No. SC88890

IN THE SUPREME COURT OF MISSOURI

CORTEZ STRONG,

Respondent/Cross Appellant,

v.

AMERICAN CYANAMID COMPANY,

Appellant/Cross Respondent.

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

Respondent adopts the jurisdictional statement of Appellants.

STATEMENT OF FACTS

Cortez Strong submits the following Statement of Facts supporting the verdict, as necessary for the Court's understanding of the cross-appeal, and in response to the Appellant's Statement of Facts.

A. Time Line Relevant in this Case

Although Cortez Strong was stricken with Polio in 1987, the events at issue had their genesis much earlier. In 1954 Dr. Jonas Salk developed the first polio vaccine, which used an inactivated (killed) virus and had to be administered by injection. Dr. Albert Sabin developed an oral polio vaccine that was administered initially on a sugar cube and used "attenuated" (live) polio virus (Tr. 406, 1584). In 1960 the Division of Biologic Standards, the regulatory agency of the United States, began the process of issuing regulations and furnished to all potential vaccine manufacturers the final regulations in March of 1961. 42 C.F.R. § 73 et seq. The regulations required that manufacturers who sought licensure for any strain of polio vaccine had to perform numerous safety tests and furnish to the regulator the tests for their review and acceptance as being compliant. 21 C.F.R.§ 630.10 The regulations remained in effect until

after 1987 when Cortez Strong was vaccinated (Tr. 691).[1] The regulations were adopted as a result of the Congressional mandate contained in 42 U.S.C. § 262 (d).

In 1988 the U.S. Supreme Court handed down *Berkovitz v. United States*, 486 U.S. 531 (1988), 858 F.2d 122 (3rd Cir. 1988)(on remand).[2] *Berkovitz* addressed the issue raised in this case that the seeds must be tested and that the failure to perform the test and submit the test to the regulator for their review results in the vaccine manufacturer's inability to be licensed and results in the regulator being held equally responsible if a license was issued without the submission assuring compliance with the safety regulations.

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[1] The regulations as initially enacted were contained at 42 C.F.R. § 73 et seq. and later were amended, 21 C.F.R.§ 600 et seq. The regulations in regard to testing of oral polio seeds were found initially at 42 C.F.R. § 73.110 et seq., later amended at 21 C.F.R. § 630.10 et seq.

[2] Two cases were pending before the Supreme Court – *Baker v. United States*, 817 F.2d 560 (9th Cir 1987) and *Berkovitz v. United States*, 822 F.2d 1322.(3rd Cir. 1988) The court granted the Petition for Certiorari in *Berkovitz*, reversing *Berkovitz* and affirming *Baker*.

When the *Berkovitz* case was first before the 3rd circuit, 822 F.2d 1322, the regulator stated that the vaccine manufacturer had to submit the safety tests that are at issue in this litigation but claimed that the regulator did not have to review the test results and could issue a license in the blind. The majority opinion agreed with the regulator. *Id.* The *Baker* court found that both the vaccine manufacturer was required to submit the test results and the regulator was required to insure that those tests were reviewed and met the requirements of the regulations. *Id.* The Supreme Court, in a unanimous decision authored by Justice Marshall, reversed the *Berkovitz* holding and affirmed the *Baker* holding, which placed upon the regulator the duty to enforce the mandatory regulations in regard to submitting test results of each seed used in manufacture. *Berkovitz*, 486 U.S. 531.

Thereafter the *Baker* and *Berkovitz* plaintiffs became part of a multi-district litigation tried before the Honorable Frederick J. Motz. *In Re Sabin Product Liability Litigation*, 763 F.Supp. 811 (Dist. Md. 1991). The court handed down its decision on April 19, 1991, finding that the Type III 45B85 and the Type III 45B165 (the Pfizer seed RSO+1) failed to meet the regulatory requirements, which rendered the regulator also liable for the failure to enforce these mandatory regulations. *Id.* On May 8, 1991, the FDA, at the behest of American Cyanamid, attempted to change the

regulations to remove the requirements in regard to 45B165 (RSO+1) and to change the testing methods and evaluations used in regard to the neurovirulence of the vaccine. See Federal Register, Vol. 56, No. 89 (May 8, 1991)(Appellants Appendix at A-22). American Cyanamid challenged the second part of the proposed amended regulations. (LF842-849) Today, and since 1999, oral polio vaccine is not sold in the United States and only killed polio vaccine (the Salk vaccine) has been utilized for the past eight years with no cases of vaccine-induced polio occurring. (Tr.294; LF3939, 3962, 4005)

A graphic view of the timeline is shown in Figure 1, below:

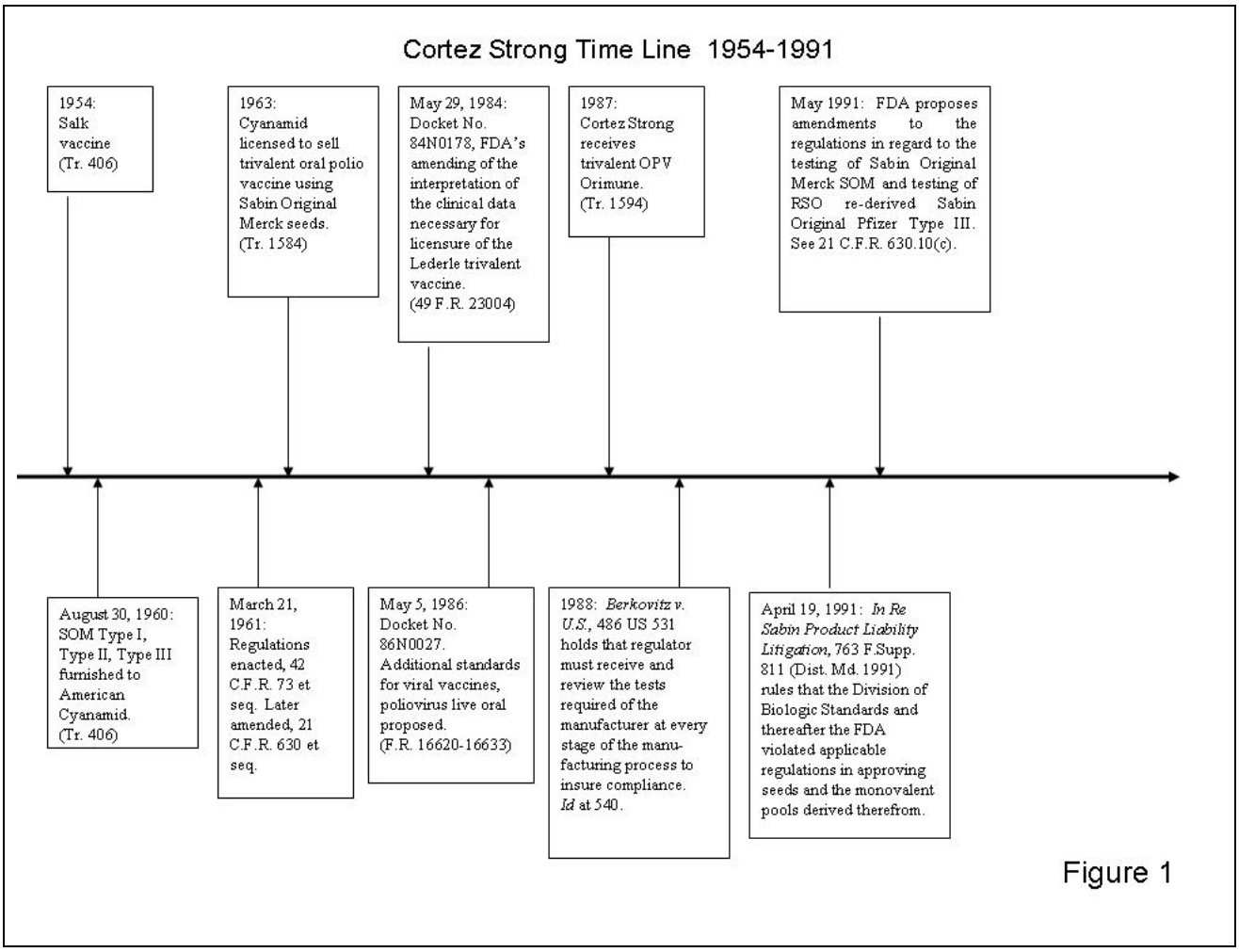

Figure 1

B. Cortez Strong Is A Polio Victim.

Dr. Burris evaluated Cortez Strong (Tr. 872) and testified that, in his opinion; Cortez was suffering from vaccine-induced paralytic polio (VAPP) (Tr. 890). His opinion was based on the temporal relationship to the vaccine administration (Tr. 888), the acute flaccid paralysis, and the lack of other causes related to the neurological deficits suffered by the Plaintiff (Tr. 891). The medical diagnosis of Cortez Strong as a VAPP victim was

confirmed by the Centers for Disease Control in 1988/89 and was printed in their annual review (Tr. 938).

Yet, his medical condition became a factual question before the jury. Defendants-Appellants claimed that he was not a victim of their vaccine, but was instead paralyzed from some other, unrelated condition (Tr. 432-434). Defendants-Appellants' could not claim that Cortez Strong was a case of polio but it was caused by the wild poliovirus since no cases of polio (wild) had occurred in the United States since 1979. (LF 3962, LF 4005) On the other hand, each case of paralytic poliomyelitis that occurred in the United States after 1979 was caused by the Orimune vaccine, and in particular; Cortez Strong was the sixth victim who suffered paralysis in the state of Missouri as a result of the Orimune product (L.F. 4004).

C. Paralytic Poliomyelitis And The Oral Polio Vaccine, Orimune.

The Polio vaccine is a trivalent vaccine. There are three strains of virus that produce paralytic polio. These three viruses are referred to throughout this brief as Type I, Type II and Type III. (Tr. 407). Orimune vaccine is only as safe as its attenuation,[3] (Tr. 97-98) 42 CFR § 73.110

[3] "Attenuated basically means that it is weakened and it means that it can still grow but it is not able to cause disease the way a virulent or wild

(b)(3) and 21 C.F.R. § 630.10 (b)(3), "No seed virus shall be used for the manufacture of polio virus vaccine unless its neurovirulence in macaque monkeys is no greater than that of the reference attenuated polio virus distributed by the Bureau of Biologics." Orimune vaccine has a devastating effect: it causes paralytic poliomyelitis when the Defendants-Appellants fail to conduct all the necessary tests through each passage of the manufacturing process to insure its proper attenuation (Tr. 1701-02). Lederle did not follow the regulatory requirements (Tr. 1708-09).

Lederle challenged the expertise of Plaintiff's expert, Mr. Tom Bozzo, on several separate occasions. It challenged his opinions in two motions for Summary Judgment, which were denied, in a motion in limine filed immediately before the trial, and after *voir dire* at time of trial (Tr. 590-638). Defendant-Appellant challenged Mr. Bozzo's expertise in its motion for directive verdict (L.F. 4015-4018). That motion was denied. Following the trial, Defendant challenged Mr. Bozzo's expertise in its motion for judgment notwithstanding the verdict, or in the alternative, for a new trial or remittitur (L.F. 4042-4051). These motions were also denied by the trial court (L.F. 4196).

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strain polio would be able to cause disease." Defendant's expert Ritchey, (Tr. 1592)

Mr. Bozzo was a compliance expert and testified about compliance with the federal regulations. On direct exam he stated that there were no neurovirulence tests conducted by American Cyanamid for the seeds at issue in this litigation until the Defendant-Appellant manufacturer reached the last seed in the process, which was the working seed (Tr. 674-675). Lederle's defense was that it was not necessary to test each and every seed used in production. Defendant's-Appellant's witness Dr. Mary Ritchey claimed that Lederle was not required to test these seeds both in the 1960's and again in the 1970's when it created the ultimate working seeds used in the vaccine administered to Cortez Strong (Tr. 1608, 1713-14). The underlying scientific facts are reflected in the testimony of Mr. Bozzo (Tr. 590-826) and are supported by the regulatory system in place. See 42 C.F.R. 73.110 et seq., 21 C.F.R. § 630.10 et seq., and by the courts that interpreted these regulations.[4]

[4] *Berkovitz v. United States*, 486 U.S. 531 (1988), 858 F.2d 122 (3rd Cir. 1988) (*on remand*), 822 F.2d 1322 (3d Cir. 1987); *Baker v. United States*, 817 F.2d 560 (9th Cir. 1987); *Loge v. United States*, 662 F.2d 1268 (8th Cir., 1982); *In Re Sabin*, 743 F. Supp. 410 (D. Md. 1990), 763 F. Supp. 811, 774 F. Supp. 952, aff'd, 984 F.2d 124 (4th Cir 1993); *Campagna v. American Cyanamid*, 767 A.2d 996 (NJ App. Div. 2001); *Rivard v. American Home Products, et al.*, 391 N.J.Super 129, 917 A.2d 286 (App. Div. 2007).)

Sabin Original (hereafter sometimes referred to as “SO”) was sent to Merck Sharp & Dohme by Dr. Albert Sabin in 1955 where three master seeds were produced for each of the three types of polio and designated as Sabin Original Merck (hereafter “SOM”) Type I, SOM Type II, and SOM Type III. In 1977 American Cyanamid produced two master seeds for Type I and for Type II and designated them 45B157 (I) and 45B158 (II) (L.F. 790, 798). American Cyanamid listed, in the historical documents, as to the preparation of the various seeds, the following nomenclature for 45157 and 45B158 as master seeds (Tr.1601-1605)(L.F. 2324-2325) – the same nomenclature that it utilized for the initial seeds used both as master seeds and production seeds – seeds 45B23 and 45B24 in 1960 (L.F. 2425-2426).

When American Cyanamid described how it prepared the Type II seed in 1977 it stated the following to the regulator:

> Two vials of Sabin’s original Master Seed (P712-ch-2ab) were thawed and neutralized for SV40 (45B158, 45B159) by Department 471 for use in preparing two working seeds. The first passage or intermediate seed made using 45B158 (5.8 TCID 50/ml) was harvest 801-S (1.810 liters, 7.0 TCID 50/ml).

Intermediate seed 801-S was used to make harvest 802-S (11.830 liters, 7.4 TCID 50/ml.

(L.F. 995)

American Cyanamid described how it produced the four harvests that ultimately became 45B160. It explained that it utilized as an intermediate seed, 701S. (L.F. 785 (a diagram listing the various seeds), 2508, 2514, 2520, 2526, 2606). Intermediate seeds 701S (I) and 801S (II) were created from 45B157 and 45B158 respectively (Tr. 1601-05). From these two intermediate seeds were produced the harvests, which were then combined to produce 45B160 Type I and from a single harvest, 45B162 Type II (Tr. 1601-05, 727-729).

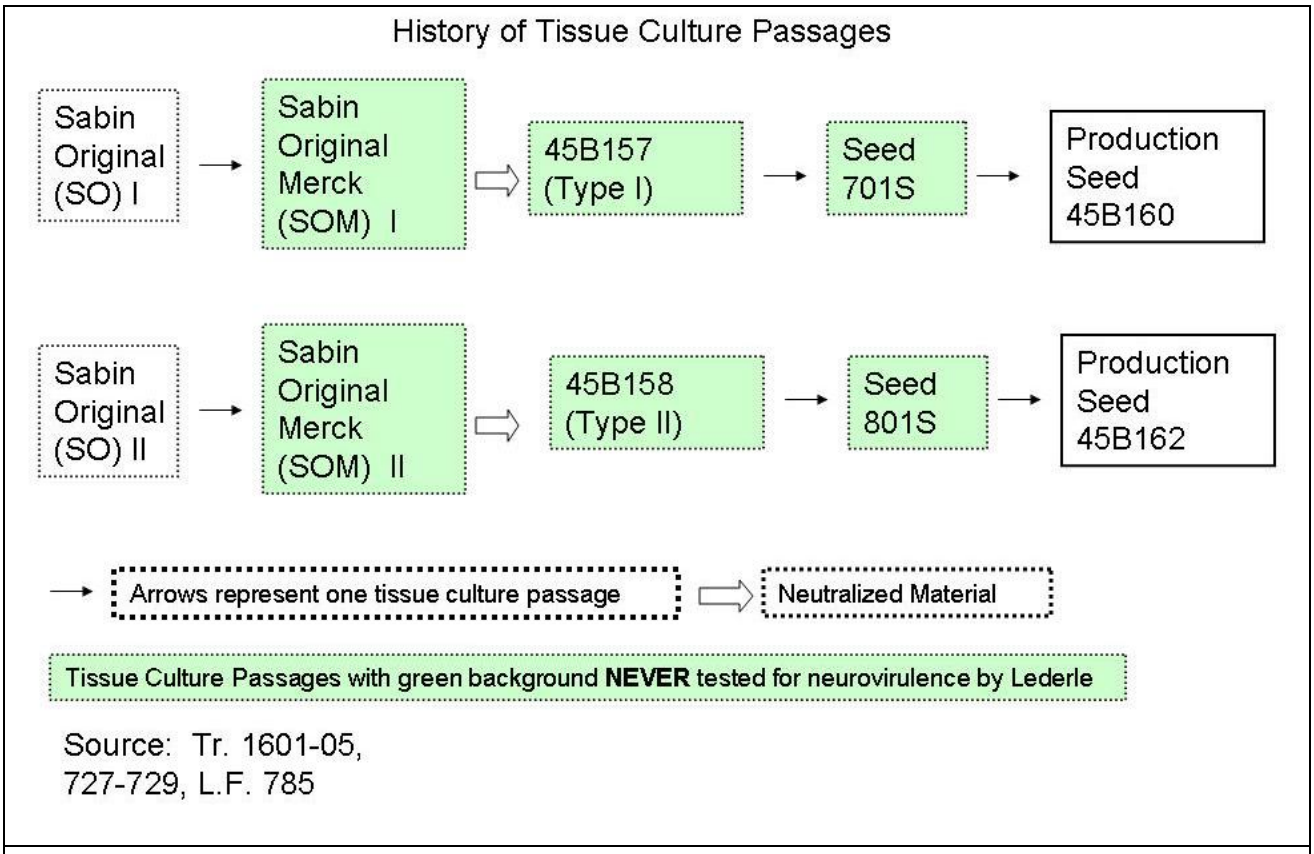

Figure 2. History of Type I and Type II Seeds

The Type III vaccine utilized in the trivalent bulk administered to Cortez Strong had a different historical derivation. It also began with Sabin Original and Sabin Original Merck Type III sent by Dr. Albert Sabin to Pfizer Laboratories. (Tr. 580) Pfizer Laboratories, in Sandwich, England, thereafter cloned the Sabin Original Type III and passed it through four other monkeys (four other intermediate seeds – 127B, 438/3/c, 440/1, and 457), which then became Lederle's 45B164 from which Lederle produced working seed 45B165. (Tr.629) American

Cyanamid identified in its manufacturing records the seed used to make 45B165 – Lederle designation 45B164 (L.F. 2486, LF 2494, LF 2601-2604).

