Revised April 30, 2002

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 01-30654

Thomas PIPITONE,
and Bonnie PIPITONE,

Plaintiffs-Appellants,

v.

BIOMATRIX, INC.,

Defendant-Appellee.

Appeal from the United States District Court
for the Eastern District of Louisiana

April 18, 2002

Before GARWOOD, JOLLY, and DAVIS, Circuit Judges.

W. EUGENE DAVIS, Circuit Judge:

Thomas Pipitone and his wife, Bonnie, brought suit against Biomatrix, Inc. ("Biomatrix"), alleging that a product that Biomatrix manufactures, known as Synvisc, caused Mr. Pipitone to develop a salmonella infection in his knee after a physician injected his knee with Synvisc. The district court excluded the testimony of the plaintiffs' experts, Doctors Millet and Coco, under the standard set forth in Daubert v. Merrell Dow

Pharmaceuticals, Inc.[1] The district court concluded that without the testimony of their two witnesses, the plaintiffs could not establish their case and granted summary judgment in favor of Biomatrix. Because we conclude that the district court abused its discretion in excluding the testimony of Dr. Coco, we reverse the district court's grant of summary judgment in favor of Biomatrix and remand the case to the district court.

I.

In June 1999, Thomas Pipitone sought treatment from his physician, Dr. Murray, for an ulcer that had developed on his toe. Because Pipitone was a 58 year-old, insulin-dependent diabetic, Dr. Murray hospitalized Pipitone and placed him on antibiotics as a precaution. Dr. Chad Millet, an orthopedic surgeon, examined Pipitone in the hospital and agreed with Dr. Murray's diagnosis and prescription of antibiotics. Dr. Millet continued treating Pipitone for the ulcer on his toe until September 1999, when Dr. Millet noted that the ulcer was healing.

In October 1999, Pipitone returned to Dr. Millet, this time complaining of severe osteoarthritic pain in his knees. Dr. Millet specializes in joints, especially hips and knees, for which he undertook an additional year of training at John Hopkins Hospital. Dr. Millet injected Pipitone's left knee with Cortisone in an attempt to alleviate the pain.

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[1] 509 U.S. 579 (1993).

In November 1999, Pipitone suffered a stroke. As a result, when Pipitone returned to Dr. Millet on January 11, 2000, still complaining of knee pain, he was no longer a candidate for knee replacement surgery. As an alternative to surgery, Dr. Millet suggested treatment with Synvisc.

Synvisc is a replacement synovial fluid manufactured by Biomatrix. Synvisc is made from rendered rooster combs, which are bathed in formaldehyde for a full day and then subjected to other chemical and detergent treatments. The product is put through a sterile filtration system and into syringes. Biomatrix packages Synvisc in boxes of three, factory-sealed syringes to be administered by injection directly into the knee once a week for three weeks. When injecting Synvisc, the doctor supplies only the needle.

The Food and Drug Administration ("FDA") granted Biomatrix's pre-market approval application in August of 1997, and classified Synvisc as a "Class III" device for purposes of the Medical Devices Act. Over four million syringes of Synvisc have been manufactured since 1998, but it is unclear from the summary judgment record how many have actually been consumed.

Pipitone decided to go forward with the Synvisc treatment. He filled the prescription for Synvisc at a Walgreen's pharmacy and returned to Dr. Millet's office on the morning of January 25, 2000, to receive the injection. Dr. Millet's nurse, who was not

scrubbed down, opened the Synvisc package and one of the shrink-wrapped syringes inside. She also opened the packaging for the needle and aspiration syringe, both of which Dr. Millet's office supplied. The nurse then attached the needle, still in its sterile sheath, to the empty aspiration syringe, and placed all of these items on an injection tray next to unsterile gauze.

Wearing unsterile gloves, Dr. Millet prepared Pipitone's knee with an antibiotic cleanser and then with alcohol. Following Biomatrix's instructions, Dr. Millet inserted the needle attached to the empty aspiration syringe into Pipitone's knee and withdrew a small amount of synovial fluid. He noted that the fluid was clear and normal in appearance and indicated no sign of infection. Dr. Millet then detached the fluid-filled aspiration syringe from the needle, which remained in place in Pipitone's knee, removed the rubber tip from the Synvisc syringe, and attached the Synvisc syringe to the needle. Dr. Millet then injected the Synvisc and removed the needle. He placed a bandage over the entry site, and Pipitone went home.

