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. 9318

Bartle, J. July 10, 2014

The Estate of Michael L. Jones ("Estate"), a representative claimant under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether the Estate has demonstrated a reasonable medical basis to support its claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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

2. Jan E. Jones, the spouse of Michael L. Jones ("Mr. Jones"), also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify Diet Drug

(continued...)

To seek Matrix Benefits, a representative claimant[4] must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The representative claimant completes Part I of the Green Form. Part II is completed by an attesting physician, who must answer a series of questions concerning the Diet Drug Recipient's medical conditions that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, if the representative claimant is represented by an attorney, the attorney must complete Part III.

In June, 2012, Michael L. Jones, Jr., the independent executor of the Estate, submitted a completed Green Form to the Trust signed by the attesting physician, Robert L. Rosenthal, M.D. Based on an echocardiogram dated May 23, 2002,

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3. (...continued)
Recipients 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 the Diet Drug Recipient'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 representative claimants where the Diet Drug Recipients were diagnosed with serious VHD, they took the drugs for 61 days or longer, and they 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 representative claimants where the Diet Drug Recipients were registered as having only mild mitral regurgitation by the close of the Screening Period, they took the drugs for 60 days or less, or they were diagnosed with conditions that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. Under the Settlement Agreement, representative claimants include estates, administrators or other legal representatives, heirs, or beneficiaries. See Settlement Agreement § II.B.

Dr. Rosenthal attested in Part II of the Green Form that Mr. Jones suffered from moderate mitral regurgitation and that he died as a result of a condition caused by VHD or valvular repair/replacement surgery.[5] Based on such findings, the Estate would be entitled to Matrix A-1, Level V benefits[6] in the amount of $1,078,215.[7]

In the report of the echocardiogram dated May 23, 2012, the reviewing cardiologist, George G. Miller, M.D., F.A.C.C., stated that Mr. Jones had moderate mitral regurgitation, which he measured at 21%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view

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5. Dr. Rosenthal also attested that Mr. Jones had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™ and that he suffered from an abnormal left atrial dimension, New York Heart Association Functional Class IV symptoms, and a left ventricular ejection fraction < 40% at any time six months or later after valvular repair or replacement surgery. These conditions are not at issue in this claim.

6. Under the Settlement Agreement, a representative claimant is entitled to Level V benefits if the Diet Drug Recipient suffered "[d]eath resulting from a condition caused by valvular heart disease or valvular repair/replacement surgery which occurred post-Pondimin® and/or Redux™ use supported by a statement from an attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist, supported by medical records ...." See Settlement Agreement § IV.B.2.c.(5)(c).

7. Mr. Jones previously received Matrix B-1, Level III benefits in the amount of $146,733. According to the Trust, if entitled to Matrix A-1, Level V benefits, the Estate would be entitled to Matrix Benefits in the amount of $1,224,948. The amount at issue, therefore, is the difference between the Matrix B-1, Level III benefits already paid and the amount of Matrix A-1, Level V benefits. See Settlement Agreement § IV.C.3.

is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In August, 2012, the Trust forwarded the claim for review by Noyan Gokce, M.D., F.A.C.C., F.A.S.E., one of its auditing cardiologists. In audit, Dr. Gokce concluded that there was no reasonable medical basis for finding that the May 23, 2002 echocardiogram demonstrated moderate mitral regurgitation. Dr. Gokce explained, "In my opinion, using the Singh criteria, [mitral regurgitation] is mild. My tracings at most demonstrated a mitral RJA/LAA of 5.02/36.5 = 14% in the apical views, consistent with mild [mitral regurgitation]."[8] Dr. Gokce also observed, "This finding is also in agreement with the report by [Jeffrey S. Fierstein, M.D., F.A.C.C.] who calculated a ratio of 12%."[9]

The Settlement Agreement requires the payment of reduced Matrix Benefits when a Diet Drug Recipient is diagnosed

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8. Under the Settlement Agreement, mild mitral regurgitation is defined as "(1) either the RJA/LAA ratio is more than five percent (5%) or the mitral regurgitant jet height is greater than 1 cm from the valve orifice, and (2) the RJA/LAA ratio is less than twenty percent (20%)." Id. § I.38.

