IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCTS LIABILITY LITIGATION

MDL NO. 1968

THIS DOCUMENT RELATES TO ALL CASES

PRETRIAL ORDER #87
(Memorandum Opinion and Order re Dispositive and *Daubert* Motions)

Pending are the **(1)** Actavis defendants' Motion for Summary Judgment [Docket 523], their Motion to Exclude Plaintiffs' General Liability Experts [Docket 525], their Motion to Exclude Unreliable Hearsay [Docket 527], their Motion to Strike the Affidavit of Lynne Farrell [Docket 572], their Motion to Strike Plaintiffs' Exhibit 620, which is the declaration of David M. Bliesner, Ph.D. [Docket 579], and the Mylan defendants' Motion for Summary Judgment and to Exclude Expert Testimony [Docket 528], all of which are filed in 2:08-md-1968; **(2)** the defendants' Motions for Summary Judgment and to Strike Plaintiffs' Exhibit 621, which is the declaration of Reynolds Delgado III, M.D., both of which are filed in the *Vega* case [Docket 55 and 68 in 2:09-cv-00768], and **(3)** the defendants' Motions to Exclude the Decedent's Postmortem Blood Digoxin Concentration and the Expert Testimony of Richard Mason, M.D., and Keith Gibson, and for Summary Judgment [Docket 120], their Motion to Strike the Affidavit of Lynne Farrell [Docket 144], and their additional request to Strike Plaintiffs' Exhibit 620, the declaration of Dr. Bliesner [Docket145], all of which are filed in the *McCornack* action, 2:09-cv-00671.

I do not reach the defendants' MDL motions for summary judgment [Docket 523 and 528] or their motion to exclude plaintiffs' general liability experts [Docket 525]. I **GRANT** the other motions.

I.

This case is about a pharmaceutical manufacturing plant that experienced quality control problems. A few of the problems at the plant over a two-decade period had to do with a brand of digoxin called Digitek®. A recall of that drug occurred in 2008. It was trumpeted as a public-safety success story by the Food and Drug Administration ("FDA").

The trouble started with a plant worker who spotted a couple of double-thick Digitek® pills. A massive visual search of the entire batch ensued by those experienced in making the drug. Eighteen more tablets were found. The total of 20 tablets never made it to market of course. The recall was an understandable precaution by the FDA. The 20 pills represented about 0.0004 percent of the entire batch that the workers visually inspected.

Mass litigation followed. Thousands of plaintiffs alleged that double-thick tablets hit the market and injured consumers. Not one of them produced a double-thick tablet. The cases have essentially now settled or have been dismissed but two individual actions remain. There has been no evidence that either of the decedents in those two cases, or their loved ones, ever saw a double-thick Digitek®. That is true as well of their pharmacists, nurses, and doctors. Some of the plaintiffs still have many untested pills in their possession. The ones they have had tested were fine.

The decedents had serious medical problems of their own. They were also taking other drugs known to interact with digoxin and make its blood levels spike. Digoxin itself is tricky to manage even without other drugs in the mix. Taking too little has no effect. Taking too much can kill you. There is a narrow therapeutic range that provides relief. Keeping the drug in the helpful range proves tough at times and people die as a result.

The defendants say the plaintiffs have failed to prove, as a matter of law, that a defective product caused their family members to die. The plaintiffs' theory comes down to an attempt to use

speculation about a defect to prove causation and speculation about causation to prove a defect. I **GRANT** summary judgment.

II.

A. Background Common to All Cases in the MDL[1]

Digitek® is a tablet brand name that includes an active pharmaceutical ingredient ("a.p.i.") called digoxin. Digoxin is a plant-based pharmaceutical. It has been used for hundreds of years. Doctors often prescribe it to treat two diseases, (1) an arrhythmia called atrial fibrillation, and (2) congestive heart failure. The rub is that it has a narrow therapeutic window. That means there is a fine line between therapy and toxicity. There are a variety of reasons why a person taking digoxin might have elevated digoxin blood levels or digoxin toxicity symptoms. One is a too-high dose of digoxin. Other reasons are (1) drug interactions, (2) reduced elimination, and (3) increased sensitivity. So even at the right dosage digoxin has serious risks.

Digitek® was first sold in the early 1990s by Amide Pharmaceuticals. Amide produced Digitek® until 2005. Actavis Totowa ("Actavis") acquired Amide at that time and took over production. Actavis continued production until April 2008. All Digitek® manufactured by Amide and Actavis after 1999 was sold to Mylan. Mylan either distributed it or sold it to its subsidiary, UDL Labs, for distribution.

In the spring of 2008, the FDA inspected Actavis in advance of the company transferring certain functions from one facility (Little Falls, NJ) to another (Riverview, NJ). The agency looked at a number of production aspects. One focus was an Actavis report about a manufacturing defect

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[1]Much of the factual history is taken from an undisputed background statement submitted by the defendants [Docket 522].

investigation it performed on Digitek® batch 70924A. Batch 70924A was made between November 17 and 20, 2007. The investigation led to the recall of all Digitek® lots produced.

On November 30, 2007, batch 70924A was being packaged. A line operator found two thick tablets. The operators promptly shut down the line. They then visually inspected several buckets of tablets. They found one additional oversized tablet. They resumed packaging at that point. They later found two more double-thick tablets. Actavis's Quality Assurance and Manufacturing departments met. They placed the batch on hold pending a more thorough investigation.

Between January 15 and 18, 2008, Actavis unpackaged batch 70924A. Employees visually inspected the tablets. Fifteen more double-thick tablets were found, resulting in a total of 20. The entire batch was just under 4.8 million tablets. On January 22, 2008, Actavis conducted an additional, tightened sampling inspection. It randomly tested 40 tablets from each of 33 full buckets and 10 from a partial 34th bucket. No further double-thick tablets were found. The batch was repackaged and released for distribution on January 28, 2008. It was sent to Mylan a short time later.

When the FDA learned about the difficulty with batch 70924A, it suggested a recall. It was first said that only batch 70924A should be taken back. On April 24, 2008, however, Actavis and the FDA agreed to recall all Digitek® batches then on the market and within expiration dates. That amounted to 171 batches,[2] or 680 million tablets manufactured since early 2006.