Later that evening, Pipitone began having severe pain in his knee. His wife took his temperature, which was 101 degrees, but they did not report these symptoms to a doctor at that time because they believed that they were attributable to the injection. As Pipitone's knee pain worsened, the Pipitones made several attempts to contact Dr. Millet's office and succeeded in

meeting him on the morning of January 27, two days after the injection. Dr. Millet aspirated some of the synovial fluid from Pipitone's knee and found that it was cloudy and turbid, indicating infection. Dr. Millet immediately hospitalized Pipitone and drained Pipitone's infected knee completely. The hospital laboratory tested the fluid from Pipitone's knee and discovered that the infection was salmonella, which is extremely rare in joints.

Because the culture showed such a rare infection, Dr. Millet asked Dr. Jeffrey Coco, a physician who limits his practice to infectious diseases, to examine Pipitone. When Dr. Coco evaluated Pipitone in the hospital, he found that Pipitone had no fever, chilled sweats, diarrhea, nausea, or vomiting. Dr. Coco also found that the ulcer on Pipitone's toe had scabbed over and was healing nicely. Dr. Coco ordered a second check of the synovial fluid from Pipitone's knee, but the laboratory had already rechecked the fluid due to the rarity of the result. The second test showed again that the infection was salmonella.

When Biomatrix was informed of Pipitone's infection, it tested the other two syringes in the Synvisc package that Pipitone purchased and found no evidence of salmonella. It also tested the twenty syringes held back from the production lot that had included the Synvisc sold to Pipitone and found no salmonella.

In April 2000, the plaintiffs filed suit against Biomatrix and Wyeth Laboratories[2] in Louisiana state court alleging causes of action arising under state tort, products liability, and redhibition laws. The defendants timely removed the suit to federal court.

In February 2001, the Pipitones filed a medical malpractice action against Dr. Millet. After taking Dr. Millet's and Dr. Coco's depositions, however, the plaintiffs were persuaded that fault must have been in Biomatrix's manufacture of the Synvisc. The plaintiffs then voluntarily dismissed their action against Dr. Millet.

In April 2001, the district court held a hearing to consider Biomatrix's motion for summary judgment. The court first granted defendant's motion in limine to exclude the testimony of Dr. Millet and Dr. Coco as unreliable under Daubert. The district court then held that the Medical Devices Act preempted most of plaintiffs' state law claims.[3] The only claims that survived preemption were the plaintiffs' claims for manufacturing defect

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[2] The plaintiffs voluntarily dismissed Wyeth Laboratories without prejudice on March 21, 2001.

[3] Specifically, the district court held that the MDA preempted plaintiffs' claims for design defect, inadequate warning, and nonconformity with express warning under the LPLA, and therefore, dismissed these claims with prejudice. The plaintiffs had already moved to voluntarily dismiss these claims without prejudice, however, and these issues are not before this court on appeal.

and redhibition.[4] After holding that redhibition claims are limited to economic loss only, the district court granted summary judgment to Biomatrix on both claims. The district court reasoned that without the testimony of Dr. Millet and Dr. Coco, the plaintiffs had not presented a genuine issue of material fact tending to show that the injection of Synvisc into plaintiff's knee caused his salmonella infection.[5] The Pipitones now appeal the district court's exclusion of the experts' testimony, grant of summary judgment, and holding that redhibition is limited to economic loss only.

II.

The plaintiffs first argue that the district court erred in excluding the testimony of Dr. Millet and Dr. Coco as unreliable under the standard set forth in Daubert v. Merrell Dow Pharmaceuticals, Inc.[6] We review the district court's determination of admissibility of expert evidence under

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[4] Neither party takes issue with this holding, and we do not consider it.

[5] Circumstantial evidence may be sufficient under the facts of a case to establish causation for purposes of liability under the LPLA. See Joseph v. Bohn Ford, Inc., 483 So. 2d 934, 940 (La. 1986). The plaintiff need not absolutely negate all other possible causes of the injury to meet his burden on causation, see Joseph, 483 So. 2d at 940; rather the plaintiff may prove causation by establishing "with reasonable certainty that all other alternatives are impossible." Todd v. State, 699 So. 2d 35, 43 (La. 1997) (emphasis added).

