PUBLISH

UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

MICHELLE GRAHAM, an infant under the age of eighteen who sues by her parents, guardians, and next friends, Charles Graham and Tammy Graham,	)	
Plaintiffs-Appellees,	)	No. 88-1337
	)	No. 88-2302
vs.	)	No. 89-3066
	)	No. 89-3121
WYETH LABORATORIES, DIVISION OF AMERICAN HOME PRODUCTS CORPORATION,	)	
Defendant-Appellant.	)	

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS, Case No. 85-1481

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Before SEYMOUR, Circuit Judge, MOORE, Circuit Judge, and GARTH, Circuit Judge.*

Garth, Circuit Judge:

This appeal arises as a result of a $15,000,000 verdict against Wyeth Laboratories (Wyeth), the manufacturer of a DTP vaccine. It presents us with a number of evidentiary and legal questions. The most significant of these are: (1) should judgment NOV have been granted to Wyeth? (2) Are state tort awards for the improper manufacture of vaccines preempted by federal regulation? (3) Does Kansas allow for tort awards based upon strict liability or the negligent manufacture of an "inherently unsafe" vaccine? (4) Were a number of Wyeth's experts improperly excluded from testifying at the trial? (5) What is the correct procedure for the use, redaction and admission of "learned treatises" as evidence under Fed. R. Ev. 803(18)? And (6) was Wyeth entitled to post-judgment relief when one of Graham's experts recanted much of his testimony in subsequent

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*. The Honorable Leonard I. Garth, Senior United States Court of Appeals Judge for the Third Circuit, sitting by designation.

court proceedings? Other less significant allegations of error have also been raised, and will be addressed in the course of this opinion.[1]

Our standard of review in reviewing a denial of motion for judgment NOV has been prescribed as follows:

> The standard for determining whether to grant a motion for a Judgment N.O.V., as for a directed verdict, is not whether there is literally no evidence to support the party opposing the motion, but whether there is evidence upon which the jury could properly find a verdict for that party. The court may not weigh the evidence, pass on the credibility of witnesses, or substitute its judgment for that of the jury. Rather, it must view the evidence most favorably to the party against whom the motion is made and give that party the benefit of all reasonable inferences from the evidence. On appeal, we employ the same standard of review as does the trial court.

Brown v. McGraw, 736 F.2d 609, 612-13, (10th Cir. 1984).

On the other hand, we test the various individual evidentiary rulings made by the district court and the denial of Wyeth's Fed. R. Civ. Pro. 60(b) motions, for an "abuse of

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1. One additional issue raised was whether one of Graham's counsel should be disqualified based on a conflict of interest. That issue will not be addressed here. At oral argument, we ruled that the conflict precluded representation of Graham by the firm of Michaud & Hutton of Wichita, Kansas. We announced that our ruling would be the subject of an opinion to be filed. Oral argument was then presented by Graham's co-counsel, attorney Warshafsky, of Warshafsky, Rotter, Tarnoff, Gesler, Reinhardt & Bloch, of Milwaukee, Wisconsin.

discretion"; see In re International Coating Applicators, 647 F.2d 121, 124 (10th Cir. 1981). On issues related to interpreting federal law the standard of our review is plenary, and on interpreting Kansas law we give some deference to the district court's interpretation, but review is ultimately de novo. See Wilson v. Al McCord Inc., 858 F.2d 1469, 1473 (10th Cir. 1988) ("The issue for our consideration is the trial judges legal interpretation of state law to which we give some deference but ultimately review de novo.")

We will affirm the denial of judgment NOV, reverse the denial of the motion for a new trial, and remand to the district court for a new trial on all issues. Additionally, we will reverse the district court's denial of Wyeth's Fed.R.Civ. Pro. 60(b) motion for post-judgment relief. Inasmuch as we are ordering a new trial on all issues, we assume that the subject matter of Wyeth's 60(b) motion will find expression during that proceeding.

I.

A.

This appeal originated from a $15,000,000 jury verdict in favor of Michelle Graham ("Graham") and against Wyeth for the defective manufacture of Wyeth's DTP vaccine. Wyeth manufactured

a DTP vaccine which is used to immunize children against the diseases of diphtheria, tetanus (lockjaw) and pertussis (whooping cough). The vaccine is administered to infants at two, four, six and eighteen months. A booster injection is administered prior to the child's entrance into school.

The DTP vaccine is comprised of three component parts, diphtheria toxoids, tetanus toxoids, and a pertussis whole cell vaccine. It is the pertussis component of the vaccine that is the subject of this litigation and which allegedly caused the severe reaction suffered by Graham. While Graham contends that the pertussis component of this vaccine could have been safer, and that in fact safer versions of the vaccine are available, she does not argue that a pertussis vaccine is generally unnecessary or that it has not saved thousands of lives.[2]

The DTP vaccine containing the "whole cell" pertussis vaccine was licensed by the FDA in 1949. Due to the widespread

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2. In the early 1900's, pertussis was a leading cause of death in children in this country. In 1934, when this country suffered its worst pertussis epidemic, there were 265,000 reported cases of pertussis that year, and 7500 related deaths. By the early 1940's, pertussis was responsible for two and one-half times the number of deaths as all of the following diseases combined: measles, mumps, rubella, diphtheria, polio, meningitis, chicken pox, and scarlet fever. See Hinman and Koplan, Pertussis and Pertussis Vaccine: Re-Analysis of Benefits, Risks and Costs, 251 Journal of the American Medical Association (JAMA) 3109 (June 15, 1984).

use of the vaccine in this country, pertussis has virtually been eradicated. However, because of the persistent nature of the pertussis bacterium, there is a continuing and substantial risk of epidemics if the use of the vaccine was to be discontinued or was to decline significantly, and in fact epidemics have occurred in countries that have eliminated the pertussis vaccine from their list of mandatory vaccines.[3]

The nature of the DTP vaccine and its component parts was recently described by the Ninth Circuit as follows:

> By introducing an antigenic factor into the body, vaccines stimulate the production of antibodies that protect against disease. Some infectious organisms, such as those causing diphtheria and tetanus, excrete soluble toxins insolable [sic] by medical research. The toxin is inactivated with formaldehyde and transformed into a toxoid. The toxoid is then used in a vaccine, as it can immunize against disease by stimulating the production of antibodies in the recipient, even though it has lost its own poisonous qualities.
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> This is not the case, however, with [the pertussis component]. [The pertussis vaccine] is a so-called whole cell vaccine because it contains whole killed pertussis organisms. The whole organism is used because the pertussis organism contains fifteen or sixteen different antigens, and medical science has yet to isolate the one

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3. For an extensive comparison of the various countries' practices, and the epidemiological results, see Loveday v. Renton, (Queens Bench, England) March 31, 1988 (available on Lexis, No. 1982 L 1812).

> that stimulates protection against the disease.

Toner v. Lederle Laboratories, 779 F.2d 1429, 1430 (9th Cir. 1986).

Because the whole cell vaccine retains its poisonous qualities, it is neurotoxic and can cause adverse reactions which may be mild or severe. Mild reactions may include swelling, fever, irritability, and crying spells. Severe reactions can perhaps include encephalopathy,[4] paralysis and death. In recognition of the dangerous propensities of the whole cell vaccine, efforts have been made to develop a fractionated cell pertussis vaccine without any of the harmful toxoids. During the 1950's, the Eli Lilly Company developed a "split cell" vaccine called Tri-Solgen. Early studies indicated a fractionated vaccine was less toxic than the whole cell and it was approved by the FDA in 1967. At that time, Lilly occupied a substantial share of the DTP market. In 1975, Lilly withdrew from the vaccine business and sold its Tri-Solgen vaccine to Wyeth. According to Graham, in an effort to save on cost, Wyeth substituted its own "ingredients" (or "strains") into the Lilly "recipe" for the split cell vaccine. Wyeth then attempted to license this vaccine, but no license was granted by the FDA.

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4. "Any disease of the brain", Stedman's Medical dictionary, 5th ed. (1982).

Wyeth has made no further attempts to license a fractionated cell vaccine and no such vaccine is licensed in this country[5] today. Moreover, pharmaceutical companies are prohibited from marketing a product absent a license -- to do so would constitute a criminal offense; (21 U.S.C. §§ 331(d), 333(a), 355(a)).