An FDA-approved, April 25, 2008, Digitek® recall press release said that "[t]he voluntary all lot recall is due to the possibility that tablets with double the appropriate thickness may have been commercially released." Pharmacy customers received the same notice. The FDA-approved recall package said: "Digoxin tablets exceeded tablet thickness specifications." The focus was thus on the

[2]Of the 171 batches, 152 had actually been distributed beyond Mylan or UDL to pharmacies.

possibility that double-thick tablets were released. The FDA confirmed as much. In 2009, it weighed in on the threat posed by the event:

> In March 2008, FDA performed a scheduled inspection of the Actavis production facility and identified products that were not manufactured to required specification over a period of time extending back to the year 2006. Included in this list of products was one particular lot of Digitek. Actavis detected a very small number of oversized tablets in this lot (specifically, 20 double-sized tablets in a sample of approximately 4.8 million tablets).
>
> Although Actavis attempted to remove the affected Digitek tablets through visual inspection, FDA determined that this method of removal was inadequate to assure the product's quality and consistency in accordance with current Good Manufacturing Practice (cGMP) regulations.[3]
>
> Since the detection of the manufacturing problem, FDA has been actively engaged with this company to ensure that **ALL** potentially affected lots of Digitek tablets have been recalled. *In our best judgment, given the very small number of defective tablets that may have reached the market and the lack of reported adverse events before the recall, harm to patients is very unlikely.*

U.S. Food and Drug Administration, *Facts and Myths About Generic Drugs*, *available at* http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm (emphasis added).[4]

Different types of defects can occur during the tableting process. One is oversized pills. Another is a normal size tablet with too much a.p.i. The two defects are very different. The plaintiffs have focused until recently on the former.[5] Years after the recall, however, and following

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[3]The term "cGMP" refers to "current good manufacturing practices." It is the mandatory standard of compliance set by the FDA for pharmaceutical manufacturing. *See* 21 U.S.C. § 351(a)(2)(B). The regulations help guarantee that the drug in the bottle matches what is on the label.

[4]Defendants have requested that the court take judicial notice of the FDA's statement. Since it satisfies *Federal Rule of Evidence* 201(b)(2), I grant the defendants' request.

[5]During a September 14, 2011, hearing, the *McCornack* plaintiffs' lawyer described Digitek® as "defective in a very unusual manner and methodology . . . double strength, or well above strength, and some were below strength."

a large amount of discovery, neither the Plaintiffs' Steering Committee nor any individual plaintiff's counsel has ever identified a single defective Digitek® tablet in their clients' hands.

Every aspect of the Digitek® manufacturing process was approved by the FDA as part of the Abbreviated New Drug Application ("ANDA") process on December 23, 1999. The ANDA must be supported by a showing of proper equipment and methods to consistently make the drug within specification. Every manufacturing aspect, including the equipment and processes, must be "validated" by the company and approved by the FDA.[6] That occurred with Digitek® and a report was submitted to the FDA in December 1994. Process validations occurred multiple times after 1994 when the company increased batch sizes. The processes need not be revalidated. They remained validated through 2008. The FDA never cited nor warned Actavis about validation issues.

Companies like Actavis weigh, count, and/or test their product at every stage of the manufacturing process. They maintain extensive "batch" records for each step to ensure in-specification production and control over the validated process. An FDA-approved specification, formula, or regulation governs every step of the manufacturing process. This includes (1) the formula (weighing and measuring raw materials); (2) blending (process, equipment, quality-control measures and testing of samples to assure blend uniformity); (3) tableting (process, equipment, and quality-control measures for inspection of tablets for thickness, weight, appearance and hardness and weighing and counting of final product to reconcile with amount of raw ingredient used); (4) packaging (equipment and process of packaging operation); and (5) affirmative product testing (chemical testing of finished tablets to ensure specifications on a.p.i. ("assay") and content uniformity or consistency in dose from tablet to tablet).

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[6]Process validation involves repeated manufacturing and dose testing. It assures every step of the process works, and repeats, correctly to assure a product consistently produced according to FDA-approved specifications.

Thick tablets can be detected at a number of these steps along the way. They are also detectable post-production during distributor repackaging, FDA inspections, or by pharmacists, consumers, or their lawyers. None occurred in connection with recalled Digitek®. There were also no outbreaks of toxicity in the United States or increased adverse event reporting to the FDA.

The defendants point to two sets of direct evidence supporting consistent production of correct tablets -- company records and third-party testing records. The defendants say these show that the FDA-approved manufacturing processes worked as planned. They note detailed production records for each of the 152 distributed and recalled batches.

The FDA's "batch certification" program in the 1990s provided for pre-release analysis of pharmaceutical batches by the FDA. In June 1995, the FDA certified nine Amide-manufactured Digitek® batches. Amide's compliance led the FDA in July 1995 to exempt Digitek® from further batch certification requirements. Then, between 2002 and 2008, the FDA collected at least 11 other samples under a special surveillance program for drugs with a narrow therapeutic window. There were four samples in 2002, two in 2007, and five in 2008. Using United States Pharmacopeia ("USP") test methods, the FDA subjected each sample to assay, content uniformity, and dissolution testing. All tested within specification. Seven of the samples came from the 152 recalled batches. No one has ever disputed these results.

Mylan sold to UDL a portion of the Digitek® it bought from Actavis. UDL received the tablets in bulk bottles and repackaged them into blister packs. It is undisputed that a double-thick tablet would not have fit into a UDL blister pack. The packs are designed to hold tablets that are at most up to 110 percent of Actavis's maximum tablet thickness. The defendants say two things would happen with tablets over that threshold: (1) the blister pack cavity would be damaged, and (2)

the packaging equipment would shut down. UDL also did random thickness tests for each Digitek® batch it received. It never found any tablets that were too thick or thin.

UDL had 34 Digitek® batches tested by independent laboratories. The results corroborated Actavis's own testing and within-specification results. Eleven of the 34 batches were part of the recall. Nineteen of the recalled batches were also scrutinized by an FDA-approved auditor. The results reflected that manufacturing and laboratory records reliably confirmed the identity, strength, quality and purity of Actavis's products, including Digitek®. None of the PSC experts dispute the results of any of this independent testing or review.

The plaintiffs examined Actavis's relationship with the FDA and produced documents alleging a history of regulatory violations. The plaintiffs argue that these documents are circumstantial evidence of the production of defective Digitek®. A basic understanding of how the FDA regulates drug manufacturing is essential to the concepts of "defective" and "adulterated."

The primary mechanism through which the FDA regulates the drug manufacturing process is set forth in 21 C.F.R. §§ 210 and 211. These are the cGMP regulations applied to pharmaceuticals. The cGMP regulations list many requirements. They regulate everything from employee qualifications and labeling to lab testing prior to distribution.[7] These and other FDA-enforced preventative regulations are policed through regulatory action and not lawsuits.

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[7]One court explained the cGMP provisions as "prophylactic measures" designed to "prevent the distribution of poorly manufactured drugs and devices 'by giving the Food and Drug Administration . . . additional authority to require that sound methods, facilities, and controls be used in all phases of drug manufacturing and distribution.'" *United States v. 789 Cases, More or Less, of Latex Surgeons' Gloves*, 799 F. Supp. 1275, 1285 (D.P.R. 1992). Put another way, "the [c]GMP regulations are intended to be preventative." *Id.*

When a manufacturing process falls short of a cGMP requirement, the product is referred to as "adulterated." This term has a specific meaning:

> A drug or device shall be deemed to be adulterated . . . if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter . . . .

21 U.S.C. § 351(a)(2)(B). If a drug is "adulterated" it may still be safe for consumption and as represented on the label. The question is only whether the manufacturing process satisfied the FDA's regulations. A drug will be rendered "adulterated" if any aspect of the manufacturing process did not fully comply with any cGMP. That could be something as mundane as inadequate lighting or the lack of hot and cold running water in the building. The FDA's website says this:

> If a company is not complying with cGMP regulations, any drug it makes is considered "adulterated" under the law. This kind of adulteration means that the drug was not manufactured under conditions that comply with cGMP. *It does not mean that there is necessarily something wrong with the drug.* . . . .The impact of cGMP violations depends on the nature of those violations and on the specific drugs involved. A drug manufactured in violation of cGMP may still meet its labeled specifications, and *the risk that the drug is unsafe or ineffective could be minimal.*

(Def. Ex. 55) (emphasis added).[8]

So while "defect" may also mean "adulteration," the converse is not necessarily true. For example, a pharmaceutically perfect drug could be manufactured, sealed, and packaged, and yet still be rendered "adulterated" because the label on the drug is upside-down.

The plaintiffs have consistently relied on documents alleging Actavis produced "adulterated" Digitek®. They cite inspection reports and letters issued by the FDA. They have not disputed the defendants' explanation of the various regulatory forms which include:

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[8]The defendants request that the court take judicial notice of this FDA statement. I grant the request pursuant to *Federal Rule of Evidence* 201(b)(2).

Establishment Inspection Reports - This is a narrative report stating what occurred and what was undertaken during an FDA inspection. It is the inspector's observations in terms of compliance with cGMPs. These are not typically made available to the manufacturer and are not used as notification of conditions the investigator believes reflect a cGMP deficiency.

Form 483s - This is the first formal notice received by a manufacturer for alleged cGMP deficiencies. It is the investigator's opinion and not an official FDA position. It begins the dialog between the manufacturer and the FDA about ways to correct process problems.

Warning Letters - This communicates the FDA's position on alleged cGMP violations. It is an informal and advisory method that does not commit the FDA to taking enforcement action. They are for violations of regulatory significance but do not constitute final agency action.

Of the documents that the plaintiffs believe are relevant to key regulatory issues in this case, only three contain a reference to Digitek®. They involved adverse event reporting issues occurring in 2003 or earlier, cleaning validation issues in August 2006 and February 2007 (which were corrected to FDA's satisfaction), and an issue in 2008 with the way a manufacturing investigation was conducted when Actavis encountered blend uniformity test issues. The 2008 issue related to the technical aspects of investigating out-of-specification core samples and did not relate to true blend failures. The only Digitek®-specific issue related to the FDA criticism of Actavis's decision not to reject batch 70924A, which led to the recall.

The plaintiffs' experts' opinions rely on the one and only verified instance of an extra thick Digitek® tablet making it to market in 2004. A pharmacist found and returned the tablet to Actavis. A manufacturing investigation was conducted and the situation was reported to the FDA. After reviewing the investigation, the FDA said:

> No additional complaints or reports of thick tablets have been received for this high volume product. The event was considered an isolated incident and corrective actions were put in place to prevent its reoccurrence. Corrective actions (procedural enhancements and review of complaint files) were verified during the inspection.

(Def. Ex.71 at 6).

This is the only verified report of a thick tablet leaving Actavis's facilities. The tablet was made in 2003. All recalled Digitek® was produced in 2006 or later. Since 2003, over one billion Digitek® tablets have been made and distributed to the marketplace. This single 2003-produced tablet is the only Digitek® tablet in the marketplace found and confirmed to be out of specification.

On September 1, 2010, Lead Counsel in the Digitek® MDL executed a Settlement Agreement. It established a program designed to resolve the cases in the MDL[9] through a claims process and a settlement fund. The appointed special master's decisions in the claims process are generally final and nonappealable. The matter of attorney fees for the MDL lawyers has been resolved by settlement as well, and the claims process is winding down.

At its peak there were 1,053 civil actions in the MDL. All but two actions have either been dismissed or, having not opted out, are subject to the terms of the settlement program. The two remaining individual cases opted out of the settlement program and are now before me to address the defendants' motions for summary judgment and related pretrial requests. The first is *McCornack v. Actavis Totowa, LLC*, No. 2:09-0671. The second is *Vega v. Actavis Group hf*, No. 2:09-0768.

B. Background of the *McCornack* Individual Case

Daniel McCornack, Sr., had a long history of atrial fibrillation. He was also overweight and mildly hypertense. His renal function was fine. His atrial fibrillation primarily caused discomfort. It caused some negative impact as well when he strenuously exerted himself. He had taken digoxin in conjunction with diltiazam for more than a decade without incident. His regularly tested digoxin levels never exceeded the therapeutic range. His cardiologist, Dr. Lawrence E. VonDollen, treated

[9]Over 2,100 tolled claims and state cases were also included in the Settlement Agreement.

him for more than a decade. Dr. Gordon Lemm was Mr. McCornack's treating physician for 14 years. He co-managed Mr. McCornack's treatment with Dr. VonDollen. Mr. McCornack's family and doctors say he followed his medication regimen.

Mr. McCornack's family says that early on March 22, 2008, the family packed and left for a week long camping trip with extended family and friends. Mr. McCornack packed his own clothes and personal items. He also packed his medications in a pill organizer. They arrived at the campsite in early afternoon. Mr. McCornack spent the remainder of the day setting up camp, doing activities with his children, and eating dinner. He drank between one and six cans of beer. At some point he told his wife he was tired.[10] After dinner he said he was bloated. He had taken his medications (including Digitek®) before leaving home that morning and at dinner time between 6:00 to 8:00 p.m.

Just after midnight on March 23, 2008, Mr. McCornack made an odd noise while sleeping. It woke his wife. She found him blue and non-responsive. Family members performed CPR. A sheriff's deputy and paramedics arrived later. They were unable to resuscitate him. He was pronounced dead at 12:52 a.m. Three days later, on March 26, 2008, Santa Cruz County Coroner Dr. Richard T. Mason performed an autopsy. The examination came 78 to 79 hours after the death. Dr. Mason followed his normal procedures, conducting a physical examination, collecting blood and tissue samples, and dictating his initial report. On April 7, 2008, he issued a death certificate. The cause of death was listed as cardiac arrest due to ventricular arrhythmia, atrial fibrillation, hypertensive and arteriosclerotic cardiovascular disease with contributory exogenous obesity. Dr. Mason had originally ordered a standard therapeutic and abused drug blood screen which did not include digoxin. The results were returned on April 16, 2008.

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[10]Mrs. McCornack verified references in the medical record over a long period of years of Mr. McCornack feeling tired.