[6] 509 U.S. 579 (1993).

Daubert for abuse of discretion.[7]

A.

The Supreme Court's landmark case of Daubert v. Merrell Dow Pharmaceuticals, Inc.[8] provides the analytical framework for determining whether expert testimony is admissible under Rule 702 of the Federal Rules of Evidence.[9] Under Daubert, Rule 702 charges trial courts to act as "gate-keepers," making a "preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue."[10] In short, expert testimony is admissible only if it is both relevant and reliable.[11] This gate-keeping

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[7] See Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152 (1999); see also St. Martin v. Mobil Exploration & Producing U.S. Inc., 224 F.3d 402, 405 (5th Cir. 2000).

[8] 509 U.S. 579 (1993).

[9] 509 U.S. 579; see also Seatrax, Inc. v. Sonbeck Int'l, Inc., 200 F.3d 358, 371-72 (5th Cir. 2000).
Rule 702 of the Federal Rules of Evidence provides in full:

> 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, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

[10] Daubert, 509 U.S. at 592-93.

[11] Id. at 589.

obligation applies to all types of expert testimony, not just scientific testimony.[12]

Many factors bear on the inquiry into the reliability of scientific and other expert testimony.[13] In Daubert, the Supreme Court offered an illustrative, but not an exhaustive, list of factors that district courts may use in evaluating the reliability of expert testimony.[14] These factors include whether the expert's theory or technique: (1) can be or has been tested; (2) has been subjected to peer review and publication; (3) has a known or potential rate of error or standards controlling its operation; and (4) is generally accepted in the relevant scientific community.[15] In the later case of Kumho Tire Co. v. Carmichael,[16] the Supreme Court emphasized that the Daubert analysis is a "flexible" one, and that "the factors identified in Daubert may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony."[17] The district

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[12] Kumho Tire Co. v. Carmichael, 526 U.S. 137, 147 (1999).

[13] Daubert, 509 U.S. at 593; Skidmore v. Precision Printing and Packaging, Inc., 188 F.3d 606, 617 (5th Cir. 1999); Seatrax, 200 F.3d at 372.

[14] Daubert, 509 U.S. at 593.

[15] Id. at 593-94; see also Moore v. Ashland Chem., Inc., 151 F.3d 269, 275 (5th Cir. 1998) (en banc).

[16] 526 U.S. 137 (1999).

[17] Id. at 150.

court's responsibility is "to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field."[18]

With these guidelines in mind, we turn to the facts in the present case. We discuss the district court's exclusion of the testimony of plaintiffs' experts, Dr. Millet and Dr. Coco, in turn below.

B.

First, plaintiffs argue that the district court abused its discretion by excluding Dr. Millet's testimony that Synvisc caused the salmonella infection in Pipitone's knee. Plaintiffs' primary argument is that the district court erred in excluding the testimony as unreliable under Daubert. They point to the fact that Dr. Millet is an orthopedist who specializes in joints. He received one year of specialized training in joints at Johns Hopkins Hospital and has been performing knee injections for nearly twenty years.

Assuming, without deciding, that Dr. Millet's testimony is sufficiently reliable to meet the Daubert standard, however, we conclude that his testimony fails the relevancy prong of Daubert and was properly excluded. As discussed above, expert testimony

[18] Id. at 152.

is admissible under Daubert only if it is both relevant and reliable.[19] In Daubert, the Supreme Court stated that Rule 702 requires that expert testimony "assist the trier of fact to understand the evidence or to determine a fact in issue."[20] Thus, to be admissible under Daubert, Dr. Millet's testimony must not only be reliable, but also must be relevant to the issue of causation of the salmonella infection.

In his deposition testimony, Dr. Millet stated that it was as likely as not that the Synvisc syringe that he administered to Pipitone contained the salmonella bacteria that infected Pipitone's knee. He testified that he had no "scientific evidence" to support the conclusion that it was more likely than not that the infection occurred in this way. Dr. Millet then deferred to Dr. Coco for any other explanation of how the joint became infected.