B.

This lawsuit had its origins in the tragic history of the plaintiff, Michelle Graham, a child who has suffered, and is suffering from brain damage, and who requires continuous treatment and care. Michelle Graham (by her parents) alleged that she sustained severe and irreversible brain damage after being vaccinated against diphtheria, pertussis and tetanus with a defective vaccine produced by Wyeth.

On March 17, 1980, Michelle Graham, who was only a few months old, was administered Wyeth's DTP vaccine by a nurse at a county office of the Missouri Department of Health. Shortly thereafter Graham was diagnosed as having suffered from a severe and irreversible neurological condition known as encephalopathy which caused retardation and prevents Graham from ever leading a

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5. Japanese companies have developed and are currently using a pertussis toxoid (i.e., acellular) vaccine. This vaccine is purported to be as efficacious as the whole cell vaccine, but far less reactive. There appear to be some problems with the acellular vaccine as well; see Loveday, supra note 2, at 43-47.

normal life. Graham sued Wyeth alleging that its DTP vaccine caused the brain damage, and that this type of injury could have been avoided if only Wyeth had used more care in controlling the level of toxoid in its vaccine. Wyeth denied that its DTP vaccine did in fact cause Graham's brain damage, or that the DTP vaccine even could, in fact, cause this particular type of damage. Wyeth additionally maintained that, as a matter of law, it could not be liable even if the vaccine did cause Graham's injury because, vaccines, under applicable Kansas[6] law, are to be treated as inherently dangerous products and thus the vaccine manufacturers are deemed immune from liability.[7]

The district court determined according to Kansas law[8] that Graham could proceed on its negligence theories. In the district court's summary judgment opinion, however, it held for

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6. Both parties stipulated that Kansas law applied to this case, which was brought pursuant to our diversity jurisdiction, 28 USC § 1332; Graham v. Wyeth Laboratories, 666 F.Supp. 1483, 1485 (D. Kan. 1987).

7. As a general matter, Kansas subscribes to the principles of strict (products) liability for manufactured goods; see Brooks v. Dietz, 218 Kan. 698, 699-703, 545 P.2d 1104 (1976) and Note, Strict Liability in Tort Adopted in Kansas, 25 Kan.L.Rev. 462 (1977). This court in Symons v. Mueller Co., 493 F.2d 972 (10th Cir. 1974) forecast that Kansas would adopt such a rule.

8. See Graham v. Wyeth Laboratories, 666 F.Supp. 1483, 1484-86 (D. Kansas 1987) for the district court's analysis of all the pre-trial issues.

Wyeth, and against Graham, on the strict liability "warning" issue. On Graham's "design defect" strict liability claim, the court determined that there was an issue of material fact as to whether the vaccine was "unavoidably unsafe" within the meaning of Restatement of Torts §402A comment (k), thereby precluding summary judgment for Wyeth on its comment (k) defense. The court therefore permitted Graham to seek to establish that Wyeth's vaccine was "avoidably unsafe"; see infra p. 13-16.

After more than seven weeks of trial during which numerous experts testified as to causality, and others were excluded from testifying, the jury returned a verdict in favor of Graham for $15,000,000 in compensatory damages. Motions for judgment notwithstanding the verdict and for a new trial based on evidentiary errors were made by Wyeth and denied by the district court. Wyeth appealed. Thereafter, Wyeth, claiming to have discovered new evidence after its notice of appeal was filed, brought two Fed. R.Civ.Pro. 60(b) motions in the district court for relief from the judgment and for a new trial. Those motions were denied by the district court, and an appeal from those denials was taken as well.

II.

We turn first to Wyeth's contention that the district court erred in denying Wyeth's motion for judgment N.O.V. As we have observed, the appropriate standard to be satisfied for a judgment notwithstanding the verdict where proofs are at issue is "whether there is evidence upon which the jury could properly find a verdict for" the non-moving party, Brown v. McGraw, 736 F.2d 609, 612-13, (10th Cir. 1984) -- in this case, Graham.

Wyeth contended that no evidence which would prove a causal relationship between the DTP vaccine and Graham's injury was adduced. Wyeth focused on Graham's hypothesis that the whole cell DTP vaccine contains two components (endotoxin and pertussis toxin) which can cause retardation, and argued that no such proofs appear of record.

Because of the critical significance of a causal connection between the DTP vaccine and Graham's injury -- a connection bitterly disputed by the parties -- we requested additional briefing on this issue. We were thereupon directed to Graham's evidence that at birth, Graham was normal (Tr. 1416-1422); that she experienced no health problems prior to her vaccination (Tr. 2028-2034); that Dr. Gilmartin, a pediatric neurologist, testified that Graham's retardation was caused by the DTP vaccine (Tr. 1570, 1573)); that Dr. Gilmartin did not believe her injury was due to a stroke occurring prior to her

vaccination (Tr. 1587-1588, 1619); that endotoxin can injure blood vessels from the inside out (Dr. Zahalsky) (Tr. 302-307, 313-320); and that endotoxins can cause stroke (Dr. Guggenheim) (Tr. 3801-3803, 3870-3877).

Wyeth, which claimed among other theories, that Graham had suffered a stroke prior to her vaccination and that it was the pre-vaccination stroke which resulted in her disability, took issue with each of Graham's experts and with the evidence of causation. However, in ruling on a motion for judgment N.O.V., the district court and this court, are precluded from weighing the evidence, passing on the credibility of witnesses, or substituting a court's judgment for that of the jury. Yazzie v. Sullivent, 561 F.2d 183, 188 (10th Cir. 1977). Thus, the fact that Wyeth alleged that the evidence of causation was misconceived and that examined properly, the evidence would result in a finding of no causal connection between the DTP vaccine and Graham's injury, is of no relevance. Viewing, as we must, the evidence most favorably to the party against whom the motion was made -- here, Graham -- and giving Graham the benefit of all reasonable inferences, we are satisfied that the district court did not err in denying Wyeth's motion for judgment N.O.V. addressed to causation.

Wyeth also moved for judgment N.O.V., relying essentially, among other grounds, on various theories of law and the failure of Graham's evidence to meet her requisite burden of proof. Wyeth claimed that Graham's design defect theory was barred as a matter of law, and was unsupported by the evidence; that Graham's claims of inadequate warning based upon negligence were legally insufficient and not supported by evidence; and that Graham's claims were preempted by federal law.

Although our review of motions for judgment NOV relating to evidentiary errors is to determine whether there is any evidence on the record, our review of a district court's legal conclusions is plenary. We are in agreement with the district court's legal analysis of Wyeth's preemption claim,[9] and its determination that Wyeth's defense of adequate warning was a jury function. See Graham v. Wyeth Laboratories, 666 F.

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9. We note that since the district court correctly analyzed the pre-emption issue, two State Supreme Courts and two Federal Courts of Appeal have addressed this issue as well. Each has determined that pre-emption does not apply. See Abbot v. American Cyanamid, 844 F.2d 1108 (4th Cir. 1988); Hurley v. Lederle, 863 F.2d 1173 (5th Cir. 1988); White v. Wyeth Laboratories, Inc., 533 N.E.2d 748 (Ohio 1988) and Shackil v. Lederle Laboratories, 561 A.2d 511 (N.J. 1989). We agree with their rulings that federal pre-emption does not prevent state tort law awards arising from improperly manufactured drugs or vaccines, even in situations where the drugs or vaccines have met the FDA's minimum standards for licensing.

Supp. 1483, 1488 (pre-emption), 1494 (application of Kansas law), 1498 (adequacy of warning), (D. Kan. 1987).

We recognize, of course, that the district court opinion was written in response to Wyeth's motion for summary judgment. However, the same legal principles and arguments with which the district court treated, albeit in a summary judgment context, have now been advanced by Wyeth on appeal as grounds for reversing the district court's ruling which denied Wyeth's motion for judgment N.O.V. Because our reading of the record and our analysis of the relevant authorities cited by the parties and the district court are in accord with the conclusions reached by the district court in its summary judgment opinion and with its denial of Wyeth's motions, we do not deem it necessary to discuss these issues (other than Wyeth's §402A comment (k) defense to Graham's "design defect" claim) in any greater detail than the district court discussed them in its opinion. And, to the extent that Wyeth put in issue the proofs adduced with respect to each legal ground advanced, our independent review of the record satisfies us that judgment NOV in favor of Wyeth should not have issued.