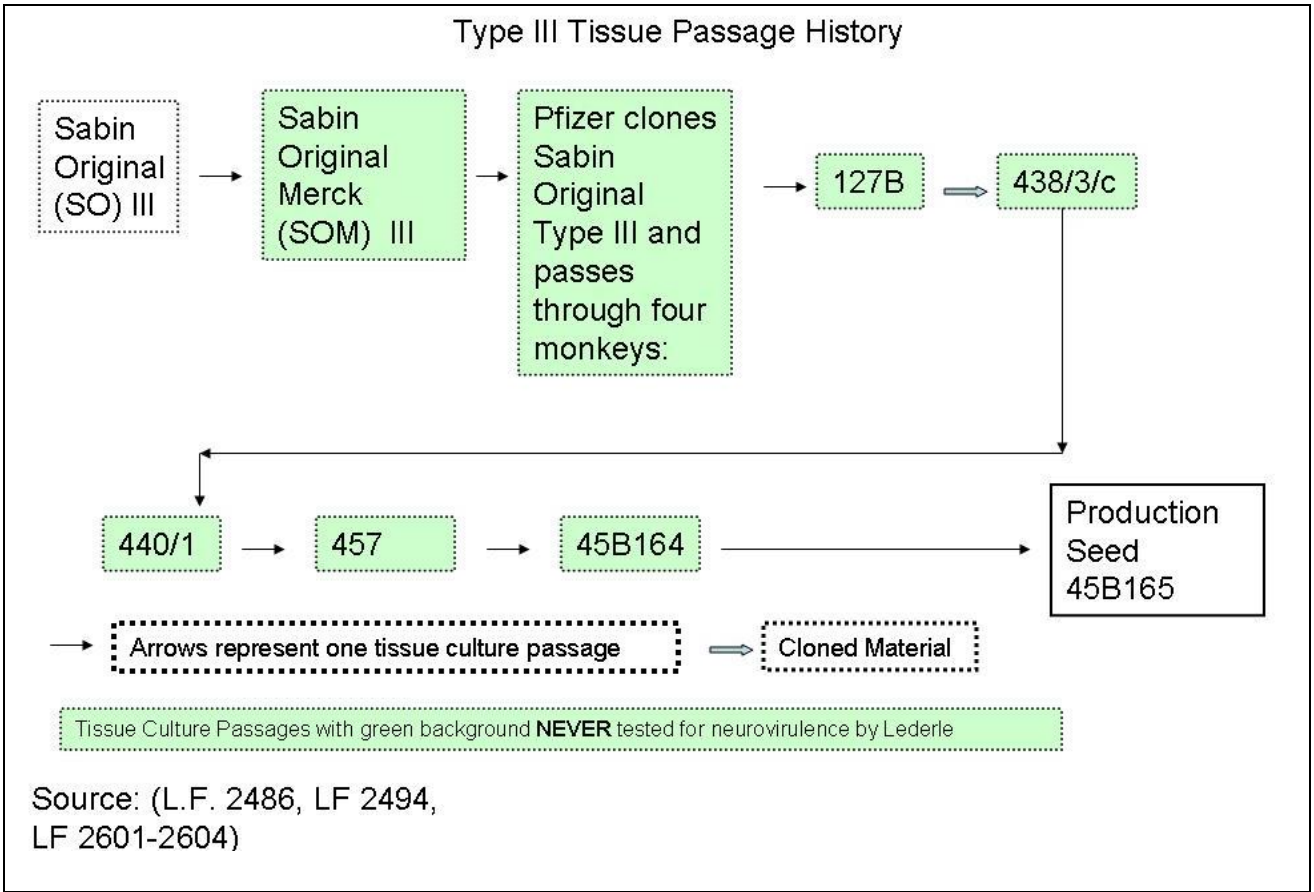

Figure 3. The history of the Type III strains that are different from the Types I and II.

Each tissue culture passage in a monkey creates a new harvest, which can be used as seed material and/or monovalent pool material (Tr. 671-674). It is for this reason that Judge Motz found a violation of the regulations in regard to the tissue culture passages of 45B165 in his *In Re Sabin* decision. It was this finding, which required the immediate

amendment to the Code of Federal Regulations as pertains to how many tissue culture passages were permitted from the Sabin Original. Those regulations stated:

> (a) Virus passages. Virus in the final vaccine shall represent no more than five tissue culture passages from the original strain, each of which shall have met the criteria of acceptability prescribed in § 630.10(b)

21 C.F.R. § 630.13(a) (See Appellants Appendix at A-14).

Because the Type III seeds used in monovalent pool 45B165 had been through more than five tissue passages (see above graphic), without an amendment the Orimune vaccine could not be sold as a trivalent vaccine. 21 C.F.R. § 630.13(a). Type I and Type II met the tissue culture passage requirements. Type III did not. Most cases of vaccine-associated polio were traced to Type III viruses. (LF3866). Id. The failure to test the various seeds is graphically represented in Figure three, below:

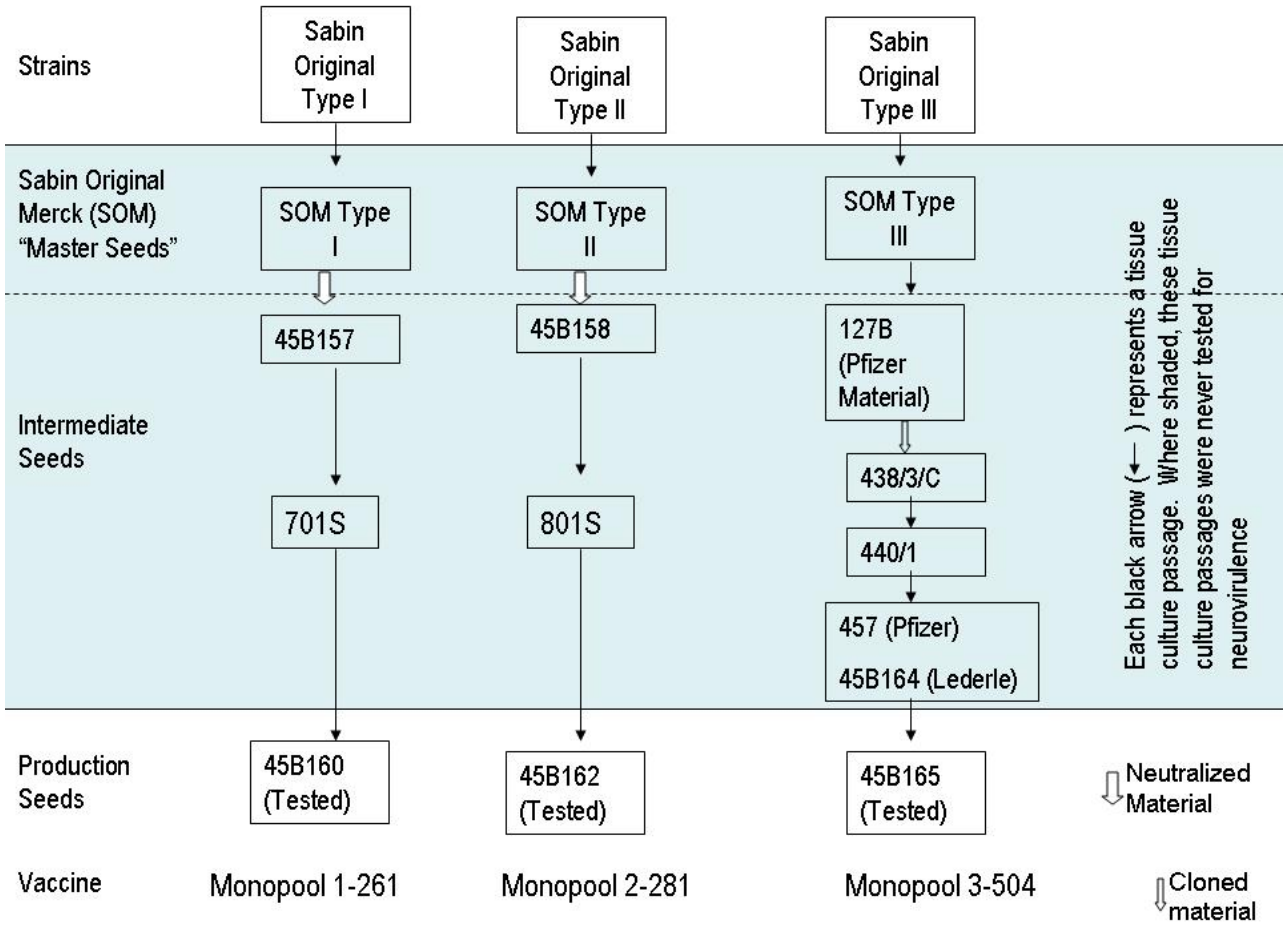

Figure 4 – Graphic representation of the various seeds, including intermediate, used in the production of Cortez Strong's vaccine and for which American Cyanamid has no records that it conducted neurovirulence tests on these seeds.

Mr. Bozzo testified that neurovirulence testing was not performed on any of the Sabin Original, on any of the Sabin Master seeds, Type I 45B157, Type II 45B158, or Type III (Tr. 668-69, 710-712, 714-715, 725-726), and was not performed on the intermediate seeds 701S, 801S,

45B164-457, 440/1, 438/3/c, and 127B (Tr. 674-75). Without testing one cannot insure the safety, purity and potency of this product (Tr. 626). After establishing that the company would have produced multiple seeds in making the vaccine, Mr. Bozzo testified as to the lack of the performance of neurovirulence testing on the seeds. (Tr. 685-693). He stated that Lederle did not perform testing on the Sabin Original, the Sabin Master seeds, and all of the intermediate seeds. Mr. Bozzo testified to the lack of regulatory compliance specifically as follows:

- "Number one, there is no documented testing by American Cyanamid Company of the Sabin original or Sabin Original Merck seed virus utilized to manufacture oral polio virus vaccines for neurovirulence or extraneous microbial agents." (Tr. 689)
- "The second item that I found is that there was no documentation or no documented testing of each seed virus to demonstrate freedom from extraneous microbial agents, …" (Tr. 691).
- "The third item that I found is that there is no documented testing by American Cyanamid Company of each seed virus for neurovirulence." (Tr. 691)

Defendant's-Appellant's only witness to testify as to their fulfilling the minimum requirements was Dr. Mary Ritchey, as they removed Dr. Vincent Racianello as a testifying expert in regard to the neurovirulence and regulatory compliance of the Defendant prior to the trial. (Tr. 1929) The Federal regulations remained in effect from 1960 through 1991. See 21 CFR § 630.10 et seq. (Appellants Appendix at A-10-42) Defendants-Appellants claimed that full compliance with the regulations was unnecessary and that some of these requirements were specifically waived by the regulatory agency in which Mr. Bozzo served (Tr. 1608, 1708-1709). During the trial not a single document was introduced to support this contention (See Tr. 1581-1869). Nowhere in the entire regulatory history of this product other than in 1991 were the Sabin strains mentioned, let alone required to be utilized (Tr.1681-1682). Defendants-Appellants did not produce documentary evidence of the non-existent testing waiver. Likewise they failed to produce any document where the government had purported to demand that the Sabin strains be the only strains used, and the defendant's employee, Dr. Mary Ritchey, admitted as much:

> Q And you could use another strain because the regulations as they existed from 1960 through 1990 did not require the use of the Sabin strains, isn't that correct?
>
> *** [overruled objection]

A Yes, I do. I think he's trying to talk about some specific language in the regulation. But what I am telling you is that when they -- that my understanding and some reading that I've done, not a lot, is that when various poliovirus vaccine attenuated strains were being developed, such as the Sabin strains and the Cox strains, studies were done, discussions were had by the government advisory bodies, and that the outcome of those studies was that the Sabin strains had the best profile in terms of their clinical response in the field and safety and that people should use those particular strains. You know, he's right that the government didn't, you know, say in the regulations or force you that you must use it, but that's what the government said would be the best to use.

(Tr.1687-88)(emphasis added).

Dr. Mary Ritchey, on behalf of Defendant-Appellant, claimed that full compliance with the mandatory testing was unnecessary and that some of these requirements were specifically waived by the regulatory agency in which Mr. Bozzo served as a compliance officer. (Tr.1713) During the trial not a single document was introduced to support this defense. In the entire regulatory history of this product other than in the proposed

regulations of 1986 fought by American Cyanamid and the proposed regulations of 1991, once again challenged by American Cyanamid, (LF0746, 0842) were the Sabin strains even mentioned, let alone required to be utilized. (LF 1672, 1674-1689, and 1690-1714)

American Cyanamid does not, in their factual statement or brief, discuss the 1986 proposed amendments and the United States of America does not discuss the proposed amendments of 1986 or the amendment to the licensing requirements enacted in 1984.

Dr. Mary Ritchey, the corporate designee of American Cyanamid, testified on the crucial issues of attenuation of vaccine and the lack of a need to test intermediate seeds and all of the seeds prior to the production seeds (Tr. 1701-1717). Cyanamid's overall theme at trial was that the vaccine was safe and that there were no problems with the attenuation. Respondent advanced its theory that failure to test the intermediate seeds created neurovirulent "hot lots" that were not detected when small samples of the finished product were tested. Dr. Ritchey cited to that phenomenon when she stated as follows:

> Q So if the progeny of the seeds for some reason were not safe, does that indicate to you that the SOM was not safe?
>
> A Well, it may or may not. Each passage is an

> independent event and so you test the passage and it speaks about the passage. It has some relevance to the parent but doesn't necessarily tell you everything about the parent.

(LF1757-58)

The World Health Organization issued a consultative report on poliomyelitis vaccines, which found the following:

> The joint field and laboratory studies of established and new strains demonstrate that, especially in relation to type 3 virus, neurovirulence tests do not necessarily detect all batches of vaccine which are capable of causing occasional cases of paralysis. This important observation underlines the essential need for laboratory tests to be complemented by effective surveillance as a part of every immunization programme.

(L.F. 1727)

As to the proposed May 1991 changes to the regulations, Defendant-Appellant filed objections and requested a public hearing pursuant to § 701 of the Food, Drug and Costmetic Act (21 USC § 371(e)) relating to the proposed final rule. They challenged every part of those proposed regulations other than the right to utilize the RSO+1 material (the Pfizer seed 45B165) even though it was beyond five tissue culture passages. (LF

1649-1664, 1672, 1674-1689, and 1690-1715) In the various submissions made to the docket of 86N0027 from 1986 through 1991, American Cyanamid challenged any changes to the neurovirulence testing claiming that it would hamper the safety of the vaccine in regard to neurovirulence. It claimed that throughout these submissions the necessity of compliance with the regulations as originally enacted was vital. (LF 1649-1664, 1672, 1674-1689, and 1690-1715)

The words "intermediate materials," "intermediate seeds," nor any other such nomenclature, exists in the regulations in regard to the testing of vaccine material. See generally 21 CFR 630.10 et seq, (Appellant's Appendix at A-10 to A-42)

In 1996 an additional amendment to the regulations was adopted and the license application of each of the vaccine manufacturers became the standard by which one was to judge the safety requirements of oral polio vaccine virus. American Cyanamid's 1962 license application for monovalent and its 1963 license application for trivalent both stated the following:

4.0 Definitions:

4.1 Poliovirus Master Seed –

A master seed is a satisfactory, homogeneous pool of designated type of attenuated poliomyelitis virus stored in such

manner as to supply poliovirus for the preparation of production seed over a prolonged period of time. (LF0997)

4.2 Poliovirus Production Seed –

A production seed is a satisfactory, homogeneous pool of designated type of attenuated poliomyelitis virus stored in such manner as to supply poliovirus for vaccine manufacturers over a prolonged period of time. (LF0998)

6.0 Additional Test Applied to Seed –

An intramuscular neurovirulence test is performed on each master and production seed as described in Addendum 2, Test No. 6.4. (LF0999)

(Tr. 626, 669, 673, 674-77, 684-87)

Between 1960 when the regulations were first proposed, and March of 1961 when they were enacted, and 1998 when the last dose of oral vaccine was prepared by the Defendant-Appellant the requirements remained the same. The requirements were that each seed used in production had to be tested for all of the necessary safety tests. 21 CFR 630.10 et seq.

D. Facts as to Cortez Strong's Appeal Against Defendant Jawaid

Defendant Jawaid claimed during her direct examination that the standard of care did not require her to advise Cortez's mother of the availability of Inactivated Polio Vaccine (IPV) as an alternative to Oral Polio Vaccine (OPV) (L.F. 4094). Defendant's expert, Elizabeth Diehl, had previously testified that the standard of care required the mother to be informed of both options (L.F. 4094). Plaintiff cross-endorsed Diehl, but did not offer her testimony in its case in chief (L.F. 4093).

Dr. Jawaid testified on direct examination that she did not have a memory of advising Cortez Strong's mother of the alternative vaccine of Inactivated Polio Virus (IPV), (Tr. 1973), and that the standard of care did not require it:

> Q (By Mr. Germeroth) Well, did you discuss --
> let's talk about the -- I think you have the Red Book and
> you've talked about the Red Book, correct? And the Red
> Book sets forth how you go about to do your practice as a
> pediatrician in dealing with patients' parents, correct?
> A That's right.
> Q And that kind of sets forth -- I think what
> you're saying, that sets forth the guidelines on how
> you're going to work, correct?

A On how I'm going to give the vaccines.

Q And that includes what type of information you're going to give the patients' parents, correct?

A That is correct.

Q And so in your understanding of the Red Book, do you feel that the way you would have given that vaccine complied with the guidelines of the Red Book?