Dr. Millet's testimony on causation is not helpful to the fact-finder because of his inability to conclude that it was more likely than not that the Synvisc caused the infection in Pipitone's knee. A perfectly equivocal opinion does not make any fact more or less probable and is irrelevant under the Federal Rules of Evidence.[21] Therefore, the district court did not abuse

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[19] Daubert, 509 U.S. at 589.

[20] Id. at 591.

[21] See Fed. R. Evid. 401 ("'Relevant evidence' means evidence having any tendency to make the existence of any fact that

its discretion in excluding Dr. Millet's testimony.[22]

C.

The plaintiffs next attack the district court's exclusion under Daubert of Dr. Coco's testimony that the Synvisc syringe caused the salmonella infection. The district court based its decision to exclude Dr. Coco's testimony on several factors. First, after discussing Dr. Coco's great expertise in the area of epidemiology and infectious diseases, the district court noted that Dr. Coco performed no epidemiological study in the instant case. The district court also found that Dr. Coco's literature search, which yielded no report of any salmonella infection arising from a contaminated injectable knee product of any kind, undermined Dr. Coco's hypothesis that Synvisc caused the salmonella infection in this case. Finally, the district court stated that Dr. Coco had failed to eliminate "many viable alternative sources" for the salmonella infection.

The four factors identified in Daubert form the starting point of the inquiry into the admissibility of expert testimony.[23] However, as the Supreme Court noted in Kumho Tire,

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is of consequence to the determination of the action more probable or less probable than it would be without the evidence.").

[22] Of course, this is not to say that Dr. Millet cannot testify as a lay witness to describe the administration of the injection, his sterilization procedures, or even his experience with Synvisc or other injectables. See Fed. R. Evid. 602.

[23] See Black v. Food Lion, Inc., 171 F.3d 308, 311 (5th Cir. 1999).

"the factors identified in Daubert may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony."[24] It is a fact-specific inquiry.[25]

First, Dr. Coco did not test his hypothesis that a Synvisc syringe that contains salmonella would cause a salmonella infection in a knee injected with the Synvisc. Neither side disputes, however, that if the Synvisc was in fact contaminated, Pipitone's knee would probably have been infected. Dr. Coco did not conduct an epidemiological study of Pipitone's infection. He explained, however, that such a study is not necessary or appropriate in a case such as this in which only one person is infected.

Dr. Coco did conduct a literature search and found no evidence of a salmonella infection arising from any injectable knee product, such as Cortisone, which has been injected into joints for years. Dr. Coco excluded Synvisc from his search. The district court found that excluding the defendant's product from the search discredited Dr. Coco's conclusion that the Synvisc was the source of the salmonella.

Dr. Coco decided to exclude Synvisc from his search of the relevant scientific literature primarily because Synvisc is the

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[24] Kumho Tire Co., 526 U.S. at 150.

[25] See Skidmore, 188 F.3d at 618; Seatrax, 200 F.3d at 372.

only knee injectable product made from chicken parts, a known source of salmonella. By excluding Synvisc, he sought to isolate the question he was researching--whether a salmonella infection had ever arisen from the injection process. Dr. Coco reasoned that if Pipitone's salmonella infection in this case was caused by unsterile injection technique or some other cause unrelated to Synvisc, one would reasonably expect to find other occurrences of salmonella infections arising from injections of any product into the knee.[26]

The lack of literature on injection-related salmonella infections of the joint does not undermine Dr. Coco's hypothesis. As the Supreme Court explained in Kumho Tire, "[i]t might not be surprising in a particular case, for example, that a claim made by a scientific witness has never been the subject of peer review, for the particular application at issue may never previously have interested any scientist."[27] Where, as here, there is no evidence that anyone has ever contracted a salmonella infection from an injection of any kind into the knee, it is difficult to see why a scientist would study this phenomenon. We conclude, therefore, that the lack of reports in the literature

[26] Neither party contends that Dr. Coco would have found reports in the scientific literature of a salmonella infection arising from a Synvisc injection. In fact, Nancy Larsen, Biomatrix's Vice-President of Biomaterials Research, states in her affidavit that Biomatrix has not received any other report of a salmonella infection related to Synvisc.

