.W.3d at 395. He endured at least two grand-mal seizures during which he lost control over his bladder and bowels, along with having permanent cognitive deficit, depression, dementia, and sexual dysfunction. *See id.* at 395-396. He was permanently disabled and unemployable. *Id.* at 396. A jury awarded plaintiff $28.8 million, which was reduced on remittitur to

$7.7 million, of which $6 million was for non-economic damages. *Id.* at 394. To award Strong a *larger* sum for non-economic damages is unjustifiable. McCormack's injuries and ongoing disabilities were far more substantial. *See also Barnett v. La Societe Anonyme Turbomeca France*, 963 S.W.2d 639, 658 (Mo. App. W.D. 1997) (reducing non-economic damages to $3.5 million in case of helicopter pilot who "consciously suffered pain for three to five minutes as he bled to death after his thoracic aorta was severed upon impact"). In contrast, in two cases involving injuries more comparable to Strong's (though still more severe), the sustained damage awards were far lower. *See King v. Unidynamics Corp.*, 943 S.W.2d 262, 268 (Mo. App. E.D. 1997) (awarded $150,000 for dislocated shoulder, torn rotator cuff, and axillary nerve injury which caused pain and an injured arm that was 33-51% weaker than the uninjured one); *Larabee v. Washington*, 793 S.W.2d 357, 358-59 (Mo. App. W.D. 1990) (awarding $100,000 where plaintiff sustained permanent injuries including chronic pain, loss of ability to move right shoulder freely, inability to kneel or squat, extensive headaches, and reduction in range of activities at work and leisure).

A $6.5 million award for non-economic damages in this case is "so grossly excessive that it shocks the conscience," particularly when Strong's injuries are compared with those of other plaintiffs. *Redfield*, 42 S.W.3d at 713. At a minimum, the Court should order a remittitur, eliminating the economic damages entirely because of the absence of evidence, and reducing the non-economic damages to an amount in line with the *Larabee* and *King* awards.

B. In The Alternative, the Court Should Order a New Trial.

"[W]hen a jury's bias and prejudice result in an excessive verdict a new trial is required." *Lay*, 37 S.W.3d at 333; *see also Ince v. Money's Bldg. & Dev., Inc.*, 135 S.W.3d 475, 478 (Mo. App. E.D. 2004). Courts will infer bias and prejudice "when the verdict is so excessive it shocks the conscience of the court." *Emery v. Wal-Mart Stores, Inc.*, 976 S.W.2d 439, 448 (Mo. banc 1998). Thus, a new trial will be granted if it appears that "the verdict, viewed in the light most favorable to the prevailing party, was glaringly unwarranted and that some trial error or misconduct of the prevailing party was responsible for the prejudicing the jury.'" *Lay*, 37 S.W.3d at 333 (quoting *Willman v. Wall*, 13 S.W.3d 694, 699 (Mo. App. W.D. 2000)).

Strong began this case with a claim that his vaccine did not comply with the FDA's regulations. At trial, he limited his theory to Bozzo's contention that, under the federal regulations, the Sabin strains and certain intermediate materials should have been tested for monkey neurovirulence and for adventitious agents. So limited, the trial should have taken no more than three or four days. Instead, it took twelve days, with Strong's case-in-chief occupying nine of them, all because Strong was never barred from introducing evidence having nothing whatsoever to do with Bozzo's theory in general or Strong's vaccine in particular.

Strong, for example, devoted days to reading deposition testimony of former Cyanamid employees, the large majority of which had nothing whatsoever to do with either this case, Strong's theory of liability, or Strong's vaccine. The trial court seemed to recognize this, *see, e.g.*, Tr. 1290-1301, but it declined to take any corrective measures.

Indeed, at one point, the trial court exclaimed that "generally I don't have to go through a week and a half of trial to see the plaintiff's theory come through . . . and that's why I'm having so much trouble with the—these witnesses because I don't see the—I don't see where we're getting the link." Tr. 1295. As to all of this irrelevant testimony, however, the court held, "I'm going to let it in. I'm pretty much going to let you put on your case." Tr. 1301.