The sample that Dr. Mason drew from Mr. McCornack was taken from a non-ligated axillary vein. The causes of death first identified by Dr. Mason were all plausible based upon his health and sudden death. (Dep. of Richard T. Mason, M.D. at 63 ("If you don't find anything better, then you use those. That's the way it works.")). Neither Mr. McCornack's primary care physician nor his cardiologist learned of any signs of digoxin toxicity shown by him at or near his death. (Dep. of Gordon Lemm, M.D. at 68 (agreeing with counsel that Mrs. McCornack "did not describe to . . . [him] something about . . . [Mr. McCornack's] course that day or night that made . . . [him] suspect digoxin toxicity"); (Dep. of Lawrence Von Dollen, M.D. at 68 ("Sounded like a usual day.")).

On April 25, 2008, the Digitek® recall occurred. On May 21, 2008, Dr. Mason ordered additional digoxin tests. He chose NMS Laboratories ("NMS") to do the follow-up. He sent the sample to NMS for a reason: "This laboratory has a pretty heavyweight reputation and they are noted to do good work in forensic analysis." (Dep. of Dr. Mason at 28). NMS' lab report was signed by Dr. Edward J. Barbieri, another expert for the plaintiffs who is a forensic toxicologist with a degree in pharmacology. The NMS report says that Mr. McCornack's blood contained two drugs, diltiazem and digoxin. The test results say both of these drugs showed up in the bloodstream at the 78-hour mark in excess of their therapeutic levels in living individuals. The digoxin concentration was 3.6 nanograms per milliliter ("the 3.6 level"). A 2.0 level is the maximum therapeutic mark.

Fifteen months after receiving the 3.6 level, Dr. Mason changed Mr. McCornack's death certificate to list ventricular arrhythmia, digoxin toxicity, and digoxin poisoning as the causes of death. Dr. Mason had been retained by the plaintiffs at the time the death certificate was changed.

C. Background of the *Vega* Individual Case

In 1996, Mrs. Vega was diagnosed with new-onset congestive heart failure. She was prescribed digoxin and other medications from 1996 to 2002. From as early as 2002 her echocardiogram showed severe impairment of her heart muscle, specifically the left ventricle. She was also obese and hypertense.

In 2002, Mrs. Vega began long-term treatment with Reynolds Delgado, III, M.D. No one quarrels with the plaintiffs' contention that he is a world-renowned, board-certified cardiologist that practices in one of the world's best heart institutes. He continued Mrs. Vega on digoxin. He prescribed both dosages at different times. He believed those amounts were fine and that a double dose would not necessarily lead to toxicity.

In 2002, Dr. Delgado referred Mrs. Vega to a bariatric surgeon. Her obesity was an obstacle to qualifying her for the heart transplant list. In 2005, she got an implantable defribrillator. In March 2007, she had the bariatric procedure. As of the end of 2006, Mrs. Vega had five heart-failure-related hospital admissions. In 2007, she had six. Dr. Delgado does not appear to claim digoxin caused Mrs. Vega harm in 2007. He never diagnosed or treated her for digoxin toxicity at any time.

In October 2007, Mrs. Vega was admitted to the hospital. The likely cause was progressive heart failure. During that admission Dr. Delgado performed a right heart catheterization. He determined that she had heart failure and severely deranged hemodynamics. The handwritten medical notes also refer to a workup for a ventricular assist device ("VAD") and a heart transplant. She was also started on intravenous milrinone in October 2007 as a bridge to transplant therapy.

In November 2007, Mrs. Vega was readmitted to the hospital. She was once again diagnosed with heart failure. Her status was said to be "homebound due to fatigue, SOB, decreased

endurance." At this point Dr. Delgado thought that is was likely Mrs. Vega would need a left ventricular device ("LVAD"). The milrinone infusions continued from the time of discharge until the end of January 2008. No concerns about digoxin were ever charted by any of her treating physicians and no digoxin serum levels were drawn.

On January 22, 2008, Mrs. Vega was admitted to the hospital again. Her admission came after she skipped her Lasix medication for four to five days. This caused a volume overload and worsened her congestive heart failure. Her failure to take her prescribed medications exacerbated her heart failure on at least three prior occasions. When she was admitted on January 22, 2008, she complained of shortness of breath, nausea, and vomiting. She was taking digoxin 0.25 mg daily and carvedilol. Dr. Delgado continued as her attending physician. On January 23, 2008, her digoxin level was 1.2 ng/ml ("1.2 level"). Again, no mention was made of any concerns about her digoxin treatment. In fact, she was kept on 0.25 mg digoxin during her hospitalization and discharge. This is important because Dr. Delgado would not give a patient digoxin if he thought it was causing harm. On January 25, 2008, she was discharged. She was instructed at that time to add amiodarone to list of medications. Amiodarone and carvedilol can both increase digoxin levels.

Six days later she was readmitted for shortness of breath, nausea, and vomiting. On February 5, 2008, Dr. Delgado performed a right and left heart catheterization. He diagnosed her with cardiogenic shock. He did not have a diagnosis or theory to a reasonable degree of probability as to why Mrs. Vega's heart failure changed to become cardiogenic shock. On February 11, 2008, Mrs. Vega had an LVAD implanted. Her postoperative diagnosis was "end stage" heart failure. On February 28, 2008, she still had the 1.2 level. Again, digoxin was never suspected as causing her harm. On March 10, 2008, she was discharged. On April 25, 2008, the FDA posted the Digitek®

recall. Dr. Delgado was aware of it. He did not participate in any meetings with his cardiology colleagues or the hospital pharmacy to discuss the recall.

Mrs. Vega's LVAD had multiple failures and device changes were required. On July 9, 2008, her third LVAD was exchanged with another model. The device failures perplexed her doctors. But no one attributed them to digoxin. On August 19, 2008, Mrs. Vega's deteriorating condition required a bilateral below-the-knee amputation. On September 2, 2008, she had a heart transplant. On September 28, 2008, she died. Dr. Delgado completed the death certificate just five months after the recall. Mrs. Vega's death was attributed to congestive heart failure and cardiomyopathy. Dr. Delgado never made an adverse event report about Digitek®. The death certificate has never been changed.

Neither Dr. Delgado nor any caregiver thought digoxin was linked to Mrs. Vega's problems during her treatment. Following her death he expressed a different opinion. He thinks Mrs. Vega took defective Digitek® tablets from October 2007 through April 2008. He bases that opinion on (1) her two 1.2 levels on January 23 and February 28, 2008, and (2) the fact that she developed cardiogenic shock and heart failure in early 2008 and ultimately died. Dr. Delgado says Mrs. Vega began "falling off a cliff" in January or February 2008.

