SUPERIOR COURT OF NEW JERSEY

CHARLES J. WALSH
JUDGE

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RE: IN RE: DIET DRUG LITIGATION
Master Docket No. BER-L-7718-03

MARGARET COMPAROTO v. WYETH, INC.
Docket No. BER-L-332-04MT

KRIS GRIMES v. WYETH, INC.
Docket No. BER-L-565-04MT

HOLLY HARRIS v. WYETH, INC.
Docket No. BER-L-6818-03MT

LILLIAN HENRIE v. WYETH, INC.
Docket No. BER-L-8202-03MT

GERALDINE LaROCCA v. WYETH, INC.
Docket No. BER-L-8260-03MT

JOY McPHAIL v. WYETH, INC.
Docket No. BER-L-562-04MT

DONNA MINTER v. WYETH, INC.
Docket No. BER-L-7027-03

Dear Counsel:

This matter is before the Court on applications by Wyeth Corporation, as the successor to American Home Products Corporation ("AHP") and each of its former subsidiaries, affiliates and divisions (collectively "Wyeth or defendants") challenging the eligibility of seven (7) plaintiffs to exercise opt-outs from the Nationwide Class Action Settlement ("CAS"). These plaintiffs are: Margaret Comparoto ("Comparoto"); Kris Grimes ("Grimes"); Holly Harris ("Harris"); Lillian Henrie ("Henrie"); Geraldine LaRocca ("LaRocca"); Joy McPhail ("McPhail"); and Donna Minter ("Minter").

The Court conducted an evidentiary hearing which began on August 23, 2004 and concluded on September 8, 2004. During that period, the Court heard testimony from: Martin E. Goldman, M.D. ("Dr. Goldman"); Charles Gibbs Vasey, M.D. ("Dr. Vasey"); Sanjiv Kaul, M.D. ("Dr. Kaul"); Louis Evan Teichholz, M.D. ("Dr. Teichholz"); Stephen E. Weinberg, M.D. ("Dr. Weinberg"); Dilip Viswanath, M.D. ("Dr. Viswanath"); Jason Lazar, M.D. ("Dr. Lazar"); Muhamed Saric, M.D. PhD ("Dr. Saric"); Mark V. Sherrid, M.D. ("Dr. Sherrid"); Arthur Millman, M.D. ("Dr. Millman"), all of whom were cardiologists; and Frank Miele ("Miele"), an engineer and physicist. The Court was present at the videotaped deposition of Dr. Viswanath taken to rebut testimony given by Dr. Sherrid. Much of the direct testimony of each of these witnesses was presented through affidavits, certifications or reports which were adopted during the course of the evidentiary hearing. In addition, the Court considered the contents of several treatises which were recognized in the proceedings as reliable under **N.J.R. Evid.** 803 (c)(18), including: Harvey Feigenbaum, **ECHOCARDIOGRAPHY** (5th Ed. 1994) ("Feigenbaum Text"); Arthur Weyman, **PRINCIPLES AND PRACTICES OF ECHOCARDIOLOGRAPHY** (2nd Ed. 1994) ("Weyman Text"); Novin C. Nanda, **ATLAS OF COLOR DOPPLER ECHOCARDIOGRAPHY** (1989); J.P. Singh, et al., *Prevalence and Clinical Determinants of Mitral, Tricuspid, and Aortic Regurgitation (The Framingham Heart Study)*, 83 *Am. J. Cardiology* (1999) ("Singh"); and *The Task Force on Valvular Regurgitation Recommendation for Evaluation of the Severity of Native Valvular Regurgitation with Two-dimensional and Doppler Echocardiography ("ASE Standards"), J. Am. Soc. Echocardiography,* 16: 777 (2003).

The Court previously discussed the standards to be used in assessing these eligibility challenges. *In Re: Diet Drug Litigation*, BER-L-7718-03 (Law Division April 13, 2004) ("*Eligibility Standards Opinion*") (slip op. at 31-36). Each plaintiff seeking to exercise an IOO or BEOO is required by the CAS to establish that he or she is FDA Positive by a qualifying echocardiogram. FDA Positive, as defined, contains two standards. First, the quantitative measurements that constitute FDA Positive heart valve regurgitation are as follows:

> Aortic Valve – Mild or greater regurgitation, defined as regurgitant jet diameter in the parasternal long-axis view (or in the apical long-axis view, if the parasternal long-axis view is unavailable), equal to or greater than ten percent (10%) of the outflow tract diameter (JH/LVOT).

> Mitral Valve – Moderate or greater regurgitation, defined as regurgitant jet area in any apical view equal to or greater than twenty percent (20%) of the left atrial area (RJA/LAA).

CAS § I.22.b.

The CAS also requires that specific criteria be used in determining whether these levels of valvular regurgitation are present. Singh at 897-98.

Second, the CAS requires the echocardiograms be performed and evaluated by "qualified medical personnel" in accordance with the methodology set forth in two (2) referenced texts – The Feigenbaum Text and the Weyman Text. *Eligibility Standards Opinion* (slip op. at 12-16).

This Court already has determined that "Wyeth [may] disqualify an IOO or BEOO if it establishes that the performance and/or evaluation of the echocardiogram (at issue) was medically unreasonable as a matter of law. Stated another way, Wyeth [may] . . . disqualify . . . [an] IOO or BEOO if it can show that . . . [an] expert's conclusions respecting the echocardiogram supporting the opt-out could not 'reliably flow from the facts known to the expert and the methodology used.'" *Eligibility Standards Opinion* (slip op at 31) (citations omitted).

For the reasons which follow, the Court finds that Wyeth has satisfied the Court that the echocardiograms supporting claims of Comparoto, Harris, Henrie, LaRocca, McPhail and Minter have not been performed and/or interpreted in a medically reasonable manner. Accordingly, the Complaints filed by these plaintiffs are dismissed and those plaintiffs are returned to the Class. The Court, however, finds that Wyeth has failed to support its eligibility challenge as to Grimes. Accordingly, Wyeth's motion to dismiss will be denied as to her. The findings of fact and conclusions of law supporting these determinations are reported below.

I

A.

In order to determine whether Wyeth's challenges have merit, one has to understand the underlying medical conditions claimed by these plaintiffs and the tools used to detect and treat those conditions. Mild aortic and moderate mitral

regurgitation are the two (2) medical conditions that permit either an IOO or BEOO. These conditions involve the backward or reverse flow of blood through defective valves during the heart's pumping cycle.

The heart consists of four (4) chambers: the right atrium, the right ventricle, the left atrium and the left ventricle. The right atrium receives deoxygenated blood from the body and ejects that blood into the right ventricle though the tricuspid valve; the right ventricle then pumps that blood across the lungs through the pulmonic or pulmonary valve for oxygenation. The oxygenated blood, in turn, is received by the left atrium, which ejects blood into the left ventricle through the mitral valve. The left ventricle then pumps that oxygenated blood into the aorta through the aortic valve, and from there to the rest of the body. The heart chambers are connected by valves that open to allow blood to pass through and then close to prevent significant backflow. This process ensures the proper directional flow of blood through the heart.

The chambers of the heart fill and empty in a two-phase cardiac cycle that comprises diastole - - the filling cycle, and systole - - the emptying cycle. For our purposes, we are concerned with the active contraction of the left ventricle and pumping of blood into the aorta through the open aortic valve during systole. Throughout this phase the mitral valve is closed to prevent backward flow or regurgitation from the left ventricle into the left atrium. We are also interested in the other phase of the cardiac cycle -- diastole -- which occurs when blood enters the left ventricle through the open mitral valve. During this phase the aortic valve is closed to prevent leakage or regurgitation from the aorta back into the left ventricle.

Healthy heart valves rarely prevent all regurgitation. When these valves are closed there may be a minimal amount of leakage -- trace regurgitation. Moreover, during routine valve closure, blood caught between the valve leaflets is displaced backward resulting in some blood backflow. This backward displacement of blood is considered part of the closing process, and is not regurgitation. According to Weyman, "true" mitral regurgitation "should last throughout most or all of systole." Weyman Text at 429. A brief or non-sustained jet of mitral regurgitation is an indication that the regurgitation is usually less than mild. The same source teaches that "true" aortic regurgitation should continue "throughout diastole." *Id.* at 529. Aortic regurgitation that is brief or non-sustained is usually less than mild.

Normally blood flows at a uniform velocity in a forward direction. This normal blood flow is laminar. Regurgitant flow, on the other hand, produces a jet

of mixed velocities which is turbulent. It is this turbulent flow which is one of the focuses of echocardiography.

According to Singh, the degree of valvular regurgitation or valvular insufficiency is classified as trace, mild, moderate, or severe. Trace aortic regurgitation and trace and mild mitral regurgitation are common in the general population and are considered normal findings. Singh at 900.

B.

Echocardiography is a principal technique used to evaluate the heart, including its function, structure and the flow of blood through it. The underlying principle involved in echocardiography is the use of high frequency sound waves. A transducer is placed on the patient's chest wall which emits sound waves that bounce off of the heart's structures, and that information is translated into moving images of those structures on a screen. There are several different techniques available in echocardiography. The technique relevant here is Doppler echocardiography. "Doppler echocardiography is based on the change in frequency of a sound wave that occurs when it strikes a moving target – in this case the red blood cells." Weyman Text at 143.

Color flow Doppler is used to display the movement of blood flow through the heart by assigning different colors depending upon the direction and velocity of the blood flow. By convention, laminar blood flowing towards the transducer is depicted in shades of red, and laminar blood flowing away from the transducer is depicted in shades of blue; darker shades indicating slower velocity and lighter shades higher velocity. *See* Feigenbaum Text at 33. Turbulent blood flow is depicted in a "mosaic," multi-colored pattern, thus displaying the different velocities and directions of the blood in the area under study. The absence of blood flow is depicted by black on color flow Doppler. Thus, in Doppler echocardiography blood flow is represented as discrete color areas (jets) in real time, superimposed on two-dimensional images of the heart's structure.