9. In connection with the earlier claim for which Mr. Jones received Matrix B-1, Level III benefits, Dr. Fierstein reviewed the May 23, 2002 echocardiogram. In a letter dated April 25, 2004, Dr. Fierstein stated that the echocardiogram demonstrated mild mitral regurgitation with an RJA/LAA ratio of 12%. Dr. Fierstein explained, in pertinent part, "I utilized the Singh method to measure these jets and the left atrial area. These jets exist in more than one frame, seen in real time, and confirmed by [Continuous Wave] Doppler, and they are appropriately and tightly traced personally by me."

with mild mitral regurgitation by an echocardiogram that was performed between the commencement of Diet Drug use and the end of the Screening Period.[10] See id. § IV.B.2.d.(2)(a). As the Trust does not contest the Estate's entitlement to Level V benefits, the only issue before us is whether the Estate is entitled to payment on Matrix A-1 or Matrix B-1.

Based on Dr. Gokce's finding that Mr. Jones had only mild mitral regurgitation between the commencement of Diet Drug use and the end of the Screening Period, the Trust issued a post-audit determination that the Estate was entitled only to Matrix B-1 benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), the Estate contested this adverse determination.[11] In contest, the Estate argued that the auditing cardiologist's calculation was "flawed" because he ignored the maximum regurgitant jet and instead "selected measurements for the RJA and LAA that result in a skewed and artificially low RJA/LAA ratio." In support, the Estate

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10. The Screening Period ended on January 3, 2003 for echocardiograms performed outside of the Trust's Screening Program and on July 3, 2003 for echocardiograms performed in the Trust's Screening Program. See id. § I.49.

11. 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 Pretrial Order ("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 the Estate's claim.

submitted a declaration from Dr. Rosenthal, who stated, in relevant part:

> 4. On the apical 4 chamber view there are multiple jets displayed which by the Singh method of visual assessment fill 20% or greater of the simultaneously displayed left atrium. The one jet outlined in the 4 chamber view at 7:54:09 also fills more than 20% of the left atrium....
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> 5. On the apical 2 chamber view at 7:55:36 there is a jet outlined measuring 8.35 cm. sq. which by the Singh method of visual assessment fills 20% or greater of the simultaneously displayed left atrium.... The auditing cardiologist has chosen to ignore this jet which if used in the calculation he provides would yield an RJA/LAA ratio of 22.87% (8.35 cm. sq./ 36.5 cm. sq.). Instead, the auditing cardiologist chose to use an inferior jet which is not the maximum regurgitant jet.
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> 6. Furthermore, the LAA of 36.5 cm. sq. is found in the 4 chamber view. The LAA in the 2 chamber view is smaller than the LAA in the 4 chamber view. Thus, if the auditing cardiologist uses the appropriate LAA from the 2 chamber view, the RJA/LAA ratio is greater than 22.87%.

Dr. Rosenthal attached two still frame images from the echocardiogram that purportedly demonstrated moderate mitral regurgitation.[12]

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12. In his declaration, Dr. Rosenthal also stated that "current echocardiography guidelines and best practices recommend the use of additional echocardiographic methods to determine the severity of mitral regurgitation, including determination of vena contracta width." According to Dr. Rosenthal, the vena contracta width supports the conclusion that there is a reasonable medical basis for finding moderate mitral regurgitation.

Although not required to do so, the Trust forwarded the claim to the auditing cardiologist for a second review. Dr. Gokce submitted a declaration in which he again concluded that there was no reasonable medical basis for the attesting physician's finding that echocardiogram demonstrated moderate mitral regurgitation. Dr. Gokce stated, in relevant part:

> 11. Dr. Rosenthal reports an RJA/LAA ratio of greater than 20%, based in part upon his measurement of a smaller LAA in the 2 chamber view. This LAA is smaller than the measurement I made and used in my assessment. The LAA cited by Dr. Rosenthal appears falsely small, however, and results in an underestimation of the true left atrial dimension, and an inflated RJA/LAA ratio. My measurement of the LAA was taken at end systole, and I measured the RJA in the same 4-chamber view. My measurements were taken at a point in the study when both the RJA and LAA are representative of what is seen throughout the study, and result in an accurate RJA/LAA ratio. As I noted at audit, Dr. Fierstein, who prepared a report based upon his review of the May 23, 2002 study, measured an even larger LAA, at 40.47 cm^2. I would also like to point out that at 7:56:25, the LAA was measured as significantly enlarged at 40.42 cm^2 in the 4-chamber view as clearly displayed on the echocardiogram at that specific time point.
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> 12. Dr. Rosenthal also states that, when evaluated using the vena contracta ("VC") method, mitral regurgitation on the May 23, 2002 study falls into the severe range, citing to frames in the parasternal view. However, the mitral regurgitation in this study is slightly eccentric, which renders evaluation via the VC method less accurate than under normal circumstances. The VC method is

not utilized as part of the audit process. Regardless, Dr. Rosenthal indicates that the VC measurement of 0.7 would "fall into the severe regurgitation range", however it is clear that [mitral regurgitation] is not severe. Further, applying Singh criteria, mitral regurgitation is mild. Dr. Fierstein's independent assessment was in agreement with my audit finding of mild [mitral regurgitation].

