

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
_____	)	
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9134

Bartle, J. August 21, 2013

Donna M. Rivas ("Ms. Rivas" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>2</sup>

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with (continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In March, 2010, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Paul W. Dlabal, M.D., F.A.C.P., F.A.C.C., F.A.H.A. Based on an echocardiogram dated June 28, 2002, Dr. Dlabal attested in Part II of claimant's Green Form that Ms. Rivas suffered from mild aortic regurgitation and moderate mitral regurgitation and had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™.<sup>3</sup> Based on

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2. (...continued)

serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Dr. Dlabal also attested that claimant suffered from an abnormal left atrial dimension, a reduced ejection fraction in the range of 50% to 60%, and New York Heart Association

(continued...)

such findings, claimant would be entitled to Matrix A-1, Level III benefits in the amount of \$671,107.<sup>4</sup>

In the report of claimant's echocardiogram, the reviewing cardiologist, George G. Miller, M.D., F.A.C.C., stated that claimant had moderate mitral regurgitation of 28%. Under the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In August, 2010, the Trust forwarded the claim for review by Alan Bier, M.D., one of its auditing cardiologists. Dr. Bier accepted the attesting physician's representations that claimant had mild aortic regurgitation, moderate mitral regurgitation, and surgery to replace her aortic and mitral valves. Dr. Bier also determined, however, that there was no reasonable medical basis for Dr. Dlabal's representation that Ms. Rivas did not suffer from aortic sclerosis at the time she was first diagnosed as FDA Positive.<sup>5</sup> Pursuant to Court Approved

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3. (...continued)

Functional Class I symptoms. These conditions are not at issue in this claim.

4. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Settlement Agreement § IV.B.2.c.(3)(a).

5. Under the Settlement Agreement, the presence of aortic sclerosis in claimants who were sixty (60) years of age or older at the time they were first diagnosed as FDA Positive requires  
(continued...)

Procedure ("CAP") No. 11, the Consensus Expert Panel<sup>6</sup> subsequently reviewed the claim and determined that it should be re-audited because the "[g]roup does not find [a] [reasonable medical basis] for [the] auditor['s] findings of no [mitral annular calcification] and moderate [mitral regurgitation]." In November, 2010, the Trust informed Ms. Rivas that it had accepted the Consensus Expert Panel's recommendation that her claim be re-audited.

In November, 2010, the Trust forwarded the claim for review by another auditing cardiologist, M. Michele Penkala, M.D. Dr. Penkala concluded that there was a reasonable medical basis for the attesting physician's findings that claimant had mild aortic regurgitation and surgery to replace her aortic and mitral valves. Dr. Penkala also determined, however, that there was no

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5. (...continued)  
the payment of reduced Matrix Benefits for claims based on damage to the aortic valve. See Settlement Agreement § IV.B.2.d.(2)(c)i)c). FDA Positive is defined, in pertinent part, as "mild or greater regurgitation of the aortic valve...." See id. § I.22.a.

6. The Consensus Expert Panel consists of three cardiologists, one designated by each of Class Counsel, the Trust, and Wyeth. See Pretrial Order ("PTO") No. 6100 (Mar. 31, 2006). We approved creation of the Consensus Expert Panel to "monitor the performance of the Auditing Cardiologists and to develop procedures for quality assurance in the Audit of Claims for Matrix Compensation Benefits." Id.

7. Under the Settlement Agreement, the presence of mitral annular calcification requires the payment of reduced Matrix Benefits for claims based on damage to the mitral valve. See Settlement Agreement § IV.B.2.d.(2)(c)ii)d). Given our disposition with respect to claimant's level of mitral regurgitation, we need not reach this issue.

reasonable medical basis for Dr. Dlabal's representation that Ms. Rivas did not aortic sclerosis at the time she was first diagnosed as FDA Positive and that there was no reasonable medical basis for Dr. Dlabal's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Penkala observed:

The claimant appears to have had at most trace/trivial [mitral regurgitation] present prior to the end of the screening period. The putative [mitral regurgitation] jets that were traced clearly demonstrate low velocity brief duration flow limited to early systole consistent with typical "backflow." These jets are seen during the early systolic "red-blue" portion of the cardiac cycle. The [color wave] signal also demonstrates only very minimal early systolic flow.<sup>8</sup>