With respect to Wyeth's §402A Comment (k) defense the Kansas Supreme Court has recently addressed this issue in Johnson v. American Cyanamid, 718 P.2d 1318 (Kan. 1986) and, as this

court's jurisdiction is based on diversity, the pronouncements of that tribunal bind us on this issue. Under the guidance of Johnson we are satisfied, as was the district court, that Kansas has accepted comment (k) as the law. The rationale underlying comment (k) is that since the manufacturer is using the best technology available to it in order to produce a product that under current technology is "inherently dangerous" (i.e. "unavoidably unsafe") we should not hold the manufacturer strictly liable for any injury that may result. The over-arching goal of strict liability is to force manufacturers to lessen, if not eliminate, the danger of their products. The comment (k) exemption is granted in the case of "inherently dangerous" products since it is assumed that the products cannot be improved: thus no liability should attach.

Wyeth claimed that because its DTP vaccine was "unavoidably unsafe", it could not be held liable on a strict liability "design defect" theory. In its opinion denying summary judgment to Wyeth on this claim, the district court determined that a material dispute of fact existed as to whether the DTP vaccine produced by Wyeth was "unavoidably unsafe". The district court referred to an affidavit by Dr. Zahalsky, one of Graham's experts, which asserted that Wyeth had the capability to produce a safer vaccine. Hence the question was presented as to whether

the "unsafety" of the vaccine produced by Wyeth was "unavoidable."

The district court read Johnson to require a determination at the outset as to whether the vaccine was "unavoidably unsafe". The district court found that a material dispute of fact precluded that determination at the summary judgment stage. Applying Johnson to such a circumstance,[10] the

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10. Johnson v. American Cyanamid, 718 P.2d 1318, 1323 (1986) states unequivocally that "The trial judge should have heard the evidence on the [unavoidably unsafe product] issue outside the presence of the jury and made the determination thereon."

Despite this statement the Kansas Supreme Court in Johnson did not remand the §402A comment (k) issue for a factual determination. Instead the court determined as a matter of law that the vaccine in question was an "unavoidably unsafe" product and thus subject to a §402A comment (k) defense.

As we indicate in text, the district court, finding a material dispute of fact with respect to the issue of unavoidable "unsafety", delayed ruling on this issue until mid-trial, when the court struck Wyeth's §402A comment (k) defense. We cannot say that the district court abused its discretion in declining to hold a "mini-trial" prior to trial limited to the issue of "unavoidable unsafety." see Moe v. Avions Marcel Dassault-Breguet Aviation, 727 F.2d 917, 935 (10th Cir. 1987) (Although arising in a different context, this Court, among other things, stated: mini-trials can result in "undue delay, waste of time, and needless presentation of cumulative evidence").

Wyeth argued below and reasserts here that the comment (k) defense, if successful, also precluded a design defect negligence action. We disagree. Exempting manufacturers from strict liability clearly differs from exempting them from negligence liability. In Johnson, 718 P.2d at 1319, the Kansas Supreme Court made clear in its first syllabus that a plaintiff may proceed on a theory of negligent design defect where she is

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district court then permitted Graham to proceed on a "design defect" theory, both as to negligence and strict liability, stating:

> [C]omment k's application does not shield the seller of a product from negligence claims. Such a result fits within the policy of comment k -- i.e., by denying plaintiffs recovery based on finding the manufacturer strictly liable if the drug is dangerous, and requiring the plaintiff to prove negligence, the policy of encouraging the production and marketing of safe, useful products is furthered.
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> Of course, the inquiry into whether a manufacturer acted negligently is, in a general sense, similar to the comment k inquiry of whether a drug is unavoidably unsafe. Thus, in a case such as this where both theories (strict liability and negligence) are asserted, the evidence from

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10. (...continued)
prohibited by comment (k) from proceeding on a strict liability design defect theory.

This is as well the position taken by the California Supreme Court in its most recent discussion of this issue. In Brown v. Superior Court, 751 P.2d 470, 482, n.12 (Cal. 1988) the Court stated:

> Our conclusion [that drug manufacturers are not strictly liable for the damage their product causes] does not mean, of course, that drug manufacturers are free of all liability for defective drugs. They are subject to liability for manufacturing defects, as well as under general principles of negligence and for failure to warn of known, or reasonable knowable side effects.

(Emphasis added.)

> which the court must determine if the product is unavoidably unsafe need not be heard outside the presence of the jury as it will be the same evidence from which the jury will determine negligence.

666 F.Supp at 1498 (citations omitted).

At a subsequent hearing during trial, the district court struck Wyeth's §402A comment (k) defense, as the district court found that it was not an available defense to Wyeth in light of the proofs developed at trial. Wyeth contends we should construe Johnson to hold that the comment (k) defense precludes a strict liability design defect claim as a matter of law in all cases involving licensed prescription vaccines. Other state Supreme Courts are divided on how to address comment (k) defenses. Compare Brown v. Superior Court, 751 P.2d 470, 481-83 (Cal. 1988) with Toner v. Lederle Laboratories, 732 P.2d 297, 3050309 (Idaho 1987). We view the Johnson opinion as unclear on this issue. Given the range of views of other state courts, see generally, Note, A Prescription for Applying Strict Liability: Not all Drugs Deserve Comment K Immunization, 21 Ariz. St. L. J. 809, 819-20 (1989), we are not inclined to disturb the district court's interpretation of Kansas law.

In view of these rulings, and particularly its summary judgment determination, we construe the jury's response to the

"design defect" interrogatory as well as to the negligence charge[11] as having its roots in the same evidence: that is, that Wyeth's vaccine would have been safer if the level of endotoxin had been reduced -- a subject to which we refer in section V, infra.[12] Thus, the jury's affirmative answer to interrogatory 4 ("design defect") must be read as a jury finding that Wyeth's vaccine was "avoidably," and not "unavoidably," unsafe and that a reduction of endotoxin levels was technologically feasible.

We have also considered the other errors asserted by Wyeth, in connection with the district court's charge. Because we are ordering a new trial, we do not find it necessary to discuss or rule on the errors which Wyeth claims, over its objections, were committed by the district court judge. This is particularly so, because it is unlikely that the same errors will occur again on retrial, and we are confident that Wyeth will have

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11. Special verdict form question 3 asked:

> 3. In March of 1980, was defendant Wyeth negligent in connection with testing, designing, and/or warning in regard to its DTP whole cell vaccine, which was the legal cause of plaintiff's injuries?
>
> The jury answered "Yes."

12. In that section we refer to Wyeth's newly discovered evidence of miscalculation made by Graham's experts as to endotoxin levels.

an opportunity to address itself to any such new instructions that will be given at a new trial.

III.

Wyeth raises numerous issues as grounds for the granting of a new trial, and we find many of them persuasive. In particular we conclude that numerous evidentiary errors occurred at trial and were of such a degree as to mandate a new trial.

A.

In our view, one of the most serious evidentiary errors committed at the trial was the exclusion of critical portions of Dr. Cibis' testimony. Dr. Cibis, a pediatric ophthalmologist who had treated Graham, was prepared to testify, and did so testify at deposition,[13] that Graham had suffered a stroke before her vaccination and that accordingly the DTP vaccine was not the cause of her disability. The essence of Dr. Cibis's testimony was that, in light of the CT scan which had been made available to him after his initial diagnosis of Graham, he would now attribute to an eye problem (Cogan's Apraxia), a clear manifestation of stroke. (Tr. 3974-81, 4002-4006). He

13. The deposition of Dr. Cibis took place the morning he testified. The district court judge attended parts of the deposition.

originally, and without the benefit of a CT scan, diagnosed Graham's eye problem as minor. The thrust of his testimony would thus support Wyeth's contention that Graham had already suffered her stroke before she had been vaccinated, since Dr. Cibis' examination occurred before the DTP vaccine had been administered.