13. Both at 7:45:09 and 7:55:36, the mitral "regurgitant jet" measurement is overestimated in the echocardiogram because the tracings erroneously incorporate the flow convergence signal that is located on the left ventricular side of the mitral valve ..., which is not part of the regurgitation signal proximal to the valve plane into the left atrial cavity, as described by the Singh methodology. Further, the borders of the regurgitant jet are loosely traced. Real-time examination of the mitral regurgitant jet in multiple views in the apical 4-chamber and 2-chamber images throughout the entire [echocardiogram] study are most consistent with mild [mitral regurgitation]. Parasternal short axis views (at 7:52:21 per contest letter) are not part of the standard [mitral regurgitation] quantification assessment and are misleading.

14. Accordingly, I affirm my findings at audit, that there is no reasonable medical basis for a finding that Claimant had moderate mitral regurgitation. Mitral regurgitation on the May 23, 2002 study is only mild, and there is no reasonable medical basis to conclude that moderate mitral regurgitation is present. I also affirm my finding that there is no reasonable medical basis to conclude that Claimant had greater than mild mitral regurgitation in between commencement of Diet Drug use and the close of the Screening Period.

The Trust then issued a final post-audit determination, again determining that the Estate was entitled only to Matrix B-1, Level V benefits. The Estate 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 the Estate's claim should be paid. On March 12, 2013, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 9026 (Mar. 12, 2013).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. The Estate then served a response upon the Special Master. The Trust submitted a reply on June 12, 2013, and the Estate submitted a sur-reply on July 9, 2013. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[13] to review claims after the Trust and the Estate have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review

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13. 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.

the documents submitted by the Trust and the Estate 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 the Estate has met its burden of proving that there is a reasonable medical basis for finding that Mr. Jones suffered from moderate or greater mitral regurgitation on an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period. See Audit Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in the 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 its claim, the Estate reasserts the arguments it made during contest. The Estate also argues that there is a reasonable medical basis for the claim because: (1) the opinion of the attesting physician is entitled to deference; (2) the attesting physician, Dr. Rosenthal, adequately rebutted the findings of the auditing cardiologist; and (3) the reviewing cardiologist, Dr. Miller, also agreed that the May 23, 2002 echocardiogram demonstrated moderate mitral

regurgitation. In addition, the Estate submitted a supplemental declaration from Dr. Rosenthal, in which he again opines that the echocardiogram reveals the presence of moderate mitral regurgitation.[14] Dr. Rosenthal states, in pertinent part:

> 2. I re-reviewed the 5/23/02 echocardiogram disc in light of Dr. Noyan Gokce's recent declaration dated 2/19/13.
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> 3. The LAA in the 2 chamber view is not "falsely small," and the use of revised LAA measurements of 40.47 cm sq and 40.42 cm sq is inappropriate in this case. Such LAA measurements are not representative of the LAA seen throughout the study. In his initial report, Dr. Gokce chose to ignore the 8.35 cm sq jet present on the apical 2 chamber view at 7:55:36 which by the Singh method fills 20% or greater of the simultaneously displayed left atrium. In paragraph 11 of his declaration, Dr. Gokce indicates that the LAA in the 2 chamber view appears "falsely small" but offers no proof that the LAA in any 2 chamber view on the recording is larger. Instead, Dr. Gokce indicates he prefers to use the, in his words, "significantly enlarged" left atrial area in the 4 chamber view, which is not appropriate, as this is not the same 2 chamber view in which the jet is identified. Dr. Gokce had initially reported his measurement of 4 chamber LAA at 36.5 cm sq and now revises that to be perhaps 40.42 or 40.47 cm sq. Furthermore, Dr. Gokce admits these measurements are "significantly enlarged". In fact, a LAA of 40 cm sq is classified as "severely enlarged" with a normal LAA being less than 20 cm sq.... So instead of the appropriately measured left atrial 2 chamber being "falsely small", Dr. Gokce's measurement appears to be

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14. Dr. Rosenthal also again asserts that methods other than the Singh method confirm the presence of moderate mitral regurgitation. The Settlement Agreement, however, requires the use of the Singh method in determining the level of mitral regurgitation. Settlement Agreement § I.22.