The quality of an echocardiogram depends on a number of factors including: the patient's body; the technical skill of the physician or sonographer performing the study; the equipment used and its settings; and, the physician's interpretation and measurements. The proper performance of an echocardiogram in the cases before this Court must follow the guidelines set forth in the Weyman and Feigenbaum Texts.

Settings on the echocardiographic equipment can have a substantial impact on the quality of the images and the accuracy of the recordings. Two (2) key settings on the equipment are referred to as the Nyquist limit and gain setting. The Nyquist limit establishes the maximum velocity of laminar blood flow that can be detected in a monochromatic fashion (solid color).[1] When the velocity of the turbulent blood flow exceeds the pre-set Nyquist limit the color depicting the blood flow "wraps around" so that if the flow is laminar it appears to be flowing in the opposite direction. The blood flow in such circumstances may also appear as a "mosaic," multi-colored pattern. If the Nyquist limit is set too low, the velocity of normal blood flow may exceed a low Nyquist setting and will appear as turbulent regurgitation, even though it is actually normal non-regurgitant flow. Additionally, when the Nyquist limit is set too low it will exaggerate the degree of any regurgitation present by including normal blood flow velocity in the turbulent regurgitant jet area. Virtually all the experts who testified here agree that a higher Nyquist limit generally leads to a more reliable echocardiogram. A recent consensus report by the American Society of Echocardiography stressed the importance of an appropriate Nyquist limit.

> Numerous technical, physiologic and anatomic factors affect the size of the regurgitant area and therefore alter its accuracy as an index of regurgitation severity. Jet size is affected by instrument factors, especially pulse repetition frequency (PRF) and color gain. Standard technique is to use a Nyquist limit (aliasing velocity) of 50/60 cm/sec, and a color gain that just eliminates random color speckle from non-moving regions. Jet area is inversely proportional to PRF, and *substantial error can be introduced with use of higher or lower settings* than the nominal settings to which echocardiographers have become accustomed.

ASE Standards at 777-778 (emphasis added).

A color Doppler gain setting is another important variable in the echocardiographic system. If the gain on echocardiographic equipment is set too

[1] As the Feigenbaum Text at 29 notes: "The major disadvantages of pulsed Doppler is that the velocity one can measure is limited. The pulsed system inherently has a pulsed repetition frequency or PRF. The PRF determines how high a Doppler frequency the pulse system can detect.... The inability of a pulsed Doppler system to detect high-frequency Doppler shifts is known as "aliasing." The upper limit of frequency that can be detected with a given pulsed system is known as the "Nyquist" limit or number. This limit is defined as one half the pulse repetition frequency or PRF. *See* Miele Certification at ¶¶ 16, 17, 31 and 32.

high, the image has "a background noise" or "speckling," seriously degrading the quality of the echocardiogram and making it difficult to assess true regurgitation. As Weyman teaches, the "detection of the Doppler frequency shift is critically dependent on the signal/noise ratio, and every effort must be made to maximize this relationship." Weyman Text at 256.

Another important technical aspect of echocardiographic acquisition relates to the angle the transducer is placed relative to the heart when images are recorded. If those images are not acquired in the appropriate angle or plane, the amount of regurgitation and the sizes of the chambers of the heart may appear larger or smaller than they really are. Again, Weyman teaches that "doppler frequency shifts are maximal when the sound beam is parallel to the flow vector (i.e., aligned parallel to the path of blood flow in the vessel of interest).... The Doppler beam, therefore, is ideally aligned parallel, rather than perpendicular, to flow because larger frequency shifts are easier to detect and the output is less subject to random fluctuation." Weyman Text at 256.

FDA Positive heart valve regurgitation involving the aortic valve requires that two (2) measurements be made: (1) the height of the jet of aortic regurgitation ("JH"); and (2) the height of the left ventricular outflow tract ("LVOTH" or "LVOT").[2] The JH measurement is the linear width of the jet of aortic

[2] The same diagram illustrating how this measurement is actually made is displayed in the Feigenbaum Text at 285, Fig. 6-101, and the Weyman Text at 534. The illustration as it appears in Weyman is reproduced below.

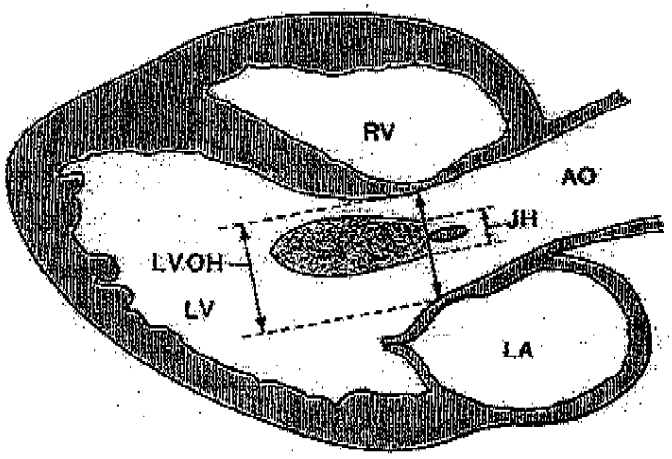

Fig. 19–61. The measurement of regurgitant jet height. Regurgitant jet height (JH) is measured at the aortic valve level in the parasternal long axis view. AO = aorta; LA = left atrium; LV = left ventricle; LVOH = left ventricular outflow tract height; RV = right ventricle. (From Perry GJ, et al.: Evaluation of aortic insufficiency by Doppler color flow mapping. J Am Coll Cardiol 9:952, 1987. Reprinted with permission from the American College of Cardiology.

regurgitation as it leaks backward into the left ventricle. Feigenbaum tells us that this measurement must be made as close as possible to the point of origin of that jet on the ventricular side of the aortic valve. Feigenbaum Text at 283. Otherwise, the measurement will be exaggerated by the spray or "nozzle effect" that occurs when high velocity liquid (regurgitant blood) is ejected through a narrow orifice into a lower pressure chamber (the left ventricle in diastole). *Id.* at 283. The LVOT is the region of the left ventricle below the aortic valve. These two (2) measurements are then expressed as a ratio, JH/LVOT. Current technology utilizes digitally calibrated calipers or cursors, which can measure the linear width of the JH and LVOT on a frozen frame or image using a digitally calibrated caliper or cursors, from commercially available software packages.

The definition of FDA Positive mitral regurgitation also requires two (2) measurements to be made: (1) the regurgitant jet area, or "RJA"; and (2) the left atrial area, or "LAA." Unlike the linear width measurements made of the JH and LVOT, the RJA and LAA are area measurements. Again these measurements are expressed as a ratio, RJA/LAA, in assessing the degree of mitral regurgitation. These measurements of the RJA and LAA can be done while the sonographer is acquiring the study, or off-line, and are referred to as tracings or planimetry when using the technology just described.

II

A.

The Court considered the qualifications of the experts as required by **N.J.R. EVID.** 702. *Kemp ex rel Wright v. State*, 174 N.J. 412, 427 (2002). Overall, the Court found the experts called by Wyeth and the plaintiffs to be well qualified, or at least qualified, in the areas offered.

The Court finds Drs. Goldman, Kaul, Teichholz and Vasey well qualified in the field of echocardiography. Dr. Goldman is a Professor of Medicine at the Mt. Sinai School of Medicine in New York and has taught at that medical school for over twenty (20) years. Dr. Goldman has written extensively in the field of echocardiology and holds positions as a director of the American Society of Echocardiography ("ASE"), one of the bodies seeking to promote advances in the field of echocardiography, as well as several of its committees. Dr. Kaul is currently a Professor of Medicine and Biomedical Engineering at the University of Virginia where he holds an endowed chair. He also is the Director of the Cardiovascular Imaging Center at the same institution. Dr. Kaul has published

extensively, has held numerous editorial board positions at leading cardiology journals in the Untied States and has been a board member of the ASE. Dr. Teichholz is currently the Chief of the Division of Cardiology in the Department of Internal Medicine and the Medical Director of Cardiac Services at the Hackensack University Medical Center. He is presently a Professor of Medicine at the University of Medicine and Dentistry of New Jersey and an adjunct Professor of Medicine at the Mount Sinai School of Medicine. Dr. Teichholz has been active in the field of echocardiography for thirty (30) years, particularly as this science was being developed, and has served on the board of the ASE. Dr. Vasey, too, has strong credentials in the field of echocardiography. He presently serves on the board of the ASE, as well as its operating committees. Copies of the curricula vitae of these four (4) physicians are part of the hearing record.

The plaintiffs, too, produced qualified witnesses. Dr. Weinberg is a physician practicing cardiology at Cardiovascular Associates of the Delaware Valley and has over twenty-five (25) years of clinical experience. Dr. Viswanath is a board certified cardiologist with the same practice group as Dr. Weinberg. Dr. Lazar is a board certified cardiologist with Level III echocardiographic training. He is currently an Echocardiography Attending Physician at New York Hospital in Queens and the Director of Non-Invasive Cardiology and Associate Director of Cardiovascular Training at the Medical Center at SUNY-Brooklyn (Downstate Medical Center).[3] The curricula vitae of these experts also are included as part of the record.

The expert cardiologists appointed by the Court under the terms of the *Eligibility Standards Opinion* also are well qualified. Dr. Saric is presently the Director of the Echocardiography Laboratory at the University of Medicine and Dentistry of New Jersey and has Level III echocardiographic training. In addition to his M.D. degree and board certifications in cardiology and echocardiography, Dr. Saric holds a PhD in medical sciences from New York University. Dr. Sherrid is presently the Director of the Echocardiography Laboratory at St. Luke's Roosevelt Hospital Center and serves as an Associate Professor of Clinical Medicine at the Columbia University College of Physicians and Surgeons. Dr. Sherrid presently is the President of the New York Echocardiography Society. Dr. Millman is the Chief of Cardiology at Trinitas Hospital in Elizabeth, New Jersey. He has had extensive experience in echocardiography and teaches cardiology

[3] Mr. Miele provided general information about the laws of physics governing echocardiography and the equipment used in its practice. He also provided specific information on Nyquist limits and the effect of transducer angles on color Doppler as they relate to Henrie and LaRocca. As noted later in this Letter Opinion, the Court found Mr. Miele quite knowledgeable in these areas. Mr. Miele's resume is part of the record.

fellows from the Seton Hall Graduate School of Medical Education. The curricula vitae of these experts also are part of the record.