The district court prevented Dr. Cibis from so testifying, ruling that for any expert who testified as to causation the expert had to be knowledgeable about the workings, nature and medical literature concerning endotoxins. (Tr. 3924-26) This was error.

Dr. Cibis would have testified that the vaccine did not cause Graham's injury. The lack of knowledge by Dr. Cibis as to the workings or nature of DTP, his lack of expertise as to endotoxin, or his unfamiliarity with the course of this particular litigation, was not relevant to that testimony. To promulgate a rule that one must be an expert in DTP or endotoxin in order to testify as to that particular substances' effect may be perfectly reasonable; but to use such a criterion to exclude experts from testifying that the vaccine was not the cause of injury (because Graham had already suffered the stroke at the time of the original examination) had to remove from the jury

significant evidence that Wyeth's vaccine was not responsible for Graham's condition.[14]

> As a general rule,
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> to warrant or permit the use of expert testimony, two conditions must be met: first, the subject matter must be closely related to a particular profession, business or science and not within the common knowledge of the average layman; second, the witness must have such skill, experience or knowledge in that particular field as to make it appear that his opinion would rest on substantial foundation and would tend to aid the trier of fact in his search for truth.

Bridger v. Union Railway Co., 355 F.2d 382, 387 (6th Cir. 1966); see Bratt v. Western Airlines, 155 F.2d 850 (10th Cir. 1946). There is little doubt that in this case scientific (medical) evidence was needed to resolve a number of critical disputes. Furthermore, few would contend that these medical disputes were

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14. An illustration by analogy points out the district court's error. If Dick sues Dentist Jane for dental malpractice, and Jane's defense is that her dental technique could not have caused the injury, expert dental testimony would be needed to determine if in fact, Jane's technique could have caused the injury. Furthermore, in such a context it would be an abuse of discretion for the court to not limit those who can testify on this issue to "experts" qualified to issue an opinion on dental technique.

If Jane's defense, however, was that Dick had suffered the injury of which he complains when he was struck in the mouth during a fight, the experts who could testify as to correctness of that possibility need not have the same qualifications as those needed for Jane's "technique" defense -- in fact it would be an abuse of discretion to require the same standard.

within the knowledge of the average layman absent expert testimony. Thus the evidentiary issue presented to the district court concerned Dr. Cibis' qualifications as an expert to give testimony as to whether Graham suffered a stroke prior to her receiving DTP vaccine.[15]

Dr. Cibis was a pediatric ophthalmologist who had received training in neurology as it relates to the eye. He was additionally one of Graham's original treating physicians. Dr. Cibis, upon the recommendation of Dr. Hertenstein, Graham's

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15. The Federal Rules of Evidence as they concern expert testimony are found in Rules 702 and 703 respectively. They read:

> Rule 702. Testimony by Experts
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> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.
>
> Rule 703. Bases of Opinion Testimony by Experts
>
> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

pediatrician, examined Graham on February 27, 1980 (when Graham was 11 weeks old and three weeks before her DTP vaccine) for an eye problem which he diagnosed as Cogan Apraxia (congenital motor apraxia). (Tr. 1153-54).

The district court's approach to the admissibility of expert witness' testimony in this case was evidently fashioned by what it believed to be the central issue in the case: could endotoxins cause this type of damage? It ruled that no expert could testify who was not familiar with toxins. The district court stated the rule as follows:

> I don't know how anyone can fairly assess the significance of the time of that stroke in this case without addressing an awareness of the endotoxin, rule it in or rule it out.

(Tr. 2925).

> The minute the [expert] says: "I have no wherewithal in the field of neurology, I have no appreciation of endotoxin or their significance or effects, if any" the witness isn't going to testify.

(Tr. 4585).

This approach forced Wyeth to limit the experts it called, to those who testified to alternative theories of injury to Graham. Thus, the district court compelled Wyeth to forgo critical testimony of a treating physician that Graham had suffered a stroke prior to her vaccination -- testimony that if

believed by the jury would have resulted in a verdict that Wyeth was not liable. It deprived Wyeth of a primary defense that it was not liable, due to an intervening cause (i.e., that a pre-vaccination stroke caused Graham's injury) and instead left Wyeth with only an alternative theory that the DTP vaccine could not, rather than did not, cause a stroke.

While under the Federal Rules of Evidence a district court has substantial discretion in deciding which experts can and cannot testify, the district court may not employ that discretion to restrict viable and relevant theories offered by a party. In this instance the district court, by excluding Dr. Cibis' testimony, deprived Wyeth of crucial testimony, which if available to the jury, may well have swayed the jury in its determination. We cannot regard the exclusion of such evidence as harmless because it affected the substantial rights[16] of the

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16. Fed.R.Civ. Proc. Rule 61 states:

> Rule 61. Harmless error
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> No error in either the admission or the exclusion of evidence . . . is ground for granting a new trial . . . unless refusal to take such action appears to the court inconsistent with substantial justice. The court at every stage of the proceeding must disregard any error or defect in the proceeding which does not affect the substantial rights of the parties.

(continued...)

defendant Wyeth, particularly when other expert testimony bearing on the same defense was also excluded.

B.

Dr. Breckbill, another physician called by Wyeth, was a specialist in pediatric radiology. Dr. Breckbill's credentials as a pediatric radiologist were detailed during his examination, and are extensive. On May 12, 1987, Graham underwent a CT head scan under the direction of Dr. Breckbill. He determined that she had suffered a stroke. A large part of his testimony at trial dealt with the manner in which head scans are conducted. He testified that it was not uncommon for family practitioners or pediatricians to fail to diagnose brain lesions in infants, because of their young age, and the difficulty that physicians have in distinguishing normal from abnormal gross reflexes in infants. (Tr.3573-74).

During his testimony he acknowledged that he knew Graham had received a DTP vaccine on March 17, 1980 (Tr. 3580). After having reviewed the medical records and after acquainting

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16. (...continued)
See, e.g., Lusby v. T.G.& Y. Stores, Inc., 796 F.2d 1307 (10th Cir. 1986) (harmless error doctrine); Prebble v. Brodrick, 535 F.2d 605 (10th Cir. 1976) (same).

himself with the testimony of other experts who testified as to the cause of Graham's disability, Dr. Breckbill stated:

> My opinion would be that the child had suffered a stroke when seen by Dr. Hertenstein, [she] had the stroke previous to the time that child was seen by him.

(Tr. 3895). We note parenthetically that Dr. Hertenstein examined Graham on February 2, 1980, more than six weeks before her DTP vaccination.

Dr. Breckbill explained the basis for his opinion that the stroke occurred sometime before February 2, 1980 by referring to the CT scan and the changes in both Graham's skull and brain. No objection was raised either as to Breckbill's qualifications or to his testimony at that time. An extensive cross-examination occurred. On redirect examination, Wyeth inquired as to whether it was still Dr. Breckbill's opinion that Graham's stroke occurred before February 20, 1980 (the date of Dr. Cibis's examination). That question elicited an objection from Graham's counsel:

> The following colloquy took place:
>
> MR. WARSHAFSKY [Graham's attorney]: I object on the grounds that with the totality of the examination and now with what the Doctor had to examine and his background, I don't think the Doctor is qualified to give the opinion.
>
> THE COURT: Sustained.

> MR. WARSHAFSKY: And I move that his opinions given during direct testimony on the same subject be stricken.
>
> MR. HERRINGTON [Wyeth's attorney]: Your Honor, there was no objection made during the direct examination.

(Tr. 3693).

* * * *

> MR. HERRINGTON: I'm not sure I'm clear. What is the Court ruling with regard to moving to strike his opinion with regard, on direct testimony that he gave?
>
> THE COURT: Sustained.
>
> MR. HERRINGTON: Where no objection was raised at the time.
>
> THE COURT: Well, you've reraised it and you restated it. Now it's raised, and now I rule on it.
>
> MR. HERRINGTON: I'd like to make a proffer, your Honor, outside the hearing of the jury.