Based on Dr. Penkala's findings that claimant had mild aortic regurgitation, surgery to replace her aortic valve, and aortic sclerosis at the time she was first diagnosed as FDA Positive, the Trust issued a post-audit determination that Ms. Rivas was entitled only to Matrix B-1, Level III benefits. The Trust also determined that claimant was not eligible to receive benefits for damage to her mitral valve because she did not have an echocardiogram that demonstrated the presence of at least mild mitral regurgitation between the time of Diet Drug use and the end of the Screening Period. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant

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8. As noted in the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue, trace, trivial, or physiologic regurgitation is defined as a "[n]on-sustained jet immediately (within 1 cm) behind the annular plane of <+ 5% RJA/LAA."

contested this adverse determination.<sup>9</sup> In contest, Ms. Rivas disputed Dr. Penkala's determination that claimant's level of mitral regurgitation was less than moderate.<sup>10</sup> Ms. Rivas argued that Dr. Penkala did not properly apply the standards set forth in the Settlement Agreement. She also contended that the Trust improperly submitted her claim to the Consensus Expert Panel because it was not satisfied with Dr. Bier's conclusions. Ms. Rivas also asserted there was a reasonable medical basis for Dr. Dlabal's determination that Ms. Rivas had moderate mitral regurgitation. In support, Ms. Rivas submitted declarations from Michael E. Staab, M.D., F.A.C.C., Leon J. Frazin, M.D., F.A.C.C., and Dr. Dlabal. Dr. Staab stated, in relevant part, as follows:

4. On the basis of my review of this study, I found moderate mitral regurgitation (MR).

5. I re-measured the left atrial area (LAA), and I found that it measured 19.7 cm<sup>2</sup>.

6. The mitral regurgitant jet area (RJA) was accurately measured at time 12:13:22 and 12:13:49, where the RJAs measured 4.2 cm<sup>2</sup> and 3.8 cm<sup>2</sup>, respectively.

7. Accordingly, the RJA/LAA ratio was in the moderate range (RJA/LAA = 21.32%) at time

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9. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to this claim.

10. Ms. Rivas did not contest the Trust's determination that she only was entitled to Matrix B benefits on her claim for damage to her aortic valve based on the Trust's finding that she had aortic sclerosis as of the time she was first diagnosed as FDA Positive.

12:13:22, and the RJA/LAA ratio was close to the moderate range (RJA/LAA = 19.29%) at time 12:13:49. The average of the two ratios was in the moderate range (RJA/LAA avg. = 20.30%).

8. The jets that I identified as showing moderate and close-to-moderate regurgitation were representative of the level of regurgitation seen throughout the study, and these jets represented true regurgitation at the levels specified.

9. I also reviewed the Attestation of Auditing Cardiologist dated 11/29/10, and I could easily refute all of the opinions which were expressed in Section II of that attestation.

10. Clearly, the regurgitant jets that I found were typical holosystolic jets. They were not low velocity and they were not backflow.

Dr. Frazin observed, in pertinent part, that:

4. On the basis of my review of this study, I found moderate mitral regurgitation (MR), which was best seen in the apical 2-chamber view.

5. The left atrial area (LAA) was measured at 22 cm<sup>2</sup>, at time 12:16:45.

6. Regurgitant jet areas (RJAs) were accurately measured at four (4) different times, as follows:

RJA = 6.51 cm<sup>2</sup> at 12:16:19  
RJA = 7.11 cm<sup>2</sup> at 12:16:40  
RJA = 6.21 cm<sup>2</sup> at 12:16:59  
RJA = 7.17 cm<sup>2</sup> at 12:17:17

7. Accordingly, the RJA/LAA ratios were 29.59%, 32.32%, 28.23%, and 32.59%, with an average of 30.68%.

8. The jets that I identified as showing moderate regurgitation were representative of the level of regurgitation seen throughout

the study, and they represented true regurgitation at the moderate level.

9. I also reviewed the attestation of Auditing Cardiologist dated 11/29/10.

10. In contrast to the opinions of the Auditing Cardiologist, the moderate mitral regurgitant jets were not consistent with any backflow, because the regurgitant jet plume traveled to almost 75% of the superior-inferior [sic] length of the left atrium. With the Nyquist limit appropriately set, the regurgitant jets revealed aliasing, or were beyond aliasing at their distal portions.