Strong's objective was obvious: because he had no evidence to link his claims of regulatory violations—*any* of them—with the safety of his vaccine, he resorted to a blunderbuss approach of introducing matters that had no relationship to his vaccine, all to create an impression that Cyanamid must have done *something* improper. For example, Strong introduced extensive testimony on SV40, a monkey virus having nothing at all to do with paralysis. *See* LF XX:3480, 3484-85; *see also* LF XX:3486-94, 3496-501. (At one point during discovery, Strong had been prohibited by another judge from taking further depositions about SV40, because "plaintiff has not alleged that SV40 caused harm to plaintiff." LF II:329.)

Likewise, over objection, Strong read deposition testimony to the jury covering topics such as (a) whether polio vaccine was produced in the late 1970s in the basement of "Building 60" before that building received formal FDA approval, *see* Supp. LF I:026, 056; LF XIX:3234-38; Tr. 1691, 1726-28, 1737-38, 1746-47, 1839-40; (b) what kind of documents may be included in a "batch record," *see, e.g.*, LF XIX:3237-40, 3244-51, 3255-65, 3269, 3280-82, 3286-88, LF XX:3538-3542, 3606; (c) what kind of monkeys were used to make vaccine, *see, e.g.*, LF XX:3438-39, 3481, 3545-47, 3553-54; Supp. LF

I:021, 043; (d) whether "roller bottles" or "Povitsky bottles" were used in vaccine production, *see, e.g.*, Supp. LF I:028, 038-39; Tr. 1739-42; and (e) why Cyanamid employees did not work on weekends, *see, e.g.*, Supp. LF I:036. Strong failed to link *any* of this testimony to any alleged defect in his vaccine, because there *is* no such link.

Strong's counsel also interrogated Dr. Ritchey for seventeen pages of trial transcript, Tr. 1730-47, on gauge readings taken in 1977—a decade before Strong's vaccine was even given—from a "laminar flow hood" that was used in the laboratory. Strong's point: that one such hood had at one time been broken. But never did he even attempt to introduce evidence that a broken laminar flow hood in 1977 had anything to do with Strong's vaccine or its safety. Of course, there is no way that it could have.

Strong's strategy of bombarding the jury with days and days of irrelevant evidence in the hope that it would somehow be convinced that Cyanamid had done *something* wrong was not limited to the testimony. In closing argument, Strong's counsel repeatedly stated that Cyanamid did not care at all about safety and was motivated only by greed and the desire to make and sell vaccine. Tr. 2094. Once again, however, there was no evidence to support even an inference that supply or profit ever caused Cyanamid to do anything to the detriment of anyone, much less Strong. In fact, there was no evidence whatsoever about supply *or* profit at all—the only other mention of the topic occurred in Strong's opening statement, *see, e.g.*, Tr. 408. The argument was made all the more inappropriate, given that Strong had dropped his claim for punitive damages.

It is, of course, difficult to know what motivates a jury in any case. But here, it certainly could not have been evidence that would support an $8.5 million verdict in

favor of the plaintiff. There was no such evidence. Were the Court to conclude that remittitur is not warranted, it should order a new trial.

CONCLUSION

The Court should grant judgment in favor of Cyanamid notwithstanding the verdict. Alternatively, the Court should order remittitur or a new trial.

Respectfully submitted,

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Dated: February 6, 2008

CERTIFICATE OF COMPLIANCE

The undersigned counsel hereby certifies pursuant to Rule 84.06(c) that this Appellant's Substitute Brief: (1) contains the information required by Rule 55.03; (2) complies with the limitations contained in Rule 84.04(b); and (3) contains 12730 words, exclusive of the Sections exempted by Rule 84.06(b)(2) of the Missouri Rules of Civil Procedure based on the word count which is part of Microsoft Word 2003. Finally, the undersigned certifies that the diskette accompanying this Appellant's Substitute Brief under Rule 84.05(a) has been scanned for viruses using Trend Microscan and is virus-free.

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No. SC88890

IN THE SUPREME COURT OF MISSOURI

CORTEZ STRONG,

Respondent,

v.

AMERICAN CYANAMID COMPANY,

Appellant.

On Appeal From The Circuit Court Of The 22nd Judicial Circuit, City Of St. Louis
Hon. Michael B. Calvin, Circuit Judge
Cause No. 9920880

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