(Tr. 3697). Wyeth's counsel proffered the testimony of Dr. Breckbill as follows:

> MR. HERRINGTON: Based upon the information in the medical records that I asked you to review and that you have reviewed and the portions of Dr. Hertenstein's deposition that you were furnished and your reliance upon the head charts and their significance . . . do you still hold the same opinion you expressed yesterday that the stroke of Michelle Graham occurred before February 20, 1980 when the

> right fixed gaze was found by Dr. Hertenstein[17] [sic]? Do you still have the same opinion?
>
> DR. BRECKBILL: Yes.

(Tr. 3719). Thus, the testimony of Dr. Breckbill, which focused on events occurring before the DTP vaccination of Graham, was removed from the jury's consideration.

We do not focus on the fact that no objection was initially raised by Graham because we are satisfied that Dr. Breckbill's testimony should not have been stricken. His testimony not only bolstered Dr. Cibis' testimony but was directed to the very essence of Wyeth's defense, and was both highly relevant and material to that defense.

C.

In line with its earlier approach that no expert's testimony could be considered unless the doctor or expert had an appreciation of endotoxins or its effect, the district court also sustained Graham's objection to the testimony of Dr. Deitch.

Wyeth made an offer of proof outside the presence of the jury as to Dr. Deitch's testimony. Dr. Deitch, a Board

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17. Although the substance of Dr. Breckbill's testimony is unchanged, in fact it was Dr. Hertenstein who examined Graham on February 2, 1980 and Dr. Cibis who examined her on February 20, 1980.

certified pediatrician, reviewed Graham's medical history and had noted the fixed right gaze which had earlier been observed by Drs. Hertenstein and Cibis. The significance of this was, in Dr. Deitch's view, that "one of the things to be ruled out at that time [of Dr. Hertenstein's examination] was a stroke sometime prior to that [the time of Graham's DTP vaccination]." (Tr. 4353).

Dr. Deitch would also have testified that even a thorough pediatric examination of a child between two and three months of age [Graham was 7 weeks old at the time of Dr. Hertenstein's examination and 11 weeks old at the time of Dr. Cibis'] would not necessarily reveal a stroke that had occurred because a loss of functions, slurring of speech, and distortions of the face, which manifest themselves when adults have strokes, do not show up in children at that young age.

The relevant and particular question that was excluded from jury consideration was: "Would the result of that stroke be apparent to a competent pediatrician performing such an examination at that time?" (Tr. 4161). Dr. Deitch's answer to that question would have been: "No." Thus, the effect of the district court's ruling was to prevent the jury's consideration of Dr. Deitch's confirmation that Dr. Hertenstein might not have initially recognized the manifestations of a stroke even though

Graham might have suffered a stroke at a time prior to her vaccination.

D.

In sum, the result of the district court's rulings which prevented any evidence of a pre-vaccination stroke from reaching the jury, effectively vitiated a relevant theory which Wyeth was entitled to establish. As we have noted above, Wyeth's experts would have testified that Graham was originally diagnosed by her treating physician (Dr. Hertenstein) as having an eye problem which he, as a pediatrician, could not diagnose. Dr. Hertenstein referred Graham to Dr. Cibis, a pediatric ophthalmologist, who examined Graham three weeks before her DTP vaccination. At that time, Dr. Cibis identified Graham's eye problem as relatively minor. Approximately one month later, Graham was vaccinated by Wyeth's DTP vaccine, and after that event, she was diagnosed as suffering from brain damage, which was caused by a stroke.

Graham thereafter had a CT scan taken by Dr. Breckbill. When the results of this CT scan were disclosed to Dr. Cibis, he indicated that, given what he now perceived from the CT scan, he would now have diagnosed Graham as having suffered a stroke prior to his original examination.

Supporting Dr. Cibis' diagnoses was Dr. Breckbill, a pediatric radiologist and a pediatric neuro-radiologist, who was prepared to testify that Graham had suffered a stroke before she had been vaccinated. Dr. Deitch, a Board certified pediatrician, was prepared to testify that it would not be uncommon for a pediatrician to fail to recognize signs of a stroke in an infant, thus giving additional credence to Wyeth's theory of pre-vaccination injury.[18]

While we obviously cannot, and do not, find that Graham's DTP vaccination occurred after she had suffered a stroke (fact finding here was a function for the jury), it is clear that causation evidence of this import could not be withheld from jury consideration. Thus, whether the district court's rulings excluding Dr. Cibis' testimony is considered alone, or is considered in conjunction with the exclusion of the testimony of Drs. Breckbill, and Deitch, we are satisfied that the district court prevented the jury from hearing the opinion of these experts on the cause of Graham's injury. Moreover, as we have earlier observed, an error of this magnitude inevitably had to prejudice Wyeth's defense, and cannot be deemed harmless.

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18. We do not elaborate on the district courts's ruling restricting Dr. Pollack's examination, as Dr. Pollack's testimony was not focused specifically on the issue of pre-vaccination injury. In light of our disposition of this appeal, we express no opinion on the admissibility of Dr. Pollack's testimony.

IV.

Wyeth also argues that the district court abused its discretion when it admitted an American Medical Association Ad Hoc Panel Report, "Pertussis Vaccine Injury," 245 JAMA 21:3083 (December 6, 1985) (PX376) into evidence, when it redacted the Report, and when it, contrary to the provision of Fed. R. Evid. 803(18), not only permitted the report to be read to the jury in its redacted form but then permitted the jury to receive the document as an exhibit. Wyeth charges that this document was so fatal to Wyeth's case that Wyeth was obliged to move for a mistrial.[19]

The Report's first sentence stated its objective:

> In an effort to ensure an adequate and uninterrupted supply of vaccines for mandated pediatric immunization and to encourage the continued timely administration of these vaccines, the American Medical Association formed a commission to explore the need for a compensation system for vaccine-injured patients.

The remainder of that paragraph and a portion of the succeeding paragraph addressed itself to the issue of establishing a federal vaccine compensation program as an exclusive remedy for any individual injured by a mandated vaccine and noted that there was

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19. The district court characterized the AMA Report as "the smoking gun we have been looking for . . ." (Tr. 1627) and denied Wyeth's motion.

only one remaining supplier of DTP -- a supplier who might be unable to obtain insurance renewal.

Other portions of the exhibit, while acknowledging that the Report did not have as its purpose stringent proof of causation of injury by the vaccine, did refer to injuries "reputed" to be vaccine-related and reported by television and radio news programs, newspapers or parents groups but whose relationship to DTP vaccine was not necessarily supported by medical evidence. It went on to state that it was the impression of the AMA panel that about 10% of patients exhibiting seizures may have residual brain damage after one year. Other probabilities of related injuries were discussed in the Report, although the panel noted that there was "no evidence that killed vaccine (such as [Wyeth's] pertussis vaccine) can cause any prolonged insidious or delayed deleterious effects (in contrast to live attenuated organism vaccine)." While the Report did not address the issue of whether DTP could cause retardation -- but rather addressed itself to a proposed legislative solution to compensate vaccine victims -- some of its content could be read as relating to the issues in this case. We reproduce in full in

the margin, the one and one-half paragraphs of text redacted by the district court.[20]

Wyeth objected to the admission of the Report in its entirety, claiming that the Report was neither a scientific nor a

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20. The redacted material read as follows:

> In an effort to ensure an adequate and uninterrupted supply of vaccines for mandated pediatric immunization and to encourage the continued timely administration of these vaccines, the American Medical Association formed a commission to explore the need for a compensation system for vaccine-injured patients. From these deliberations recommendations for federal legislation were made and approved by the Association's House of Delegates in June 1984. Draft federal legislation was prepared calling for the establishment of a federal vaccine compensation program as an exclusive remedy for those seriously injured by mandated vaccines. There was considerable urgency since the number of national suppliers for one of these vaccines (diphtheria-tetanus-pertussis, or DTP) decreased from three to one. There also was a reasonable possibility that the sole remaining supplier would be unable to obtain insurance renewal.
>
> The concern with DTP vaccine resides with its pertussis cell components, which occasionally induce severe neurological injury. In order to prepare an appropriate information base on potential pertussis vaccine injuries in the context of Congressional consideration of vaccine injury compensation legislation, . . .

