PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 07-1957

IN RE: DIET DRUGS (Phentermine/
Fenfluramine/Dexfenfluramine)
PRODUCTS LIABILITY LITIGATION

Gay Patterson and Kenneth Patterson,
Appellants

On Appeal from the United States District Court
for the Eastern District of Pennsylvania
MDL No. 1203
(Honorable Harvey Bartle III)

Argued March 6, 2008

Before: SCIRICA, *Chief Judge*,
FISHER and ROTH, *Circuit Judges*.

(Filed September 11, 2008)

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OPINION OF THE COURT

SCIRICA, *Chief Judge*.

Gay Patterson is a claimant seeking payment under the National Class Action Settlement Agreement ("Settlement Agreement") in this multi-district litigation.[1] Under the Settlement Agreement, Wyeth, formerly American Home Products Corporation, has contributed funds for the payment of claims. AHP Settlement Trust ("Trust") administers and reviews the claims and awards benefits to class members who qualify under the terms of the Settlement Agreement.

Patterson contends she suffers from moderate mitral regurgitation, a medical condition that, if adequately demonstrated, would qualify her for payment. Patterson submitted her claim to the Trust, supporting it with an attesting physician's interpretation of an echocardiogram. The Trust referred her claim to an independent auditing cardiologist who concluded that the attesting physician's opinion lacked a

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[1]Kenneth Patterson, Ms. Patterson's spouse, has filed a derivative claim for benefits.

reasonable medical basis. Accordingly, the Trust denied Patterson's claim.

The Trust then applied for an order requiring Patterson to show cause why the claim should be paid. The District Court issued an order to show cause and referred the matter to a special master. After the show cause proceedings, the District Court denied recovery finding no reasonable medical basis for Patterson's claim. We will affirm.

I.

A.

This case is part of a multi-district litigation concerning diet drugs previously sold by Wyeth – fenfluramine (marketed as "Pondimin"), and dexfenfluramine (marketed as "Redux"). In previous decisions, we have provided detailed descriptions of the diet drugs litigation. *See, e.g.*, *In re Briscoe*, 448 F.3d 201, 206-08 (3d Cir. 2006); *In re Diet Drugs*, 401 F.3d 143, 147-48 (3d Cir. 2005); *In re Diet Drugs*, 385 F.3d 386, 389-92 (3d Cir. 2004); *In re Diet Drugs*, 282 F.3d 220, 225-29 (3d Cir. 2002). We limit our discussion here to the facts pertinent to the present appeal.

In November 1999, Wyeth and the representatives for plaintiffs entered into the Settlement Agreement. After conducting fairness proceedings, the District Court certified a settlement class and approved the Settlement Agreement which became final upon exhaustion of all appeals.

The amount of a claimant's recovery under the Settlement Agreement is determined by damage "matrices" that assess factors such as severity of the medical condition, age of claimant, and length of illness. Patterson seeks Matrix A-1, Level II compensation in the amount of $473,032. In order to recover, a claimant must demonstrate by a reasonable medical basis that she has a qualifying condition.

The only factor in dispute is the severity of Patterson's medical condition, i.e., whether she has mitral regurgitation[2] at

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[2]The District Court has previously described mitral regurgitation:

> [Mitral regurgitation] involves the backward or reverse flow of blood through a defective mitral valve which separates the left atrium of the heart from the left ventricle.
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> The heart consists of four chambers: the right atrium, the right ventricle, the left atrium and the left ventricle. These chambers are connected by valves consisting of two leaflets. They open to allow blood to pass through and then close. This rapid process ensures the proper directional flow of blood through the heart.
>
> The chambers of the heart fill and empty in a seamless, two-phase cardiac cycle that comprises diastole, the filling cycle, and systole, the emptying cycle. Initially, deoxygenated blood

enters the heart through the right atrium. During diastole, the tricuspid valve opens and blood is pumped into the right ventricle where it collects before being expelled. As systole begins, the right ventricle contracts and the blood is ejected into the pulmonary arteries. The blood is then carried through these arteries into the lungs where it is re-oxygenated before passing back into the left atrium of the heart through the pulmonary veins. During diastole, the mitral valve opens and blood moves from the left atrium into the left ventricle. Thereafter, the mitral valve shuts. As systole begins, the left ventricle contracts and expels the blood through the open aortic valve into the aorta and the rest of the body. The aortic valve then closes to prevent any expelled blood from returning to the left ventricle.