A I believe so.

Q So if there is a -- if you will, a standard of care by this Red Book, you think you've complied with that standard of care?

A I followed their guidelines, so I guess I did it.

Q Okay. And it's your understanding of that Red Book that -- under your understanding of the Red Book, you need to advise the patients' parents of the risk of OPV, is that right?

A Yes.

***

Q Okay. When you give the advice to the parent to get their consent to give the OPV, at the same time you're

also supposed to give them the alternative of inactivated poliovirus which does not cause polio?

A I don't believe that that's a correct statement, sir, because you're presuming that I would say that at the same time I'm saying the OPV that I would give the IPV. It's not really required by the Red Book, but it would come up when I asked them if there is anybody with immune compromised situation, with cancer or AIDS, or if the mother refused the vaccine, then I would have to offer the injectable polio vaccine.

(Tr. 1994-96)

IPV does not carry the risk of vaccine-associated polio (L.F. 3925,3935,3962). Plaintiff sought to read the deposition of Dr. Diehl, whom Jawaid had abandoned as an expert at trial (Tr. 1929, 2019). Plaintiff offered Dr. Diehl's deposition in rebuttal on the issue of the standard of care, which Dr. Jawaid had testified about during cross examination. Diehl had testified in her deposition that the standard of care required a pediatrician to advise on <u>both</u> the IPV and OPV vaccines. (LF1171, 1173, 4105, 4107). This evidence was directly contrary to the evidence that Dr. Jawaid put forth in her defense. The defendant objected as improper rebuttal.

MR. GERMEROTH: Your Honor, I would like to put on rebuttal an expert that was disclosed by the defendant, Dr. Jawaid, that was cross-endorsed by us, it was disendorsed as of this morning, that goes to the standard of care, which I think directly goes to what the defendant discussed with regard to the -- her testimony, therefore I think it's proper rebuttal.

MR. ECKENRODE: Your Honor, my objection is that Dr. Diehl, whose testimony he wishes to offer, is somebody who they cross-endorsed as an expert. They deposed her. She was also a St. Louis resident subject to subpoena. She could have been called during plaintiff's case in chief and was an appropriate witness to call during plaintiff's case in chief.

There are cases on point, which I'd be happy to submit to the Court on this issue, the most recent being *Aliff v. Cody*, 26 S.W.3d 309, which states, among other things, "Rebuttal evidence is evidence tending to disprove new points first opened by the opposite party."

When Dr. Jawaid was on the stand, we asked

no questions of her regarding what the standard of care was. In fact, during my entire case in chief we did not offer any evidence on standard of care at all, so there is nothing to rebut as to the standard of care with regard to the evidence that I offered.

(Tr. 2019-2020)

While defendant Jawaid's counsel had not asked standard of care questions during his direct examination, during Dr. Jawaid's testimony on cross-examination she offered opinions on the standard of care and her adherence to it. Counsel pointed this out to the Court:

MR. GERMEROTH: Your Honor, first of all, that case is prior to the Missouri rules change wherein depositions can now be used for any reason at all. At that time there was rules dealing with the -- in regard to the availability of the witness, and that's what distinguishes that case.

Secondly, with regard to the new points they brought up that they were in fact relying on the Red Book, whereas that was not the -- although that was brought up on cross by Mr. Eckenrode with regard to Dr.

> Shanske, as I recall he was just basically -- that was his opinion, it's nationwide good practice of medicine with regard to giving both IPV and OPV, therefore he is introducing new evidence. The standard of care was that of the guideline she was relying on, and therefore I believe that new point is being raised that Dr. Diehl is directly on point with regard to -- with regard to that standard of care.

(Tr. at 2021)

The trial court did not permit this on the basis of improper rebuttal (Tr. 2020).

E. Verdict and Pre-Judgment Interest

At the close of the trial the jury returned a verdict of $8,500,000 in favor of Cortez Strong and against Defendant Cyanamid (L.F. 4038). Plaintiff moved for prejudgment interest, introducing the letter sent to Cyanamid's counsel and setting out its compliance with § 408.040 RSMo. (2000) (L.F. 4092). Defendant complained that the delay in getting to trial resulted from the plaintiff, and opposed the amendment (L.F. 4127). The trial court overruled the motion for prejudgment interest in spite of Plaintiff

having fully complied with the statute. The basis for the court's decision was not provided (L.F. 4195).

ARGUMENT

I.

Introduction

American Cyanamid's ("Cyanamid" and sometimes "Lederle") Point Relied On I assigns error to the trial court's decision to deny its motion for judgment notwithstanding the verdict. Cyanamid argues that Plaintiff Cortez Strong failed to show any violation of the FDA regulations because the meaning of the regulations (1) was a question of law for the trial court and (2) should have been resolved by deferring to the FDA's own interpretation of the regulations.

Cyanamid's Point must fail for a number of reasons:

First, the Point Relied On never addresses the legal question at trial – whether Missouri law permits an expert to testify as to regulatory compliance. Cyanamid's Point does ***not*** assign error to the trial court's decision to admit Thomas Bozzo to testify as a regulatory compliance expert. Cyanamid apparently wishes this Court to consider whether the trial court erred in allowing Thomas Bozzo, a pharmacist, the holder of a master's degree in Public Health from Johns Hopkins University, a branch chief for the FDA with over twenty-one years in the regulation of biologic products and an FDA Compliance Officer for nearly thirty years, to testify

as an expert in regulatory *compliance.* (Tr.638) The role of an FDA compliance officer is to "take information that is provided during inspections and … determine whether there is a violation of the regulations." (Tr.638). Cyanamid's indirect (at least for purposes of the Point Relied On) attack ignores, however, the fact that Mr. Bozzo's testimony was both material and relevant in the product liability claim to the existence of a defect. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY, § 4(a)(1998) (product's noncompliance with an applicable product safety statute or administrative regulation renders the product's condition defective with respect to the risks sought to be reduced by the statute or regulation).

Mr. Bozzo testified that Cyanamid failed to comply with FDA regulations by failing to test the vaccine material at each tissue culture passage when it made the vaccine that Cortez Strong received in 1987. (Tr.668). In order to attack the defective condition evidence, Cyanamid's Point Relied On must say that that is what it is doing. The Point Relied On completely fails to discuss this issue, leaving this Court to consider only whether the trial court erred as set out in the Point.

Second, Cyanamid put on no evidence as to the meaning of the regulations beyond the testimony of its own employees. The trial court did not hear evidence of the FDA's interpretation of the regulation from the

FDA. The trial court cannot be convicted of error for Cyanamid's failure to offer evidence at trial.

Third, Cyanamid fails to assign error to, but nevertheless advances a claim of error outside its Point I, that the trial court abused its discretion in permitting Mr. Bozzo to testify as to the *meaning* of the FDA's regulations relating to the manufacturing process for oral, live polio vaccine. The only time Mr. Bozzo testified as to the meaning of any regulation was when *Cyanamid* asked him to do so.

As will be shown, the trial court did not err in denying the judgment notwithstanding the verdict or abuse its discretion in permitting Mr. Bozzo to testify because (1) his testimony was consistent with the plain language of the regulations; (2) his testimony was consistent with Cyanamid's license application, which defined strains and seeds; (3) his testimony was consistent with judicial interpretations of the meaning of the regulations in effect at the time Cyanamid manufactured Cortez Strong's vaccine; (4) Missouri law permits expert testimony on the issue of regulatory compliance and (5) if there was error in permitting Mr. Bozzo to testify, the error was both invited by Cyanamid and non-prejudicial in that the testimony was consistent with the meaning of the regulations.

Standard of Review

Point I challenges the submissibility of Plaintiff's case. Where submissibility is the issue, the Court must "view the evidence in the light most favorable to the plaintiffs and give to the plaintiffs the benefit of all reasonable inferences." *Washington by Washington v. Barnes Hosp***.** 897 S.W.2d 611, 615 (Mo. banc 1994); *Majors v. Butner***,** 702 S.W.2d 539, 543 (Mo. App. W.D. 1985). "If it can fairly be inferred that defendant was negligent, the evidence is sufficient." *Cline v. William H. Friedman & Assoc., Inc.*, 882 S.W.2d 754, 758 (Mo. App. E.D. 1994). Where testimony of a medical expert is subject to differing interpretations, it should be accorded the interpretation that supports the jury verdict and submissibility of the case. *Id.* at 543. A "case may not be withdrawn from the jury unless there is no room for reasonable minds to differ" *Washington,* 897 S.W.2d at 615 [citation omitted]; *Coon v. Dryden,* 46 S.W.3d 81, 90 (Mo. App. W.D. 2001).

Whether an expert should be permitted to testify is reviewed for abuse of discretion. *Swartz v. Gale Webb Transp. Co.,* 215 S.W.3d 127, 129-30 (Mo. banc 2007). "[T]he admission or exclusion of expert opinion testimony is a matter within the discretion of the trial court, and this Court will not interfere with that discretion unless it plainly appears that it has been abused." *Eltiste v. Ford Motor Co.,* 167 S.W.3d 742, 750-51

(Mo.App. E.D.2005) (internal quotation omitted). "A trial court abuses its discretion, as to the admissibility of evidence, when its ruling is clearly against the logic of the circumstances then before the court and so arbitrary and unreasonable as to shock the sense of justice and indicate a lack of careful consideration." *Scott v. Blue Springs Ford Sales, Inc.,* 215 S.W.3d 145, 164 (Mo.App. W.D.2006).

A. No Deference Is Due the FDA Because of Its Own History of Misinterpreting its Regulations and Cyanamid's Failure to Place the FDA's Interpretation of pre-1991 Regulations at Issue Before the Trial Court.

Both the FDA and Cyanamid assert that 1991 amendments to the applicable polio vaccine manufacturing regulations state the Government's interpretation of different regulations in effect in 1986, the year Cyanamid made the vaccine from which Cortez Strong contracted polio. For both the Government and Cyanamid, the 1991 regulations look back – and are effective in reverse – no matter what the language of the regulations in effect in 1986 actually said and no matter what courts said about those regulations.

The amicus curiae brief of the United States is nothing more than an attempt to supplement the trial record by attacking Mr. Bozzo's testimony regarding compliance well after the jury heard the evidence at trial and

rendered its verdict of liability. None of this argument by Cyanamid or the Government accounts for the failure of Cyanamid to offer evidence from the FDA at trial as to the meaning of the regulations and, more important, even if the Government is to be believed, it's regulatory interpretation does not refute unchallenged evidence of Cyanamid's failure to test intermediate seeds 701S and 801S. Under neither a 1986 or a 1991 regulatory scheme are materials designated 701S or 801S anything other than seeds – which were required to be tested.

Both Cyanamid and the United States Government (as *amicus curiae*) argue that Mr. Bozzo's testimony was contrary to the FDA's own interpretation of its regulations. The Government's hands are not clean on the issue of regulatory interpretation. *In re Sabin Oral Polio Vaccine Products Liability Litigation*, 984 F.2d 124, 127 (4th Cir, 1993) held: "We conclude that DBS's [now FDA's] concerns cannot justify the [its own] violation of the regulations." Nor can the FDA adopt an "interpretation of the regulations that departed substantially from their plain meaning." *Id.* As the district court noted in the underlying case, which the Fourth Circuit affirmed,

> The power conferred upon an agency or other delegated authority must be commensurate with the responsibilities assigned to it. However, to the extent that the adoption of a

> regulatory standard has resolved underlying safety and policy issues, regulators must work within the environment which that standard creates. They may not ignore what the regulation says because they believe that it is unwise or has become outdated. Nor may they circumvent it by merely paying lip-service to its terms....
>
> However reasonable DBS's decisions might have been *dehors* the regulations, it was the regulations which provided the standard by which DBS officials were required to make their neurovirulence determinations. This standard constituted one of the critical elements of the definition of safety when public approval for the implementation of the OPV program was implicitly given through the adoption of the regulations....
>
> Their failure to live up to it [the regulation] – and their continued violation of the existing regulations – subjects the United States to liability in these actions.

In re Sabin Oral Polio Vaccine Products Liability Litigation, 763 F. Supp. 811, 822-23 (D.Md. 1991)(*Sabin II*) *aff'd.* 984 F.2d 124 (4th Cir. 1993)(emphasis added).

> In short, DBS [Department of Biological Services] [now FDA] officials arrogated to themselves the power to define what

> constituted an acceptable risk, thereby undermining the rule of law and threatening long-term public confidence in the regulatory system itself. This conduct certainly cannot be deemed to be reasonable as a matter of law and may well have been unreasonable as a matter of law. In any event, to the extent that the matter is one entrusted to me as the finder of fact, I have no hesitation in finding-just as I would urge were I a member of a jury panel-that the regulatory violations which DBS committed were, considered under the totality of all of the circumstances, unreasonable and a breach of the duty of care.

In re Sabin Oral Polio Vaccine Products Liability Litigation, 774 F. Supp. 952, 957 (D.Md. 1991)(*Sabin III*) *aff'd*. 984 F.2d 124 (4th Cir. 1993)(emphasis added).

Not to put too fine a point on it, the *In re Sabin* cases hold that the FDA's interpretation of its regulation on polio licensing violated the law and amounted to a breach by the FDA of its own safety guidelines and of its duty of care to vaccine recipients in the release of certain oral, live polio vaccine. This was because "it was not vaccine that conformed to the safety provision of the regulations." *In re Sabin*, 984 F.2d at 127.

The FDA's immediate amendment of its regulations, less than a month after *Sabin II*, achieved the purpose of limiting the FDA's future

liability to vaccine associated paralytic polio victims. The Federal Register comments to the new regulation in 1991, nearly four years *after* Cortez Strong contracted polio, admit that the changes were instigated by *Sabin II*:

> Questions about the agency's past interpretation of the oral poliovirus vaccine regulations have been raised in tort litigation brought against the United States.
>
> In a recently issued opinion, the District Court for the District of Maryland in consolidated litigation brought under the Federal Tort Claims Act [expressly citing *In re Sabin*]… found certain past agency interpretations of the oral poliovirus vaccine regulations to be impermissible..... In this final rule certain clarifying changes are being made. …
>
> Clarifications are intended both to provide less ambiguous language and, to the extent courts have found that certain interpretations are not permissible, to change the regulations appropriately.

56 F.Reg. 89, 32421-22 (May 6, 1991).

Second, changes in regulations are presumed to have been made to make a change in the statute or regulation. *Harding v. Lohman*, 27 S.W.3d 820, 824 (Mo. App. 2000). The rules applicable to statutory construction

are applicable to the interpretations of regulations as well. *Teague v. Mo. Gaming Com'n.*, 127 S.W.3d 769, 685 (Mo. App. W.D. 2003). ("The same principles of construction are used when interpreting regulations as in interpreting statutes").

And, as the *In re Sabin* decisions show, the FDA, like Cyanamid, is bound by the regulations in effect at the time the vaccine was manufactured. A differing "interpretation" of the regulations by the FDA to fit its own needs *du jour* "cannot justify the violation of the regulations." 984 F.2d at 127.

The 1991 amendments did not, however, relieve Cyanamid of its duty to test every tissue culture passage at every step of the manufacturing process during the time that it manufactured Cortez Strong's vaccine – in 1986, five years before the regulatory changes in 1991 upon which Cyanamid now relies.

The year 1986 is also important. Cyanamid's argument in this case centers on regulations adopted in 1991. Each time Cyanamid relies on the regulation in its brief, it relies on the ***1991*** version, asserting that the FDA finally said what it meant in 1991.

Regulations are not generally applied retroactively. See, *Bowen v. Georgetown University Hospital*, 488 U.S. 204, 207 (1988)("a statutory grant of legislative rulemaking authority will not, as a general matter, be

understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress …. Even where some substantial justification for retroactive rulemaking is presented, courts should be reluctant to find such authority absent an express statutory grant.") As *In Re Sabin I* makes clear, the FDA is bound by its regulations.

American Cyanamid asserts not retroactive application of the 1991 regulation, but something wonderfully more creative -- that the 1991 regulation actually reflects the FDA's interpretation of the regulations in effect when American Cyanamid manufactured Cortez Strong's vaccine in 1986. Cyanamid's position is that the FDA had just not gotten around to amending the regulations to reflect its interpretation.

The issue of the FDA's asserted pre-1991 interpretation of its polio vaccine regulations must be addressed and addressed in the context of its own malfeasance already set out. *Sabin II* points out the FDA had three options on how to handle the fact that 45B165 violated 42 C.F.R. § 73.113(b) by authorizing a vaccine more than five tissue passages from the original strain.

> [T]he interpretation of § 73.113(b) [now 630.13(b)] which the Government now urges is contrary to what was for years the accepted understanding of the section [as Mr. Bozzo testified concerning "seeds" here]. [A] memorandum of a meeting

> between DBS and Lederle officials on November 6, 1980, states that Dr. Elisberg indicated that DBS would have to make a decision to "(1) do something with the regulations to allow the use of the seed, i.e., a change in the regulations themselves; (2) interpret what Pfizer did as being not outside the regulations; or (3) redefine the regulations in some manner to indicate this is a rederivation of Sabin's original seed." ….
>
> In effect, what has been played out in this litigation is the third of the options attributed to Dr. Elisberg in Lederle's memorandum of the November 6, 1980 meeting: "redefin[ing] the regulations in some manner to indicate this is a rederivation of Sabin's original seed."

763 F.Supp. at 824-5. That is precisely the scenario played out here. The FDA redefined "strain" to protect itself and its sole American manufacturer of vaccine, Cyanamid, from liability – and did so without amending the regulations.

As *Sabin II* concludes: "The Government's argument on this point is somewhat disturbing. It is tantamount to saying that something is so because we say it is so…." *Id.*

Third, as noted above, there is no need to defer to the FDA's *post hoc* rationalization of its rules in 1991 where the injury occurred in 1987 and the events leading up to that injury occurred even earlier.

Fourth, deference to agency determinations is appropriate in cases where the agency presents its views to the trial court, not where the agency plays no role in the litigation and there is no evidence regarding the agency's position. In advancing its claim that this Court should view Cyanamid's conduct in 1986-87 through the lens of the FDA in 1991, and adhere to what it claims is the FDA's retrospectoscopic view of the regulations, Cyanamid alleges that this Court is bound to give deference to the FDA's view. But the issue here is not the proper interpretation of the regulations as an academic exercise, but whether the trial court erred in ruling as it did at trial – on the issues and evidence presented to it. Aside from the fact that Mr. Bozzo's own experience in the FDA directly refuted Cyanamid's position, Cyanamid put on no testimony from the FDA at trial that supported its position. Cyanamid wholly failed to place this question at issue at trial.