B.

As in the past, the Court's decisions in these individual eligibility cases are based largely on the quality of the echocardiograms. The initial reports of physicians with respect to virtually all these challenged echocardiograms significantly overstated the pathology observed. Accordingly, as in the eligibility hearings on the Group 1 plaintiffs (*see Armstrong et al v. Wyeth, Inc.*, (BER-L-7024-03MT) Letter Opinion dated August 4, 2004, slip op. at 10-12), the plaintiffs' experts spent much of their time seeking to excuse and explain these overstatements. For example, FDA Positive aortic regurgitation was diagnosed while Henrie's cardiac cycle was in systole -- plainly an impossibility. Nevertheless, one of the plaintiffs' experts denied the echocardiogram revealed this obvious error while at the same time conceding that the mitral valve was closed -- a telltale sign that mechanical systole had not concluded.[4]

In other instances, Nyquist limits of 43 cm/sec, well below the Nyquist limits outlined in the ASE Standards at 777-778 (50-60 cm/sec) and in the Weyman Text at 245 (60-90 cm/sec), appear in the echocardiogram supporting the Comparoto opt-out. In the face of such obvious deviations from proper echocardiographic practice, other plaintiffs' experts were left to opine that the clear capacity that this low Nyquist limit to inflate any observed regurgitant jet were overwhelmed by angle effects where views were taken in the parasternal long-axis view ("PLAX").

In many instances, the techniques used in acquiring the echocardiographic images fell so far below appropriate practice as to make the data reported and

[4] Dr. Lazar's testimony in this regard is telling:

Q. This is where measurements are being made, do you see that, Doctor?
A. I do.
Q. And then you see down here in the left atrium, does that appear to be a regurgitant jet?
A. I don't know if it's regurgitant or backflow or I don't know what it is.
Q. If it's backflow, the valve is closing, isn't it?
A. Yep.
Q. So it would be unusual to see aortic regurgitation in a scenario where the mitral valve is closed as well, wouldn't it?
A. That's true.

conclusions made by plaintiffs' experts virtually worthless in either diagnosis or treatment.

Plaintiffs were aware that the qualifying echocardiograms in issue would be used to support the opt-outs sought. As will be seen, however, in six (6) of the seven (7) cases reviewed here, the submitted echocardiograms were of such poor quality or were interpreted in a manner so plainly at odds with good medical practice that they cannot, as a matter of law, support those plaintiffs' claims to qualify as FDA Positive.

The findings with respect to the seven (7) plaintiffs follow in the next section of this Letter Opinion. Where credibility determinations are made here, they are reflected in the findings reported below.

III

A. Margaret Comparoto

Comparoto relies on a September 16, 2002 echocardiogram performed by Cardiovascular Associates of the Delaware Valley, P.A. ("CADV") and a report of Dr. Annie M. Peter. Dr. Peter found that Comparoto had moderate mitral regurgitation ("MMR") using the CAS criteria -- RJA/LAA = 32%.

The September 16, 2002 echocardiogram was reviewed by three (3) experts: Dr. Treichholz, Dr. Sherrid and Dr. Vaswanath. Both Drs. Teichholz and Sherrid found that the claimed diagnosis of MMR was medically unreasonable. Dr. Teichholz noted that the Nyquist limit of 43 cm/sec was set "unusually low and exaggerates the degree of regurgitation present on the study by increasing the area of the 'mosaic' pattern." Dr. Sherrid was of the same view. Moreover, both physicians found that Comparoto's RJA was "vastly overtraced" by "including both laminar blue low velocity flow and black static blood in multiple tracings."

Dr. Viswanath does not deny that the Nyquist limit is low, but excuses this by saying that the Hewlett-Packard echocardiographic equipment at CADV automatically adjusts the Nyquist limit "on that machine ... down to a limit of 40.... This suggests that HP considers the machine reliable down to a limit of 40." The Court rejects this assertion as complete nonsense. Dr. Viswanath offers no scientific evidence that his *ipse dixit* has any support. The Court finds it telling that Miele, a well-qualified witness with significant echocardiographic machine design experience, was never asked to support this conclusion. Moreover, the

significant departure in this echocardiogram from the Nyquist limits reported in the medical literature already discussed, dooms it as an appropriate diagnostic tool. The Nyquist limit setting here in and of itself makes the performance of the echocardiogram medically unreasonable and renders the MMR diagnosis based on it medically unreasonable.

Dr. Viswanath contends that the low "Nyquist limit only becomes an issue when there is significant aliasing occurring in areas of low velocity flow." According to Dr. Viswanath that is not the case here. This effort to excuse a clear deviation from proper practice fails for three (3) reasons. First, the failure to follow proper procedure, in the Court's view, renders the echocardiogram unreliable. Second, Dr. Viswanath's tracing does not confirm his claim since it contains non-aliased blood. Third, Dr. Viswanath's tracings are medically unreasonable.[5] The Court viewed the tracings produced by Dr. Viswanath. The

[5] Dr. Teichholz addressed Dr. Viswanath's RJA tracing in the following testimony which the Court finds credible. The echocardiographic views support Dr. Teichholz's claim that Comparoto's RJA is vastly overtraced.

> Q. Dr. Teichholz, just putting aside the Nyquist limits and the technical limitations of the study, if one wants to do a tracing here, what would one trace?
> A. On this frame?
> Q. Yeah.
> A. Right here, and I couldn't look at the left atrium. I'd have to look at another frame. And again, the left atrium should be measured at its largest, which is end systole and this is really early systole.
> JUDGE WALSH: But in any event, you would certainly agree that simply because they planimetered this left atrium that you could certainly go to another part of this apical view and particularly, as you say in systole and trace it at its maximum area.
> WITNESS: Absolutely.
> JUDGE WALSH: Which is what should be done?
> WITNESS: Absolutely. There are other tracings of this jet which are very similar. Sometimes the jet has a little more turbulence in it, but it's as I said here, no more than mild to moderate regurgitation.
> JUDGE WALSH: Looks like there's almost no turbulence. Maybe a little at the top of the tracing. Am I correct?
> WITNESS: That's correct.
>
> * * * *
>
> Q. Okay. So I want to go to Defense Exhibit 2045. This was a frame that the plaintiff's expert traced as purportedly mitral regurgitation. Do you have any criticism -- now, I understand your testimony about the technical limitations of the study, but just putting that aside, do you have any additional criticisms of this tracing?
> A. Well, I'm concerned because of a low Nyquist, forget about the technical, that will allow nonalias --
> JUDGE WALSH: I think that's what he was talking about.
> WITNESS: But that would allow nonalias flow to appear as flow.
> JUDGE WALSH: He said disregard that for a time being and get on to the tracing itself.
> A. Here we see something that may represent MR. There are two things that are a problem here. Normally, the MR is tear shaped. It starts as a jet and stands out.
> JUDGE WALSH: Could we acentric [sic] [eccentric], couldn't it?

Court considered the criticisms of those tracings by Drs. Teichholz and Sherrid[6] and, in light of all the evidence, finds these criticisms to be persuasive on this subject, even disregarding the inappropriate Nyquist limit.

B. Kris Grimes

Grimes relies on an echocardiogram report by Dr. Gregg L. Fortino of CADV dated December 9, 2002 to establish that she is FDA Positive. Dr. Fortino reported that Grimes has severe mitral regurgitation using the CAS criteria -- RJA/LAA = 42%. No worksheets from CADV were introduced in evidence.

The December 9, 2002 report and the accompanying echocardiogram were reviewed by three (3) experts: Dr. Kaul, Dr. Sherrid and Dr. Viswanath. Both Drs. Kaul and Sherrid found that Dr. Fortino's diagnosis of severe mitral regurgitation and Grimes' claim of FDA Positive mitral regurgitation were medically unreasonable. Both Drs. Kaul and Sherrid found that the mitral regurgitation observed did not last through most or all of systole as would be expected. Weyman Text at 428-429. Specifically, the Weyman Text notes that:

> Mitral regurgitation characteristically produces a high velocity, turbulent, systolic flow disturbance (jet) in the left atrium, which can be detected by pulsed ..., continuous wave, or color flow Doppler. The high peak velocity of the jet (i.e., 5 to 6 m/sec) is due to the large pressure difference between the left ventricle and left atrium during systole.... Jet turbulence produces a wide range of velocities, which broadens the frequency spectrum of the Doppler signal. *Mitral regurgitant flow*

A. Could be acentric [sic], but this is sort of zigzagging, which, to be honest, is something we don't normally see.

So I'm really concerned that there's black, all this black in here, which I believe means that this flow here is probably noise. But more important, if you look at this side of it, again, we see the same thing. There is dark blue --

JUDGE WALSH: This time we're on the left side of the tracing as you face it?

WITNESS: Correct. There is dark blue, and there's black, and even at the end here, that is being traced, black on this side, as well, that is being traced that again, makes this larger than it actually -- even if the Nyquist were correct than it actually is.

Q. So would it be medically reasonable for any sonographer or cardiologist to trace this, either proper tracing or the improper tracing as a representative mitral jet in this study?

A. I don't think so.

[6] Dr. Sherrid made two (2) RJA/LAA measurements after his review of Comparoto's echocardiogram. These measurements resulted in area percentages of 18% and 5%, respectively. According to Dr. Sherrid, these are most likely overtraced.

> *typically begins immediately after mitral closure and continues throughout most or all of systole.* (Emphasis added.)

Dr. Kaul notes in his Affidavit that "[t]he jet of mitral regurgitation on this echocardiogram only lasts one or two frames, indicating it is no more than mild." During his testimony, however, Dr. Kaul conceded that the phenomenon which he admitted was a regurgitant jet, lasted for longer than that, though it was, in his view, not holosystolic. Dr. Sherrid concurred and also pointed out that the echocardiogram indicated several irregular heartbeats during which greater regurgitant mitral jet volume would be expected and would make any MMR diagnosis based on such cycles suspect. Moreover, both physicians believed that portions of the left ventricle above the mitral valve leaflets were being traced as part of the RJA.