[27] Kumho Tire Co., 526 U.S. at 151.

that any knee injectable other than Synvisc has caused a salmonella infection, supports, rather than contradicts, Dr. Coco's conclusion that the infection did not arise due to unsterile technique or other source not related to Synvisc.

There is no known or potential rate of error or controlling standards associated with Dr. Coco's hypothesis. Again, however, this factor is not particularly relevant, where as here, the expert derives his testimony mainly from first-hand observations and professional experience in translating these observations into medical diagnoses.

The final consideration under Daubert is whether Dr. Coco's hypothesis is generally accepted in the relevant scientific community. Dr. Coco based his opinion on how Pipitone contracted salmonella in large part on accepted medical knowledge of the ways in which salmonella functions as an organism and how it infects humans. Dr. Coco's elimination of various alternative causes, as discussed more thoroughly below, such as infection through the gastro-intestinal ("GI") tract or the blood stream, were based on generally accepted diagnostic principles related to these conditions. Dr. Coco personally examined Pipitone in the hospital and found him to be lacking the symptoms that a physician would expect to find if salmonella had been introduced into the body through one of these alternative routes.

In a case such as this one, however, it is appropriate for

the trial court to consider factors other than those listed in Daubert to evaluate the reliability of the expert's testimony. In this case, the expert's testimony is based mainly on his personal observations, professional experience, education and training. The trial court, therefore, must probe into the reliability of these bases when determining whether the testimony should be admitted. The Advisory Committee notes to Rule 702 specifically contemplate this approach:

> Nothing in this amendment is intended to suggest that experience alone–or experience in conjunction with other knowledge, skill, training or education–may not provide sufficient foundation for expert testimony. To the contrary, the text of Rule 702 expressly contemplates that an expert may be qualified on the basis of experience.[28]

Likewise, in Kumho Tire, the Court explained that "no one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience."[29] Accordingly, this circuit has upheld the admission of expert testimony where it was based on the expert's specialized knowledge, training, experience, and first-hand observation while supported by solid evidence in the scientific community.[30]

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[28] Fed. R. Evid. 702 advisory committee's note.

[29] Kumho Tire Co., 526 U.S. at 156.

[30] See Skidmore, 188 F.3d at 618 (holding that the district court properly admitted testimony of a psychiatrist who diagnosed plaintiff because the psychiatrist "testified to his experience, to the criteria by which he diagnosed [the plaintiff], and to the standard methods of diagnosis in his field"); St. Martin v. Mobil Exploration & Producing U.S., Inc., 224 F.3d 402, 406-07 (5th Cir. 2000) (holding that ecologist's first-hand observation of flooded

As stated before, Biomatrix does not dispute Dr. Coco's opinion that the Synvisc syringe used by Pipitone, if contaminated with salmonella, would have caused his infection. Biomatrix takes issue only with Dr. Coco's finding that, in light of all of Dr. Coco's knowledge of and experience with salmonella and how people do and do not contract it, as well as his observation of Pipitone, the Synvisc syringe was the source of the contamination.

Dr. Coco specializes in infectious diseases. He is employed by three local hospitals in the area of hospital epidemiology and concentrates in this area as it relates to infectious diseases and the prevention thereof. He has been on the Specialty Board of Infectious Diseases and has written on the subject. For the last twelve years, Dr. Coco has been a Clinical Assistant Professor at Louisiana State University School of Medicine in the Department of Infectious Disease. Dr. Coco drew on this experience when he personally examined Pipitone in January 2000. Based on his experience as an infectious disease specialist and

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marsh at issue combined with his expertise in marshland ecology were sufficiently reliable bases of his opinion on causation under Daubert to admit the testimony). Compare with Moore v. Ashland Chem., Inc., 151 F.3d 269, 278 (5th Cir. 1998) (holding that the district court did not abuse its discretion in excluding expert testimony on the cause of plaintiff's "RADS" where there was no evidence that the chemical agent plaintiff was exposed to caused RADS); Black v. Food Lion, Inc., 171 F.3d 308, 312-13 (5th Cir. 1999) (holding that expert testimony should have been excluded under Daubert where, contrary to the expert's opinion, there was no solid medical evidence that trauma could cause fibromyalgia).

his personal observation of Pipitone and his symptoms, Dr. Coco concluded that the most likely cause of Pipitone's infection was the Synvisc that had been injected into his knee two days before. Specifically, Dr. Coco based this opinion on the timeliness of the infection (symptoms of which began to appear hours after the Synvisc injection), the source of the Synvisc, the type of organism (salmonella) that infected Pipitone, and the elimination of all other likely alternatives.