Now, throwing a Hail Mary pass that ignores its trial failures, Cyanamid cites *Willard v. Red Lobster*, 926 S.W.2d 550, (Mo. App. E.D. 1996). *Willard* was an appeal from a finding by the Labor and Industrial Relations Commission that dealt with that Commission's rule regarding

appeals of awards. The Commission's decision was before the Court, and it was proper to give deference to that Commission's interpretation of its own rule. *Id.* Similarly, *Nat'l Assn of Home Builders v. Defenders of Wildlife*, 127 S.Ct. 2518, 168 L.Ed.2d 467, 75 USLW 4543 (2007) involved a claim by interest groups that the EPA had made a decision in an arbitrary and capricious manner. The Supreme Court gave deference to the agency's reasonable determination because the agency was before the Court as a party in the case.

Likewise, in *Thomas Jefferson University v. Shalala*, 512 U.S. 504 (1994) the issue before the court was the legal import of a redistribution regulation issued by HHS. The Supreme Court said:

> Petitioner challenges the Secretary's construction of § 413.85(c) under the Administrative Procedure Act (APA), 5 U.S.C. § 551 *et seq.* The APA, which is incorporated by the Social Security Act, see 42 U.S.C. § 1395oo(f)(1), commands reviewing courts to "hold unlawful and set aside" agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). We must give substantial deference to an agency's interpretation of its own regulations.

Id. at 512. Importantly, the agency whose regulation was being questioned was before the court and was arguing for the particular result.

This case differs significantly. At trial, Cyanamid attempted to impeach Mr. Bozzo based on the 1991 change in regulations. The 1991 regulations were not introduced as substantive evidence. The FDA was not before the Court, and its interpretation of the 1987 regulations could not logically be introduced by statements made in 1991 in the Federal Register. The 1991 regulations were (and are) legally irrelevant to the issues in the case.

As explained below, the issue of the agency's interpretation came in as a result of Cyanamid's cross-examination of plaintiff's expert. If this was a fundamental issue for Cyanamid, it had the opportunity to produce its own regulatory compliance expert at trial and deal with the issue of neurovirulence testing head on. Yet, while claiming that the trial court should have deferred to the FDA's view of the regulation, Cyanamid did not offer any evidence on the subject of the meaning of the regulations, except through the testimony of its employees, whom the trial court and the jury could rightly choose to find not credible given their employment affiliation.

The trial court cannot now be convicted of error because of Cyanamid's failure of proof of facts or persuasion on the legal issue when the claim was directly refuted by the only FDA employee to testify.

B. The Trial Court Properly Admitted Thomas Bozzo's Testimony

Reduced to its essence, Cyanamid contends that the dispute in Point I is about whether certain intermediate manufacturing material used in the production of oral, live polio vaccine in 1986 was a *seed* or a *strain*. Cyanamid's brief admits that there is virtually no dispute about whether tests were (or were not) performed – the dispute is whether the tests were required to be performed.

Cyanamid takes the position that it was not required to test *strain* material. Cortez Strong asserts that the intermediate material Cyanamid failed to test was both a tissue culture passage and *seed* material. Thomas Bozzo so testified. The regulations are clear. Seeds (and tissue culture passages) must be tested; strains need not be tested. However, no regulation defines a seed or a strain. And, as noted, Cyanamid's argument ignores the fact that under any definition 801S and 701S were seeds, were required to be tested, and were not tested in making Cortez Strong's vaccine.

1. Thomas Bozzo's Testimony was Consistent with the Plain Language of the Regulations.

21 C.F.R. § 630.10(b)(4)(1987) which was in effect and applied to Cyanamid (and the Government) when Cyanamid manufactured Cortez

Strong's vaccine in 1986, provides:

> No seed virus shall be used for the manufacture of polio virus vaccine unless its neurovirulence in Macaca monkeys is no greater than that of the reference attenuated polio virus distributed by the Office of Biologics Research and Review. The neurovirulence of the seed virus shall be demonstrated by the following tests to be performed by the manufacturer….

Id.

21 C.F.R. § 630.13, which was also in effect when Cyanamid made Cortez Strong's vaccine, provided:

> (a*) Virus passages*. Virus in the final vaccine shall represent no more than five tissue culture passages from the original strain, each of which shall have met the criteria of acceptability prescribed in § 630.10(b).

Id. Under the plain language of the regulations, ***each*** tissue culture passage must be tested for neurovirulence. See, *In re Sabin Oral Polio Vaccine Products Liability Litigation*, 763 F.Supp. 811, 824 (D. Md. 1991)(*Sabin II*)("the fact that SOM proved … satisfactory in the original clinical field trial is wholly immaterial to the problem at which the section

[711.113(b)][5] is directed, potential genetic instability of vaccine which is more than five tissue culture passages from the strain material"). The regulation draws no distinction between seeds or strains, but makes the tests mandatory for each tissue culture passage.

Mr. Bozzo testified that there were no tests of the tissue culture passages.[6] This is consistent with the plain language of the regulations.

2. Thomas Bozzo's Testimony was Consistent with Judicial Interpretations of the Regulations in Effect When American Cyanamid Manufactured Cortez Strongs' Vaccine.

In the early 1980's, vaccine associated paralytic polio victims, including Kevan Berkovitz, questioned whether the FDA had properly certified the vaccines they received as compliant with the authorizing statute, § 351(d), 58 Stat. 702-703, as amended, 42 U.S.C. § 262(d), and

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[5] The regulations were renumbered. Section 73.113(b) is now 21 C.F.R. § 630.13

[6] In the polio vaccine manufacturing process, a manufacturing stage occurs when polio virus seed is place in monkey kidney tissue and polio virus is harvested. This is called a tissue culture passage. Regulations require testing of the vaccine at each stage of the manufacturing process or each tissue culture passage.

the regulations promulgated under that statutory authority. In the first of its interpretative errors about its regulations, the FDA argued that it did not need to examine test data to license vaccine; apparently the FDA believed that it could rely on a manufacturer of the vaccine in the United States, Cyanamid, to self-report without verification of Cyanamid's assurances as to its manufacturing processes' faithfulness to the regulatory requirement.

The authorizing statute for oral polio vaccine and the language of the regulations were explicit regarding the licensing requirements for oral, live polio vaccine, however. The fox cannot self-report on the health and safety of the hens.

> "Licenses for the maintenance of establishments for the propagation or manufacture and preparation of products [including polio vaccines] may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards. All such licenses shall be issued, suspended, and revoked as prescribed by regulations. . . ."

§ 351(d), 58 Stat. 702-703, as amended, 42 U.S.C. § 262(d) (emphasis supplied). The applicable regulations 21 C.F.R. § 600.1 et seq, demanded that the FDA require certain testing in order to approve applications to license vaccines for polio. The polio victims asserted that the FDA had failed to fulfill its statutory and regulatory mandate and sued.

Kevan Berkovitz's case reached the Third Circuit on interlocutory appeal after the district court denied the Government's motion to dismiss. The majority opinion in *Berkovitz v. United States*, 822 F.2d 1322 (3rd Cir. 1987), reached a different conclusion than both *Baker v. United States*, 817 F.2d 560, 566 (9th Cir. 1987)(regulation required the FDA to enforce its mandatory duties and "not issue a license for manufacturing poliovirus vaccine unless the relevant test data had been submitted") and *Loge v. United States*, 662 F.2d 1268, 1273 (8th Cir. 1981) ("The Secretary [of Health and Human Services] has no discretion to disregard the mandatory regulatory commands pertaining to criteria a vaccine must meet before licensing its manufacture or releasing a particular lot of vaccine for distribution to the public."), cert. denied, 456 U.S. 944 (1982).

The United States Supreme Court granted certiorari to resolve the conflict among the Circuits. A unanimous court held that the FDA had violated is non-discretionary duties under the statute and regulations. *Berkovitz v. United States*, 486 U.S. 531 (1988).

The Supreme Court considered the language of the regulations then in effect to see what consequences naturally followed if the vaccine manufacturer failed to supply the safety data, in particular the test results proving the absence of the adventitious agents, and that the neurovirulence of the seeds met the requirements contained of then 42 C.F.R. §§ 73.110(b)(3) and (b)(4), as amended, 21 C.F.R. § 630.10 et seq. The Supreme Court examined with particularity those regulations which required seed testing and how the tests were to be conducted. [7]

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[7] Additional tests were also required to ascertain that the seeds and vaccine did not contain any other adventitious agensts. See, 21 CFR §§ 630.16(a)(5) & (a)(7). "Adventitious" means "occurring spontaneously or accidentally" WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 31. The regulation requires this testing because, as Cyanamid informed the FDA, testing only a small sample from the end product might miss virulent hot spots in the vaccine pool.

> Lederle [Cyanamid] scientists have determined, however, that because of the heterogenous nature of the virus particles in even the best seeds, certain variables in the manufacturing process may indeed influence neurovirulence. These factors include, among others, incubation temperature; the nature of

Additional tests were also required to ascertain that the seeds and vaccine did not contain any other adventitious agent. The Court held that those mandatory regulations were explicit and required the licensor -- the FDA -- to assure itself that the licensee -- Cyanamid -- had conducted the precise tests in the manner required by regulatory mandates.

> Under federal law, a manufacturer must receive a product license prior to marketing a brand of live oral polio vaccine. See 58 Stat. 702, as amended, 42 U.S.C. § 262a). In order to become eligible for such a license, a manufacturer must first make a sample of the vaccine product. See 42 CFR § 73.3 (Supp. 1964); 21 CFR § 601.2 (1987). This process begins with the selection of an original virus strain. The manufacturer grows a seed virus from this strain; the seed virus is then used

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> the cell substrate used to propagate the vaccine; and multiplicity of infection.

(LF0605). Cyanamid's witness at trial, Dr. Mary Ritchey, confirmed this concern. She testified that each passage of the manufacturing process risked loss of attenuation. Ritchey said: "Something could happen in making the passage that allowed the passage that you made to change… there was the potential for the characteristics to change slightly when you went from passage to passage to passage….." (Tr.1758).

to produce monopools, portions of which are combined to form the consumer-level product. Federal regulations set forth safety criteria for the original strain, see 42 CFR § 73.110(b)(2) (Supp. 1964); 21 CFR §§ 630.10(b)(2)(1987), the seed virus, see 42 CFR §§ 73.110(b)(3), (4) (Supp. 1964); 21 CFR §§ 630.10(b)(3), (4)(1987), and the vaccine monopools, see 42 CFR §§ 73.114 (Supp. 1964); 21 CFR § 630.16 (1987). *Under the regulations, the manufacturer must conduct a variety of tests to measure the safety of the product at each stage of the manufacturing process.* See 42 CFR §§ 73.110, 73.114 (Supp.1964); 21 CFR §§ 630.10, 630.16 (1987). Upon completion of the manufacturing process and the required testing, the manufacturer is required to submit an application for a product license to the DBS. See 42 CFR § 73.3 (Supp.1964); 21 CFR § 601.2 (1987). In addition to this application, the manufacturer must submit data from the tests performed and a sample of the finished product. *Ibid*.

486 U.S. at 540, 541(emphasis added).

Thereafter the *Baker* and *Berkovitz* plaintiffs became part of *In Re Sabin Product Liability Litigation*, 763 F.Supp. 811 (D. Md. 1991).

When the *In re Sabin* litigation discussed the seed/strain issue, it supported Mr. Bozzo's responses on cross-examination. It directly addresses the lineage of 45B165 as follows:

> The actual lineage of ***Seed*** 45 B 165 is not in dispute. The seed had the following phases of development: (1) Sabin Original-MERCK (SOM) was produced from the original Sabin material (SO); (2) ***Seed*** 127 B-III was produced from SOM; (3) a material known as PS 438/3/C/a/1 was produced from ***Seed*** 127 B-III; (4) PS 440/1 (now known as SOR) was produced from PS 438/3/C/a/1; (5) ***Seed*** 457-III was produced from SOR; and (6) ***Seed*** 45 B 165 was produced from Seed 457-III. A seventh passage occurs when vaccine lots are manufactured from Seed 45 B 165.

Sabin II, 763 F.Supp. at 823 (emphasis added). *Sabin II* is thus a judicial determination that material that follows the original is a master seed or a production seed, not a strain. Not until the FDA changed its regulations, after Cyanamid gave Cortez Strong polio, could the court have reached a different conclusion from the regulations.

Cyanamid's 45B165 is, of course, the material from which Cyanamid produced the Type III portion of the vaccine Cortez Strong received. Cyanamid will be quick to point out that it tested 45B165 and so it did.

But two admissions are inherent in that assertion: first, that Cyanamid needed to test 45B165 because it was a tissue culture passage and two, its failure to test 45B157, 45B158, 45B169, 701 S and 801S violated the regulations, as each was produced as an tissue culture passage between the original strain and the final vaccine production.

Judge Motz decribed the journey of the seed material from France to Cyanamid as follows:

> Dr. Elisberg [the DBA official responsible for evaluating neurovirulence] suggested to Lederle that it explore the possibility of obtaining a portion of the ***seed*** material which Pfizer had produced from SOR. Acting upon this suggestion, Lederle contacted Institut Merieux, which had acquired Pfizer's ***seeds*** when Pfizer had gone out of the OPV business. In February 1981 Institut Merieux shipped a portion of the Pfizer material to Lederle, and Lederle then produced its own ***seed*** from the material. This ***seed***, denominated ***Seed*** 45 B 165, was approved for use by DBS in 1983, and it has since been the source for all of the OPV used in the United States.

Sabin II, 763 F.Supp. at 821 (emphasis added). It is clear from this judicial conclusion that 45B165 was both a seed and was produced itself from a French seed.

To the extent that Cyanamid elicited testimony from Mr. Bozzo regarding the meaning of the regulations, and Mr. Bozzo concluded that each intermediate production was required to be tested, Mr. Bozzo's testimony was consistent with *Berkovitz* and the *In re Sabin* cases. There could have been no prejudice to Cyanamid from Mr. Bozzo's expert testimony because that testimony was consistent with these judicial understandings of the regulations.

3. Cyanamid's License Application and Protocols Defines Seeds to Include Intermediate (Tissue Culture Passage) Material

That the intermediate material used in the production of oral, live polio vaccine was a seed until 1991 is clear from Cyanamid's license application. Cyanamid's application for a license to produce the vaccine identified material that was a "seed" and what was a "strain."

Error! Objects cannot be created from editing field codes.Error! Objects cannot be created from editing field codes.

Error! Objects cannot be created from editing field codes.

Error! Objects cannot be created from editing field codes.

Under Cyanamid's application, SOM Type I, SOM Type II and SOM Type III, 45B157, 45B158, 45B164, 701 S and 801S were all either master seeds or production seeds because they were not listed as strains by

Cyanamid itself. Based on this application and the assurances and definitions it contained, the FDA issued the license to Cyanamid.

Second, before there were lawyers and litigation and the word games began, Cyanamid's specific record of protocols for the production of the Cortez Strong vaccine for Types I and II also listed 45B157 , 45B158, 701A and 801S as seeds – because that's what they were. **Error! Objects cannot be created from editing field codes.Error! Objects cannot be created from editing field codes.**

Error! Objects cannot be created from editing field codes.

4. The Trial Court Properly Allowed Thomas Bozzo to Testify as a Regulatory Compliance Expert.

Plaintiff established Mr. Bozzo's expert credentials on direct examination and after a contentious voir dire by Cyanamid's counsel. Mr. Bozzo:

- Is "a consultant to the biologics pharmaceutical and tissue industries."
- Provides "advice to those organizations in that -- in those industrial areas for compliance with FDA requirements."
- Spent "over 21 years in the Food and Drug Administration, and the vast majority of that time, probably 20 of those years, were

in the regulation of biologic products. And I also spent a previous four or five years before biologic products in this country were regulated by the FDA with that organization that did regulate them.... The Division of Biologic Standards in the National Institutes of Health."

- Testified that "[b]iologics are made primarily from living material, but not exclusively. Whereas, drug products are made from inorganic chemicals for the most part, sometimes organic chemicals, I should say organic, But also, drug products are used primarily to treat conditions, and biologic products, at least the vaccine products, are used primarily to prevent disease."
- Holds bachelor's degree in pharmacy and a master's degree in public health from Johns Hopkins University.
- His "Master's degree in public health provides education having to do with epidemiology; that is, the causes of disease, how you determine what the cause of an infectious disease is, how you may determine what -- how a chronic disease progresses, and ... how chronic diseases are caused, also biostatistics to determine statistically -- to evaluate statistically the

information that is received having to do with a particular disease."

- Was "branch chief or a branch director in a variety of areas in the Food and Drug Administration, including those having to do with good manufacturing practices, assuring that products are made according to the good manufacturing practices."
- "I was always a compliance officer in FDA."
- "[C]ompliance officers in FDA … take information that is provided during inspections whereby analyses of products, and they determine whether or not that information constitutes a violation of regulations or the law."
- His last five to six years with the FDA, "I was the Director of the Office of Compliance in the Center for Biologics Evaluation and Research."
- Written "six or seven articles" in the field of regulatory compliance.
- Is a frequent lecturer to such organizations as the Regulatory Affairs Professional Society, the Food and Drug Law Institute, and the Parental Drug Association.
- Was a compliance officer and inspector dealing specifically with oral polio vaccine.

- Was one of the people who would determine the compliance of such manufacturers as American Cyanamid, Lederle, during his time at the FDA.

(Tr.592-95). The trial court considered these credentials and the purpose of Mr. Bozzo's testimony and permitted his testimony.

a. Expert Witnesses May Properly Testify about Regulatory Compliance under Missouri Law.

Cortez Strong proffered Mr. Bozzo as an expert to discuss whether Cyanamid complied with the regulations regarding the manufacture of the oral, live polio vaccine given him. The fact of compliance is just that – a fact based on Mr. Bozzo's actual and personal review of the records of the FDA and Cyanamid. "If an expert witness has firsthand knowledge of material facts, he may describe what he has observed and give his inferences…" I MCCORMICK ON EVIDENCE, § 14

Mr. Bozzo's purpose for testifying was set out in the qualification questions by Strong's counsel.