He says that digoxin toxicity led to a cascade of events in early 2008 that caused Mrs. Vega's decline and demise. He bases the opinion on her clinical presentation and "highly abnormal" EKG rhythms recorded on her telemetry monitor. While they are within the therapeutic range, Dr. Delgado refers to Mrs. Vega's two 1.2 levels as the "signal" that digoxin caused her death. He bases the view on an article authored primarily by Kirkwood Adams, M.D. (the "Adams article"). He goes so far as to say that the Adams article contains his explanation of the connection between the1.2 levels and Mrs. Vega's death. Dr. Delgado's change of opinion as to Mrs. Vega's cause of death

occurred after he was contacted by the plaintiffs' lawyers. He first expressed his digoxin-related theory of death to the plaintiff's counsel and not Mrs. Vega's family.

III.

A. Introduction

First I will rule on some miscellaneous motions. Second, I will address the missing link common to all of the MDL cases. It is the absence of proof on defect and causation. Third, I will review the medical expert testimony in the *McCornack* and *Vega* cases. The plaintiffs offer that evidence to overcome the other defect and causation deficits in the case, but it falls victim to *Daubert*.

B. Miscellaneous Motions

First, I have taken as true the testimony of Dr. Bliesner and his fellow general liability experts. There is no need to reach the Actavis defendants' motion to exclude them and the Mylan defendants' motion to exclude Mark Kenny. I **DENY** those motions as moot.

Second, I **DENY** as moot the Actavis defendants' motion for summary judgment in the MDL and the Mylan defendants' motion for summary judgment. As I have said, I **GRANT** these defendants judgment as a matter of law for the reasons I will discuss in the next sections.

Third, I **GRANT** the motions in the MDL and the *McCornack* case to strike plaintiffs' exhibit 620, which is Dr. Bliesner's late declaration. The declaration is an attempt to change Dr. Bleisner's opinions in violation of Federal Rule of Civil Procedure 26(e) in order to avoid summary

judgment. *See, e.g., Gallagher v. S. Source Packaging, LLC*, 568 F. Supp. 2d 624, 630-31 (E.D.N.C. 2008); *see also S. States Rack & Fixture, Inc. v. Sherwin-Williams Co.*, 318 F.3d 592, 695-96 (4th Cir. 2003). The document adds little to the evidentiary mix but reads like a brief supporting the challenged opinions. The defendants are right, however, that it must be excluded. It violates *Rule* 26, prejudices the defendants, and is not saved by considering the *Southern States* factors.

Fourth, I **GRANT** the motion to strike exhibit 621, which is Dr. Delgado's declaration in the *Vega* case. I do so for the same reasons relating to Dr. Bliesner's declaration. This is another supplemental expert report written and filed after reading the defendants' *Daubert* challenge. As with Dr. Bliesner's declaration, no good cause is shown for the late and improper filing, and the document works to the defendants prejudice.

Fifth, I **GRANT** the motions in the MDL and *McCornack* cases to strike Nurse Farrell's affidavit and to exclude unreliable hearsay. Ms. Farrell is a nurse in Massachusetts. Her affidavit mentions a thick digoxin, not Digitek®, tablet. The alleged pill was never produced much less tested. The affidavit is late without good cause and prejudices the defendants.

C. Missing Link -- The Absence of Proof on Defect and Causation

No complicated choice-of-law issues are present. The parties agree that the plaintiffs must show a product defect that caused harm. Defect may be proven by (1) direct evidence, (2) expert testimony, or (3) circumstantial evidence that the product must have malfunctioned due to a defect.[11]

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[11]Defendants say that the circumstantial evidence approach does not apply in this prescription drug context. Their argument has some merit. Sometimes injured parties are taking more than one medication that may cause a harmful interaction. At other times users just have idiosyncratic reactions. The drug taken may have been completely safe. *See In re Serzone Prod. Liab. Litig.*, 231 F.R.D. 221, 225-26 (S.D. W. Va. 2005) ("With drug-induced liver injury, however, a medication (continued...)

The defendants assert that the plaintiffs have failed as to all three means of proving a defect in Digitek® that reached the market and harmed consumers. They identify two theories relied upon by plaintiffs. The first is the plaintiffs' longstanding theory that double-thick pills got into consumer hands. The second that sometimes surfaces is that Digitek® out-of-specification in some other way hit pharmacy shelves and injured recipients.

The defendants raise a host of challenges including these: (1) none of the plaintiffs' experts have reported any observation or opinion that Actavis put out-of-specification Digitek® into the stream of commerce, (2) Actavis used FDA-approved methods and sample sizes to test all of the 152 recalled batches of Digitek® and the lots were within specification, (3) the FDA itself examined 7 Digitek® samples that were part of the recalled batches, all of which were in specification, (4) independent laboratories tested 11 of the recalled batches, all of which were in specification, and (5) an independent regulatory consultant Actavis hired audited the records for 39 batches of Digitek® in 2007, 19 of which were part of the recall, and concluded that the manufacturing and laboratory records reliably confirmed the identity, strength, quality, and purity of Actavis's products. They also point out a very perplexing fact: "[S]ome Plaintiffs possess, but have refused to test (or reveal any testing of), an ample supply of unused Digitek® tablets." (Defs.' MDL Mot. for Summ. J. at 8 n.6).

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[11](...continued)
capable of causing severe liver damage in some people may cause no liver harm at all in the vast majority of patients taking the drug."). One commentator recently said this:

> Although patients injured by medical devices may rely on a product malfunction approach, injuries associated with drug products rarely lend themselves to this sort of an analysis: given the variability in patient response and the inevitably of unexpected adverse events, a seemingly inexplicable failure of a metabolized chemical hardly bespeaks some deviation from the manufacturer's specifications.

Lars Noah, *This Is Your Products Liability Restatement on Drugs*, 74 Brook. L. Rev. 839, 842 (2009). I do not have to resolve the issue. Commonsense dictates though that a court must be diligent in this setting when considering circumstantial evidence of a defect.

The plaintiffs in the *McCornack* case tested six Digitek® tablets from those in their decedent's possession when he died. All were within specifications. They have at least 90 others in hand.

The plaintiffs counter that "there is ample evidence that defective, excess-strength Digitek® reached the marketplace and were consumed by Plaintiffs." (Pls.' Opp'n. to Defs.' MDL Mot. for Summ. J. at 1). First, they point out that 20 double-thick tablets were found in the 4.7 million tablet batch that was eventually recalled, and second, that Actavis reported in January 2009 that it had received nine complaints between August 2008 and January 2009 of double-thick Digitek® found in the marketplace. Neither of these assertions raises a genuine issue of material fact. First, the 20 double-thick tablets obviously never reached the market. Second, the nine complaints came post-litigation and were unverified.