Finally, Dr. Dlabal stated, in pertinent part, that:

4. On the basis of my review of this study, I found moderate mitral regurgitation (MR).

5. The left atrial area (LAA) was measured at 23.5 cm<sup>2</sup>. This measurement was excessive, because it included pulmonary veins and the appendiceal ridge. Therefore, I re-measured the LAA, and I found that it measured 20.0 cm<sup>2</sup>.

6. In the apical 4-chamber view, regurgitant jet areas (RJAs) were accurately measured at four (4) different times, as follows:

RJA = 4.21 cm<sup>2</sup> at 12:13:00  
RJA = 4.30 cm<sup>2</sup> at 12:13:23  
RJA = 3.84 cm<sup>2</sup> at 12:13:47  
RJA = 4.34 cm<sup>2</sup> at 12:14:20  
RJA Average = 4.17 cm<sup>2</sup>

7. Accordingly, in the apical 4-chamber view, RJA/LAA ratios were 21.0%, 21.5%, 19.2%, and 21.7%, with an average of 20.8%.

8. However, moderate [mitral regurgitation] was best seen in the apical 2-chamber view. In that view, RJAs were accurately measured, as follows:

RJA = 6.5 cm<sup>2</sup> at 12:16:18  
RJA = 7.1 cm<sup>2</sup> at 12:16:41



RJA = 6.2 cm<sup>2</sup> at 12:16:58  
RJA = 7.2 cm<sup>2</sup> at 12:17:17  
RJA = 7.0 cm<sup>2</sup> at 12:17:30  
RJA Average = 6.8 cm<sup>2</sup>

9. Accordingly, in the apical 2-chamber view, RJA/LAA ratios were 32.5%, 35.5%, 31.0%, 36.0%, and 35.0%, with an average of 34.0%.

10. The jets that I identified as showing moderate [mitral regurgitation] were representative of the level of regurgitation seen throughout the study, and they represented true regurgitation at the moderate level.

11. I also reviewed the Attestation of Auditing Cardiologist dated November 29, 2010.

12. In rebuttal to the Auditing Cardiologist's Attestation, there is no possible argument for "backflow" in this case.

13. Backflow jets are rarely measured due to their small sizes, but if measured, backflow jets would be expected to have RJA/LAA ratios of no more than 1 to 5%. Backflow jets would not have average ratios of 20.8% and 34.0%, as in this case.

14. Further, the jets that I found were predominately multi-colored, indicating aliasing. Also, the edges of the jets were irregular. These features singly and together confirm the pathological nature of the jets, as opposed to backflow which-when present-is a physiological phenomenon.

Accordingly, Ms. Rivas argued that she was entitled to Matrix A-1, Level III benefits for her mitral valve claim.<sup>11</sup>

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11. If claimant's level of mitral regurgitation was determined to be moderate, Ms. Rivas would be entitled to Matrix A-1, Level III benefits. If, however, claimant's level of mitral regurgitation was determined to be mild, Ms. Rivas would be  
(continued...)

Although not required to do so, the Trust forwarded the claim for a second review by the auditing cardiologist.

Dr. Penkala submitted a declaration in which she again concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Rivas had moderate mitral regurgitation. Dr. Penkala stated, in relevant part, that:

7. In light of Claimant's Contest, I was contacted by the Trust and asked to review Claimant's Contest Materials, as well as Claimant's June 28, 2002 echocardiogram tape.
8. In accordance with the Trust's request, I reviewed the Claimant's claim file and medical records, and the June 28, 2002 echocardiogram tape. I also reviewed Claimant's Contest Materials, including the declarations of Drs. Staab, Frazin and Dlabal.
9. I confirm my finding at audit that there is no reasonable medical basis to conclude that Claimant had moderate mitral regurgitation at the time of the June 28, 2002 echocardiogram study.
10. At Contest, I reviewed the entirety of the June 28, 2002 echocardiogram study. I also reviewed those specific points in the study identified by Drs. Staab, Frazin and Dlabal. Although the claimant did eventually go on to develop at least moderate mitral regurgitation, as seen on her subsequent echo (9/20/08) and heart [catheterization] (9/24/08), there is no reasonable medical basis to find moderate mitral regurgitation on the study dated June 28, 2002.