American Medical Association Ad Hoc Panel Report, "Pertussis Vaccine Injury," 254 JAMA 3083 (December 6, 1985).

clinical study nor a learned treatise. It also objected to the court's sua sponte redaction of the introductory portion of the Report which, as noted, dealt with a proposed compensatory and insurance scheme. In addition, Wyeth contended that when the district court permitted the jury to have the redacted document in its possession during deliberations as a written exhibit, the district court had acted contrary to the express provision of Fed. R. Evid. 803(18) which provides that if a learned treatise is admitted "the statements may be read into evidence but may not be received as exhibits."

A.

Wyeth claimed among other things that the Report did not qualify as a learned treatise because Graham's expert had not established that it was a reliable authority within the meaning of Fed. R. Evid. 803(18).[21] Wyeth also claimed that in order to

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21. Fed. Rule of Evid. 803(18) reads:

The following are not excluded by the hearsay rule, even though the declarant is available as a witness:

* * *

(18) Learned treatises. To the extent called to the attention of an expert witness upon cross-examination or relied upon by the expert witness in direct examination, statements contained in published treatises, periodicals, or pamphlets on a subject of history, medicine, or other science or art,

(continued...)

be admitted into evidence, the Report would have to be demonstrated to be relevant to the facts of the case at issue.

Dr. Gilmartin, who testified on behalf of Graham, testified only that the panel was a prestigious panel, and that the Journal of the American Medical Association, in which the Report appeared, was an authoritative publication. Significantly, Dr. Gilmartin did not testify that the Report itself was a reliable authority or that it constituted a learned treatise. Moreover, because the Report did not deal with the causal relationship between DTP and stroke, Wyeth asserted that a specific issue in this case which focused on causation was not addressed and therefore the Report was irrelevant.

Our reading of the record does not disclose Wyeth's specific objection to the introduction of this Report on the ground that the foundation for its introduction was inadequate. Rather, Wyeth objected strenuously to the Report on the grounds that its purpose was not to establish causation, but was rather tangential in the sense that it advocated a legislative compensatory scheme. Indeed, Wyeth's strongest objection was to the sua sponte redaction of a portion of the Report which

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21. (...continued)
established as a reliable authority by the testimony or admission of the witness or by other expert testimony or by judicial notice. If admitted, the statements may be read into evidence but may not be received as exhibits.

deprived the jury of knowledge that the Report did no more than propose a plan to compensate any DTP victims. In the absence of a specific objection to the manner in which Graham laid the foundation for the Report's introduction, we cannot say that the district court judge would have abused his discretion had he permitted the entire Report in evidence, leaving it to Wyeth to cross-examine Dr. Gilmartin on the purpose of the Report. By doing so, Wyeth could have clarified the relevance and import of the Report itself.

B.

Whether or not the full Report was admissible in evidence within the ambit of Fed. R. Evid. 803(18), the district court's subsequent action in sua sponte redacting a significant portion of the Report stands on a different footing. After Wyeth had objected to the relevancy of the Report because the panel had not established a causal relationship between DTP vaccine and encephalopathy, the district court on its own motion redacted the first paragraph and a substantial portion of the second paragraph of the Report. The sentences redacted, as we have noted earlier, contained a statement as to the purpose of the Report (compensation) and a reference to the possibility that insurance might be unavailable. The district court recognized that the

issue of compensation as presented in the Report was irrelevant to the issues of this case, but by redacting all reference to compensation the court unwittingly distorted the thrust of the Report. Not only was the purpose and theme of the article withdrawn from the jury's consideration, but the district court explicitly ordered that Wyeth could not cross-examine any witness on the material which appeared in the redacted paragraphs.

The district court answered Wyeth's observation that the subject of the Report's purpose would have to be addressed in cross-examination, by stating:

> THE COURT: Let me see if I can make it clear then. You're entitled to get into it [the Report], but you're admonished not to get into anything mentioned in the first paragraph.[22] (Tr. 1629).
>
> * * *
>
> THE COURT: You can take out the first paragraph which gives rise to the reason it [the Report] was formulated, ostensibly, because they were about the formation of some kind of a compensation program. After the first paragraph, there isn't a thing in this paper you can't go into. (Tr. 1667).

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22. We cannot reconcile the district court's order redacting only the first paragraph with the actual redaction of the exhibit which included an additional portion of the second paragraph. No explanation appears as to why more than the first paragraph was redacted. Inasmuch as we hold that the district court improperly redacted any part of the report once it had decided to admit the entire report into evidence, the additional redaction only added to the error.

* * *

> THE COURT: Very well. I only say, seem [sic] to me we could cut out the first paragraph. I've already told the jury the first paragraph's irrelevant. It's no longer of concern to them. Take it out. All of you can use the exhibit. . . . (Tr. 1667).

Through its redaction, the district court admitted evidence into the case which could only mislead the jury. By prohibiting cross-examination about the true purpose of the Report the district court compounded its error. Moreover, although Dr. Gilmartin testified to some statements in the redacted Report having to do with the panel's recitation of probability of vaccine causation, (Tr. 1631) the entire redacted Report was given to the jury for their study during deliberations. What the last provision in Fed. R. Evid. 803(18) seeks to preclude by prohibiting the receipt of the written exhibit into evidence is described in Weinstein's Evidence as:

> To insure that the jurors will not be unduly impressed by the treatise, and that they will not use the text as a starting point for conclusions untested by expert testimony, the last paragraph of Rule 803(18) bars the admission of treatises as exhibits so that they cannot be taken into the juryroom.

J. Weinstein & M. Berger, 4 Weinstein's Evidence ¶803(18)[02].

Thus, as Wyeth contends in its brief on appeal -- a contention with which we agree:

> The redacted portion of the report was critical. It explained the background and limited purpose of the report, namely to provide an information base on potential pertussis vaccine injuries for Congressional consideration of vaccine injury compensation legislation.
>
> The redaction of such material made the redacted report prejudicially [sic] misleading. By excluding such information, PX376 was made to look like an AMA report on causation, when it was not. In fact, the reported stated that "[w]ithin the purpose of this report," which purpose was redacted, "stringent proof of causation by the vaccine was not required." Nonetheless, the trial court described the report as a "smoking gun" on the issue of causation, and, indeed, in its redacted form it was a deadly weapon. The judge then admonished the parties not to mention anything contained in the redacted portion of PX376.
>
> Wyeth was severely prejudiced because of its inability to counter the portions of PX376 read into evidence by Dr. Gilmartin (plaintiff's medical expert) over Wyeth's objection, which appeared to establish that the AMA had concluded that DTP causes encephalopathy, when there is no scientific evidence establishing such causation.

(Wyeth br. at 88-1339, p. 51) (Internal citations omitted).

We are satisfied that the district court abused its discretion in redacting the portions of the Report which explained the Report's purpose and background and in prohibiting Wyeth from addressing those issues on cross-examination or through its own witnesses. We are also satisfied that it was improper to submit the Report in its redacted version to the jury

in contravention of Fed. R. Evid. 803(18). We need not decide if this abuse of discretion on the part of the district court, even though it may have been well intentioned, would by itself require a reversal of the judgment in favor of Graham. We are convinced however, that when we consider both the exclusion of the testimony of Wyeth's experts (Drs. Cibis, Breckbill, and Deitch) which the district court ordered, together with the unfortunate redaction of the Report and its submission to the jury as an exhibit, the judgment in favor of Graham cannot stand.

V.

Wyeth has also asserted additional alleged errors which do not require extensive discussion in light of our disposition of this appeal. All of the other errors asserted are matters which were peculiar to the trial whose judgment we are reversing, and hence may not occur, or may not be the subject of error, at the new trial which we have directed the district court to hold. Indeed, Wyeth's appeal from the district court's denial of its Fed. R. Civ. Pr. 60(b) motions fall within the same category. In normal course we would not discuss in this appeal the denial of Wyeth's post-trial motions, as it is apparent that at the retrial the very information which Wyeth claims to have newly discovered will, if it desires, become part of its defense.

Nevertheless, because the evidence which was the subject of Wyeth's 60(b) motions goes to the heart of the testimony of Graham's experts and would in our opinion require a new trial, even had we not decided that the evidentiary errors on direct appeal required reversal, we will explain our conclusion that a new trial was required on the grounds of newly discovered evidence.