Next, the plaintiffs cite a host of production-related deficiencies at the Actavis plant. They note the FDA's issuance of 26 Form 483s discussing quality control deficiencies, six warning letters citing deviations from cGMPs, and four product recalls occurring between 1990 and 2008. They provide a bullet-point listing of 20 issues from Dr. Bliesner's expert report.[12] Dr. Bliesner served as the plaintiffs' expert on cGMPs and quality safety regulations governing the pharmaceutical industry. He says generally that Actavis has a documented 27-year failure to comply with cGMPs.

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[12]The defendants say this about the 20 bullet points:

> In short, of the 20 pieces of circumstantial evidence that Plaintiffs cite in their response, only four have any plausible connection to out-of-specification Digitek® in the market. One was identified in 2004—years before the recall that precipitated this litigation. Another was an unconfirmed report filtered through at least one, and possibly multiple layers of hearsay, that is the subject of one of Defendants' evidentiary motions. And the remaining two are unsubstantiated consumer reports, which have never been validated, regarding tablets that have never been measured, or tested.

(Defs.' Reply at 6).

He also says that Actavis systemically failed to use quality control systems and to comply with safety regulations. He concludes that adulterated Digitek® must have reached the market based upon these failures. Three other pharmaceutical and compliance experts retained by the plaintiffs agree. The plaintiffs also discuss the FDA's March to May 2008 inspection of Actavis's facility and its criticisms of the manufacturer, along with the April 24-25, 2008, nationwide recall of all Digitek®.

I cannot find that (1) the failure to comply with the FDA cGMPs, (2) the FDA determination of drug adulteration, (3) the recall, or (4) the similar problems the plaintiffs identify give rise to a reasonable inference that defective Digitek® reached the market and caused harm to either of the plaintiffs' decedents. The cases cited in defendants' memorandum of law explain why. *See, e.g.*, *McClain v. Metabolife Intern., Inc.*, 401 F.3d 1233, 1250 (11th Cir. 2005) ("'The FDA's approach differs from ours in another critical aspect. The FDA will remove drugs from the marketplace upon a lesser showing of harm to the public than the preponderance-of-the-evidence or more-likely-than-not standards used to assess tort liability. . . . The FDA's 1994 decision that Parlodel can cause strokes is unreliable proof of medical causation in the present case because the FDA employs a reduced standard (vis-a-vis tort liability) for gauging causation when it decides to rescind drug approval.'") (quoting *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 991 (8th Cir. 2001)).

But even setting aside that well-reasoned law, one need look no further than the FDA's explanation of things, of which I take judicial notice:

> **If a manufacturer is not following cGMPs, are drug products safe for use?**
>
> If a company is not complying with cGMP regulations, any drug it makes is considered "adulterated" under the law. This kind of adulteration means that the drug was not manufactured under conditions that comply with cGMP. It does not mean that there is necessarily something wrong with the drug.

> For consumers currently taking medicines from a company that was not following cGMPs, FDA usually advises these consumers not to interrupt their drug therapy, which could have serious implications for their health. Consumers should seek advice from their health care professionals before stopping or changing medications. Regulatory actions against companies with poor cGMPs are taken as a preventive measure because the manufacturing processes do not meet FDA's regulatory standards. By focusing on the procedures and processes used to make these drugs, FDA is working to ensure that drugs meet their quality standards and are safe and effective. The impact of cGMP violations depends on the nature of those violations and on the specific drugs involved. A drug manufactured in violation of cGMP may still meet its labeled specifications, and the risk that the drug is unsafe or ineffective could be minimal. Thus, FDA's advice will be specific to the circumstances, and health care professionals are best able to balance risks and benefits and make the right decision for their patients.

United States Department of Health and Human Services, United States Food and Drug Administration, *Facts About Current Good Manufacturing Practices (cGMPs)*, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105.htm. The same is true of the recall. The FDA exercised the better part of caution. To say that it did so on the basis of a proven product defect is a leap of epic size and simply untrue.

So the plaintiffs are right that a recall occurred. They are right that the Actavis plant had quality control and regulatory problems over a 20-year period. They may even be right on everything said by their quality control and assurance experts. But there are other undisputed facts that upset the wagon as a matter of law.

Again, it was not a pharmacist, doctor, or plaintiff who found a double-thick pill. It was one of the plant workers in the midst of producing a veritable sea of Digitek® tablets. A stop-the-presses order came next. The plant staff familiar with the drug spent days looking at the vast, millions of tablets to spot more double-thick pills just like those already found. They succeeded. But they found only 18 more or a total of 20. That works out to 0.0004 percent of the batch.

So the two plaintiffs who remain theorize that more double-thick tablets escaped from the plant. That is speculation, not evidence. First, the fugitive pills would have had to have made it past any other internal processes at the plant. Second, they would have had to slip by the repackaging processes at the distributors' factories. It is undisputed that UDL at least would have experienced a machine failure if a double-thick tablet found its way in. Third come the pharmacists and their technicians nationwide. It is easy to imagine how clearly one would see a double-thick tablet of any variety while conducting the familiar process of measuring out drugs for packaging, assuming they were not already in blister packs. Fourth, if the patient was hospitalized, there would have been a nurse intermediary who delivered the drug. The plaintiffs say just such a person spotted a double-thick pill in a nursing home but she did not say it was Digitek®. Those patients not hospitalized do not have a nurse intermediary. But they probably had taken the same Digitek® pills for months, if not years or decades, just like the deceaseds in this case. Despite these multiple layers of trained or well-experienced individuals, not a single double-thick Digitek® was ever found outside the plant.

For the sake of argument, I will say that all of these well-trained observers and guardians failed and allowed double-thick tablets to slip by. If that happened, one would expect to see either a spike in digoxin toxicity nationwide or at least increased adverse event reporting. Neither happened.

I have viewed the record in the light most favorable to the plaintiffs. I have taken all reasonable inferences in their column. I **FIND** that there is completely lacking a cogent argument or genuine issue of material fact on the questions of defect and its cause of resulting harm. I **GRANT** the defendants summary judgment on all remaining claims in the two individual cases.

The result would not change if I found a genuine issue on defect or causation. Summary judgment would still be required based upon the *Daubert* motions relating to medical expert testimony. My findings and conclusions on them are found below.

D. The Defendants' *Daubert* Challenges

1. *Daubert* Standard

Federal Rule of Evidence 702 says that expert testimony is admissible if it will assist the jury and is (1) "based upon sufficient facts or data," (2) "the product of reliable principles and methods," and (3) "the principles and methods [have been applied] reliably to the facts of the case." Fed. R. Evid. 702. A two-part test governs admissibility of expert testimony. The evidence is admitted if "it rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to "prove" anything. He must, however, "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm-O-Disc., Inc.*, 137 F.3d 780, 784 (4th Cir.1998).

The district court is the gatekeeper. It is an important role: "[E]xpert witnesses have the potential to be both powerful and quite misleading[;]" the court must "ensure that any and all scientific testimony . . . is not only relevant, *but reliable*." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (emphasis added) (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir.1999) and *Daubert*, 509 U.S. at 588, 595). As stated in *Westberry*, "The inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95).