Dr. Viswanath disagreed, arguing that Grimes has domed mitral valve leaflets which justified the tracing made by the sonographer. He further argued that the mitral value regurgitation was holosystolic, at least with respect to three (3) cardiac cycles which he identified during his deposition on September 8, 2004. Dr. Viswanath concedes that Dr. Sherrid correctly identified irregularities in Grimes' heartbeat known as premature ventricular contractions ("PVC"). According to Dr. Viswanath, these PVCs cause extra blood and concomitant pressure to be present in the left ventricle thereby causing a larger volume jet to be expressed into the left atrium. But, Dr. Viswanath indicated that on the next beat the volume and pressure in the left ventricle would normalize and this cardiac cycle would be appropriate for measurement.[7]

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[7] Dr. Viswanath's testimony on this subject is instructive:

> Q. Dr. Viswanath, I'm going to ask you some questions in response to Dr. Sherrid's testimony on Chris [sic] Grimes. I'm going to represent to you that Dr. Sherrid testified that Chris [sic] Grimes had some premature ventricular contractions on some beats on her echo. Is that testimony accurate?
> A. Yes, it is.
> Q. Can you explain what premature ventricular contractions are?
> A. Premature ventricular contractions are extra heart beats that emanate from the bottom portion of the heart called the ventricle. What that does is it creates an electrical disturbance is the normal rhythm pattern of the heart, typically the PVC or the premature ventricular contraction comes in at an earlier time than normal cardiac cycle. What that does is it causes a delay in the depolarization of the ventricle. It's a slowing of the conduction system because it's not along the normal pathway. What that encompasses, the beat comes in early. For one thing means that there's a delay afterwards so one would have an extra beat that comes in early but then a pause which is the normal chain of events. It's called a compensatory pause.
> Q. Now, he also testified that it's medically unreasonable to measure a mitral regurgitant jet around a -- around the time of a PVC. Do you agree with that testimony?

The Court carefully reviewed the testimony of the experts and the other evidence, including the echocardiogram tape. While Drs. Kaul and Sherrid make strong points, the Court believes that there is sufficient counter evidence so that it cannot say that Wyeth has established that a diagnosis of MMR is medically unreasonable. The claimed doming of the mitral valve was challenged. But even if the Court were to credit the challenge, the planimetry shows an RJA/LAA greater than 20%. While the claim that the mitral valve regurgitation is not holosystolic has been established by Wyeth with respect to some cardiac cycles, there are several cycles where the jet is present over all or most of systole. Accordingly, the Court finds that Wyeth has failed to satisfy it that the conclusion that Grimes has at least MMR is medically unreasonable.

C. Holly Harris

Harris relies on an echocardiogram report by Dr. Mark D. Gelernt, M.D. of CADV, dated January 30, 2002, to establish that she is FDA Positive. Dr. Gelernt found that Harris had moderate aortic regurgitation using the CAS criteria -- JH/LVOT. No worksheets from CADV were introduced in evidence.

A. Yes, there is some truth to that. Certainly it is well-known because of that compensatory pause after the PVC, that extra beat, the beat that starts right after it, the exact post PVC beat has a longer time to fill the ventricle, therefore results in a higher pressure in the ventricle so a larger amount of mitral regurgitation would be seen after that one beat.
Q. Now, how about -- so let's for purposes of the terminology let's call the beat, actual beat after the PVC, the PVC beat.
A. Okay.
Q. Is it medically unreasonable to measure a mitral regurgitant jet in the beat after the PVC beat?
A. No. That's a return to the normal cardiac cycle, therefore, the R to R interval or the normal cardiac cycle restores itself.
Q. Were any of the regurgitant jets you looked at that you relied upon for Chris [sic] Grimes in diagnosing her as having moderate mitral regurgitation, were any of those on PVC beats?
A. No, the majority of the ones we looked at were on the post PVC beats or some other normal R to R cycle, so non-post PVC beats.

Dr. Sherrid disagreed with Dr. Viswanath on this score:

Q. When you say, I think I heard you say it's improper to planimeter around when there's -- when you're around premature beats? Is that the word you used, "around"?
A. Basically, the beat of the premature beat, you wouldn't want to planimeter that.
Q. How about the next beat?
A. You wouldn't want to that either, because both of those are subject to artifact.
Q. How about the beat after that one?
A. The beat after that is getting better, but it's not perfect.
Q. But it's not perfect?
A. Not perfect. Imagine your electrical appliances two seconds after a power surge.

The January 24, 2002 echocardiogram was reviewed by three (3) experts: Dr. Teichholz, Dr. Sherrid and Dr. Lazar. Both Drs. Teichholz and Sherrid found no evidence of mild aortic regurgitation ("MAR") in the PLAX. Dr. Teichholz pointedly observed that "Harris' echocardiogram does not show any aortic regurgitation in the ... [PLAX]. The ... [PLAX] was adequately visualized on this echocardiogram. No aortic regurgitation is seen in the ... [PLAX] in the motion frames of ... Harris' echocardiogram."[8] Dr. Sherrid was equally clear: "[t]he aortic regurgitation jet is inconsistent and trivial in degree."

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[8] Dr. Teichholz explained that the PLAX was available and the only spot on the echocardiogram in early diastole was artifact:

> Q. Dr. Teichholz, we're going to play the parasternal long axis view in a minute, but was the parasternal long axis view available on this echocardiogram?
> A. Yes, it was.
>
> * * * *
>
> MR. AGNESHWAR: The problem with this tape, Judge, is that this, the sonographer skipped around all the place, so there's not like a nice clean shot of the parasternal long axis view. So unfortunately, we're going to have to pause.
> A. This is a parasternal long axis view. This is aortic root here. Mitral valve here. Left atrium behind. Some color in the out flow track, aortic valve somewhere right at the edge of where their sector of color is. Nyquist is 77 in this case.
> Q. Let's just go through it frame by frame, if we could. This is a 10:44:01. If we can just step through it a little bit.
> A. And here's the EKG to show so we are in early diastole showing over here after the T-wave and I don't see any color here on that frame. Next. Next. The mitral valve is still basically closed, going to start to open. Next. Next. Here's the mitral valve opening and in this sequence here, go, no, more, more, there was nothing seen. There's another sequence where there's --
>
> * * * *
>
> Q. Dr. Teichholz, if you could just say stop as soon as the PLAX view begins in color and then we'll go frame by frame.
> A. So that view, I didn't see anything, and it was a technical -- here's another view.
> Q. Stop.
> A. Stop here.
> Q. Go frame by frame.
> A. Valve is opening, so we're in diastole. You can see by EKG, and again, go, I'm sorry, new frame. Systole. So we're in systole here. Systole here. Now, by the way, just the point, even though the Nyquist is good, there's noise on every echocardiogram that you see, color noise. Notice this sharp line here. There's no flow pattern that has that kind of flow pattern. That's just a noise that we see that you adjust the gain to minimize that, but still see your echos. Next line. Okay.
> Q. Next.
> A. Next, and this is probably flow systolic going out the aorta. Next.
> Q. Next.
> A. Next, next, we're still in systole, next, still in systole. Now, we're basically at the end of systole.
>
> This may represent a little more of that aortic flow. Here's your mitral. Next slide. Next point. Now, here we're in early diastole and there is one speck of what I'm not sure is white representing some artifact of wall or color because if you look on our color scale, it doesn't correspond to anything. So that's a frame. Next frame. It's gone. So there's a speck there that exists in one early diastolic frame. It doesn't have a jet-like appearance.

Dr. Lazar, on the other hand, found the "[a]ortic regurgitation was present in the PLAX, Apical 3 chamber, Apical 5 chamber, and short axis views." During his testimony, Dr. Lazar measured the JH/LVOT as .25 cm over 1.4 cm -1.6 cm or 17.9% - 15.6% which, if credited, amounts to MAR.

The Court finds that Dr. Lazar's conclusion that Harris' echocardiogram supports a diagnosis of MAR is medically unreasonable. The PLAX plainly is available in this echocardiogram. Therefore, if MAR is not visible in this view, Harris cannot qualify as FDA Positive. Review of the Harris echocardiogram indicates, as reported by Drs. Teichholz and Sherrid, that the momentary speck or phenomenon is not holodiastolic -- the *sine qua non* for a diagnosis of aortic regurgitation. Dr. Lazar admits that the phenomenon he measured appears in only two (2) frames which, because the frame rate exceeds the PRF, actually reports the same image.

> By Mr. Gholson:
> Q. It's not advancing through the cardiac cycle, is it?
> A. No.
> Q. Okay. And 15:02 is the one that you measured?
> A. Correct.
> Q. And based on both of those, those single frames, there's no way for you to determine whether or not that purported jet was represented holodiastolically for either one of those frames [the other was 14:38], can you, Doctor?
> A. The answer is unless you're capturing a frame that happens to be weighed in diastole, then you're -- sure it's impossible.

This also was the case where Dr. Lazar sought an apical view to confirm aortic regurgitation.

> By Mr. Gholson:
> Q. So it only lasted for those two frames, correct?
> A. That's correct.

In conclusion, while one (1) and perhaps two (2) measurements of the phenomenon might be observed in the PLAX, the Court finds that Wyeth has established that it is not medically reasonable to conclude that the phenomenon was MAR as defined in the CAS.

D. Lillian Henrie

Henrie relies on a December 4, 2001 echocardiogram performed and read by Dr. Richard L. Mueller. Dr. Mueller found that Henrie had MAR and MMR using the CAS criteria -- JH/LVOT and RJA/LAA. Henrie has withdrawn her claim of MMR and is relying solely on her claim of MAR.