The district court grounded its decision to exclude Dr. Coco's testimony on causation largely because it found that Dr. Coco had identified "many viable alternative sources" of the salmonella infection in Pipitone's knee. After a careful review of the summary judgment record, we are satisfied that the record does not support this statement. Dr. Coco methodically eliminated the alternative sources of the infection as viable possibilities. After doing so, he stated that he was "99.9%" sure that the source of the salmonella was the Synvisc syringe.

One of the alternatives rejected by Dr. Coco was that Pipitone ingested salmonella, the bacteria infected his GI tract (a condition called gastroenteritis), translocated into his bloodstream (a condition called bacteremia), and traveled directly to his knee, causing the infection. Another alternative source was that the salmonella infected his scabbed-over toe, traveled in his bloodstream (also producing bacteremia), and

infected his knee. Dr. Coco rejected both of these alternatives, however, on the grounds that Pipitone showed none of the symptoms associated with either gastroenteritis or bacteremia when Dr. Coco examined him in the hospital. Dr. Coco testified that when he examined Pipitone, Pipitone "did not have diarrhea, nausea, or vomiting"--the symptoms of gastroenteritis. Dr. Coco also testified that Pipitone was not running a fever at the time of his entry into the hospital, nor did he have chills or severe inflammatory response associated with bacteremia.[31] Dr. Coco also noted that it is nearly impossible to contract salmonella through even an open traumatic wound, much less the scabbed-over surface of Pipitone's toe. Based on the lack of these symptoms and his specialized knowledge and experience, Dr. Coco ruled out these alternatives.

Another possible cause of the salmonella infection that Dr. Coco rejected as a viable alternative was Dr. Millet's technique in administering the injection. Dr. Coco interviewed Dr. Millet about the technique he used in giving Pipitone the Synvisc injection. Dr. Coco testified that the alcohol and the antibiotic cleanser that Dr. Millet used to clean Pipitone's knee before the injection would have killed any salmonella on the

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[31] Dr. Coco also made clear that the fact that Pipitone was diabetic and that he was on Zantac only affected his likelihood of contracting gastroenteritis, not a salmonella infection in any other way. These facts made Pipitone no more predisposed to bacteremia, for example.

skin. Dr. Coco further testified that he learned from Dr. Millet that the injection needle was in a protective sheath until Dr. Millet injected Pipitone. Even if the needle had been removed from the sheath some time before the injection, however, Dr. Coco stated that salmonella does not exist in sufficient quantities on the hands to contaminate an injection needle nor does it exist in saliva in an individual's mouth. Dr. Coco testified that if unsterile injection technique could cause salmonella infection in a joint, he would have expected to have found reports of such an occurrence in the literature, regardless of the drug being injected. Yet, Dr. Coco's research revealed no evidence of any injectable causing a salmonella infection in a knee. Given all of this information, Dr. Coco concluded that the content of the Synvisc syringe injected into Pipitone was the most likely source of the salmonella that infected his knee.[32]

Finally, Biomatrix argues that Dr. Coco's unfamiliarity with the Synvisc manufacturing process and his "inability" to explain the lack of salmonella in the other Synvisc syringes held back

[32] Dr. Coco rejected a number of other alternatives which we do not discuss in depth here. For example, he stated that it was extremely unlikely that salmonella could have entered Pipitone's knee through the needle tract, which was open momentarily when the aspiration syringe was replaced with the Synvisc syringe. He testified that he had never seen any report in the medical literature of a salmonella infection occurring in this way. Moreover, Dr. Coco stated that this alternative is subject to the same question presented above; that is, if this was likely, one would expect there to be some evidence of a salmonella infection occurring in this manner in the past with the injection of any type of joint injectable.