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11. (...continued)  
entitled only to Matrix B-1, Level III benefits. See Settlement Agreement § IV.B.2.d.(2)(a).

11. I reviewed those specific points in the study, 12:13:22 and 12:13:49, where Dr. Staab indicates moderate mitral regurgitation is seen. At both of these points in the study, very early systolic flow of brief duration is seen during the 'red-blue' period, which is consistent with backflow. At 12:15:10, the Color Wave Doppler mitral regurgitation signal clearly demonstrates very early systolic flow ONLY, and there is no evidence whatsoever to support a finding of "typical holosystolic jets" described by Dr. Staab in his statement.
  
12. Dr. Frazin states that moderate mitral regurgitation is best seen in the "apical 2-chamber view," and identifies four frames where he says moderate mitral regurgitation is present: 12:16:19, 12:16:40, 12:16:59 and 12:17:17. I reviewed the June 28, 2002 tape with specific attention to these frames. Each of these frames demonstrates brief duration early systolic flow at the very beginning of the QRS complex. The 12:16:19 and 12:16:40 frames are taken from the apical 2-chamber view and, along with the other two frames, clearly demonstrate flow characteristic of physiologic backflow.
  
13. I disagree with Dr. Frazin's statement that the flow seen in these frames cannot be backflow because "the regurgitant jet plume traveled to almost 75% of the superior-inferior [sic] length of the left atrium," and because there is "aliasing" of the regurgitant jets. Backflow describes physiologic displacement of blood in the left atrium as the mitral valve closes in end-diastole. The [mitral regurgitation] identified here is brief duration early systolic flow at the very beginning of the QRS complex. Further, this study was recorded on a Cypress machine, a portable device which tends to make the jets appear more mosaic than

they would on a more conventional non-portable device. This appears to be the case on this recording.

14. I also reviewed the tape with specific attention to the frames described by Dr. Dlabal, who describes moderate mitral regurgitation in several frames in the apical 4-chamber (12:13:00, 12:13:23, 12:13:47 and 12:14:20) and apical 2-chamber views (12:16:18, 12:16:41, 12:16:58, 12:17:17 and 12:17:30). I reviewed each of these points in the study. Each occurs on the QRS in very early systole during the 'red-blue' period of flow and is consistent with very brief duration backflow.
15. I disagree with Dr. Dlabal's assertion that the 'regurgitation' present on this study cannot be backflow. Dr. Dlabal states that "backflow jets are rarely measured due to their small sizes, but if measured ... would be expected to have RJA/LAA ratios of no more than 1-5%." Backflow is related to the *timing* of the flow as well as the size. Further, the size of a 'jet' changes based on the machine utilized, machine settings, etc. While Dr. Dlabal describes the "multi-colored ... aliasing ... irregular" nature of the jets and states that these findings "confirm the pathological nature of the jets," the 'jet' appearance is a result of this study being recording [sic] on a Cypress machine.
16. All of the jets identified at Contest as representative of moderate mitral regurgitation show backflow. There is no evidence of mid- or late-systolic mitral regurgitant flow. When one looks at the [left atrium] when the EKG is on the T wave there is no regurgitant flow whatsoever present. This finding is confirmed with the [color wave] tracing as described above.

The Trust then issued a final post-audit determination, again determining that Ms. Rivas was entitled only to Matrix B-1, Level III benefits for damage to her aortic valve and that Ms. Rivas was not entitled to Matrix Benefits for damage to her mitral valve. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why this claim should be paid. On April 13, 2011, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8634 (Apr. 13, 2011).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on August 3, 2011, and claimant submitted a sur-reply on November 28, 2011. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor<sup>12</sup> to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a

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12. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that Ms. Rivas had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Rivas reasserts the arguments made in contest. Claimant also argues that the reasonable medical basis standard requires that deference be given to the conclusions of her attesting physician. In addition, Ms. Rivas argues that Dr. Penkala was neither qualified to serve as an auditing cardiologist nor independent from the

Trust.<sup>13</sup> Finally, Ms. Rivas submitted a declaration of Dr. Dlabal wherein he stated, in pertinent part, that:

2. I am personally unaware of any information suggesting that the Cypress Echocardiograph is somehow known for exaggerating Mitral Regurgitation. It is a member of the Accuson line of cardiac ultrasound devices, which are widely regarded as an industry standard.