The echocardiogram supporting Henrie's claim was reviewed by three (3) experts: Dr. Kaul, Dr. Millman and Dr. Lazar. Dr. Kaul found that "[t]he tracing of JH that Dr. Mueller presumably relied upon for calculating the degree of aortic regurgitation on this echocardiogram was made during the incorrect cardiac cycle. The tracing was made during systole when the aortic valve is open and the aorta is filling, not during diastole which is when the aortic valve is closed and when aortic regurgitation occurs if it is present."[9]

Dr. Kaul reviewed Henrie's echocardiogram in its entirety and believes that when properly assessed "it shows no more than trace aortic regurgitation." Dr. Millman also agreed that the echocardiogram did not support a diagnosis of MAR. He further indicated that the echocardiogram was performed in a medically unreasonable manner with the Nyquist limit set at 46 cm/sec.

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[9] Dr. Kaul amplified his conclusions about the wrong measurements in his testimony:

> Q. In reviewing this study, Doctor, did you find any evidence of a regurgitant jet --
> A. No, I don't. I don't see any regurgitant jet and this is made -- this measurement is made in systole.
> JUDGE WALSH: This is another one that's done in systole?
> WITNESS: Yes.
> JUDGE WALSH: Are you sure about that, Doctor?
> WITNESS: I'm sure, and I'll show you a much better example as we go along.
> LEFT1: Let's look at FDI LH.3, it's at counter number 020:97.14.
> A. Yeah, this is a classic example here because you see they're going to make a measurement here. First of all, they've cut off their anterior aortic wall, as I said. They're going to make a measurement in systole because there's a small closing volume of mitral valve. Mitral valve is closed. That's systole. You can't have aortic regurgitation and mitral regurgitation at the same time. So this is a classic example. They did the same in the last patient, except they didn't have any MRs, so you couldn't see it. Here's the little closing body and you can see this is where they make the dimension.
> JUDGE WALSH: How is that possible? I mean, you're saying that even an amateur like me, after I saw enough of these, could say this is impossible?
> WITNESS: Yeah.
> JUDGE WALSH: How is it possible for a competent physician to make this -- you're saying it's impossible?
> A. It is impossible, and I --
> JUDGE WALSH: Okay. I got the picture.

Dr. Lazar, on the other hand, "found that the echocardiogram ... [of Henrie] was performed and interpreted according to the settlement criteria utilizing the proper methodology." He also concluded that "[a]ortic regurgitation was measured appropriately in diastole...."

The Court finds that the echocardiogram was performed in a medically unreasonable way. The Nyquist limit was far too low. As Weyman teaches, "[i]n the adult, the color flow Nyquist limit is typically between 0.6 and 0.9 cm/sec but can be raised by decreasing the sector depth or using a lower frequency transducer." Weyman Text at 245.

The Court is aware that Miele indicated in his testimony that the angle effects dominate where views are taken in the PLAX. While this may be true as a matter of physics, this does not excuse a departure from appropriate echocardiographic standards.[10] Those standards are set by the medical community and are apparent in the literature (*see ASE Standards*; Weyman Text at 245). There is no justification for the departure from appropriate practice. In short, the echocardiogram was performed in a medically unreasonable manner.

In any case, the PLAX was available on this echocardiogram. Therefore, MAR must be documented in that view under the criteria expressed in the CAS. Both Drs. Kaul and Millman have indicated that there is virtually no aortic regurgitation and the Court agrees with them based on its review of this echocardiogram. There is sufficient evidence on this basis to reject Dr. Lazar's conclusion that a diagnosis of MAR is medically reasonable.

In sum, the Court finds that Wyeth has established that this echocardiogram was performed and interpreted in a medically unreasonable way. While there evidently is a disagreement between Drs. Kaul and Sherrid on the one hand, and Dr. Lazar on the other, as to whether the JH/LVOT measurement shows MAR, that

[10] Dr. Kaul indicated this fact in his testimony:

> So over years, we have developed our own thing, and I don't agree with him [Miele]. I don't agree with him that a low Nyquist limit -- in fact, a low Nyquist limit makes a study technically uninterpretable for Doppler.
> JUDGE WALSH: Because of the introduction of potential artifact?
> WITNESS: That's correct. Now, if this would have looked like this, one could have said, Well, it's already changing color, but that would have been at 45 centimeters per second. That's very low velocity.
> JUDGE WALSH: 46.
> WITNESS: 46. That's very low velocity, and so this is what I said you could dial things in and out.
> JUDGE WALSH: Right.

is insufficient in itself to take the matter to a jury. The poor technical quality of the echocardiogram, as acknowledged by Dr. Lazar, the contrary testimony of Drs. Kaul and Sherrid, and the plain views of the echocardiogram by the Court which show no MAR, doom this opt-out.

E. Geraldine LaRocca

LaRocca relies on a December 4, 2001 echocardiogram performed and read by Dr. Richard L. Mueller. Dr. Mueller found that LaRocca had MAR and MMR using the CAS criteria -- JH/LVOT and RJA/LAA. LaRocca has withdrawn her claim of MMR and is relying solely on her claim of MAR.

The echocardiogram supporting LaRocca's claim was reviewed by three (3) experts: Dr. Kaul, Dr. Millman and Dr. Lazar. Both Drs. Kaul and Millman conclude that LaRocca's echocardiogram was performed in a medically unreasonable manner. The Nyquist limit used in LaRocca's echocardiogram was 43 cm/sec, which is "too low" and "has magnified the regurgitant lesions." Moreover, both physicians concluded that even if the technically deficient echocardiogram was to be credited, there was no MAR. Instead, LaRocca has only trace aortic regurgitation. Finally, Dr. Kaul testified that in the particular frame used by Dr. Lazar to find MAR, the LVOT could not be determined.

Dr. Lazar disagrees with Drs. Kaul and Millman, although he acknowledges that the technical quality of the echocardiogram is poor. He measured the JH/LVOT at frame 126:95:09 and concluded that the MAR is 14.3%.

For the reasons already articulated in Henrie, the Court finds that the echocardiogram was performed in a medically unreasonable manner. First, the Nyquist limit is inappropriately low. Second, the signal to noise ratio (the gain) is set too high, thereby significantly degrading the quality of the echocardiogram. For these reasons alone, the Court finds that Wyeth has satisfied its burden and shown that this echocardiogram is not reliable.

The Court also finds Dr. Kaul's testimony persuasive on the question of whether the LVOT could be measured in the frame relied upon to Dr. Lazar. Dr. Lazar conceded that he could not see the LVOT in the frame he measured to support his MAR finding.[11] But he claimed he could "see it well in real time."

[11] Dr. Lazar testified as follows on this subject:

Q. The first one is about Ms. LaRocca, correct?

Weyman, however, indicates that because measurements of JH/LVOT are so sensitive:

> The size of the regurgitant orifice can be approximated from the cross-sectional area and/or height of the regurgitant jet as its origin just below the aortic valve, and this "orifice size" has been used as a measure of the severity of regurgitation (Fig. 19-61) [which shows the proper measurement technique].... *To ensure that the jet is imaged at its origin, measurements should be made only in areas where valve components are also recorded.* Weyman Text at 534 (emphasis added).

Plainly, in real time, the two (2) dimensional structures, such as the LVOT, torque and distort as the heart beats, making the LVOT reading referred to by Dr. Lazar necessarily imprecise.

In conclusion, the Court finds that Wyeth has established that LaRocca's echocardiogram was not performed or evaluated in a medically reasonable way.

A. Uh-huh.
Q. The first note is that mild AI?
A. Yes.
Q. And under that, anulus is seen, is that what you've got?
A. Yes.
JUDGE WALSH: And he gives a frame.
MR. GHOLSON: Frame reference, yes, sir.
Q. Now, over on the right, on the upper part, what did you write there?
Can I just put it up here? That highlighted part right there. What does that say?
A. Nyquist 46.
Q. And under that, what does it say?
A. Perpendicular to transducer.
Q. Perpendicular to transducer?
A. Yeah, that's a -- yeah, this is a perpendicular sign.
Q. Okay.
A. This is actually classic -- perpendicular, I think that is a physics abbreviation.
JUDGE WALSH: At least geometry.
A. Yes, yes.
Q. And is under that, that I highlighted there, what does it say there?
A. Don't see LVOT in that view, *but see it well in real-time.* (Emphasis added.)

F. Joy McPhail

McPhail relies on an echocardiogram report of Dr. Stephen E. Weinberg dated February 18, 2003. The echocardiogram was performed by CADV. Dr. Weinberg found that McPhail had MMR using the CAS criteria -- RJA/LAA. No worksheets from CADV were introduced in evidence.

The echocardiogram was reviewed by three (3) experts: Dr. Vasey, Dr. Saric and Dr. Viswanath. Both Drs. Vasey and Saric found that McPhail did not have MMR. Both physicians found that the RJA supporting Dr. Weinberg's conclusion that McPhail had MMR was vastly overtraced. Dr. Vasey put it this way:

> The sonographer's on-line tracings, or planimetry, of the regurgitant jets included predominantly low velocity, or non-aliased, displaced flow. The sonographer planimetered outside the area of the true mitral regurgitant jet on each separate measurement, resulting in significant overtracings, including laminar blue and black signal. In fact, one of the purported RJA tracings (5.02 cm^2) not only included non-aliased flow, but also appeared to incorporate some flow within the left ventricle (which cannot be mitral regurgitation), rather than the left atrium.... Additionally, the sonographer failed to measure, or trace, the left atrial area (LAA).

At the hearing, it became apparent that Dr. Viswanath had traced an island of blue color separated from the rest of the regurgitant jet. Dr. Saric concurred, stating that the RJA was overtraced and the LAA was absent.

Dr. Viswanath disagreed, finding that his retracing of a 5.04 cm^2 RJA easily correlated with the sonographer's initial finding of 5.02 cm^2. Dr. Viswanath claimed that McPhail's mitral valve is domed-shaped and, as a result, Drs. Vasey and Saric had underestimated the RJA. Dr. Viswanath appears to agree that the LAA was not initially traced, but measured the LAA at 23 cm^2 during the hearing. Thus, according to him, the RJA/LAA yields a percentage of 22% -- MMR. During his testimony, Dr. Viswanath also reported a RJA of 5.22 cm^2 and a LAA of 23.2 cm^2 at a different portion of the echocardiogram tape. Unfortunately, Dr. Viswanath's color photograph of the planimetry done by him was virtually worthless. It simply could not be read.