from Pipitone's production lot renders his testimony "unreliable" under Daubert. We disagree with Biomatrix's characterization of Dr. Coco's deposition testimony. Dr. Coco stated that while he would have expected other samples of Synvisc in the same manufacturing lot to be contaminated, the absence of salmonella in those few other samples tested did not undermine his conclusion. Dr. Coco explained that only a small number of Salmonella organisms would be required to infect a joint that was directly exposed to the organism. He also stated that in his epidemiological experience, a batch that produces a contaminated sample may contain no other contaminated samples.[33] Therefore,

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[33] Dr. Coco based this conclusion on basic epidemiologic principles and his experience as an epidemiologist for three hospitals, where he has studied incidents of contamination related to various batched medicines. Specifically, Dr. Coco testified:

> Q: I guess in order to understand the contamination of the injection, is it in your experience then that if one injection is contaminated, others would be as well?
>
> A: No, it doesn't have to be.
>
> Q: What's your experience?
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> A: The experience is, generally, if a specific product is batched, the entire batch is suspect. But in epidemiologic surveys, batches of product, generally, not all of them are contaminated. Only a small percent of them. No one understands why this occurs. But, for instance, you can have 10,000 recalled of a certain thing and only a few be actually contaminated.
>
> Q: When you say a few, would you expect more than one in a batch?
>
> A: It could be–it could be between one and all of them. It does not have to be all of them. It doesn't have to be

we disagree with the defendant's contention that this testimony renders Dr. Coco's testimony unreliable under Daubert.

Based on the summary judgment record in this case, we believe that the answer to the critical causation question will depend on which set of predicate facts the fact-finder believes: the plaintiffs' contention that the content of the Synvisc syringe administered to Pipitone was contaminated or the defendant's that it was not. The Advisory Committee notes to Rule 702 speak to the precise problem in today's case:

> When facts are in dispute, experts sometimes reach different conclusions based on competing versions of the facts. The emphasis in the amendment on "sufficient facts or data" is not intended to authorize a trial court to exclude an expert's testimony on the ground that the court believes one version of the facts and not the other.[34]

It bears reminding that "the trial court's role as gatekeeper [under Daubert] is not intended to serve as a replacement for the adversary system."[35] Rather, as Daubert makes clear, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but

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more than one.

(R. at 797-98).

[34] Fed. R. Evid. 702 advisory committee's note.

[35] Fed. R. Evid. 702 advisory committee's note, citing United States v. 14.38 Acres of Land Situated in Leflore County, Mississippi, 80 F.3d 1074, 1078 (5th Cir. 1996).

admissible evidence."[36] Thus, while exercising its role as a gate-keeper, a trial court must take care not to transform a Daubert hearing into a trial on the merits. In this case, we conclude that the standard of reliability that the district court applied to Dr. Coco's testimony was overly stringent. The fact-finder is entitled to hear Dr. Coco's testimony and decide whether it should accept or reject that testimony after considering all factors that weigh on credibility, including whether the predicate facts on which Dr. Coco relied are accurate.

III.

Biomatrix next argues that even if Dr. Coco's testimony is admissible, summary judgment for Biomatrix was still appropriate because the plaintiffs produced no significant evidence that Biomatrix deviated from its FDA-approved manufacturing procedures. The district court apparently agreed.

The parties agree that the mantle of FDA approval protects the manufacturer from liability arising from defective design of the product–not defective manufacture or construction. The only issue we must decide, therefore, is whether plaintiffs have presented a genuine issue of material fact as to whether Biomatrix deviated from its FDA-approved procedures in manufacturing the Synvisc at issue in this case.

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[36] Daubert, 509 U.S. at 596.

According to the affidavit of Nancy Larsen, Vice President of Biomaterials Research at Biomatrix, "[t]he salmonella organism simply cannot survive the rigorous sterilization, environmental control, cleaning and testing procedures attendant to the manufacture of Synvisc." It follows that if the content of Synvisc syringe with which Pipitone was injected was in fact infected with salmonella, a fact-finder could find that Biomatrix deviated from its prescribed procedures. We conclude, therefore, that a genuine issue of material fact exists as to whether Biomatrix deviated from its FDA-approved procedures in manufacturing the Synvisc syringe at issue. Therefore, we reverse the district court's grant of summary judgment in favor of Biomatrix on plaintiffs' defective construction and redhibition claims.