"falsely enormous" indicating the subject's left atrium is more than twice normal size. Of course, substituting a more normal left atrial area as seen in the appropriate 2 chamber view lowers the denominator and makes the ratio of the jet greater. Regardless, the jet of 8.35 cm sq. is greater than 20% of all of Dr. Gokce's left atrial measurements, however inappropriate and enlarged they may be. (Interestingly, Dr. Gokce does not continue to assert that the RJA measures 5.02 cm sq. In contrast, I reaffirm the sizes of the jets that I previously identified, and I affirmatively state that these jets are representative of other moderate [mitral regurgitant] jets, which I observed on the still frames and in real time.)

4. Dr. Gokce also indicates that the jets are "loosely traced" which is a subjective opinion for which no factual evidence is submitted. I believe that the jets are appropriately traced. Dr. Gokce indicates that the jet measurements are overestimated because the tracings incorporate the flow convergence signal that is located on the left ventricular side of the mitral valve. I do not believe that to be the case, but that is an argument which Dr. Gokce needs to be cautious in advancing because a flow convergence jet of any size would be further evidence of moderate to severe mitral regurgitation.... [T]he "Flow Convergence Method" is a quantitative tool for measuring the severity of mitral regurgitation with increasing flow convergence indicating more severe mitral regurgitation. Using the standard and accepted PISA formula method, a flow convergence jet with a radius of only .71 cm (enough to reduce the Jones measured jet size by 10%) at this Nyquist limit of 51 cm/sec. would give an ERO of 0.3 cm. sq. indicating moderate to severe mitral regurgitation .... In my opinion, any argument offered that a significant flow convergence jet is present is further evidence that the mitral regurgitation jet is moderate or even severe.

Finally, the Estate asserts that the Settlement Agreement "guarantees supplemental payments to class members whose conditions deteriorate to certain levels."

In response, the Trust argues that the Estate has not established a reasonable medical basis for Dr. Rosenthal's representation that Mr. Jones had moderate mitral regurgitation between the commencement of Diet Drug use and the end of the Screening Period and that the reasonable medical basis standard does not require that deference be given to the findings of the attesting physician. In addition, the Trust contends that the auditing cardiologist is not required to rely on the maximum jet of mitral regurgitation if that jet is not representative of the regurgitation through the echocardiogram.

The Technical Advisor, Dr. Vigilante, reviewed the May 23, 2002 echocardiogram and concluded that there was no reasonable medical basis for finding that it demonstrated moderate or greater mitral regurgitation. Specifically, Dr. Vigilante stated, in pertinent part:

> I reviewed the videotape and DVD of the Claimant's May 23, 2002 echocardiogram.... All of the usual echocardiographic views were obtained. This study was limited due to poor ultrasound transmission from obesity. However, the Nyquist limit was appropriately set at 50 cm per second at a depth of 20 cm in the parasternal views and 51 cm per second at a depth of 18 cm in the apical views. There was somewhat increased color artifact although the study was diagnostic.
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> .... Visually, mild mitral regurgitation appeared to be present. I digitized the cardiac cycles in the apical four and two

chamber views in which the mitral regurgitant jet was best appreciated. I then traced the representative RJAs as well as the LAA in the apical four and two chamber views. In the apical four chamber view, the largest representative RJA was 5.1 cm2. The LAA was 38.4 cm2. Therefore, the largest representative RJA/LAA ratio was 13.3% qualifying for mild mitral regurgitation. The largest representative RJA in the apical two chamber view was 6.1 cm2. The LAA in the apical two chamber view was 33.9 cm2. Therefore, the largest representative RJA/LAA ratio was 18.0% diagnostic of mild mitral regurgitation. The sonographer planimetered supposed RJAs of 5.86 cm2 in the apical four chamber view and 8.35 cm in the apical two chamber view. However, these determinations were inaccurate as they contained low velocity and non-mitral regurgitant flow. The sonographer also obtained a supposed LAA of 40.42 cm2 in the apical four chamber view. However, this tracing occurred outside the inter-atrial septum and partly within the right atrium and was inaccurate. The sonographer did not demonstrate an LAA determination in the apical two chamber view. I paid particular attention to the time frames quoted by Dr. Rosenthal in his Declarations. These time frames demonstrated the same inaccurate RJA determinations by the sonographer. I did not evaluate the vena contracta in this study as this determination is not pertinent to the Settlement Agreement.

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... [T]here is no reasonable medical basis for the finding of moderate or greater mitral regurgitation based on the Claimant's echocardiogram of May 23, 2002. That is, this study demonstrated mild mitral regurgitation with comments as above. An echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study even taking into account the issue of inter-reader variability when appropriate measurements are taken of the RJA and LAA in the apical four and two chamber views.