The Court reviewed the echocardiogram examined by Dr. Viswanath and finds that the tracing of the RJA is medically unreasonable. Dr. Viswanath traced an island of blue color separated from the regurgitant jet. None of the color appeared to be mosaic and it was quite separate from the rest of the phenomenon referred to as the jet. Even assuming that McPhail's mitral leaflets are domed, a medical conclusion hotly contested by Drs. Vasey and Saric, the mitral regurgitation does not approach MMR and no medically reasonable tracing can support an MMR diagnosis. Dr. Vasey measured the same RJA and characterized the blue island distinct from the rest of this regurgitant jet as "very low velocity flow. It's entirely distinct from what you see happening up here ... [the regurgitant jet], and, if anything, it's blood that was preexistent in the left atrium ... [that] has been pushed backwards, but it's certainly not part of a mitral regurgitant jet." Dr. Saric traced the RJA/LAA from the echocardiogram tape and, using a much smaller LAA of 15.12 cm^2, came to the conclusion that McPhail had no more than mild mitral regurgitation.[12]

The Court completely agrees with Dr. Vasey and finds no reasonable medical disagreement is possible here, even if the Court were to measure the area represented by the controversial "domed mitral leaflets" as part of the RJA. Dr. Viswanath's tracings here are medically unreasonable and Wyeth has demonstrated that to be the case. Accordingly, Wyeth has satisfied its burden to show that McPhail's MMR finding is medically unreasonable.

G. Donna Minter

Minter relies on a July 24, 2002 echocardiogram performed by CADV and an undated report of Dr. Stephen E. Weinberg. Dr. Weinberg found Minter had MMR using CAS criteria -- RJA/LAA.

The July 24, 2002 echocardiogram was examined by three (3) experts: Dr. Goldman, Dr. Saric and Dr. Weinberg. Both Drs. Goldman and Saric found that, while the study was of acceptable quality, the sonographer and Dr. Weinberg

[12] Dr. Saric testified that it is methodologically possible that a finding of RJA/LAA is medically reasonable. The Court does not believe this testimony indicates this MMR finding relied upon is medically reasonable:

> Q. Now, in McPhail's case you measured the ratio at 16.3 percent.
> A. That's correct.
> Q. You think it might be medically reasonable to say it's 20 percent?
> A. It might be possible. It might be possible. It might be a range. The difference is there is a standard deviation. That's mathematically possible.

significantly undertraced the LAA, reporting the LAA as 13.7 cm^2. According to Dr. Goldman, the LAA should have been at least 18.6 cm^2.[13] He further observed that the RJA was overtraced and contained "non-turbulent monochromic laminar blue."

Dr. Saric observed that even with the gross underestimation of the LAA, the RJA/LAA calculation made by the sonographer did not establish MMR -- 2.2 cm^2/13.7 cm^2 = 16%. Other tracings made by the sonographer led to similar readings: Minter was not shown to have MMR.[14] In any case, Dr. Saric traced the

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[13] Dr. Goldman used the sonographer's figure of 18.6 cm^2. Dr. Weinberg later retraced this LAA as 19.7 cm^2.

> Q. And it's been marked as Exhibit P-2066. I'll just put it on the overhead and let the doctor first -- Dr. Weinberg, can you just explain the circumstances under which this digital photo took place and why it was done this way?
> A. We were asked to relook at the jets to determine if the measurements were accurate and whether -- to what extent they would denote the amount of mitral insufficiency and, more particularly, to have photographic images made to substantiate what we're saying.
> Initially, when we did the images, after we looked at them again, and when I looked at them the first time -- first time I saw the images, as I do with most of these, we look over the study and look at it in real-time, do the stock frames and might or might not agree with the technician in terms of what she offered, but I would then make my quantitive and qualitative judgment as to what I thought the relevance was of the jet.
> Then we were asked to be more precise to go back and to measure stock frames to substantiate what we found or what I found and so we had my technician go back with my supervision and she stock framed the studies and went and imaged the jets, but we had at that time, and still don't have, actually, printing capabilities to print the studies. We don't use printed material any longer. It's obsolete, in essence. So --
> JUDGE WALSH: Behind in the times, Doctor.
> WITNESS: That's one of those things. This is nice technology here, though.
> A. So in preparation for today, we had to come up with another set of tracings that were hard copied to enable us to demonstrate in black and white, if you will, or blue and white, et cetera, what we were talking about. So it's under those circumstances that these images were produced.
> Q. And this is your personal measurement of the LAA on Donna Minter?
> A. This is my personal measurement, yes.
> Q. And, actually, you came to a level higher number than Dr. Goldman 19.7 square sonometers?
> A. That's correct.
> Q. You're saying the number in Dr. Goldman's certifications medically unreasonable?
> A. No, I think there's a margin of error. There's a frame-by-frame difference. The left atrium gets a little bigger, smaller in the different parts of the cardiac cycle. The difference between his measurement and my measurement is probably clinically insignificant.
> Q. All right. Let's go -- we can go to the tape and I think you have it cued up to --
> JUDGE WALSH: What was your measurement?
> A. 19.7.

[14] Dr. Saric's testimony is as follows:

> THE COURT: Let's mark this as 206 B and C. The first being the apical four-chamber view. It's indicated as A4C, meaning apical four-chamber view. For Donna Minter. This will be 206 B. And the apical two-chamber view for Miss Minter, which will be marked as 206 C.
> A. That's correct, your Honor.

RJA/LAA in two (2) views, concluding that the RJA/LAA ranged from 9.3% to 10.5% -- clearly mild mitral regurgitation.

Dr. Weinberg reached a different conclusion. He reportedly traced RJAs of 7.77 cm^2 and 7.82 cm^2 and LAA of 24.7 cm and reported them in his Affidavit. These measurements produced RJA/LAA percentages of 31% and 31.6%, respectively. Another RJA/LAA comparison (5.04 cm^2/23.2 cm^2), done at the hearing, produced a percentage of 22%. Arguing that "[a]ccording to the Weyman textbook the maximum jet area occurring at any point during systole is taken as the representative value" of RJA, Dr. Weinberg stands by his judgment that Minter has

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Q. I was going to give it to you, Doctor, as soon as the clerk gets these marked. What we'll do is let you describe in narrative fashion what your findings were. And, of course, you can refer to the report and your pictures and addendum, if you wish.

I'll give you all the exhibits, Doctor, and you may proceed.

A. These are my reports.

Q. Just in narrative fashion, can you describe those?

A. Your Honor, I was asked to review the tape of or study of Donna Minter performed on July 24th, 2002. I was provided with both the tape and a digital version of the study. I was asked about the aortic regurgitation and the mitral regurgitation on the study, and I found no aortic regurgitation to be present in any of the views. In the study, however, there was present much regurgitation, and I tried to evaluate the severity of it as well as to comment on the findings that are performed by the sonographer who did this study.

I commented that the color gains, or technical aspect of the study, was all right, that it was an acceptable study. The overall study was of acceptable quality. That the color gains were set appropriately, and the Nyquist limit was generally set to greater than 50 centimeters per second. I concluded to the best of my knowledge no measurement on the original study supports the diagnosis of at least moderate mitral regurgitation.

I also commented on the finding by the sonographer, and I said that on the original study the sonographer performed both RJA and LAA measurements, and even by all those measurements MR is less than moderate. For instance, in one set of measurements in which the RJA was generously traced and that provided the numbers that the jet area was between 2.17 on 3.07 centimeters squared, is in the same view the measurement of left atrial area of 18.6, and if you make a ratio of the two you will come a bit less than 20 percent.

In another set of measurements the area again is less than 20 percent. RJA was 2.2. Left atrial area was 13.7 and the ratio was 16 percent, despite the generous underestimation of the left atrial size in this view. And also I performed my own measurements, and I did actually two sets of measurements for apical four-chamber view and the apical two-chamber view. They're provided in the table. And you will see that according to my calculation in apical four-chamber view the right RJA was 1.51 centimeters squared, the left atrium area was 16.17, and the ratio of the two was 9.3 percent. The apical two-chamber view the jet area as 2.03. Left atrial area was 19.28, and the ratio 10.5 percent. And based on these calculations I concluded that regurgitation is mild.

Q. Any other comments you feel are appropriate with respect to the Minter study? And if not we'll move on to the next one, which is the Pezzino study.

A. Even if you look at the original report, the original report on the study, the sheet, the work sheet of the study, the original work sheet of the study, you see that the most measurements also support what I found, the ratio was 16 percent to 18 percent, 19 percent, and only one measurement was 24 percent, so this is the original report of the study that you have seen.

MMR.[15] At the hearing, additional tracings also were reported by Dr. Weinberg, however, the planimetry done in advance of the hearing and captured on photographs taken by a digital camera were actually worthless in supporting that conclusion because of poor color fidelity.[16]

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[15] By the hearing, the parties had agreed that an LAA of 18.6 cm^2 was medically reasonable. The real debate here concerns the RJA.

> JUDGE WALSH: I mean, I take it that the debate here, now that you have Dr. Goldman talking 18.6, you talking 19.7, Dr. Saric, who recently entered the fray here, with his own planimetry, talking about 16.2 and 19.3, so if you average those, they all are within a -- less than 10 percent of one another, so the real debate here is going to be over the size of the jet.
> MR. CUKER: That's correct.
> JUDGE WALSH: Regurgitant jet area.

[16] Dr. Weinberg admitted that the digital photographs depicting the tracing done could not be read and critiqued. But so the record is complete, the frames supporting Dr. Weinberg's position are set out in this footnote.