IV.

Finally, the plaintiffs argue that the district court incorrectly held that their redhibition claim was limited to economic loss only. Specifically, plaintiffs argue that the re-enactment of the title of the Louisiana Civil Code containing the redhibition articles impliedly repealed portions of the Louisiana Products Liability Act ("LPLA") that had been interpreted to restrict redhibition to recovery of economic loss only. In light of our conclusion that the plaintiffs' redhibition claim survives summary judgment, we must now address this issue. We review this

question of law de novo.[37]

Article 2520 of the Louisiana Civil Code provides a cause of action against manufacturers for breach of "warranty against redhibitory defects."[38] The Code defines "redhibitory defects" as those defects that "render[] the thing useless, or its use so inconvenient that it must be presumed that a buyer would not have bought the thing had he known of the defect."[39] The remedy for such a breach of warranty is recission of the contract.[40] If the seller knew of the defect, he could also be liable for damages and attorney's fees.[41] If the seller is also the manufacturer of the product, the seller is conclusively presumed to know of the defect.[42]

The LPLA, enacted in 1988, provides that it "establishes the exclusive theories of liability for manufacturers for damages caused by their products."[43] The statute defines "damage" by explicitly excluding amounts recoverable under redhibition for

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[37] See Waco Intern., Inc. v. KHK Scaffolding Houston Inc., 278 F.3d. 523, 528 (5th Cir. 2002).

[38] La. Civ. Code art. 2520 (West 2001).

[39] Id.

[40] Id.

[41] La. Civ. Code art. 2545 (West 2001).

[42] See, eg., Dickerson v. Begnaud Motors, Inc., 446 So. 2d 536, 540 (La. Ct. App. 1984).

[43] La. Rev. Stat. Art. 9:2800.52 (West 2001).

damage to the product and other economic loss.[44] Courts have interpreted the LPLA as preserving redhibition as a cause of action only to the extent the claimant seeks to recover the value of the product or other economic loss.[45]

In 1993, the Louisiana legislature reenacted the entire title of the Louisiana Civil Code which includes the redhibition provisions. Plaintiffs argue that this re-enactment impliedly repealed the provisions of the LPLA to the contrary and resurrected redhibition as a full alternative theory of liability against a manufacturer.

We are not persuaded. Under Louisiana law, there is a strong presumption against implied repeals.[46] Moreover, laws on the same subject must be interpreted in reference to each other.[47] The 1993 re-enactment of the redhibition articles did nothing to change the LPLA's definition of "damage." Continuing to read the redhibition articles in product liability cases as limited to providing a remedy to recover economic loss harmonizes the two statutes. We hold, therefore, that the district court

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[44] See La. Rev. Stat. 9:2800.53(5) (West 2001).

[45] See, eg., Greiner v. Medical Eng'g. Corp., 243 F.3d 200, 206 n.5 (5th Cir. 2001); Monk v. Scott Truck & Tractor, 619 So. 2d 890, 893 (La. Ct. App. 1993).

[46] See State v. Piazza, 596 So. 2d 817, 819 (La. 1992); Standard Supply & Hardware Co. v. Humphrey Bros., 26 So. 2d 8, 10 (La. 1946).

[47] See La. Civ. Code art. 13 (West 2001).

correctly held that the plaintiffs' redhibition claims are limited to recovery of economic loss only.

V.

In conclusion, we hold that the district court properly excluded the expert testimony of Dr. Millet. However, we conclude that the district court abused its discretion by excluding Dr. Coco's testimony under the standards set forth in Daubert. Having concluded that Dr. Coco's testimony is admissible, it follows that summary judgment for Biomatrix on either plaintiffs' defective construction or redhibition claim is inappropriate. We also conclude that a genuine issue of material fact exists as to whether Biomatrix deviated from its FDA-approved procedures in manufacturing the Synvisc syringe at issue in this case. Finally, we are persuaded that the district court properly limited the scope of plaintiffs' redhibition claims to economic loss only.

We therefore reverse the judgment of the district court and remand the case to that court for further proceedings consistent with this opinion.

REVERSED AND REMANDED.