A.

A final error was committed by the district court in its denials of post-trial relief to Wyeth under F.R.Civ.P. 60(b) when Wyeth sought a new trial on the grounds of newly discovered evidence. The grant of denial of a Rule 60(b) motion is reviewed for abuse of discretion; In re International Coating Applicators, 647 F.2d 121, 124 (10th Cir. 1981).[23]

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23. It is unclear if jurisdictionally a district court can ever grant a rule 60(b) motion after a notice of appeal has been filed. The procedure approved by us in this case is for the district court to indicate that it would grant the 60(b) motion if it had jurisdiction, and for the our court to then remand the case to the district court for that court to decide the motion; see Blinder, Robinson & Co. v. SEC., 748 F.2d 1415, 1420 (10th Cir. 1984) ("In ordinary civil cases the rule is that after an appeal has been taken the district court retains jurisdiction to consider and deny a rule 60(b) motion and, if it indicates that it will grant the motion, the movant may then ask the court of appeals to remand the case so that the district court may act.") quoting Aune v. Reynders, 344 F.2d 835, 841 (10th Cir. 1965); see also United States v. 397.51 Acres of Land, 692 F.2d 688, (10th (continued...)

B.

At the conclusion of trial the jury awarded Graham $15,000,000 in compensatory damages. Through later depositions taken in other DTP cases unrelated to the instant proceeding, Wyeth discovered that two of the key expert witnesses who had testified on Graham's behalf, had erred in their testimony as to the toxicity of Wyeth's vaccine. These two witnesses, Dr. Geier and Dr. Zahalsky, both misstated[24] in their testimony to the Graham jury, the results of Dr. Geier's experimentation respecting the levels of endotoxin in Wyeth's DTP vaccine. This

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23. (...continued)
Cir., 1982).

As we reconstruct the sequence of events from the docket sheets, the jury verdict in favor of Graham was entered on October 15, 1987. Timely motions were made by Wyeth for judgment NOV or for a new trial. These were denied on February 2, 1988 followed by a timely notice of appeal, the time for which had been tolled by Wyeth's post trial motions. Thereafter, on April 15, 1988, Wyeth moved for relief from the Graham judgment pursuant to Fed. R. Civ. Pro. 60(b). On July 19, 1988, the district court denied Wyeth's 60(b) motion which was followed by Wyeth's motion for reconsideration -- a motion that was also denied by the district court. Wyeth then appealed on April 17, 1988 from the denial of its original 60(b) motion.

On October 13, 1988, Wyeth moved again for relief of judgment under Fed. R. Civ. Pro. 60(b). That motion was also denied on February 16, 1989. A timely appeal was taken from that denial as well.

24. We assume that any error that occurred in Drs. Geier's and Zahalsky's testimony was due to unintentional mathematical miscalculation.

evidence was addressed to Wyeth's alternative defense: that DTP vaccine could not have caused Graham's stroke. Both of Wyeth's 60(b) motions concerned this testimony.

At trial, in the present case, Dr. Geier had testified extensively as to the critical relationship between the toxicity of any pertussis vaccine and the level of endotoxin. The thrust of his testimony was that the higher the level of endotoxin, the greater the danger that any given vaccination would lead to adverse reactions, including those allegedly suffered by Graham. Dr. Geier stated that the "[m]ore the endotoxin, the more severe [the] reaction" (Tr. 892). Specifically, Dr. Geier stated that the endotoxin content of Wyeth's vaccination was 240 micrograms per milliliter (Tr. 1028) -- a level four times higher than that of the next most toxic pertussis vaccine made by other pharmaceutical companies and 2400 times higher than the least toxic of the other pertussis vaccines. (Tr. 1028-31).

In fact, it later appeared that Dr. Geier had erred in his computation of the toxicity of the Wyeth's DTP vaccine. Instead of Wyeth's vaccine having an endotoxin level of 240 micrograms per milliliter, it actually had only a level of 20 micrograms per milliliter. Thus, when Dr. Geier was deposed in a later case entitled Talley v. Wyeth Laboratories, (case no. 87-349-C, E. D. Okla., Feb. 24, 1988), he testified:

> Q: Your initial estimate of this Lederle [DTP vaccine] made by Wyeth was that it had 240 micrograms per milliliter, and then on subsequent reflection and further testing, you found that it had tenfold less than that; is that correct?
>
> A: That's right, that one looks like an error of -- what we call an order of magnitude error, that is when I did the calculation, I must have missed a zero
>
> Q: And a tenfold difference can be pretty significant in terms of your opinion, can't it?
>
> A: Sure.

(Tr. 468).

Dr. Geier, in a number of other depositions, had given substantially identical testimony to the effect that Wyeth's vaccine is not as toxic as he originally thought it was.[25] This testimony substantially undermined the weight of the evidence to which he testified in Graham's case.

Almost by definition, any error in Dr. Geier's testimony had to affect the testimony and conclusions of Dr. Zahalsky, who when he testified, relied on Dr. Geier's calculations. Thus Dr. Zahalsky testified at trial that:

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25. In the cases of McLean v. Wyeth, 86-4077 (W.D. Ark. 1988), Cavallo v. Wyeth, Circuit Court, Milwaukee County, Milwaukee, Wis. 716-507, and Cooper v. Wyeth, 86-1177C (E.D. Miss. 1987), Dr. Geier acknowledged the error of his testimony in the Graham case. These depositions can be found in Wyeth's Addendum of Exhibits, Volume I, 89-3066.

> And the reason I chose to identify this [a high endotoxin value] as probably the more likely value, the higher value, is because I had discussed with Dr. Geier what his analysis revealed. . . . I chose to take this value here [the higher endotoxin number] because he [Dr. Geier] had actually assayed [Wyeth's vaccine] which had 240 micrograms per mil[lilleter].

(Tr. 639). Dr. Zahalsky also identified himself as a "collaborator" with Dr. Geier on those experiments (Tr. 498) and at the Graham trial, Dr. Zahalsky substantiated the validity of his results by identifying them with the results of Dr. Geier's experiments. Thus, any error in Dr. Geier's experiments had to affect the testimony of any other expert who relied on Dr. Geier's results.

C.

After discovering that Dr. Geier's testimony in Graham had an erroneous basis, Wyeth filed its F.R.Civ.Pro. 60(b) motions in the district court, seeking post-trial relief from Graham's judgment based upon these errors in the testimony.

Federal Rule of Civil Procedure 60(b) provides for relief from judgments or orders. Subsection (b) specifies that such relief may be available where among other things:

> (2) Newly discovered evidence which by due diligence could not have been discovered in time to move for a new trial under rule 59(b); or

* * *

> (6) Any other reason justifying relief from the operation of the judgment.

The district court denied Wyeth's motions for post-judgment relief. We cannot agree with the district court's resolution of Wyeth's motions grounded on newly discovered evidence. Thus, we hold that the district court abused its discretion in refusing to grant Wyeth's rule 60(b) motions, to the extent that Wyeth predicated its motions on alleged newly discovered evidence.

D.

For newly discovered evidence to provide a basis for a new trial under Fed. R. Civ. Pro. 60(b)(2), Wyeth was required to satisfy five conditions:

Wyeth had to demonstrate that:

(1) the evidence was newly discovered since the trial;

(2) Wyeth was diligent in discovering the new evidence;

(3) the newly discovered evidence could not be merely cumulative or impeaching;

(4) the newly discovered evidence had to be material; and

(5) that a new trial, with the newly discovered evidence would probably produce a different result.

See Ag Pro, Inc. v. Sakraida, 512 F.2d 141, 143 (5th Cir. 1975), rev'd on other grounds, 425 U.S. 273 (1976).

In its July 19, 1988 disposition of Wyeth's 60(b) motion, the district court concluded that Wyeth had not met three of the five requirements for relief under 60(b). The district court found that Wyeth had not exercised diligence in obtaining the new evidence; that the evidence did not meet the test of materiality and that even with this new evidence, a new trial would probably not produce a different result.