3. All echocardiographic devices sold in the US are subject to FDA approval, and thus are required to meet established standards. If there were indeed any deviation from the standards for acoustic imaging, this issue would have been addressed in the development of the machine.

4. A literature search of this topic produces no information to suggest that this issue has been reported to the FDA, the cardiovascular community, nor has even been the topic of written discussion.

In response, the Trust argues that claimant did not establish a reasonable medical basis for Dr. Dlabal's representation of moderate mitral regurgitation because she did not adequately rebut Dr. Penkala's determination that the purported regurgitant jets identified by her cardiologists were early in systole and constituted backflow. In addition, the Trust asserts that the findings of the attesting physician are not entitled to deference and that the Trust properly applied the reasonable medical basis standard. The Trust also contends this

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13. Claimant also asserted that the Trust did not comply with Audit Rule 22, which requires the Trust to serve on the Special Master the Trust's audit file and all materials submitted to and/or completed by the auditing cardiologist. As nothing in the record reflects the Trust did not comply with Audit Rule 22, this argument is irrelevant.

claim was properly submitted for review by the Consensus Expert Panel. Finally, the Trust argues that Dr. Penkala meets the requirements for appointment as an auditing cardiologist.

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Dr. Abramson explained:

In reviewing the transthoracic echocardiogram from 6/28/02, my visual estimate is that there is only mild mitral regurgitation. I measured the mitral regurgitant jet in five different cardiac cycles. I could not measure the RJA and LAA in the same view because the LAA was foreshortened in the angle that was used to obtain the maximal LAA. I used a constant left atrial area of 23.5 cm<sup>2</sup>, which was the LAA tracing on the tape. I chose tracings that were representative of the mitral regurgitant jets from multiple cardiac cycles from each of the apical views. The measurements I used for mitral regurgitant jet area are 4.2 cm<sup>2</sup>, 4.1 cm<sup>2</sup>, 3.2 cm<sup>2</sup>, 3.8 cm<sup>2</sup>, and 4.3 cm<sup>2</sup>, which were measurements traced on the tape. These ratios are 18%, 17%, 14%, 16%, and 18%, all of which are less than 20%, which is consistent with mild mitral regurgitation. The continuous wave Doppler of the mitral regurgitant jet was faint, which is consistent with mild mitral regurgitation.

There were several larger tracings on the tape that I did not use because they were traced incorrectly. They were either overtraced or included low-velocity, non-regurgitant flow.

Dr. Dlabal chose to use a left atrial area of 20.0 cm<sup>2</sup> for all of his ratios. This is a normal left atrial area, yet he stated on the Green Form that claimant has an abnormal left atrial dimension. I do not know why he chose 20 cm<sup>2</sup> for his measurement of the left atrial area. On the tape, the technologist traced



an accurate left atrial area measurement of 23.5 cm<sup>2</sup> which appropriately excludes pulmonary veins and left atrial appendage.

In response to the Technical Advisor Report, Ms. Rivas argues that the Technical Advisor substituted her own opinion for that of claimant's cardiologists and did not consider all of the relevant evidence, including evidence supportive of claimant's arguments. Ms. Rivas also asserts that Dr. Abramson did not evaluate claimant's mitral regurgitation in the apical two chamber view, which Dr. Frazin and Dr. Dlabal said represented the largest mitral regurgitation.

After reviewing the entire Show Cause Record, we find the claimant's arguments are without merit. Contrary to claimant's assertion, the opinions of her cardiologists do not provide a reasonable medical basis for her claim. We are required to apply the standards delineated in the Settlement Agreement and Audit Rules. The context of these two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends and one that must be applied on a case-by-case basis. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating the echocardiogram setting; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom

jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation.

See Mem. in Supp. of. PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002).