> MR. CUKER: There we go. Is that your -- and that's again, that's at the same frame 5:59:1.
> JUDGE WALSH: You folks have to get a new digital camera.
> MR. CUKER: This is still better than what we had yesterday.
> JUDGE WALSH: A little bit.
> WITNESS: Six mega pixels.
> JUDGE WALSH: It doesn't have good color fidelity.
> WITNESS: I think that one can argue that you can hold this area in and come out here and up again. This is certainly mosaic. It's light blue. There's some white in here. The same thing here, and I was able to get 5.65 out of that.
> Q. 5.65 square centimeters?
> A. That's correct.
> Q. Now, did you do alternate tracings, cutting out some of these areas?
> A. Yes, I did.
> Q. Why did you do that?
> A. Well, having been down this road before, it's apparent to me that everyone is going to look at this thing a little differently, and I thought, well, let me see what the tracing would look like or the area would look like if I excluded some areas that were in question, and put areas in and then just kind of change things around a little bit. So I played a little bit with the planimeter measurements.
> Q. By the way, that last one was Exhibit 2060?
> JUDGE WALSH: 2060, is it? All right.
> MR. CUKER: In his Exhibit 2061, this is an alternate tracing of the same frame.
> MR. AGNESHWAR: What was the other one?
> JUDGE WALSH: 2060.
> WITNESS: It's the same beat, but I think those are different frames.
> MR. CUKER: I'm sorry.
> A. This is 15 versus 11, but it's the same beat, and I've took out this area here. Left in this area, and I got 5.07 so --
>
> * * * *
>
> MR. CUKER: Exhibit 2062 is a tracing you did at 559:26. Would that still be the same beat?
> A. I don't remember the last one, but it's probably -- these are one-thirtieth of a second, so this comes down here and includes this down. I disregard any of the light blue over here. I'm pulling a part of this. This, again, is a different frame of the same region.
> Q. And that measured at what, 4.62?
> A. 4.62.
> Q. Square centimeters? Okay.
> Making our way down, just show another one. This is, again, at 5:59:26 of the same frame?

JUDGE WALSH: The last picture was 2062, right?
MR. CUKER: Correct.
JUDGE WALSH: Now, we're on 2063?
MR. CUKER: This is 2063.
Q. What did you -- how did you pull this --
A. I cut off part of the bottom here and kept in this area, cut off the side area here, and tried to make it a little different just to see whether it would change the size of the area.
JUDGE WALSH: Each one of these are different frames, I take it?
WITNESS: Different frames, yes.
MR. CUKER: They're about a tenth of a second apart.
MR. AGNESHWAR: I don't think so. I think the sonographer freeze froze this picture and kept it on there for a while. So I think this is all the same frame with different measurements.
JUDGE WALSH: You do, huh? It sure looks different to me.
WITNESS: I don't think so, because when you freeze frame this, my recollection is, and I could be wrong about this, that the counter stops, and it becomes zero.
MR. AGNESHWAR: Well --
JUDGE WALSH: We'll find out on cross-examination.
MR. AGNESHWAR: Or with Dr. Goldman.
JUDGE WALSH: For what it's worth, I've looked at the same frames the doctor has and they look different. Maybe they're not.
WITNESS: And there was another one.
MR. CUKER: I'm going there.
WITNESS: I apologize.
MR. CUKER: That was 4.45 sonometers.
Q. Now, this is definitely a different image, and maybe we ought to show it as it appears on the tape. It's 554.
JUDGE WALSH: We're able to do that.
MR. CUKER: Let's get back to 554.

* * * *

Q. Now, you did a tracing of that frame, as well?
A. Yes.
Q. And we'll switch to Exhibit P-2064. That's your drawing on that. Do you want to describe that tracing?
WITNESS: Sure. I took out the bottom part here, thinking that that would be an issue and I traced it around the -- what I perceived to be the high flow areas without the bottom part here, coming in under here and back up around this way and up to here.
JUDGE WALSH: Looks like a poor representation of Great Britain.
MR. CUKER: I think a lot of them do, actually.
Q. And the measurement was?
A. 4.27, I think.
Q. Can we just go back to the image on the video again? Do you think you can -- Dr. Weinberg, maybe you want to take this picture and show on that image what you traced? What's included?
A. I came down this way. Sorry, your Honor.
JUDGE WALSH: That's all right.
WITNESS: I came down this way in here and under and I excluded this area here, came under here and tried to work my way back up here, excluded this area here.
JUDGE WALSH: Right. And you say that was 4.27?
WITNESS: 4.27, yes.
Q. All right. And this last one is -- that's Exhibit 2064.
JUDGE WALSH: This is operating 19.6, that, I guess, would get you comfortably over.
MR. CUKER: The next one gets us a little less comfortably over.
Q. This, again, was done at frame 5:59:13, back in the 559 sequence.
A. Same thing. Came down here, excluded the darker blue, excluded this area here, which is sort of a close cousin, but perhaps not part of the family, and came up this way and back up to the top again, and that was 4.0.

Dr. Goldman disagrees with Dr. Weinberg and has testified that several of the still frames, discussed by Dr. Weinberg, report the same point in the cardiac cycle.[17]

Q. Now, why don't we just see the actual video image of Frame 559:13? Can you again, Dr. Weinberg, take what you drew on here and show it on there, on the screen?
A. Uh-huh. I tried to come down this way, in these areas over here, pick up this, come under here, back up here, include this area here under that way.
Q. 4 square centimeters?
JUDGE WALSH: What was the size of that, just 4?
MR. CUKER: That was 4 even.
WITNESS: 4.0.
JUDGE WALSH: And the picture is?
MR. CUKER: 2062 -- 2065, I'm sorry. Just for the record, though, is it your testimony that the first tracing, 5.65 is medically reasonable?
WITNESS: Which one is that?
MR. CUKER: This one?
JUDGE WALSH: What's the number on it?
MR. CUKER: 2060.
WITNESS: Yes, I believe that includes the jet.
JUDGE WALSH: That's the 5.
WITNESS: 5.65.

* * * *

Q. Now, in early systole, do the leaflets form that kind of pointy shape?
A. Yes.
Q. Does that flatten out as you get into later systole?
A. Yes.
Q. Why would you -- would it be appropriate in measuring a regurgitant jet in a picture like that to use a picture from late systole -- may I have the pointer, please? Use a picture from late systole when the jets are flattened out like that and say to include this part of the jet?
A. No, you can't -- you can't say that because at this point in time in the systolic cycle, it is what it is.

You can't say that I'm going to take the jet from early systole and cut off part of it because in late systole, as the leaflets coapt and become more flat, that you want to use that as your marker. That's not reasonable. No one does that.
Q. No one does that?
A. Well, I don't think anyone does that. I mean, I haven't heard anything like that. Let's put it that way.

[17] Dr. Goldman testified:

MR. AGNESHWAR: For the record, these are Plaintiff's Exhibits 2062, 2063, 2060, 2065, 2061, and 2064.
A. Yes, sir.
Q. Based on your review of the echocardiogram study and your review of this frame and your review of Dr. Weinberg's frames, are these tracings done in the same frame or a different frame than what we see on the screen?
A. The same frame.
Q. All of them?
A. Yes, sir.
Q. The reason we brought this other screen is because I want to show two images side by side. And if we can go to the videotape of this echocardiogram and go to the same cycle as up here at the same time counter.
MR. AGNESHWAR: And, for the record, that is 6:01:02.
Q. Doctor, are those the same images, the same time counter? Feel free to get up.

The Court finds that Minter's echocardiogram was performed in a medically reasonable fashion, but the RJAs testified to by Dr. Weinberg were substantially overtraced. The Court finds that the tracings done by Dr. Weinberg which report RJA in the range of 4.27 cm^2 to 7.8 cm^2 were not medically reasonable. Examinations of the frames identified by Drs. Weinberg, Goldman and Saric convince the Court that Dr. Weinberg overtraced several jets. In one example, he expanded CADV's sonographer's finding of RJA of 3.07 cm^2 to 4.45 cm^2 by including low velocity non-turbulent flow.[18] In another, he retraced the

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MR. CUKER: I'm going to object because what Dr. Weinberg was testifying from -- And this is just a statement for the record, really. -- did not have the sonographer's tracing on it. This does, and it adds some white dots to the mix that may make it hard to follow. I'm just making that statement.

MR. AGNESHWAR: That's not the point I'm making. I want to start out by showing the two frames side by side, and what I would like to do is to go back frame by frame on the video until we --

Q. Let me ask you this: Doctor, what is the time counter on Dr. Weinberg's first tracing?

A. On 2062 it states 5:59.26.

Q. Before we do this let me ask you one question: How can you tell if two images are images of the exact same frame from the echocardiogram or if they're different? Are there any objective criteria to be able to determine that?

A. There are several external markers that you could use besides the image itself. What's very helpful is the EKG time markers. There are two markers. The white line represents the extent of the frozen loop in which this is contained, and this tells you where in that marker, or where in that loop you may be. And also, this is the EKG, and this is where this frame is -- This is a marker here showing you the interval, but you have a marker over here.

Q. Can you describe what you're pointing to so the record is clear?

A. There is a linear line going right after the QRS here. It looks like here are two arrowheads which delineate the cycle, and there's a marker right after two of those arrowheads, so that's outside of the picture itself. And then you could look at distinctive things within the picture, like this red circle relative to the two white dots, to see whether it's identical.

If this is a loop, the technologist or the physician when they're reviewing it have the ability of going back and forth to finding a frame they may want to measure, and if the videotape is still running you'll see the time marker change, but the image may not change at all.