Q And in this litigation what did I ask you to review and for what purposes as you understood?

A You asked me to review a lot of records to determine if there was any noncompliance with FDA requirements, and

those records had to do with oral polio vaccine made by Lederle [Cyanamid] labs.

Q Do you believe you're capable of giving information to the jury as to whether or not there was or wasn't compliance with the Food and Drug Act, the Division of the Public Health Act, and the safety requirements as contained in the license application of the vaccine manufacturer?

A Yes, sir.

(Tr.605)

The first mention of Mr. Bozzo interpreting a regulation arises in Cyanamid's counsel's *voir dire* of the witness prior to his acceptance as an expert by the trial court.

Q Is it fair to you say [sic] can recall a specific instance in your entire career at the FDA in which you were asked to interpret or apply an FDA regulation regarding the manufacturing or testing of polio vaccine?

A Of course I did that…

(Tr.618).

The first testimony that discusses the seed/strain issue is contained in an objection by Cyanamid's counsel.

MR. DONOVAN: Your Honor, this essentially boils down to what is in truth a legal argument about the meaning of the word seed in the FDA's regulations. What happened in 1960 is that they took out this original Sabin material and they created seeds. In 1979 they went back to freezers, got this original little bit of Sabin material and created new seeds. The FDA said you need to test the seeds but you don't need to test that original strain material. That's always been the FDA's views of the regulations, and I don't think this witness is qualified to opine that the regulations, the law, means something other than what the FDA said that it meant.

If the witness wants to testify that before the seeds in 1979 could have been used we needed to do some other test on that original strain material in 1979, I don't think -- I think that's just an issue of law for the Court, not one in which this witness can opine because the regulations require what they require.

(Tr.667-68)

At this juncture, Mr. Bozzo is not testifying about the regulations but about the Cyanamid license application and its contents. The question that drew the objection was this:

Q. Can you tell us what Exhibit 4 is, sir?

A It's the Application and Report of Manufacture of Polio Virus Vaccine, Live, Oral, Trivalent, Types I, II and III, 1962 Lederle Laboratories, Division of American Cyanamid Company, Pearl River, New York. …

(Tr.657). After the objection is overruled, Mr. Bozzo is asked what a "master seed" is. He then defines a master seed. "Master seed is a qualified seed virus that is then used homogenous, that is used then to produce following seeds." Tr.672. He later reads the Cyanamid definition from its license application.

A. Section 4.1. Polio virus master seed. "A master seed is a satisfactory homogenous pool of a designated type of attenuated poliomyelitis virus stored in such a manner as to supply polio virus for the preparation of production seed over a prolonged period of time."

Tr.673.

Mr. Bozzo also describes intermediate and production seeds.

Q What is an intermediate seed?

A An intermediate seed is a seed that is preceded by another seed and for which is -- which produces additional seeds.

Q So it's an in between seed, it produces more seeds?

A That's correct.

Q And what is known as a working seed?

A Well, the working seed is the seed that is used to produce the vaccine itself, the monopools.

Tr. 672. All of this is completely consistent with *Berkovitz,* 486 U.S. at 541. ("This process begins with the selection of an original virus strain. The manufacturer grows a seed virus from this strain; the seed virus is then used to produce monopools, portions of which are combined to form the consumer-level product.")

Reading then from the Cyanamid license application again, and not mentioning the regulation, Mr. Bozzo describes the test Cyanamid agreed to perform under its license application.

Q (By Mr. Kops) Now, did Lederle, American Cyanamid, tell the government what test they performed on the master seed in that license application?

A Yes.

Q And what do they tell them?

A In Section 6 it says, "An additional test is applied to the seed. An intramuscular neurovirulence test is performed on each master and production seed as described in addendum 2, test number 6.4."

Q Have you ever seen an intramuscular test for any of the master seeds of American Cyanamid?

A I have not seen any intramuscular tests for as you just asked the question, no, I have not.

Q Now, there are master seeds that were used in the 1960s and that same master seeds were used in the 1970s, is that correct?

A That's my understanding.

Q And did you ever see a test for -- intramuscular test now -- what Lederle says they did in their license application for those master seeds in the 1970s?

A I have not.

(Tr.674-75). Mr. Bozzo then testified that intermediate seeds 701S and 801S had not been neurovirulence tested either and that the Cyanamid license application required an intramuscular neurovirulence test for each master and production seed. Tr.675-76.

When Cortez Strong's counsel asked Mr. Bozzo if the regulations required neurovirulence testing of seeds, Cyanamid's counsel asked that the regulation be read into the record. Mr. Bozzo read the actual regulation, 21 C.F.R. § 630.10. (Tr.684-86). At no point on direct examination did Mr. Bozzo seek to inform the jury of the meaning of any

regulation. He simply informed the jury of Cyanamid's non-compliance and Cyanamid's own definitions of strain and seed.

The lack of regulatory compliance was testified to by Mr. Bozzo, specifically as follows:

- "Number one, there is no documented testing by American Cyanamid Company of the Sabin original or Sabin Original Merck seed virus utilized to manufacture oral polio virus vaccines for neurovirulence or extraneous microbial agents." (Tr.689)
- "The second item that I found is that there was no documentation or no documented testing of each seed virus to demonstrate freedom from extraneous microbial agents, …" (Tr.691).
- "The third item that I found is that there is no documented testing by American Cyanamid Company of each seed virus for neurovirulence." (Tr.691)

As to each of these failures of compliance Mr. Bozzo cites a regulation "involved." See, e.g. Tr.692 ("the regulations involved are 21 CFR 630.10 B3 and 21 CFR 630.16"). All of this testimony came in without contemporaneous objection.

On cross-examination, Cyanamid's counsel sought to secure an interpretation of the regulations from Mr. Bozzo.

Q Okay. 630.10, I'm sorry. And that's the provision that says, "No seed virus shall be used for the manufacture of polio vaccine unless its neurovirulence in macaque monkeys is shown," et cetera,... The one you read this morning.

A Yes.

Q And you interpret seed virus, the term seed virus in that regulation to include not just seed but the materials that are used to make the seed, is that fair?

A I think they're all seed viruses.

Q 701S was used to make 45B160.

A Yes.

Tr.747-48. Cyanamid's counsel pressed on.

Q We'll let the testimony speak for itself, sir. I take it you have no personal knowledge that anyone at the FDA or any manufacturer ever interpreted that regulation you just talked about, 630.10, the way that you do?

A It's my understanding that it was interpreted regularly in that manner.

Q Sir, you have no personal knowledge the FDA ever interpreted in that manner, is that right?

A The seeds are seeds and they are required to be tested.

Q I'm trying to distinguish between your interpretation in 2005 of the words on a page and your lack of involvement understanding the conversations with anyone at the FDA during the 30 years that you were there with respect to that interpretation. My question is you don't know of anyone at the FDA who ever interpreted that regulation, you don't have personal knowledge of anyone at the FDA who ever interpreted that specific regulation in the manner you've answered today, is that right, sir?

A Well, and that's because there was not a distinction -- the distinction you are making was not made at the FDA. You're making this distinction between an intermediate seed, or whatever you're calling it, and the next seed, production seed. FDA was not making that distinction. A seed is a seed, and the requirements for safety testing are the requirements for safety testing of the seed. That's the way it was interpreted. I was in on those discussions.

Q You were in on those discussions at the FDA, is

that your testimony?

A A seed is a seed, yes.

Q You were in on discussions with the FDA during the 30 years you were there at some point during the '60s,'70s, '80s, and '90s?

A As incredible as it sounds to you, yes.

Q Let me finish my question. You are testifying under oath you have a personal recollection sitting here today of being involved in a discussion with somebody else involving interpretation of that regulation in the manner you've advanced today, is that your testimony under oath,sir?

A My testimony is that your interpretation of the intermediate seed and production seeds was not the interpretation that FDA gave it. They viewed a seed as a seed. There was never that distinction made. That's what I'm saying.

Tr.750-51.

Cyanamid suggests that *Wulfing v. Kansas City Southern Industries*, 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), aids their argument that the trial court erred in permitting Mr. Bozzo to discuss the defendant's failure to abide by the regulations. It

does not. While *Wulfing* does state that an expert may not testify on issues of law, it makes a clear exception for an expert testifying about compliance with regulations.

In *Wulfing*, a minority shareholder of a liquidated corporation brought an action against the majority shareholder, alleging breach of contract. An issue arose as to the testimony by Plaintiff's expert, Mr. Granda. Defendant alleged it was error to admit the expert's testimony concerning the registration process because it

> was so replete with the legal opinions, such as: what exemptions the SEC staff would have permitted, the interpretation and application of statutes and regulations, predictions of the determinations of administrative agencies and courts and other matters of law reserved for the trial judge, as to have invaded that judicial prerogative.

Id at. 153. The court acknowledged the general rule that the opinion of an expert on issues of law is not admissible, citing *Young v. Wheelock,* 333 Mo. 992, 64 S.W.2d 950, 957[24, 25] (1933), but noted that:

> A witness qualified as an expert in securities regulation, nevertheless, is competent to explain to the jury "the step-by-step practices ordinarily followed by lawyers and corporations in shepherding a registration statement through the SEC ...

> Testimony concern[ing] the ordinary practices of those engaged in the securities business is admissible under the same theory as testimony concerning the ordinary practices of physicians or concerning other trade customs: to enable the jury to evaluate the conduct of the parties against the standards of ordinary practice in the industry." *Marx & Co. v. Diners' Club, Inc.,* 550 F.2d 505, 508[1-3] (2d Cir.1977).
>
> The testimony given by Granda conforms to the scope allowed an expert in securities law and regulation. KCSI fails to cite to a particular incursion by the witness into opinions of law. The point is denied.

Id. at 153-54 (Ellipses in original, footnote omitted).

Indeed, testimony by experts about compliance with regulations is common in Missouri. This Court approved the practice in *Nesselrode v. Executive Beechcraft, Inc*. 707 S.W.2d 371, (Mo. banc 1986). At issue in that case was compliance with 14 CFR § 23.685(D) (1981), an FAA regulation requiring the following design characteristics:

> Each element of the flight control system must have design features or must be distinctly and permanently marked so as to minimize the possibility of incorrect assembly that could result in the malfunctioning of the control system.

Id. at 380.

The *Nesselrode* Court cited the testimony of the expert saying:

> Weldon Earl Garrelts, plaintiffs' expert witness, after having actually demonstrated the reverse installation of two actuators on a replica horizontal stablizer-that portion of the airplane containing the elevators and elevator trim tabs-testified that Beech's actuators were not designed to minimize incorrect installation. He testified further that in his opinion Beech's design failed to satisfy 14 CFR § 23.685(D) (1981) and that installing Beech's actuators amounted to a game of Russian Roulette.

Id.

These holdings are no more than the application of common sense to law. An expert, by virtue of working in a field, acquires knowledge of what the regulations say, and how they are applied, and this forms the basis for an opinion about regulatory compliance. Section 490.065. RSMo (2005) permits the expert to testify by way of opinion or otherwise. Section 490.065(3) states:

> 3. The facts or data in a particular case upon which an expert bases an opinion or inference may be those perceived by or made known to him at or before the hearing and must be of a

> type reasonably relied upon by experts in the field in forming opinions or inferences upon the subject and must be otherwise reasonably reliable.

In this case, the facts – the presence or absence of tests – are those derived from Cyanamid's own records. As plainly set out in *Wulfing* and *Nesselrode*, an expert may testify to what amounts to noncompliance without invading the province of either the Court or the jury. Cyanamid's cases do not say otherwise[8].

5. Invited error

As the transcript shows, Cyanamid first raised the question of the meaning of the regulations with Mr. Bozzo. Cortez Strong's counsel was

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[8] Appellant cites *Lumbermens Mut. Cas. Co. v. Thornton*, 92 S.W.3d 259, 266 (Mo. App. W.D. 2002) for the proposition that "the meaning of regulations is a question of law 'for the court alone.'" (App. Br. at 18). The cite is apparently an oversight. That portion of the opinion states "It is universally agreed (or at least held) that the question of whether a duty exists is a question of law and, therefore, a question for the court alone." Although the case mentions 4 C.S.R. § 10-3.030(2), the holding does not touch on the applicability of the regulations.

careful to seek only testimony about compliance based on the fact of Mr. Bozzo's review of the records relating to the polio vaccine production. When asked about the regulation on direct examination, Mr. Bozzo simply read the regulation to the jury.

Because Cyanamid first directly broached the issue of Mr. Bozzo's interpretation of the regulations, any error that occurred was invited by Cyanamid. See, *Payne v. Cornhusker Motor Lines, Inc.*, 177 S.W.3d 820, 837 (Mo. App. E.D. 2005)(where defendant continued to question a witness after objecting, to issues regarding the stopping distance of a train, defendant invited the error.)

Conclusion

The trial court did not err in allowing Thomas Bozzo to testify to show the existence of a defective condition, unreasonably safe in the Orimune vaccine given to Cortez Strong. Moreover, Cyanamid has failed to show that the trial court erred in its handling of the meaning of the regulations at issue in this case.

Point I should be denied.

II.

A. Standard of Review

Cyanamid's Point II challenges the submissibility of Plaintiff's case. Whether the Plaintiff made a submissible case is a question of law, subject to *de novo* review not of the evidence, but of the submissibility question. An appellate court "will not overturn a jury verdict for insufficient evidence unless there is a complete absence of probative facts to support the jury's verdict." *Savory v. Hensick,* 143 S.W.3d 712, 716 (Mo. App. E.D. 2004).

Where submissibility is the issue, the Court must "view the evidence in the light most favorable to the plaintiffs and give to the plaintiffs the benefit of all reasonable inferences." *Washington by Washington v. Barnes Hosp.*, 897 S.W.2d 611, 615 (Mo. banc 1994); *Majors v. Butner,* 702 S.W.2d 539, 543 (Mo. App. W.D. 1985). Where testimony is subject to differing interpretations, it should be accorded the interpretation that supports the jury verdict and submissibility of the case. *Id.* The court should "disregard the defendant's evidence except as it may aid the plaintiff's case." *Benoit v. Missouri Highway and Transportation Comm'n*, 33 S.W.3d 663, 667 (Mo. App. 2000).

> "A motion for JNOV should only be granted when all the evidence and reasonable inferences to be drawn therefrom

are so strong against the prevailing party that there is no room for reasonable minds to differ." *Missouri Highway Transportation Comm'n v. Kansas City Cold Storage, Inc.*, 948 S.W.2d 679, 685 (Mo. App. 1997); *accord*, *Washington*, 897 S.W.2d at 615 [internal citation omitted]; *Coon v. Dryden*, 46 S.W.3d 81, 90 (Mo. App. W.D. 2001).

B. Introduction to Point II Argument

Plaintiff submitted two product liability causes of action to the jury – a strict products liability claim and a negligent manufacturing claim. Cyanamid now asserts that the trial court erred in submitting the case to the jury at all because Cortez Strong failed to make a submissible case on either cause of action. Though Cyanamid attempts to mix the two causes of action in its brief, its complaints about the trial court's submissibility decision are these:

1. As to the product liability claim Cyanamid argues that "….when causation is complex, Missouri law requires expert testimony to establish it." (App.Br.25). In this case, Cortez Strong put on evidence from Charles Burris, M.D. that Cyanamid's vaccine caused Cortez Strong's paralytic polio. Tr.890. Dr. Burris offered his causation opinion to a reasonable degree of medical certainty. Dr. Burris's testimony alone is sufficient to establish the causation required for submissibility under Missouri law by

Callahan v. Cardinal Glennon Hosp., 863 S.W.2d 852, 863 (Mo. banc 1993).

For purposes of the Court's analysis of the strict product liability cause of action, it must be noted that Thomas Bozzo's testimony was primarily directed at the question of whether the vaccine was in a "defective condition, unreasonably dangerous for its intended use." Although portions of Mr. Bozzo's testimony addressed issues of causation, it was the testimony of Dr. Burris that tied the plaintiff's polio to the dangerous product.

The RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY (1998) § 4(a) specifically states that a product's noncompliance with an applicable product safety statute or administrative regulation renders the product "defective" with respect to the risks sought to be reduced by the statute or regulation. For this reason, *Graham v. American Cyanamid Co.*, 350 F.3d 496, 508 (6th Cir. 2003) adopts the rule that liability attaches to a vaccine manufacturer when it can be shown that "a polio vaccine violating these FDA regulations *was any more likely to cause injury* than a fully compliant vaccine." *Id.*

Mr. Bozzo's testimony, which was admitted without objection, was sufficient proof that Cortez Strong was given a product that was "dangerous to an extent beyond that which would be contemplated by the

ordinary consumer who purchases it.…" RESTATEMENT (SECOND) OF THE LAW OF TORTS, § 402(A), Comment i. Mr. Bozzo's higher-risk-of-danger testimony conformed to the test set out in *Graham*, which, in turn, does no more than restate § 402(A), comment i. The polio vaccine administered to the plaintiff was a product that was "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it…" *Id.*

Because polio vaccine is known to very rarely cause paralytic polio in some of its recipients, it is required to be manufactured in strict conformity with regulations that require numerous tests "at each stage of the manufacturing process." *Berkovitz*, 486 U.S. at 540. "On rare occasions … the virus reproduced in the vacinee's intestinal tract reverts to the virulent form." *Graham v. American Cyanamid Co.*, 350 F.3d 496, 500 (6th Cir. 2003). Cyanamid's Point II embraces the known fact that polio can possibly occur in vaccine recipients who are given carefully manufactured vaccine and argues that even if its vaccine caused Cortez Strong to contract polio, and even if Cyanamid failed to test as the regulations required, no one can prove that Cortez Strong was just not one of the unlucky few who get paralyzed anyway. Thus, Cyanamid asserts, its failure to test the polio-bearing material at each stage of the

manufacturing process (as the regulations require) cannot be shown to be a "but for" cause of Cortez Strong's polio.