Here, Dr. Penkala reviewed claimant's echocardiogram and determined that it demonstrated only trace mitral regurgitation. She noted that the "jets that were traced clearly demonstrate low velocity brief duration flow limited to early systole consistent with typical 'backflow.'" Claimant submitted declarations from three cardiologists, Dr. Staab, Dr. Frazin, and Dr. Dlabal. Dr. Staab identified one instance of moderate mitral regurgitation and one instance of "close to the moderate range." Dr. Penkala reviewed these two specific points in claimant's echocardiogram. She explained:

At both of these points in the study, very early systolic flow of brief duration is seen during the 'red-blue' period, which is consistent with backflow. At 12:15:10, the Color Wave Doppler mitral regurgitation signal clearly demonstrates very early systolic flow ONLY, and there is no evidence whatsoever to support a finding of "typical holosystolic jets" described by Dr. Staab in his statement.

Dr. Frazin stated the regurgitant jets he identified were not backflow because "the regurgitant plume traveled to almost 75% of the superior-inferior [sic] length of the left atrium" and "the regurgitant jets revealed aliasing, or were beyond aliasing at their distal portions." Dr. Penkala

disagreed, observing that "[b]ackflow describes physiologic displacement of blood in the left atrium as the mitral valve closes in end-diastole." She explained, "The [mitral regurgitation] identified here is brief duration early systolic flow at the very beginning of the QRS complex."

Dr. Dlabal disputed that the jets he identified included backflow because "backflow jets would be expected to have RJA/LAA ratios of not more than 1 to 5%," rather than the average 20.8% and 34.0% he measured in this case. Dr. Dlabal also stated that the jets on which he relied "were predominately multi-colored, indicating aliasing" and that the irregular edges of the jets confirms "pathological nature" of the jets.<sup>14</sup>

Dr. Penkala disagreed with Dr. Dlabal's assertion, noting that "[b]ackflow is related to the *timing* of the flow as well as the size." Significantly, despite the fact that Ms. Rivas submitted a supplemental declaration of Dr. Dlabal in response to Dr. Penkala's statement that a portable echocardiogram machine exaggerates certain images on an echocardiogram, Dr. Dlabal did

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14. Contrary to claimant's argument, Dr. Penkala never observed that the jets on claimant's echocardiogram were "mosaic, multi colored, aliasing, and irregular." In paragraphs 13 and 15 of her declaration, Dr. Penkala is remarking as to Dr. Frazin's and Dr. Dlabal's determinations that the jets were "mosaic, multi-colored, aliasing, and irregular." To the extent Dr. Penkala observed these characteristics, she determined they were a result of the machine on which claimant's echocardiogram was performed. Dr. Dlabal's statement that he is unaware of the effect a portable echocardiograph machine may have on an echocardiogram does not adequately rebut Dr. Penkala's determination.

not address Dr. Penkala's specific findings with respect to the existence of backflow in his measurements or the measurements of Dr. Staab and Dr. Frazin.

Dr. Abramson also reviewed claimant's echocardiogram and determined that it did not demonstrate moderate mitral regurgitation. Dr. Abramson "chose tracings that were representative of the mitral regurgitant jets from multiple cardiac cycles from each of the apical views" and determined that each RJA/LAA ratio was less than 20%, consistent with mild mitral regurgitation.<sup>15</sup> Dr. Abramson noted that she did not rely on larger tracings on the echocardiogram because "[t]hey were either overtraced or included low-velocity, non-regurgitant flow." Dr. Abramson also observed that Dr. Dlabal used a normal left atrial area to calculate claimant's RJA/LAA despite the fact that he noted claimant had an abnormal left atrial dimension. A smaller LAA would artificially increase the RJA/LAA ratio.<sup>16</sup> Such unacceptable practices by claimant's cardiologists cannot provide a reasonable medical basis for the resulting diagnosis

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15. For this reason, we reject claimant's argument that Dr. Abramson did not evaluate claimant's mitral regurgitation in the apical two chamber view.

16. Thus, we reject claimant's argument that Dr. Abramson substituted her own opinion for that of claimant's cardiologists and did not consider all of the relevant evidence, including evidence supportive of claimant's arguments.

and Green Form representation that claimant suffered from moderate mitral regurgitation.<sup>17</sup>

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of the claim of Ms. Rivas for Matrix A benefits.

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17. For this reason as well, we reject claimant's argument that she should prevail because the reasonable medical basis standard requires that deference be given to the conclusions of her attesting physician or that it is sufficient for the attesting physician or claimant only to disagree with the auditing cardiologist to establish a reasonable medical basis for her claim.