I "need not determine that the proffered expert testimony is irrefutable or certainly correct" - "[a]s with all other admissible evidence, expert testimony is subject to testing by '[v]igorous

cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (quoting *Daubert*, 509 U.S. at 596) (alteration in original); *see also Md. Cas. Co.*, 137 F.3d at 783 (noting that "[a]ll *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful").

A specific scientific methodology comes into play in this case. It deals with differential diagnoses or etiologies. "Differential diagnosis, or differential etiology, is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated." *Westberry*, 178 F.3d at 262. The Fourth Circuit has stated as follows:

> A reliable differential diagnosis typically, though not invariably, is performed after "physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests," and generally is accomplished by determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely.

Westberry, 178 F.3d at 262. A reliable differential diagnosis passes scrutiny under *Daubert*. An unreliable differential diagnosis is another matter:

> *A differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on causation.* However, "[a] medical expert's causation conclusion should not be excluded because he or she has failed to rule out every possible alternative cause of a plaintiff's illness." The alternative causes suggested by a defendant "affect the weight that the jury should give the expert's testimony and not the admissibility of that testimony," *unless the expert can offer "no explanation for why she has concluded [an alternative cause offered by the opposing party] was not the sole cause," See also Kannankeril*, 128 F.3d at 808 (explaining that "[i]n attacking the differential diagnosis performed by the plaintiff's expert, the defendant may point to a plausible cause of the plaintiff's illness other than the defendant's actions" and "[i]t then becomes necessary for the plaintiff's experts to offer a good explanation as to why

> his or her conclusion remains reliable") . . . . *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at 764-65 (recognizing that failure to account for all possible causes does not render expert opinion based on differential diagnosis inadmissible; only if expert utterly fails to consider alternative causes or fails to explain why the opinion remains sound in light of alternative causes suggested by the opposing party is expert's opinion unreliable for failure to account for all potential causes).

Westberry, 178 F.3d at 265-66 (some citations omitted) (emphasis added).

In addition to analyzing if an acceptable differential diagnosis has been made in those cases where it might apply, *Daubert* mentions specific factors to help guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94). Despite mention of these factors, the inquiry remains a flexible one. *See Kumho Tire Co. v. Carmichael,* 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he 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.'") (citation omitted); *see also Crisp*, 324 F.3d at 266 (noting, based on *Kumho*, "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert.").

I have considered the applicable factors for the challenged testimony of the medical experts in this case. First, I have considered the *Daubert* factors. Second, I have considered the expert's qualifications to render his opinions. Third, I am influenced by the thorough decision in *McClain*

v. Metabolife Int'l, Inc., 401 F.3d 1233 (11th Cir. 2005). The *McClain* case involved product liability actions against the manufacturer of an herbal weight-loss supplement. The plaintiff users claimed the supplement caused strokes and at least one heart attack. Some of the factors that seem to me were considered there, in one form or another, are helpful here. They include: (1) whether questionable scientific principles have been used and unsubstantiated analogies drawn, and (2) whether, in formulating the ultimate opinions, overreaching or speculative conclusions were made based upon overreaching or speculative methodologies.[13] *See Metabolife*, 401 F.3d at 1240. If so, the experts' approaches are inconsistent with good science.

2. Motion To Exclude Postmortem Blood Digoxin Concentration and Motion To Exclude The Expert Testimony of Dr. Mason and Mr. Gibson

Defendants move to exclude the expert testimony of Dr. Mason and Mr. Gibson. Dr. Mason is the Santa Cruz County Coroner. He is very experienced. Mr. Gibson has an interesting array of talents. He serves in various occupations, including as a "Forensic Pharmaceutical Consultant and Expert Witness," deputy public defender, and part time administrative law judge. He is not a

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[13]One portion of the *Metabolife* decision says this:

> O'Donnell's opinions lack the indicia of reliability necessary to survive a *Daubert* inquiry and challenge under Rule 702. He draws *speculative conclusions* about Metabolife's toxicity from *questionable principles of pharmacology* . . . . He also draws *unsubstantiated analogies* between ephedrine and phenylpropanolamine, *infers conclusions from studies and reports that the papers do not authorize* . . . . In short, O'Donnell does not support his opinions with sufficient data or reliable principles, as identified by the *Daubert* rubric, and fails to follow the basic methodology that experts should follow in toxic tort cases.

Id. at 1240, 1247 (emphasis added) ("This lack of predictability, O'Donnell's use of an unreliable analogy and his inclination to draw overreaching conclusions from self-limiting medical articles, show the speculative nature of his opinions.").

medical professional. He cannot diagnose health conditions or causes of death. Both experts believe that Mr. McCornack died from digoxin toxicity. Their opinions can be summarized as follows:

DR. MASON -- (1) Mr. McCornack's postmortem blood digoxin concentration was elevated and cannot be fully explained by post-mortem redistribution ("PMR")[14], (2) the elevation confirms a toxic digoxin level and digoxin poisoning despite PMR considerations, and (3) the 3.6 level represents Mr. McCornack's digoxin level at or near the hour of his death.

MR. GIBSON: (l) Mr. McComack's digoxin level was elevated at the time of his death, (2) this was probably the result of a nonconforming Digitek® tablet that he took, (3) the elevated digoxin level caused toxicity and death, and (4) Mr. McCornack's digoxin level at the time of death was 2.5.[15]

The opinions of both Dr. Mason and Mr. Gibson hinge on Mr. McCornack's postmortem 3.6 level. It is the plaintiffs who must produce evidence to support the admissibility of that finding and the opinions related to it. They have produced a pittance. The key problem with the opinions of Dr. Mason and Mr. Gibson is that they did not adequately account for the PMR effect. Both experts struggled with the concept. (Dep. of Dr. Mason at 54-55 ("Would I want to know how exactly (PMR) worked, how it was quantified? Yeah, if I could, but I can't. There is no way for me to know these things.") ("It would be some esoteric fudge factor for me to say how much was redistributed. I don't know."); (Dep. of Mr. Gibson at 16 ("I mean, I think Dig levels with postmortem redistribution do tell you stuff, but I don't think you can extrapolate backwards on one data point.")). PMR is important for at least one critical reason. It would elevate Mr. McCornack's postmortem digoxin levels, making the 3.6 level totally unreliable for purposes of extrapolating to his pre-death mark.

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[14]PMR involves the process by which a substance stored in body tissue at relatively high concentrations while a person is alive migrates elsewhere in the body, like to the blood, after death.

[15]These experts may or may not continue to hold these opinions. At times they seemed to back away from some of them a bit during their depositions. For example, Mr. Gibson conditioned his opinion on the plaintiffs' counsel being able to prove defect.