For Cyanamid's argument, the very remote possibility that even the most safely manufactured vaccine can cause polio in a recipient becomes a complete defense when a vaccine recipient actually gets polio from its vaccine – and this is so no matter how far or often Cyanamid violates the strict requirements of the Federal regulations designed to make that which is potentially dangerous, as safe as possible.

The RESTATEMENT (SECOND) OF TORTS, § 402(A), Comment k, provides an affirmative defense for the manufacturer of a vaccine that, in some cases, causes the disease it attempts to prevent. That affirmative defense, however, exists only if the manufacturer properly prepares the vaccine:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the

> unavoidable high degree of risk which they involve. Such a product, *properly prepared*, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. ….The seller of such products, again *with the qualification that they are properly prepared* and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

§402(A), Comment k (emphasis added). Here Cyanamid did not plead the Comment k affirmative defense. *See, Pollard v. Ashby*, 793 S.W.2d 394 (Mo App. E.D. 1990)(en banc)(Comment k is an affirmative defense; failure to plead it as an affirmative defense waives its protections).

Cyanamid could not take advantage of Comment k because, as Mr. Bozzo's testimony explained, the vaccine was not "properly prepared." See, RESTATEMENT (THIRD) TORTS: PRODUCTS LIABILITY (1998), § 4(a) (product's noncompliance with an applicable product safety statute or administrative regulation renders the product defective with respect to the risks sought to be reduced by the statute or regulation).

2. As to the negligent manufacture claim, Cyanamid argues that Plaintiff did not make a submissible case because "Strong failed to adduce any expert testimony to show that Cyanamid's alleged regulatory violations caused the injury for which he now seeks relief" (App.Br. at 28). The evidence at trial met the causation standard set in *Graham,* 350 F.3d at 512, that evidence that a vaccine is "more unsafe than it otherwise would have been" establishes liability for the manufacturer of such unsafe vaccine.

On transfer to this Court, Cyanamid has abandoned its claim that Cortez Strong did not have polio. For purposes of this Court's analysis, it is now legally unassailable that Cortez Strong had polio, as confirmed in the testimony of Dr. Burris. Having abandoned its attack on Dr. Burris causation opinion, Cyanamid cannot now assert that its vaccine did not cause Cortez Strong's polio. Thus, if there is sufficient evidence that the vaccine received by Cortez Strong was unreasonably dangerous for its intended use, and therefore defective, this Court must affirm, because Dr. Burris made the necessary causal connection between the vaccine administered to Cortez Strong and his resulting diagnosis of polio. See, *Williams v. Deere & Co.*, 598 S.W.2d 609 (Mo. App. 1980) (reasonable inferences and "evidence sufficient to show that a defect likely caused plaintiff's injury").

C. Cyanamid Failed to Preserve Any Claim of Error Regarding the Defective Condition Element of the Products Liability Submission.

Cyanamid's Point II states:

> THE TRIAL COURT ERRED IN DENYING CYANAMID'S MOTION FOR JUDGMENT NOTWITHSTANDING THE VERDICT BECAUSE STRONG FAILED TO PRESENT A SUBMISSIBLE CASE OF ***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.

(App.Br.23)(emphasis added). Cyanamid's Point II does not assert, and therefore waives, any claim that the trial court erred in submitting Instruction 7. Instruction 7, the MAI requirement for strict product liability submissions, does not require the jury to find any relationship between regulatory violations and Cortez Strong's polio. It requires only that the jury find that the Orimune polio vaccine was in a "defective condition unreasonably dangerous" and that plaintiff's damage was a direct result of such dangerous condition of the vaccine:

Instruction Number 7

On plaintiff's claim based on product defect, your verdict must be for plaintiff against defendant American Cyanamid Company, if you believe:

First, defendant American Cyanamid Company sold the Orimune oral polio vaccine in the course of defendant's business, and

Second, the Orimune oral polio vaccine administered to plaintiff was then in a defective condition unreasonably dangerous when put to a reasonably anticipated use, and

Third, the Orimune oral polio vaccine was used in a manner reasonably anticipated, and

Fourth, plaintiff was damaged as a direct result of such defective condition as existed when the Orimune oral polio vaccine was sold.

LF 4028, MAI 25.04 Submitted by Plaintiffs.

Instruction 9, the negligent manufacture submission did require the jury to find a causal relationship between the regulatory violations and Cortez Strong's polio:

Instruction Number 9

On plaintiff's claim based on negligent manufacture, your verdict must be for plaintiff against defendant American Cyanamid Company, if you believe:

First, defendant American Cyanamid Company manufactured the Orimune oral polio vaccine administered to plaintiff, and

Second, the Orimune oral polio vaccine was not tested for neurovirulence in Orimune oral polio vaccine seeds SOM Type 1, SOM Type 2, SOM Type 3, 45B157, 45B158, 45B164, 701S, or 801S, and

Third, defendant American Cyanamid failed to use ordinary care to manufacture the Orimune oral polio vaccine administered to plaintiff to be reasonably safe, and

Fourth, as a direct result of such failure, plaintiff sustained damage.

LF4030, MAI 25.09, Submitted by Plaintiffs.

Because Instruction 9 is the only submission that required the jury to find an express causal relationship between the regulatory violation (failure to test) and Cortez Strong contracting polio, Point Relied On II does not challenge the strict product liability submission at all.

Even if the Point can be read broadly to attack the product liability submission, it can only be read to attack the sufficiency of the causation

evidence. Under Instruction 7, "defective condition" and "causation" are separate and independent ultimate facts a jury must find in reaching a verdict under Instruction 7. Since its Point of Error is limited to *causation*, Cyanamid has waived any assertion of error as to the sufficiency of the evidence of defective condition.

By limiting its assignment of error to *causation*, Cyanamid has abandoned any claim that Cortez Strong failed to make a submissible case for the "defective condition, unreasonably dangerous" element of Instruction 7. *Kurtz v. Fischer*, 600 S.W.2d 642, 645 (Mo.App. W.D.1980) ("We are constrained by the rules to confine our efforts solely to the points briefed"); *Kerr Const. Paving Co., Inc. v. Khazin* 961 S.W.2d 75, 82 (Mo.App. W.D. 1997) ("claim is not mentioned in Appellants' point relied on, and is … not preserved for review").

Thomas Bozzo's testimony proved that the vaccine Cortez Strong was given was in a "defective condition, unreasonably dangerous". Dr. Burris established that but for his receipt of Cyanamid's unreasonably dangerous vaccine, Cortez Strong would not have contracted polio.

Cyanamid's brief muddles negligence principles with strict liability principles, perhaps in an attempt to make more of Mr. Bozzo's testimony than should be made. It is hornbook law, however, that words like "duty" and "negligence," which oddly appear in a section entitled "Missouri Law

Requires Proof of Causation in Products Liability Cases" (App.Br.24-27), have no place in a discussion relating to a strict products liability submission. Indeed a defendant can be held strictly liable under a product defect submission even if there is no showing of negligence. *Aronson's Men's Stores, Inc. v. Potter Elec. Signal Co., Inc.* 632 S.W.2d 472, 474 (Mo., 1982)

The liability being imposed under a strict products liability cause of action is "liability based on the fact that defendant ought to have an obligation to pay for the costs attributable to damaging events caused by *defects of a kind that made the product more dangerous than it would otherwise be*." W. KEETON, PROSSER AND KEETON ON TORTS (5th ed.) §98. For this reason Instruction 7 never discussed duty or a breach of that duty – because that is not the law of Missouri as it relates to strict product liability.

In order to resolve any issues raised (and then only if this Court is generous) regarding strict products liability in Point II, all that this Court must do is determine whether Dr. Charles Burris's testimony was sufficient to make a submissible case that Cyanamid's vaccine caused Cortez Strong to contract polio. Even if the Court extends its generosity to the "defective condition, unreasonably dangerous" proof, the Court will discover that Cortez Strong's proof was submissible on that issue as well.

1. Cortez Strong Had Polio

In his first claim, Plaintiff/Respondent submitted this case to the jury under the theory of strict product liability. LF 4028. The appellant's trial strategy aimed at defeating this "unreasonably dangerous" submission was two-fold. At the trial court and before the Court of Appeals, Cyanamid argued that Cortez Strong did not have polio. Perhaps because it now realizes that the evidence that Cortez Strong had polio is so clear, those arguments have now been abandoned in this Court.

Dr. Charles Burris, M.D., served as both a diagnostic and causation expert on the issue of the existence of and the source of Cortez Strong's polio. He held teaching positions at both Cardinal Glennon and St. Louis Children's hospital. (Tr. 871) He had testified as an expert in pediatric neurology and been accepted as an expert in other cases. *Id.* He described how he went about reaching a conclusion regarding the cause of Cortez Strong's paralysis. (Tr. 872). Dr. Burris examined Cortez (Tr. 873) and reviewed his medical records. (Tr. 872). He recounted the pathophysiology of Cortez Strong's injury. (Tr. 873-79). He then testified that vaccine-induced polio caused Plaintiff's paralysis:

A. My opinion, based on the information that I've reviewed, is that this case is more likely than not, in other words, within a

reasonable degree of certainty, a case of vaccine-associated paralytic poliomyelitis.

(Tr.890)

Dr. Burris rejected the numerous other causes of Cortez's paralysis advanced by Cyanamid and concluded with the certainty required by the law that Cortez Strong contracted polio.

A. Well, first of all, in terms of reviewing the polio question, I think you asked two questions there. ... One is polio and the other is why wasn't it something else. But the reason for determination of polio is that in the beginning this was a child who had been administered an oral polio vaccine. And again, a period of four to five days later he develops a rapid, sudden onset of weakness in the arms, weakness in the arms, unaccompanied -- I'm sorry, that was a paralysis which lasted permanently, even though it did show some improvement for a period of time. So the time relationship with the polio vaccine, the acute flaccid paralysis, and the lack of other findings in the medical record in terms of causation of anterior horn cell disease, led me to that conclusion. And then finally, in the long term you can see how if I were to examine him today and do an EMG and nerve conduction today, the findings on examination

and the findings on his EMG and nerve conduction are consistent with that conclusion.

(Tr.891).

Dr. Burris was asked if Cortez Strong's injury could have been due to Enterovirus 71:

Q Thank you, Doctor. There has been some – there will be some discussion I think that was brought out concerning a EV or Enterovirus 71. Is it your understanding that that may be suggested as another explanation for his injury?

A Yes. The possibility, EV, means enterovirus, 71. It's an enterovirus in the same family as polio that can also cause paralysis.

Q Doctor, is there a -- what is your opinion with regard to whether or not he has polio or EV 71?

A My opinion is that this is a case of vaccine-associated polio.

Q And what are the factors that distinguish those two diagnoses for you?

A Well, I think the first thing is the timing. The timing means that based on the administration of the poliovirus vaccine, followed by the titers that were done in the blood, that is one factor. I think the second is when the EV 71 titers were done in

this case, they were done nine months after he had been given the vaccine.

So I think it would be very difficult for me to give you an opinion as to when this exposure or infection or exposure, if you will, to the EV virus might have occurred. Obviously, the last point is that this was submitted to a panel of experts who have given the opinion that this is consistent with vaccine-associated poliomyelitis.

(Tr. 941-42)

2. Cortez Strong Made a Submissible Case that Cynamid's Orimune Vaccine Caused His Polio.

In 1987, Cyanamid was the only manufacturer of polio vaccine used in the United States. No party disputes that Cortez Strong received an oral, live virus, polio vaccine in June, 1987, manufactured by Cyanamid, or that Cortez Strong began exhibiting paralytic polio symptoms shortly after that. Polio in the United States does not occur except by vaccine.[9]

[9] "Poliomyelitis caused by wild polio virus has been virtually nonexistent in the United States since 1980 [Tr.958] and vaccine-associated paralytic poliomyelitis (VAPP) has emerged as the predominant form of the disease." (Def.Ex.508)(LF3998). Of the 86 cases of paralytic

Cyanamid's brief never mentions Dr. Charles Burris when it claims that Cortez Strong failed to offer proof of causation. It prefers to offer a bromide divorced from the evidence: "when causation is complex, Missouri law requires expert testimony to establish it." (App.Br.25). The causation required for this products liability case is no more complex than this: did the polio vaccine cause Cortez Strong to contract polio.

To repeat, Cortez Strong's expert, Dr. Burris testified:

> Q. And so Doctor, based on that, do you have an opinion you can give us, within a reasonable degree of medical certainty, as ***to what the cause of the anterior horn cell injury that Cortez Strong suffers*** and thereforethe cause of his paralysis?
>
> A Yes.
>
> Q. What is that opinion?
>
> A My opinion, based on the information that I've reviewed, is that this case is more likely than not, in other words, within a

---

poliomyelitis cases reported during the period 1980-1989, "80 were classified as vaccine associated." (Def.Ex.508) (LF4001). The remaining statistically significant causes of polio in the United States are imported poliomyelitis (acquired during travel) and contact poliomyelitis, which occurs when an unvaccinated person, usually a caregiver, contracts the virus from the feces of an oral vaccine recipient. (Def.Ex.508)(LF4000-01).

reasonable degree of medical certainty, a case of vaccine-associated paralytic poliomyelitis.

Tr.890 (emphasis added).

Standing alone, Dr. Burris, a medical doctor whose testimony is not challenged by Cyanamid on appeal, established both "but for" causation and proximate cause. His testimony establishes the former because but for his receipt of the vaccine, Cortez Strong would not have contracted polio. It establishes the latter because it was foreseeable that Cortez Strong could get polio from a vaccine in a "defective condition, unreasonably dangerous". *See, Callahan v. Cardinal Glennon Hosp.*, 863 S.W.2d 852, 863 (Mo. banc 1993). The evidence of causation was "logical, sensible, and direct." *Sabin III*, 774 F.Supp. at 958.

3. There Was Sufficient Evidence That The Polio Vaccine Given to Cortez Strong was in a "Defective Condition, Unreasonably Dangerous".

To the extent that this Court concludes that Cyanamid's Point Relied On II permits review of the defective condition evidence or concludes that causation somehow extends to the defective condition issue, Cortez Strong still made a submissible case.

A product is in a defective condition if, when "at the time it leaves the

seller's hands, [it is] in a condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him." RESTATEMENT (SECOND) OF TORTS § 402, Comment g. "The defective condition may arise not only from harmful ingredients … but also from … the way in which the product is prepared…." *Id.* at Comment h. Further, a product is "unreasonably dangerous" if the consumer faces danger beyond the danger contemplated by the ordinary consumer.

> The rule stated in this Section applies only where the defective condition of the product makes it unreasonably dangerous to the user or consumer. …. The article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it…

Id., Comment i. *Newman v. Ford Motor Co.*, 975 S.W.2d 147, 154 (Mo. banc 1998) expressly permits jury to consider consumer expectations of danger in determining whether a product is in a "defective condition, unreasonably dangerous" within the meaning of §402(A).Thus, under the Restatement, liability attaches even if one could argue that the recipient of the vaccine should have contemplated *some* chance that he or she would contract polio if a vaccine was fully compliant. The "defective condition, unreasonably dangerous" results from the recipient being asked to unknowingly accept a danger elevated beyond the normal risk as a result

of the manufacturer's failure to take the steps required by the regulations to make the vaccine as safe as possible.

Based on settled law, the evidence in this case supports both the trial court's decision to submit the strict product liability case to the jury and the jury's verdict. The issue of regulatory noncompliance is not a necessary ultimate fact that the jury must find under instruction 7. Rather the evidence of Cyanamid's noncompliance is relevant to show that the product is more dangerous than a consumer would have expected when agreeing to submit to oral, live polio vaccine.

Mr. Bozzo testified (without objection) that Cyanamid's failure to test made the vaccine "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it...." See Comment i. The testimony was "logical, sensible, and direct." See *Sabin III*, Id.:

> Q What happens if you don't do the test?
>
> A Well, if you omit safety tests, then you raise the possibility of a product being unsafe.
>
> Q When you say you raise the possibility of a product being unsafe, what do you mean in regard to the general public who is going to receive that vaccine?

A Well, *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.*

(Tr.686)(emphasis added). This testimony came in without objection from Cyanamid. Cyanamid's trial counsel made sure the jury understood Mr. Bozzo's testimony by continuing to question him on this issue of the increased danger of polio resulting to a vaccine recipient from Cyanamid's failure to test its vaccine.

Q [By Cyanamid's counsel] I need an answer to my question, sir. You can't offer an expert opinion these records show it had any effect on the remote risk that vaccine-associated polio can result in a resulting vaccine.

A No, I don't think that's correct. I don't agree with that.

(Tr.813).

And again:

Q. Certainly. It is correct, Mr. Bozzo, that with respect to any of the opinions you're going to offer here today about alleged deviations or noncompliance with regulations, is it correct that nothing you are going to testify about – you're not going to

testify that anything you're testifying about had any effect on the safety of the vaccine administered to Cortez Strong?

A. I think, as I testified in my deposition, the lack or – the lack of vaccine safety testing increases the problem with the safety of the product.

(Tr.626) And again on cross examination:

Q. And isn't it the case, sir, that you can't say that … anything had any effect on the possibility that the vaccine administered to Cortez Strong could cause vaccine-associated polio?

A. You are absolutely wrong.

(Tr.820)

Cyanamid now says that Mr. Bozzo should not have been allowed to offer this opinion. But Cyanamid did not object to any of this testimony at trial. The evidence was therefore properly admitted and supports the verdict. Indeed, even assuming for argument's sake alone that Mr. Bozzo's testimony might not have been admitted had Cyanamid properly objected, the failure to make that objection renders that argument a nullity. As Judge Elwood Thomas wrote for a unanimous Court, "[i]nadmissible evidence received without objection may properly be considered in determining the sufficiency of the evidence." *Callahan v. Cardinal Glennon*

Hosp., 863 S.W.2d 852, 863 (Mo. banc 1993). Moreover, where a defendant continues to question a witness, defendant invites the error and cannot then complain of error on appeal when the testimony is repeated. *Payne v. Cornhusker Motor Lines, Inc.*, 177 S.W.3d 820, 837 (Mo. App. E.D. 2005).