Q. So even if the time -- The time marker might change even if the image is the same?

A. Yes, sir. Because it just says that the videotape is running and recording.

Q. Just to clarify, do you see on the EKG that these are the same, the structures are the same?

A. They're the exact same time and, obviously, it has the same markers. Yes.

[18] Dr. Goldman's testimony on this point is as follows:

Q. The time marker is the same in the still you have compared to what we see on the video?

A. Yes, sir.

Q. And that's 5:59:26.

A. Yes, sir.

Q. What RJA measurement did Dr. Weinberg get here?

A. 4.62 centimeters squared.

Q. As opposed to 3.07 that the sonographer got?

A. Yes, sir.

Q. If you can tell by looking at the hard copy of what Dr. Weinberg traced, if you could point out on the larger image what he traced to expand the regurgitant jet.

sonographer's RJA so that it expanded in area by almost 33%.[19] Finally, again taking the same view, Dr. Weinberg expanded the sonographer's tracing, this time

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A. It appears -- Again it's hard. It appears that he included anything that had color in it, including this very low-velocity nonturbulent blue and, obviously, it looked like it incorporated many areas of black.
Q. Is that medically reasonable?
A. I don't think so.
Q. And just going back to your definition of a mitral regurgitant jet, why would it not be medically reasonable?
A. Because mitral regurgitation should be turbulent mosaic high-velocity flow represented by multicolor mosaic pattern, and this is low-velocity, very dark black, dark blue nonaliased flow.
Q. There was some testimony yesterday from Dr. Weinberg that even though those areas are not mosaic they're still high velocity. Do you have an opinion about that?
A. Well, by definition if you look at the Nyquist bar, if it has an alias through that it's not going to exceed 58 centimeters per second. So that's really not high velocity. That's encompassed by the Nyquist of that blood moving away from ventricle or inflow in the ventricle, but it doesn't represent turbulent mosaic jet.
Q. And that's an appropriate Nyquist. Right?
A. Again, we always try to have the highest Nyquist possible. I don't know if that's what was possible on his machine.
Q. If you can look at your still and -- of the next frame of Dr. Weinberg's, Plaintiffs' 2063, what is the time marker on this?
A. It looks identical. 5:59:26.
Q. Same time marker?
A. Same time marker and, therefore, the same image as we're seeing on the 6:01:02.
Q. What did Dr. Weinberg get when he traced it this time?
A. 4.45 centimeters squared.
Q. So about a centimeter, a little more than a centimeter-and-a-half more than what the sonographer got.
A. Yes.
Q. And to the best of your ability based on looking at this digital photograph, can you describe to the judge what Dr. Weinberg traced to get the jet up to 4.45? And just pointing out --
A. Again I presume he incorporated within his tracing much of this area which is low-velocity nonturbulent flow.
Q. Would it be medically reasonable to include that in the tracing of a regurgitant jet, mitral regurgitant jet?
A. No, sir.

[19] Dr. Goldman testified as follows:

MR. AGNESHWAR: 2060. Plaintiffs' 2060.
Q. If you could just describe to the best of your ability, looking at the still frame, what on this image Dr. Weinberg traced to get 5.65?
A. Again, I would assume he incorporated much of this low-velocity nonturbulent flow that would not represent regurgitation.
Q. Medically reasonable?
A. I don't think so.
Q. If you go to Plaintiffs' 2065, the next frame?
A. Yes, sir.
Q. What did Dr. Weinberg get in this measurement, just looking on the screen?
A. I think 5:59:13.
Q. What just occurred when we moved to 5:59:13?
A. It's the same frame.
Q. Can you explain again how you can tell it's the same frame?

by 66%.[20] In short, it appears that the same cardiac cycle and jet were measured and remeasured with significantly different results.[21]

A. I think objectively the EKG marker is very helpful in identifying it as the same image and the same frame. Although the VCR time marker might have changed, the image is the same.
Q. When we went back through all these times did the image change at all?
A. No, sir.
Q. So what does that tell you the sonographer did?
A. The sonographer had a frozen loop and kept the VCR moving as the loop stayed in position.
Q. What did Dr. Weinberg get this time when he traced the RJA?
A. Four centimeters squared.
Q. And again that's not much higher than the sonographer's tracing, but about nine-tenths of a centimeter greater than the tracing that the sonographer did?
A. Right. Almost 33 percent greater.
Q. Can you, again looking at the still frame that you have, describe on the big picture what Dr. Weinberg traced to get up to four?
A. I presume he encompassed anything that had color, including very low-velocity areas of black that would not represent regurgitant flow.
Q. Would that be medically reasonable?
A. No, sir.

[20] Dr. Goldman's testimony is as follows:

Q. If you could look at Plaintiffs' 2061, what is the time marker on this one?
A. This is 5:59:15 or 19.
Q. I think it's 15.
And again, on the videotape, if we can just go two frames to 59:50. Did the image change?
A. No, sir.
Q. Is this the same image as all the other images we've seen and as what we see on the big screen from the echocardiogram?
A. Yes, sir.
Q. And, again, how can you tell that?
A. Using the EKG markers.
Q. I'm sorry to belabor this, but just so the record is clear, can you point out again what you're seeing on the EKG markers?
A. Again I'm using in this case the third QRS. There's a linear mark right after the QRS complex. There are two arrowheads which frame the second and third QRS, and those appear to be identical to what we're seeing at 6:01:02, which would say the frozen frame at 5:59:15 is the identical image that we're seeing at 6:01:02.
Q. What did Dr. Weinberg get in his tracing this time?
A. 5.07 centimeters squared.
Q. And how much greater is that than 3.07 that the sonographer traced?
A. Probably around 66 percent.
Q. And what did Dr. Weinberg tract, to the best you can discern it, based on the photograph there? What did he trace on this image to come up to 5.07?
A. Again, I presume he encompassed anything he saw that had a color pixel in the left atrium, which would represent nonturbulent flow.

[21] Dr. Saric is of the same view:

THE COURT: Well, just because this is an important matter, you did some planimetry which is reflected in your own examination. Could you, just for us, trace the regurgitant jet that you believe exists here? We're referring to the picture up on our state-of-the-art wall, which is I believe the same image that was photographed.
WITNESS: I presume that these are the leaflets of the mitral valve. The anterior leaflet and the posterior leaflet. That's the perimeter, the separation of the left ventricle and the left atrium. If

Dr. Goldman concluded, as the Court now does, that any RJA measurement of 7.7 cm^2 or 7.82 cm^2, reported by Dr. Weinberg in his Affidavi, is medically unreasonable. Review of the echocardiogram convinces the Court that no reasonable expert could conclude that regurgitant jets of such area exist there.[22]

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that's correct, the origin of jet would be here and continues into the left atrium. The area that I will trace would be the high alia flow around --
THE COURT: You would exclude the blue, whether it be light blue or the darker blue?
WITNESS: That's correct.
THE COURT: Why is that?
WITNESS: Because the high-velocity jets -- Let's say that the blood pressure is at least a hundred in any of the patients. So the assumption is that the jets travels at very high velocity, at least 500 centimeters, which would be the pressure of a hundred. So, therefore, regurgitant jet has to -- must alias if it travels at that velocity. And traditionally if it's a high-velocity jet it would be considered to be a regurgitant jet. There would be some area of the blue that is displacement area of a preexisting blood, intrained blood.
THE COURT: Doctor, would it be medically reasonable to include any of that what you call intrained --
THE WITNESS: In my opinion it's the high-velocity jet, high aliasing that is high-velocity jet that represents the mitral regurgitant jet.
THE COURT: All right. Anything you want to follow up on?
MR. CUKER: Sure.
Q. Dr. Saric, in your work -- First of all, do you agree that at least within these blue areas there are areas of very light blue to white that represent higher velocity areas?
A. Correct. At the level about -- It's 59? I think it's 59. So that would be approaching, but it's still not -- it's less than. It would be in the fifties range.
Q. Isn't it true, though, that the further the jet goes in the left atrium it tends to slow down in velocity?
A. That's correct.
Q. Couldn't a well trained, highly qualified cardiologist acting to the best of his ability reasonably conclude that at least some of these light blue areas could belong in the jet?
A. But they are under the Nyquist limit, so you're talking about the velocity dropping from 500 to 50. There's a ten-fold difference. It's already the velocity -- the flow in the left atrium
MR. CUKER: Could you read the question back, please.
(Whereupon, the last question is read back by the reporter.)
Q. Can you answer that question yes or no?
A. To the best of my ability I would say the jet that's traced would be the high-velocity alias jet, and I can speak for myself.
Q. Are you able to say whether other reasonable, well-qualified cardiologists acting reasonably would or would not conclude some of these light blue areas as well?
A. You would have to ask them.
THE COURT: Here's the point, Doctor. We don't care how you answer the question. And it's not whether you embarrass some other physician or say something that is either favorable or unfavorable to the physician. The questioner wants to know -- He understands what you're testifying. Now he wants to know, could a cardiologist with your training and experience, acting reasonably, could that person trace the blue or some of the blue areas, the blue white areas within that regurgitant jet and be acting in a medically reasonable way?
WITNESS: I don't think the inclusion of this area would be medially reasonable.

[22] Dr. Goldman testified as follows:

Q. The next, if you could look at Plaintiffs' 2064, and I believe this is the last one. What is the time marker on this one?
THE COURT: What as the tracing of --
MR. AGNESHWAR: Of 2061?

Moreover, the Court finds that Dr. Weinberg retraced the RJAs measured by CADV's sonographer and significantly expanded them by including non-mosaic laminar flow or black segment blood. Accordingly, the Court finds that Wyeth has established that Dr. Weinberg's conclusion that Minter has MMR is medically unreasonable.

IV

For these reasons, the Court grants Wyeth's motions to dismiss with prejudice as to Comparoto, Harris, Henrie, LaRocca, McPhail and Minter and those plaintiffs will be returned to the Class. The Court, however, denies Wyeth's motion with respect to Grimes.

An Order reflecting these determinations is enclosed with this Letter Opinion.

Very truly yours,

Charles J. Walsh, J.S.C.

CJW/len
Encl.

THE COURT: On 2061.
MR. AGNESHWAR: The tracing on 2061 was 5.07.
Q. Moving to the hard copy of 2064, this is the last tracing that Dr. Weinberg did. Correct?
A. Yes.
Q. What is the time marker on this?
A. I should say it's the last tracing that I have prints for. I don't know if he did others.
Q. I understand. That's all we have, too.
A. The time marker is 5:54.
Q. Now, I want to go back, and I want you to describe, as t he image moves, what we're seeing.
A. So looks like they're stepping through the cycle. If you look, this EKG marker is moving? So there's a frozen loop, and they're taking the loop through the EKG through the cardiac complex as noted by the change in movement of the marker here.
THE COURT: So clearly we have a new jet.
A. But then he comes back to the same yet [sic] [jet]. So he comes back to the same jet that we started. So the technician was going forward back, forward back, but 5:54, if we take those objective markers of the EKG, the two arrowheads, this linear marker are identical. So the technician was going back and forth but then ended back where he or she had started.
THE COURT: So it's the same jet all over again.
WITNESS: Yes. It looks as if it's the same yet [sic].