In so holding, the district court did not dispute that the evidence was newly discovered, i.e., that Dr. Geier's miscalculations did not come to light until after the Graham trial had concluded.[26] Nor did it find that this new evidence of Dr. Geier's was cumulative or could be characterized as impeaching. We agree that these two prongs of the five-prong test have been satisfied. Indeed, as we discuss below, we are persuaded that all five requirements of 60(b) were met by Wyeth.

We reject Graham's and the district court's assertions that Wyeth's decision not to duplicate all of Dr. Geier's experiments was a form of "lack of diligence." Rule 60(b) does not set that high a standard. If such a standard was mandated, there would be few cases where a 60(b)(2) motion could be granted, inasmuch as the movant would have to demonstrate that it could not have independently confirmed the erroneous calculation of the results.[27] As Wyeth contends, "The change in Dr. Geier's endotoxin figure was produced by a change in the value of the Reference Standard used to calculate the endotoxin content of the

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26. See Rosebud Sioux Tribe v. A. & P. Steel, Inc. 733 F.2d 509 (8th Cir.), cert.denied, 469 U.S. 1072 (1982) (a witness' perjury in his deposition and at trial, [like Dr. Geier's miscalculation of the toxicity level of DTP] constituted newly discovered evidence.

27. The intent of the diligence requirement is to insure that litigants do not "hold back" evidence so as to be granted a new trial if the first trial is lost.

Wyeth DTP vaccine (Geier Deposition in Talley v. Wyeth, L86-4077 W.D. Ark. 1988, pp. 458, 463). Since the change in the Reference Standard was not made until after Dr. Geier testified at trial, Wyeth could only have discovered the evidence after trial." (Wyeth br. at 88-2302, p. 15).

So too, we reject Graham's assertion (Appellee's br. at 88-2302, p. 20 n.4) that because Dr. Geier already knew about the potential mistakes in his research at the time of his testimony in Graham's trial, it was Wyeth's lack of "diligence" that caused Wyeth to fail to discover that fact by asking Dr. Geier if he was mistaken! We must assume that Dr. Geier was unaware of the errors in his testimony at the time he testified. Moreover, the miscalculations made by Dr. Geier changed the entire complexion of the case. Had the Graham jury been alerted to the correct calculations of toxicity, it may well have taken a different view of the case.

The third prong of the test (that the evidence must not be merely cumulative or impeaching) appears to us, (as it must have appeared to the district court) to have been satisfied because of the gravity of Dr. Geier's error in miscalculating the toxicity of Wyeth's vaccine. We cannot help but observe that this error was testified to by Graham's most significant expert -- Dr. Geier -- who testified in support of her claim.

The fourth prong of the test (that the evidence must be material) was satisfied because Dr. Geier's testimony focused on one of the most significant aspects of Graham's claim -- the allegedly high endotoxin toxicity level of Wyeth's pertussis vaccine. Dr. Geier, as noted was Graham's key witness on this issue. Without evidence being adduced as to high endotoxin levels, the case might not have even reached the jury.[28] Additionally, a proper calculation of the endotoxin level by Graham's experts might have lead the district court, in either its summary judgment opinion or in its consideration of the motion to strike Wyeth's §402A comment (k) defense to "design defect" strict liability, to rule that Wyeth's vaccine was "unavoidably unsafe" and thus exempt from liability under §402A comment (k) from all but negligence claims. We hold that the district court's perception of this testimony as not being

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28. We are also persuaded that Dr. Zahalsky's testimony was gravely undercut by Dr. Geier's failure to analyze his data. Dr. Zahalsky himself has significantly recanted much of his testimony in Graham's case in other testimony given in other cases. Thus for example he seems to have lowered his estimate of the endotoxin level in Wyeth's vaccine from 353 micrograms per milliliter (Tr. 638-639), the amount he testified to in Graham's case to somewhere between 7.5 - 75 micrograms in other cases (Overlay v. Warner Lambert (IP83-1780-C) (S.D. Ind. 1986), and Knudsen v. Connaught Laboratories (85-703-CIV-J-16) (M.D. Fla. 1987). A twelve fold decrease in Dr. Geier's measurements would lead to a decrease in Dr. Zahalsky's measurements from 353 to 30 micrograms per milliliter. These depositions can be found in Wyeth's Addendum of Exhibits, I, 89-3066.

material was an improper exercise of the district court's discretion. Contrary to the district court's view, we cannot regard the evidence in question as less than material.

Finally we are left with the fifth prong of the Rule 60(b) calculus -- whether the new evidence would have probably lead to a different result at trial. This prong of the test is logically the one that requires the most deference to the district court -- that court which heard all of the evidence, which was present at trial to examine the demeanor and credibility of all of the witnesses, and which had its finger most closely on the pulse of the trial. As we stated in Kodekey Electronics, Inc. v. Mechanex, 486 F.2d 449, 458 (10th Cir. 1973):

> Such a determination [would the new evidence have lead to a new trial?] is not particularly favored by the courts, and rests largely and almost wholly within the sound judicial discretion of the trial court. Whether the newly discovered evidence would be likely to change the result of the district court's decision is one peculiarly within the determination of but one man -- the trial judge.

However, we have observed that where the subject of a district court ruling involved experimental evidence which should not have been allowed and which misled the jury, this court has reversed the district court notwithstanding the general deference which is normally accorded to a trial judge on these matters.

See Jackson v. Fletcher, 647 F.2d 1020, 1027 (10th Cir. 1981). We recognize that Jackson was decided on direct appeal and not on appeal from a post-trial 60(b) motion, as is the case here. Nevertheless and even though not directly on point in this appeal, we are enlightened by and subscribe to Judge Doyle's statement in Jackson that, "in many instances, a slight change in the conditions under which the experiment is made will so distort the result as to wholly destroy its value as evidence, and make it harmful, rather than helpful." (Emphasis added.) (quoting Navajo Freight Lines v. Mahaffy, 174 F.2d 305, 310 (10th Cir. 1949).) This precept is even more relevant in a case such as Graham's where the jury is less able to resolve technical and scientific facts by relying on its own common sense and experience.

The district court found no impropriety or unfairness in testimony of Drs. Geier and Zahalsky even when the deficiencies in their testimony were brought to his attention by Wyeth's 60(b) motions. We are hard pressed to understand that conclusion in light of the context in which their evidence was presented at trial. Elementary reasoning and our complete review of the trial record reveals that an accurate presentation of the endotoxin level in Wyeth's vaccine could not help but dilute the total impact of Graham's case. Moreover, Rule 60(b) is intended

"to prevent the judgment from becoming a vehicle of injustice," see United States v. Walus, 616 F.2d 283, 288 (7th Cir. 1980), and the Rule is to be construed liberally to do substantial justice.

It is true, we cannot say with certainty that at a new trial Graham may not again prevail, however with the significant modification in Dr. Geier's testimony which Wyeth has now discovered, it is probable that a different result in the verdict would occur. We are not required in this context to deal with "certainties" but only "probabilities." The test is whether the new evidence introduced would probably produce a new verdict. We are satisfied, after having examined in detail the arguments of both Graham and Wyeth in light of the entire record, that in this case, that probability exists.

Having concluded that the five requirements for relief from a judgment on the grounds of newly discovered evidence were satisfied by Wyeth when it discovered Dr. Geier's miscalculations as to the toxicity of Wyeth's vaccine, we hold that the district court should have exercised its discretion by vacating the Graham judgment and by granting Wyeth a new trial.[29] Because it did not do so, we will reverse the orders of the district court

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29. Having determined that Wyeth has satisfied the requirements of Rule 60(b)(2), we do not find it necessary to address Wyeth's claim for relief from judgment under Rule 60(b)(6).

denying Wyeth's post-trial relief. In doing so, we recognize that this holding with respect to Wyeth's 60(b) claims, accords with our holding with respect to trial errors, in that the dispositions of both appeals require a new trial. We assume that the miscalculations now disclosed in Dr. Geier's testimony will be corrected or addressed at a new trial if the same issues are presented.

VI.

We have held that trial errors and the discovery of new evidence by Wyeth compel a new trial to be held. We will, therefore, reverse the judgment in favor of Graham and remand to the district court for proceedings consistent with the foregoing opinion.