Why did the repeated failure to test the vaccine render its condition defective and unreasonably dangerous? In the polio vaccine manufacturing process, a manufacturing stage occurs when polio virus seed is place in monkey kidney tissue and polio virus is harvested. This is called a tissue culture passage. As discussed at some length in Point I, tests are required at each stage of the manufacturing process because attenuated polio vaccine will, from time to time and for reasons that science cannot completely explain, revert to its wild or unattenuated form, becoming neurovirulent. When neurovirulence occurs, the vaccine causes polio in the vaccine recipient. Thus, the tests required by the regulations at each stage of the manufacturing process are important precisely because those regulations are designed to make the vaccine as safe as possible.

As Cyanamid's Vice-President for Vaccine Research and Development, Quality Assurance, Dr. Mary Ritchey, testified: "Something could happen in making the passage that allowed the passage that you made to change… there was the potential for the characteristics to change

slightly when you went from passage to passage to passage….." (Tr.1758). "Each passage is an independent event and so you test the passage and it speaks about the passage. It has some relevance to the parent but doesn't necessarily tell you everything about the parent." (Tr.1759). Thus testing is necessary "to insure that we maintained the attenuated characteristics of that Sabin original seed…[to] verify that that's maintained the attenuated characteristics." (Tr.1758).

Still, a test sample of some part of the material produced of each step of the manufacturing process is not necessarily representative of the all of the material that remains untested:

> Lederle scientists have determined, however, that because of the heterogenous[10] nature of the virus particles in even the best seeds, certain variables in the manufacturing process may indeed influence neurovirulence. These factors include, among others, incubation temperature; the nature of the cell substrate used to propagate the vaccine; and multiplicity of infection.

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[10] Heterogeneous means: "1. Differing in kind. 2. consisting of dissimilar ingredients of constituents … 3a made up of parts or elements that are not unified, compatible or proportionate…." WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY UNABRIDGED 1062 (2002).

(LF0605). That is the very reason for the mandated testing at every stage of the manufacture. Thus, the more testing done, the more likely the tests are to reveal the presence of non-attenuated (and therefore dangerous) polio virus. As Mr. Bozzo said, verifying what Cyanamid's own scientists had reported, "Well, if the product was inadequately tested for neurovirulence, then it's possible that the product simply contained particles of neurovirulent virus, and therefore when administered, it may in fact cause polio." (Tr.853).

By analogy, if a baker is making a large batch of peanut butter cookies and a few chocolate chips fall into the dough as it is mixed, any particular quarter teaspoon of the dough (a test) may be free of chocolate chips, but all of the dough is not. The more testing, the more likely the tester is to discover the heterogeneous chocolate chips and determine that the dough must be rejected.

Mr. Bozzo testified that neurovirulence testing was not performed on the material at each tissue culture passage (Tr.668-69; Tr.674-75) Without testing, Cyanamid failed to take all of the steps necessary, and required by Federal Regulations to make the vaccine as safe and pure as it should have been. (Tr.626).

After establishing that the company would have conducted numerous tissue culture passages in making the vaccine, Mr. Bozzo then simply read

the regulation that required Cyanamid to perform neurovirulence testing. (Tr.685-689). Mr. Bozzo then stated that no evidence of the required neurovirulence testing of the seeds was present in the batch records. (Tr.689).

That untested vaccine is dangerous was also consisent with the testimony of Cyanamid's own representatives. Dr. Stephen Szumski, Cyanamid's Assistant Director of the Medical Services Department (LF1429), testified by deposition that if any released lots of vaccine were outside the regulations, "I certainly would advise that they not be included." (LF3640). When asked: "Would you tell [a physician who inquired about the failure of a vaccine to meet the regulations] if there was a danger here", Dr. Szumski testified, "That's probably what I would have told him [the physician]." (LF3641) Dr. Szumski also testified that "if the pools had failed, they wouldn't be marketed." (LF3642)(Tr.1481). And as to Dr. Szumski's understanding of the proper course of action for Defendant to take if a vaccine had not met technical regulation requirements even if that had nothing to do with safety, he testified that Cyanamid "would probably act on it and not use the vaccine." (LF3643).

By analogy, if 1000 physicians were presented with the option of giving their patients a vaccine that did in fact undergo the rigorous testing required by the regulations or a vaccine that was manufactured in an

identical way but without the testing, it is a fair inference that each and every one of them would reject the untested vaccine for the reason that it is simply too dangerous for its intended use and therefore in a "defective condition". The jury clearly reached the same conclusion from the evidence in this case that the untested vaccine received by Cortez Strong was likewise in a defective condition. And this is exactly what Dr. Szumski testified.

The evidence showed that Cyanamid's failure to test the vaccine material through each step of the manufacturing process establishes proof of a "defective condition unreasonably dangerous" because the failure to test renders the vaccine "more unsafe than it otherwise would have been." This is the test adopted in *Graham v. American Cyanamid Co.*, 350 F.3d 496, 512 (6th Cir. 2003) – and the test that Cyanamid suggests ought to apply in this case. This test is entirely consistent with the meaning of § 402(A), which, as previously discussed, defines defective condition, unreasonable dangerous as a manufacturing process that creates a product that is in a less safe condition than the consumer would expect. More important, it is also the very testimony that Mr. Bozzo provided to the jury without objection by Cyanamid.

Without testing, Cyanamid made a vaccine that was "*more likely to cause injury* than a fully compliant vaccine." *Graham,* 350 F.3d at 508.

In sum, (1)(a) Mr. Bozzo established that Cyanamid failed to test the vaccine it gave Cortez Strong as required by the federal regulations and (b) that the vaccine was less safe (that is presented a higher risk of danger) than would have existed if the tests required by the regulations had been completed by Cyanamid. This is sufficient evidence for the jury to find the ultimate fact that the vaccine was in a "defective condition, unreasonably dangerous". (2) Dr. Burris established that the vaccine Cortez Strong received, which had not been tested, caused Cortez Strong to contract polio. This is sufficient evidence to permit the jury to find the ultimate fact that the vaccine caused Cortez Strong's polio.

Taken together, this evidence is sufficient for the trial court to have concluded (as it did) that Plaintiff had made a submissible case of products liability.

4. Cyanamid's Argument Ignores the Distinction Drawn in Missouri Law Between Proof of Defect and Proof of a Defective Condition and Cortez Offered Clear Proof That the Untested Polio Vaccine Was in an Unreasonably Dangerous Condition.

Aside from ignoring the testimony of Dr. Burris that the vaccine caused Cortez Strong's polio, Cyanamid's argument confuses proof of defect with proof of defective condition.

In denying the Defendant's motion for summary judgment, Judge Ohmer caught the distinction between proof of defect and proof of a "defective condition, unreasonably dangerous".

> [A] jury could reasonably conclude from the lack of documentation of the testing that the required testing did not take place and that Cyanamid violated the regulations, and this constituted a dangerous condition. The *relevant danger* is demonstrated by the unpredictable recurrence of VAPP [vaccine associated paralytic poliomyelitis] which is *made more likely by the lack of testing* of the materials used to produce the vaccine.

(Plaintiffs Appendix at A-45-46[11]). As previously shown, Judge Ohmer's reasoning accurately tracks the meaning of "defective condition, unreasonably dangerous" set out in the comments to § 402(A) and presented in Instruction No. 7.

Missouri courts grant juries wide discretion in determining the existence of a defective condition without the aid of expert testimony. In Missouri, "the concept of 'unreasonable danger' is to be treated as an ultimate issue for the jury." *Rodriguez v. Suzuki Motor Corp.*, 996 S.W.2d

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[11] Judge Ohmer's order was omitted from the legal file. A copy has been placed in the Appendix. See LF 0063-64.

47, 65 (Mo. banc 1999). *Tune v. Synergy Gas Corp.*, 883 S.W.2d 10, 14 (Mo. banc 1994) states the law:

> Synergy urges this Court to adopt a rule requiring expert testimony to establish product defect or unreasonable danger in every design defect or failure to warn case. In this case there was expert testimony that the effectiveness of ethyl mercaptan can decrease, that Synergy gave no warning of this characteristic, that propane is very dangerous without knowledge of this characteristic, and that the circumstances were consistent with there having been a significant decrease in odorant concentration. The jury had guidance and was not left to speculation and conjecture. Given this information, a reasonable jury would have no problem in determining that propane gas is unreasonably dangerous.... We decline to adopt the overly-inclusive rule proposed by Synergy in this case.

Id.

Rauscher v. GM Corp., 905 S.W.2d 158 (Mo. App. 1995) recognized the broad authority of the jury to infer a defective condition from circumstantial evidence:

> The jury has broad authority to determine whether a defective and unreasonably dangerous condition is present... *It is not*

necessary for the plaintiff to demonstrate the precise nature of the defect. *The action is based not on a defect, but on a defective condition*. The danger is demonstrated by the recurrence at unpredictable intervals, which might contribute to accidents such as the plaintiff sustained.

Id. at 160-61(emphasis added).

Uder v. Missouri Farmers Association, Inc., 668 S.W.2d 82, 93 (Mo. App. 1984) agrees that when the defective condition of the product can be inferred from the circumstances of the incident, it is not necessary to define the defect precisely:

> In the type of case in which there is no evidence, direct or circumstantial, available to prove . . . exactly how the design was deficient, the plaintiff may nonetheless be able to establish his right to recover, by proving that the product did not perform in keeping with the reasonable expectations of the user. When it is shown that a product failed to meet the reasonable expectations of the user, the inference is that there was some sort of defect, a precise definition of which is unnecessary. If the product failed under conditions concerning which an average consumer of that product could have fairly definite

> expectations, then the jury would have a basis for making an informed judgment upon the existence of a defect.

Id. at 93.

The critical distinction between evidence of the specific nature of the defect (which is not necessary) and evidence of the existence of a defective condition of the product is again made clear in *Williams v. Deere and Co.,* 598 S.W.2d 609 (Mo. App. 1980). There, the plaintiff claimed that a tractor was defective because the tractor rolled and injured him after he had placed the tractor in "park". *Id.* at 611. The defendant argued against submissibility because there was no evidence of a specific defect in the tractor. *Id.* at 612.

> The doctrine of strict liability in tort does not require impossible standards of proof. The proof must be realistically tailored to the circumstances. *The existence of a defect may be inferred from circumstantial evidence with or without the aid of expert evidence.* Considering the evidence and the reasonable inferences from it in the light most favorable to plaintiff, we believe that the *evidence was sufficient to show that a defect likely caused plaintiff's injury.*

Id. (internal citations omitted)(emphasis added). See also *Sappington v. Skyjack, Inc.*, 512 F.3d 440 at 446 (8th Cir. Mo. 2008)("a plaintiff has no

burden to prove product failure or malfunction" citing *Stinson v. E. I. Dupont De Demours & Co.*, 904 S.W.2d 428, 431 (Mo. Ct. App. 1995)). Considering these authorities, Cortez Strong presented substantial expert testimony confirming both the defective condition of the untested vaccine and the causation of Strong's polio.

Defendant relies chiefly on *United States. v. St. Louis University*, 336 F.3d 294 (4th Cir. 2003), which, in turn, relies on medical malpractice cases as the basis for its incorrect, general statement about Missouri law. Cortez Strong agrees that medical malpractice cases require expert testimony to prove causation, when the injury is such that medical experts must show the connection between the product and the injury. To the extent that expert testimony was required to show the cause and nature of Cortez's *injury*, as already explained, Dr. Burris testified that Cortez suffered from paralytic poliomyelitis caused by polio vaccine.

St. Louis University states:

> 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*.")

Id. at 303 (emphasis added). Obviously, *Wright* is a case where the nature of the *injury* was not knowable to the lay person applying common sense. Here, again, Dr. Burris met this requirement. He testified that Cortez Strong had polio and that Cyanamid's vaccine caused the polio in Cortez Strong.

5. A Finding of Submissibility on Either Cause of Action Requires Affirmance of the Verdict.

If this Court finds that Cortez Strong made a submissible case of strict product liability, it need not even consider whether he also made a submissible case under negligence. This is because the jury received two verdict directing instructions and a single, general verdict form as to which no claim of error is preserved for appeal. A strict products liability cause of action and a negligence cause of action seek redress for the *same* injuries – here polio. Both causes of action are products liability causes of action. Had either the strict products liability cause of action or the negligent manufacture cause of action been submitted alone, the damages that flowed to Cortez Strong would be the same. His damages were neither proportional (by cause of action) nor divisible (by cause of action). If this Court sustains the submissibility of either cause of action, the verdict must be affirmed.

> The jury in this case returned a general verdict in favor of KCPL as authorized by the trial court in its verdict directing instructions. That the general verdict does not indicate on which claim or claims the jury found against Rockwell does not render the verdict ambiguous, indefinite, or uncertain for purposes of supporting a judgment in KCPL's favor.

Kansas City Power & Light Co. v. Bibb & Associates, Inc. 197 S.W.3d 147, 158 (Mo.App. W.D.2006). Here, the jury specifically found Cyanamid liable on both causes of action. The verdict form (which is not challenged on appeal) required an independent assessment of liability on each cause of action. That finding, together with the unchallenged general damages verdict, allows each cause of action to stand alone, without either reference to or the necessity of a verdict on the other cause.

6. Cortez Strong Made A Submissible Case of Both Strict Product Defect and Negligent Manufacture.

Cyanamid's claim that Plaintiff failed to make a submissible case of negligent manufacture embraces the fact that polio can very rarely occur in vaccine recipients who receive carefully manufactured and tested vaccine. Cyanamid argues that even if its vaccine caused Cortez Strong to contract polio and even if Cyanamid failed to test as the regulations required, no one can prove that Cortez Strong was not just one of the unlucky rare few

who get paralyzed anyway. Thus, Cyanamid asserts, its failure to test the polio-bearing material at each stage of the manufacturing process (as the regulations require) cannot be shown to be a "but for" cause in a negligence case of Cortez Strong's polio since he might have gotten polio anyway.

With Cyanamid's argument, the remote possibility that the most safely manufactured vaccine can cause polio in a recipient becomes a complete defense when a vaccine recipient actually gets polio from its vaccine – and this is so no matter how negligently Cyanamid acted in the manufacturing process for the vaccine and no matter how cavalierly Cyanamid ignored the regulations that were designed to limit the risk to vaccine recipients and to make the vaccine as safe as possible.

Cyanamid argues that Plaintiff did not make a submissible case because "Strong failed to adduce any expert testimony to show that Cyanamid's alleged regulatory violations caused the injury for which he now seeks relief" (App.Br. at 28)

As to the negligence claim, courts that have addressed the causation issue relating specifically to polio vaccine have held that proximate causation exists when a manufacturer departs from safety regulations and that departure increases the danger a vaccine recipient faces. *Graham*, 350 F.3d 496, considered the nature of proximate cause in another case of

vaccine associated paralytic polio. That Court concluded that plaintiffs' case failed because there was no evidence of proximate cause. However, proximate cause would have existed if plaintiffs had shown that there was an increased risk of danger to the vaccine recipient as a result of the failure of the manufacturer to properly test the vaccine. *Graham* affirmed summary judgment because (unlike the present case) plaintiffs there did not show that American Cyanamid's alleged regulatory noncompliance *increased the risk* that the Orimune vaccine would cause polio in recipients…beyond the inherent risk long known to be associated with OPV. *Id.* at 508 (emphasis added).

This conclusion and the rule it announces adopts the normative principle that the law ought not to tolerate a defendant escaping liability when it fails to manufacture an unavoidably dangerous product in strict accordance with regulations that, if followed, are designed to lessen the danger to persons the product is designed to protect. This normative principle is expressed in the RESTATEMENT (SECOND) TORTS §§ 323(a):

> One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of the other's person or things, is subject to liability to the other for physical harm resulting from

his failure to exercise reasonable care to perform his undertaking, if

(a) his failure to exercise such care increases the risk of such harm, ….

Id.

Under the Restatement, liability exists for the increase in risk of harm. The unchallenged-by-objection testimony from Mr. Bozzo before the jury was that Cyanamid had failed to test its vaccine production at every stage of the production. That failure created a higher risk of danger to persons receiving the vaccine. Cyanamid argues that this is not enough because no scientist or expert could say that any particular vaccine recipient was not one of those in whom the virus reverted to its virulent state. Cyanamid's causation argument thus asks this Court to grant it a license to ignore safety testing and to manufacture vaccine in any manner it pleases, without regard to the requirements of the regulations that are themselves designed to assure the safety of the vaccine.

The law cannot be such a fool. Nor should the law permit Cortez Strong to alone bear both the risk and the burden of Cyanamid's regulatory breaches. Nor should the law allow Cyanamid to blithely ignore regulations designed to promote the greatest degree of safety in its vaccine and ask Cortez Strong to bear Cyanamid's failures.

Cyanamid required Cortez Strong to face a higher danger than the regulations required him to accept when his mother brought him to the doctor to protect him from polio. Cortez Strong had every right under the law to expect Cyanamid to have taken ***every*** step required by the law to protect him. Cyanamid took short cuts; it did not take those steps that would have made the vaccine as safe as possible. Its inactions made the vaccine unreasonably dangerous. In the face of the sufficient evidence presented by the Plaintiff, the law should not support or condone Cyanamid's position.

Cyanamid's Point II should be denied.

III.

"[W]e must expect substantial disparities among juries as to what constitutes adequate compensation for certain types of pain and suffering. This is a litigious fact of life of which counsel, clients and insurance carriers are fully aware. Once they place their fate in the hands of the jury, then they should be prepared for the result . . . . They cannot expect the court to extricate them in all cases where the award is higher or lower than hoped for or anticipated."

Morrissey v. Welsh Co., 821 F.2d 1294, 1301 (8th Cir. 1987).

Standard of Review

The trial court's refusal to grant remittitur is reviewed for abuse of discretion. *McCormack v. Capital Electric Const. Co*, 159 S.W.3d 387, 395 (Mo. App. W.D. 2005).

A. The Jury's Verdict Is Not Grossly Excessive and Does Not Shock the Conscience.

The jury awarded Cortez Strong $6.5 million for non-economic and $2 million for economic damages.