The plaintiffs point to these experts' impressive credentials. They are right. Both experts are well qualified for the tasks and duties they are typically called upon to do. They are not, however, toxicologists. They also lack any specific education, knowledge, or experience in digoxin or toxicity relating to it. Mr. Gibson has never diagnosed, nor helped a physician diagnose, digoxin toxicity. He had also never read anything about postmortem blood analysis and redistribution before he was hired as an expert for this litigation.

Dr. Mason apparently has done no PMR research. He cannot recall any case of his where digoxin was a potential or actual cause of death. He even seemed surprised that the toxicology community thinks it difficult, if not impossible, to extrapolate from postmortem levels of digoxin to pre-death levels. (*See* Dep. of Dr. Mason at 44 ("Why are we doing these analyses if the results have absolutely no significance? It sounds like the purest form of bullshit I have ever heard.")). Dr. Mason even suggested that he could not testify as to the meaning of Mr. McCornack's postmortem blood digoxin concentration or whether it was affected by PMR.

Mr. Gibson apparently came to his specific conclusions about PMR and digoxin poisoning by analogizing to a single journal article that discusses blood-draw sites different from Mr. McCornack's ("Vorpahl and Coe study" or "study"). Mr. Gibson was not concerned about the precise draw location. The Vorpahl and Coe study authors also drew their samples between 1 and 22.4 hours following death, with a mean time of 10.8 hours. The draw in this case was seven times that mean. This is critical. The effects of PMR increase with the amount of time that elapses between death and the blood draw.

It concerns me also that Dr. Mason believes the refrigeration of the body prior to the blood draw would have compensated for the delay. That conclusion is not well explained or supported.

Reliance upon the Vorpahl and Coe study under the circumstances in this case, without explanation, is unacceptable from a scientific perspective. The failure to adhere to the study's prescribed methodology for extrapolation conflicts with good scientific principles. The explanation for that failure is essentially absent. The bridge to support the analogy falls well short of the opposite bank.

Dr. Mason's reason for using the long-delayed draw in his analysis is this:"[I]t's what I've got. And that's the way I'm doing it." (Dep. of Dr. Mason at 64). That is *ipse dixit* condemned by *Daubert* and its progeny. Even the plaintiffs' own expert toxicologist says it is "more likely than not" Mr. McCornack's pre-death blood digoxin concentration was "substantially lower" than the 3.6 level when he died. (Dep. of Dr. Barbieri at 74). That same expert would not have concluded Mr. McCornack died of digoxin toxicity.

Having considered the entire record against the applicable factors, Dr. Mason's opinions, and the subsidiary ones held by Mr. Gibson, are not based upon sufficient facts or data and lack reliable principles and methods. I **FIND** that the plaintiffs have failed to come forward with evidence from which I can determine that the proffered testimony is admissible. I **GRANT** the motion to exclude the opinions of both Dr. Mason and Mr. Gibson that bear upon or relate to the 3.6 level and its usefulness for predicting the pre-death level of digoxin in Mr. McCornack's body. I also **GRANT** the defendants' motion to exclude Mr. McCornack's postmortem blood digoxin concentration.

3. Request To Exclude The Expert Testimony of Dr. Delgado

Before analyzing Dr. Delgado's opinions, I need to briefly revisit what was going on with Mrs. Vega in the year before she died. It is undisputed that she was in terrible health. She had (1) congestive heart failure spanning over a decade, (2) her left ventricle was severely impaired, (3) she

was obese and hypertense, (4) she was referred for bariatric surgery in preparation for a heart transplant, (5) she received an implanted defribrillator in 2005, (6) as of 2006 she had suffered five heart failure hospital admissions, with six more coming in 2007, (7) Dr. Delgado diagnosed her with heart failure in late 2007 and she was apparently fast-tracked for a transplant, and (8) she started taking milrinone as a bridge to transplant therapy. These serious issues are just a sampling.

No concerns about digoxin toxicity are found in her charts. The two serum levels taken in January and February 2008 were within the therapeutic range. At her discharge on January 25, 2008, amiodarone was added to her medications. It can increase digoxin levels. In February 2008 she was treated as having "end stage" heart failure. Once again, there was never any charting or apparent suspicion of harm from digoxin. On February 28, 2008, she had the same therapeutic 1.2 level. She was discharged and continued, as always, taking her digoxin. On April 25, 2008, the recall occurred. Dr. Delgado knew about it. It raised no red flags for him. Ms. Vega experienced multiple failures of her LVAD that were unexplainable. The failures led her physicians to amputate both of her legs below the knees on August 19, 2008. On September 28, 2008, she died. The death certificate completed by Dr. Delgado, to this day, says nothing about digoxin.

The defendants, as with Dr. Mason and Mr. Gibson, offer many reasons why Dr. Delgado's exclusion is necessary. The lack of a proper differential diagnosis is decisive. He does not adequately account for the many other conditions that might have caused her decline and death. Dr. Delgado dismisses why drug interactions from amiodarone and carvedilol did not cause Ms. Vega's serum digoxin levels to elevate (if they elevated at all). He does not adequately explain why this very sick woman did not "fall off of the cliff" as a result of, for example, (1) a failure to take prescribed medications, (2) multiple LVAD failures, (3) worsening heart failure having nothing to

do with digoxin, or (4) a general weakening and deterioration of her condition caused by so many hospitalizations and procedures in 2006 through 2008.

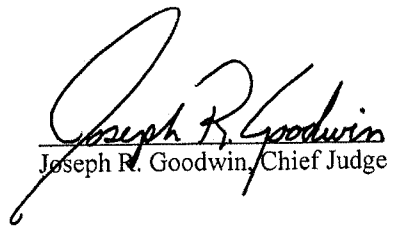
It is true that he points to the Adams article as supporting his opinions. But the analogy fails. Mrs. Vega's progressive heart failure was more severe than the study participants. The Adams article also does not appear to show that women with 1.2 levels had a statistically significant increase in digoxin-related death. This too is left unexplained.

Having considered the entire record against the applicable factors, Dr. Delgado's opinions are not based upon sufficient facts or data and lack reliable principles and methods. I **FIND** that the plaintiffs have failed to come forward with evidence from which I can determine that the proffered testimony is admissible. I **GRANT** the motion to exclude the opinions of Dr. Delgado.

This ruling results in the plaintiffs having no expert medical evidence of defect and causation. I **GRANT** summary judgment in the alternative on this independent ground.

The court **DIRECTS** the Clerk to file a copy of this memorandum opinion and order in 2:08-md-1968 and in member cases 2:09-cv-00671 and 2:09-cv-00768. The court **DIRECTS** the Clerk to post a copy of this published opinion on the court's website, www.wvsd.uscourts.gov.

ENTER: November 3, 2011



Joseph R. Goodwin, Chief Judge