In response to the Technical Advisor Report, the Estate argues that the Technical Advisor failed to apply the reasonable medical basis standard and "failed to utilize normal clinical judgment and accepted medical standards." The Estate also contends that the Technical Advisor did not provide documentary proof that the level of mitral regurgitation was less than moderate or that the sonographer's measurements on the echocardiogram were unreasonable. Finally, the Estate argues that the Technical Advisor's and the auditing cardiologist's findings were inconsistent and arbitrary.

After reviewing the entire Show Cause Record, we find the Estate's arguments are without merit. The Settlement Agreement requires that a claim for Level V Matrix Benefits be reduced to the B Matrix if the Diet Drug Recipient had mild mitral regurgitation diagnosed by an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period. Settlement Agreement § IV.B.2.d.(2)(a).

Claimant contends that the declarations of Dr. Rosenthal establish a reasonable medical basis for finding that Mr. Jones suffered from moderate mitral regurgitation before the end of the Screening Period. We disagree. We are required to apply the standards delineated in the Settlement Agreement and the Audit Policies and Procedures. The context of these two documents leads us to interpret the reasonable medical basis standard as more stringent than the Estate contends and one that must be applied on a case-by-case basis. For example, 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 echocardiogram settings; (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. Gokce reviewed the May 23, 2002 echocardiogram and determined that it demonstrated only mild mitral regurgitation.[15] Although Dr. Rosenthal identified two regurgitant jets that he contends support his opinion, Dr. Gokce reviewed these jets and determined they were "overestimated in the echocardiogram because the tracings erroneously incorporate the flow convergence signal that is located on the left ventricular side of the mitral valve ..., which is not part of the regurgitation signal proximal to the valve plane into the left atrial cavity, as described by the Singh methodology."

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15. Dr. Gokce noted that this finding is consistent with that of Dr. Fierstein who previously reviewed the echocardiogram for claimant. We cannot, as the Estate suggests, simply ignore the opinion of one of its own physicians in determining whether there is a reasonable medical basis for the claim.

In addition, Dr. Vigilante reviewed the May 23, 2002 echocardiogram and concluded that it was representative of only mild mitral regurgitation. Specifically, Dr. Vigilante observed that the sonographer's "determinations were inaccurate as they contained low velocity flow and non-mitral regurgitant flow." With respect to the frames identified by Dr. Rosenthal as demonstrative of moderate mitral regurgitation, Dr. Vigilante observed that "[t]hese time frames demonstrated the same inaccurate RJA determinations by the sonographer." Such unacceptable practices cannot provide a reasonable medical basis for the resulting Green Form representation of moderate mitral regurgitation.[16]

We also disagree with claimant's argument that the auditing cardiologist erred by not relying on the maximum jet rather than a representative jet. We previously have held that "[f]or a reasonable medical basis to exist, a claimant must establish that the findings of the requisite level of mitral regurgitation are representative of the level of regurgitation throughout the echocardiogram." Mem. in Supp. of PTO No. 6997, at 11 (Feb.26, 2007); see also In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig., 543 F.3d 179, 187 (3d Cir. 2008). "To conclude otherwise would allow claimants who do not have moderate or greater mitral

16. For this reason as well, we reject the Estate's argument that the attesting physician's representation is entitled to deference.

regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement." See Mem. in Supp. of PTO No. 6997, at 11.

Finally, we reject the Estate's assertion that the Settlement Agreement "guarantees" progression benefits on Matrix A. As noted above, the Settlement Agreement specifically requires that a claim for benefits based on damage to the mitral valve be reduced to the B Matrix if the Diet Drug Recipient had "Mild Mitral Regurgitation by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period[.]" Settlement Agreement § IV.B.2.d.(2)(a). As the Estate has failed to establish a reasonable medical basis for finding that Mr. Jones was not diagnosed with mild mitral regurgitation, the Settlement Agreement requires the claim for Level V benefits to be reduced to the B Matrix.

While the Estate contends that the Settlement Agreement guarantees payment on Matrix A, it has provided no support for this position. The Estate merely argues that it has "the right to receive additional benefits if [the Diet Drug Recipient's] condition worsens," which is exactly what has happened here. Mr. Jones was previously paid Matrix B, Level III benefits.[17] The Estate subsequently submitted the present claim, and the Trust determined that the Estate qualified for Matrix B, Level V

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17. This claim also was reduced to the B Matrix due to the presence of mild mitral regurgitation prior to the close of the Screening Period.

benefits. Nothing in the Settlement Agreement requires a supplemental claim for benefits to be paid on the A Matrix when an applicable reduction factor is present.

Therefore, we will affirm the Trust's denial of the Estate's claim for Matrix A benefits, and the related derivative claim submitted by Mr. Jones's spouse.