The issue of damages is left to the discretion of the jury. *Emery v. Wal-Mart Stores, Inc.*, 976 S.W.2d 439, 448 (Mo. banc 1998); *Fust v. Francois*, 913 S.W.2d 38, 49 (Mo. App. 1995). In Missouri, "a jury is entitled to consider certain 'intangibles' which do not lend themselves to precise calculations, such as past and future pain, suffering, affect on life style, embarrassment, humiliation, and economic loss." *Callahan v. Cardinal Glennon Hospital*, 863 S.W. 2d 852, 871 (Mo. 1993) (quoting *Eller v. Crowell*, 238 S.W. 2d 310, 316 (Mo. 1951)). The jury "is in the best position" to determine damages based on all of those tangible and intangible factors. *Id.* Accordingly, this Court allows the jury "virtually unfettered" discretion to provide awards over a "large range," *Id.* (emphasis added), because "[t]here is an enormous variance in the size of the verdict that a rational jury may return and still not be excessive, particularly in a personal injury action." *Tune v. Synergy Gas Corp.*, 883 S.W.2d 10, 21 (Mo. banc 1994).

For this reason, a court may not interfere with the jury's determination of damages unless it is convinced that the verdict exceeds fair and reasonable compensation. *Fust* at 49. In reviewing whether a verdict is excessive, this Court is "limited to a consideration of the evidence which supports the verdict excluding that which disaffirms it." *Redfield v. Beverly*

Health and Rehabilitations Services, Inc., 42 S.W.3d 703, 712 (Mo. App. E.D. 2001).

Cortez Strong bears a physical deformity from his polio. This deformity is not merely cosmetic; it manifests itself socially and economically.

For nearly all of his eighteen years, Cortez has suffered the taunts and cruel stares of his class mates and neighborhood children. Other children picked on him. (Tr.1501). They asked him questions about his deformity. (Tr.499; 1498) Kids called him "skinny" and wanted to know why he couldn't open his hand. (Tr.1496). People stared at him. (Tr.500) He became a loner. (Tr.535) He could not mow the grass, shovel snow, and do the other things kids do to earn money. (Tr.501). It was hard for him to fit in. (Tr.497). Joking and teasing continues to be a part of his life. (Tr.1497).

Although Cortez began as a good student in elementary school, the social problems that accompanied the polio and the increasing difficulty of the school work made him a poor student. He was more interested in fitting in and "trying to make sure people don't pick on me." (Tr.1501). He graduated from an alternative school, St. Louis Learning Center South. (Tr.1504). The students there were "all your wannabe gangsters, all your

so-called problem childs [sic] … just attitude problems and all that just wrapped in one." (Tr.1505).

As a result of his poor academic performance, Cortez's potential for college is diminished. He wants to be an audio engineer. (Tr.1508, 09). He doesn't know if he can get into college. (Tr.1514).

If not able to go to school, the jobs available to those who use their physical strength to earn a living are not open to him. He cannot do construction, because he can't use his hands a lot. (Tr.1510). He could not be a "cop with one hand." (Tr.1511). He "could not get into the military with my disability." (Tr.1512). In his current grocery store job, he cannot be promoted to the check-out counter because he cannot "multitask" with his hands. (Tr.1491). His arms hurt after moving carts. (Tr.1490). He must take more breaks than his co-workers at his entry level position at a Shop N Save. (Tr.1490) As a result, he got in trouble and almost got suspended from his job. (Tr.1490). He is not as productive as his employer wants him to be. (Tr.1490). He cannot stock shelves as quickly as his employer likes. (Tr.1491). He just doesn't have the strength or dexterity in his hand that he needs to do most labor. (Tr.1491). He has not discussed his disability with his employers because he didn't want to be a charity case. (Tr.1490).

He has trouble getting dressed, doing common household tasks like his washing and ironing, doing the dishes, or even brushing his dog. (Tr.1496). He has pain in his arm for "just out of the blue," when it is cold, and after using it too much. (Tr.1496).

He is scared. (Tr.1513) "I don't see myself being like a part of the normal work force or as far as like hands-on type of jobs, … I couldn't do none of that…." (Tr.1514). "And I'm just scared because I want to be able to have a family and support a family like everyone else, like all the regular people…." (Tr.1514). "I don't even know if I'll be able to help [my mother if something happens to her]…." (Tr.1514).

James England, Plaintiff's vocational expert, testified that Cortez was excluded from "60 to 70 percent of the jobs" because of his disabilities. (Tr.1104). England agreed with Cortez's assessment of his job opportunities. (Tr.1100-04). Likely jobs available for Cortez in St. Louis are entry level, unskilled jobs, with wages in the $6 to $8 per hour range. (Tr.1103) He cannot get the $20 per hour jobs that might be available to him but for his disability. (Tr.1102). Given his grades, scholarships to continue his education will be "unlikely." (Tr.1107) It will be difficult for him to get into many colleges. (Tr.1108)

From this evidence, the jury could infer that at a minimum, Cortez's earning capacity had diminished substantially over his expected 47 year

lifetime of work. The jury's award of $2 million for lost economic damages rests on sufficient evidentiary support.

B. The Verdict Is Within the Range of Similar Cases

Alcorn v. Union Pacific RR Co., 50 S.W.3d 226, 250 (Mo. banc 2001) approved a remitted $25 million damages award for a woman injured in a railroad crossing accident. Ms. Alcorn had closed head injuries but little economic damages. The Supreme Court concluded that an appellate court must "defer to the trial court's superior opportunity to observe the witnesses, including Alcorn herself, and to make a determination as to what portion of the jury's award was sustained by the evidence in the case." *Id.*

In *McCormack v. Capital Electric Construction Co.,* 159 S.W.3d 387 (Mo.App. W.D. 2005), the court approved an award of $7.7 million to a man who suffered injuries at age 39. Cortez has not had 39 years free of injuries. Mr. McCormack had acquired a skill, fully supported his family, and been an active member of his community and a well-regarded participant in a variety of sports. Cortez may have none of those opportunities.

Defendant cites cases in which juries reached lower verdicts. These are of little guidance, since "[e]ach case must be considered on its own

facts, with the ultimate test being what amount fairly and reasonably compensates the injured party." *McCormack*, 159 S.W.3d at 395.

Neither the jury nor the trial court abused its discretion in rendering and sustaining this verdict.

For this reason, there is no basis for remittitur or a new trial based on the damages.

Point III should be denied.

Conclusion

This Court should affirm the verdict and damages assessed against American Cyanamid.

CROSS-APPEAL

IV. THE TRIAL COURT ERRED IN DENYING PLAINTIFF'S MOTION TO AMEND THE JUDGMENT TO ADD PREJUDGMENT INTEREST BECAUSE PLAINTIFF IS ENTITLED TO PREJUDGMENT INTEREST IN THAT PLAINTIFF MET ALL OF THE REQUIREMENTS OF §408.040 RSMo. (2005).

Standard of Review

Whether a statute applies to a given set of facts is a question of law. *McKinney v. State Farm Mutual Ins.,* 123 S.W.3d 242, 245 (Mo.App.2003). Matters of statutory construction and application are reviewed *de novo,* without deference to the trial court's judgment. *Id.*

A. An Award of Prejudgment Interest is Mandatory in this Case.

Cyanamid admitted receipt of the demand under Section 408.040 RSMo. (2000). (LF4127-28). The prejudgment interest letter met the requirements of that statute. The letter demanded payment of $1,400,000.00 and was left open for 60 days. (LF4098) The judgment entered in this case, $8,500,000.00, exceeded the amount of the demand. (LF4038)

Section 408.040.2 provides that a prevailing tort claimant is

> entitled to prejudgment interest if: (1) the claimant made a demand for payment or offer of settlement, which was left open for sixty days; and (2) the amount of the judgment exceeds the claimant's demand or settlement offer. If these conditions are met, the claimant "shall" be awarded prejudgment interest. § 408.040.2. The interest begins to accrue sixty days after the offer was made or when the offer was rejected without counter-offer, whichever is earlier.

McCormack v. Capital Elec. Const. Co., 159 S.W.3d 387, 402 (Mo. App. W.D. 2005). The statute brooks no exercise of discretion by a trial court.

> The plain language of Section 408.040.2 does not allow the trial court discretion to deny prejudgment interest once the statutory conditions are met. See *Harrison v. King,* 7 S.W.3d 558, 562 (Mo.App.1999) (statutory use of the word "shall" evidences legislative intent to remove discretion in trial court's disqualification of guardian *ad litem*). The fairness of the award is not a relevant consideration….

Id.

Cyanamid also complains that intervening, lower settlement demands were made and were not sent in accord with the statute. This argument is incorrect. "Once a settlement demand is made pursuant to

Section 408.040.2, it is immaterial whether plaintiff made any subsequent offers of settlement." *Lester v. Sayles,* 850 S.W.2d 858, 874 (Mo. banc 1993).

Conclusion

The trial court erred as a matter of law in refusing to award prejudgment interest. This Court should reverse and remand for entry of judgment to include prejudgment interest.

V. THE TRIAL COURT ERRED IN EXCLUDING THE TESTIMONY OF DR. DIEHL BECAUSE THE TESTMONY WAS PROPER REBUTTAL IN THAT IT DIRECTLY REBUTTED THE STANDARD OF CARE EVIDENCE OFFERED BY DR. JAWAID

Standard of Review

Appellate review of error alleged in the admission or exclusion of evidence is limited to an abuse of discretion standard. *Aliff v. Cody, 26 S.W.3d 308* (Mo. App. W.D. 2000). The focus is not on whether the evidence was admissible but on whether the trial court abused its discretion in excluding the evidence. *Id.*

A. The Testimony Was Proper for Rebuttal

Defendant Dr. Jawaid testified on direct examination that she did not have a memory of advising Cortez Strong's mother of the alternative vaccine of Inactivated Polio Virus (IPV), (Tr.1973), and that the standard of care did not require it:

> Q (By Mr. Germeroth) Well, did you discuss --
> let's talk about the -- I think you have the Red Book and
> you've talked about the Red Book, correct? And the Red

Book sets forth how you go about to do your practice as a pediatrician in dealing with patients' parents, correct?

A That's right.

Q And that kind of sets forth -- I think what you're saying, that sets forth the guidelines on how you're going to work, correct?

A On how I'm going to give the vaccines.

Q And that includes what type of information you're going to give the patients' parents, correct?

A That is correct.

Q And so in your understanding of the Red Book, do you feel that the way you would have given that vaccine complied with the guidelines of the Red Book?

A I believe so.

Q So if there is a -- if you will, a standard of care by this Red Book, you think you've complied with that standard of care?

A I followed their guidelines, so I guess I did it.

Q Okay. And it's your understanding of that Red Book that -- under your understanding of the Red Book, you

need to advise the patients' parents of the risk of OPV, is that right?

A Yes.

***

Q Okay. When you give the advice to the parent to get their consent to give the OPV, at the same time you're also supposed to give them the alternative of inactivated poliovirus which does not cause polio?

A I don't believe that that's a correct statement, sir, because you're presuming that I would say that at the same time I'm saying the OPV that I would give the IPV. It's not really required by the Red Book, but it would come up when I asked them if there is anybody with immune compromised situation, with cancer or AIDS, or if the mother refused the vaccine, then I would have to offer the injectable polio vaccine.

(Tr. 1994-96)

Defendant Jawaid's testimony, that she would only have mentioned IPV if someone in the family was immunocompromised, is what established the need for a rebuttal witness. Defendant Jawaid's testimony about the standard of care was directly contradicted by the testimony of her retained

expert, Dr. Diehl. Defendant Jawaid testified she had no duty to advise on the existence of the Inactivated Polio Vaccine and the risks of the Oral Polio Vaccine. (Tr. 1994-96). Her expert, Dr. Diehl, testified otherwise:

Q Now when it came to polio, did you give them an alternative?

A Yes.

Q. What alternative did you give them.

A. The inactivated polio vaccine

***

(LF.1171, Deposition of Diehl at 18).

Dr. Diehl established the standard of care when she testified that she advised parents of IPV availability. IPV does not carry the risk of vaccine associated polio. (LF.3925,3935,3962) Defendant Jawaid said she followed the American Academy of Pediatrics Red Book, which she believed set the "guidelines" for administration of vaccines. (Tr.1995)

During the Plaintiff's case in chief, Cortez Strong's mother testified that Dr. Jawaid did not advise her on IPV (Tr.485) and that if she had been given a choice, she would have selected the IPV over the OPV. (Tr.488) During cross-examination, Defendant Jawaid testified that the Red Book was the "standard of care" for advising patients, and moved the book into evidence.

Prior to trial, Defendant Jawaid had endorsed (and Plaintiff had cross-endorsed) Dr. Jawaid's retained expert, Dr. Elizabeth Diehl. However, shortly before Defendant Jawaid completed her defense case she withdrew her endorsement of Diehl.(Tr. 1929)

Plaintiff sought to call Dr. Diehl in rebuttal. As Defendant's expert, Dr. Diehl testified in her deposition that the standard of care required a pediatrician to advise on both the IPV and OPV vaccines. (LF1171, 1173, 4105, 4107). This evidence was directly contrary to the evidence that Defendant Jawaid put forth in her defense. The Defendant objected as improper rebuttal.

> MR. GERMEROTH: Your Honor, I would like to put on rebuttal an expert that was disclosed by the defendant, Dr. Jawaid, that was cross-endorsed by us, it was disendorsed as of this morning, that goes to the standard of care, which I think directly goes to what the defendant discussed with regard to the -- her testimony, therefore I think it's proper rebuttal.
>
> MR. ECKENRODE: Your Honor, my objection is that Dr. Diehl, whose testimony he wishes to offer, is somebody who they cross-endorsed as an expert. They deposed her. She was also a St. Louis resident subject to

subpoena. She could have been called during plaintiff's case in chief and was an appropriate witness to call during plaintiff's case in chief.

There are cases on point, which I'd be happy to submit to the Court on this issue, the most recent being Aliff v. Cody, 26 S.W.3d 309, which states, among other things, "Rebuttal evidence is evidence tending to disprove new points first opened by the opposite party."

When Dr. Jawaid was on the stand, we asked no questions of her regarding what the standard of care was. In fact, during my entire case in chief we did not offer any evidence on standard of care at all, so there is nothing to rebut as to the standard of care with regard to the evidence that I offered.

(Tr. 2019-2020)

Defendant Jawaid's testimony during cross-examination delved into the area of the standard of care and her adherence to it, and her testimony directly contradicted the testimony of her expert witness, Dr. Diehl, with regard to advising patients on IPV. Counsel brought this to the court's attention:

MR. GERMEROTH: Your Honor, first of all, that case is prior to the Missouri rules change wherein depositions can now be used for any reason at all. At that time there was rules dealing with the -- in regard to the availability of the witness, and that's what distinguishes that case.

Secondly, with regard to the new points they brought up that they were in fact relying on the Red Book, whereas that was not the -- although that was brought up on cross by Mr. Eckenrode with regard to Dr. Shanske, as I recall he was just basically -- that was his opinion, it's nationwide good practice of medicine with regard to giving both IPV and OPV, therefore he is introducing new evidence. The standard of care was that of the guideline she was relying on, and therefore I believe that new point is being raised that Dr. Diehl is directly on point with regard to -- with regard to that standard of care.

(Tr. at 2021)

The trial court erred and did not permit the rebuttal.

B. The Exclusion of the Rebuttal Witness Was An Abuse of Discretion Under *Aliff* and *Waters v. Barbe*.

Plaintiff bears the burden of establishing abuse of discretion. *Klinckman v. Pharris,* 969 S.W.2d 769, 771 (Mo.App.1998). "Failure to admit evidence does not mandate a reversal of a judgment unless the error materially affected the merits of the action." *Environmental Waste Management, Inc. v. Industrial Excavating, Inc.,* 981 S.W.2d 607, 613 (Mo.App.1998).

> "A party is entitled to introduce evidence to rebut that of his adversary, and for this purpose any competent evidence to explain, repel, counteract, or disprove the adversary's proof is admissible."

Aliff, 26 S.W.3d at 315.

Aliff found that the trial court abused its discretion because a party has a right to impeach a witness through prior inconsistent statements. *Id.* at 318.

Similarly, in *Waters v. Barbe,* 812 S.W.2d 753 (Mo. App. 1991) and *St. Louis Southwestern Ry. Co. v. Federal Compress Co.*, 803 S.W.2d 40 (Mo. App. 1990), the mere fact that an item of evidence could have been offered in the case in chief did not destroy the utility of that evidence for impeachment purposes.

Here, Dr. Diehl was the Defendant's endorsed expert. The impact of the jury hearing the deposition testimony of the Defendant's own expert on the standard of care would have been significant and directly affected the jury's determination on the critical issue of whether Defendant Jawaid should have advised on the difference between the two vaccines. In other words, the exclusion went directly to the merits of the action and affected the outcome.

Precluding impeachment of Dr. Jawaid and rebuttal of her misinformation on the standard of care regarding advising parents of the alternative of IPV deprived Plaintiff of a full and fair opportunity to place Defendant Jawaid's testimony in context for the jury. It was against the logic of the circumstances, and is an abuse of discretion.

Conclusion

The exclusion of Dr. Diehl's testimony was an abuse of discretion. The Court should reverse and remand for a new trial only with respect to Plaintiff's claims against Defendant Dr. Jawaid.

Respectfully Submitted,

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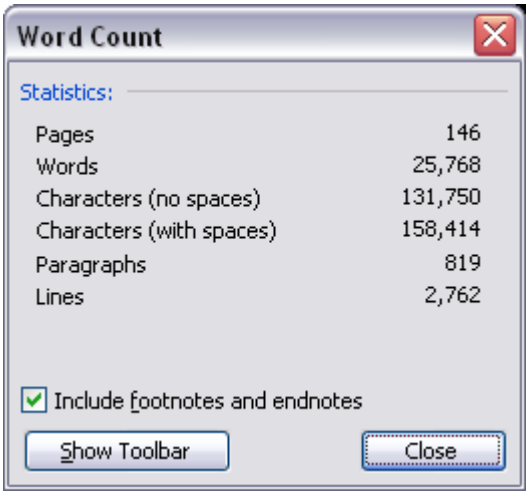
Undersigned counsel hereby certifies that this brief complies with the requirements of Missouri Rule 84.06(c) in that beginning with the Table of Contents and concluding with the last sentence before the signature block the brief contains 25,768 words. The word count was derived from Microsoft Word.



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Respectfully submitted,

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I, the undersigned, do hereby certify that a true and accurate copy of the foregoing document was served via prepaid United States mail and by electronic mail where an electronic mail address is shown this 7th day of May, 2008, to the following:

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