Mitral regurgitation occurs during the systolic phase as the left ventricle contracts and pushes blood into the aorta. Because the leaflets comprising the mitral valve have failed to shut properly, blood leaks backward, or regurgitates, into the left atrium. As a result of this reverse flow, the heart must work harder to pump the needed blood throughout the heart and into the body.

a moderate level. The District Court has noted the importance of measuring the severity of regurgitation because "not all levels of mitral regurgitation are medically significant." *PTO 2640*, 236 F. Supp. 2d at 450. "Mild and trace regurgitation, two lesser grades of valvular regurgitation identified in medical literature, are normal and exist in approximately ninety percent of the population. Only when mitral regurgitation reaches the moderate level does it become a serious medical condition." *Id.* The Settlement Agreement defines moderate mitral regurgitation "as regurgitant jet area in any apical view equal to or greater than 20% of the left atrial area but less than 40% (20 - 40% RJA/LAA)."[3]

B.

In order to make a Matrix claim under the Settlement Agreement, the claimant must submit a three-part "Green Form" to the Trust. The Green Form requires disclosure of personal and medical information as well as a physician's certification, based on a reading of an echocardiogram videotape, of the claimant's level of valvular heart disease. The District Court has previously stated: "[f]or moderate mitral regurgitation to be

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In re Diet Drugs (*PTO 2640*), 236 F. Supp. 2d 445, 450 (E.D. Pa. 2002).

[3]RJA in the numerator of the fraction represents Regurgitant Jet Area while LAA in the denominator stands for Left Atrial Area.

present, the size of the reverse flowing jet of blood at its most expansive point must encompass between twenty percent and forty percent of the area of the left atrium." *PTO 2640*, 236 F. Supp. 2d at 450.

Several attorneys, including Patterson's counsel Kip Petroff, interpreted the Settlement Agreement to require a physician's report to identify only one frame of an echocardiogram tape showing twenty-to-forty percent regurgitation. On December 19, 2000, Mr. Petroff circulated a memorandum describing "Current Developments" in the Fen-Phen litigation. The memo articulated this expansive interpretation of the Settlement Agreement:

> It is clear that cardiologists who strictly employed the methodology in the National Settlement (maximum regurgitant jet/one view only) are routinely *over-reading* the echos by at least one order of magnitude. That methodology is acceptable in the world of the National Settlement, but it is not employed in the real world. We have carefully considered this re-evaluation, and it is absolutely clear that employing the National Settlement criteria leads to across-the-board over estimates of valve regurgitation, especially of the *mitral* valve.
>
> Every client who is graded a moderate MR by National Settlement criteria is a mild at best, a

> severe is a moderate *at best*, etc. This will lead to numerous mitral valve cases going from FDA-positive to FDA-negative, and that may be one reason to opt such a client back into the National Settlement or have a new echo done using standard methodology.

Memorandum from Kip Petroff and Robert Kisselburgh to All Referring Attorneys (Dec. 19, 2000).

In a different but related case, the District Court rejected a similar interpretation. *See PTO 2640*, 236 F. Supp. 2d at 451 (holding that "[o]nly after reviewing multiple loops and still frames can a cardiologist reach a medically reasonable assessment as to whether the twenty percent threshold for moderate mitral regurgitation has been achieved"). But, because of Mr. Petroff's theory and other dubious practices by other law firms, the Trust was inundated with Green Form claims for Matrix benefits in unanticipated volumes.[4] Under the Policies

[4]"During the fairness hearing before the District Court, experts testified as to their conclusion that, after considering extensive epidemiological and demographic evidence, $3.75 billion was more than sufficient to pay all Matrix claims anticipated under the Settlement." *In re Diet Drugs*, 385 F.3d at 391. But "after approval of the Settlement Agreement, the Trust was inundated with Green Form claims for Matrix benefits in a volume not anticipated by the experts who testified at the fairness hearing." *Id.* The District Court determined that a

and Procedures for Audit and Disposition of Matrix Compensation Claims, as approved in PTO 2457 (May 31, 2002), the Trust could audit up to 5% of Matrix claims per quarter, and Wyeth could designate up to 10% of claims per quarter, for an audit by the Trust. As a result, the Trust risked paying out millions of dollars to claimants it believed to be ineligible, but whose claims it could not audit. Wyeth asserts that out of the thirty claims submitted by Petroff & Associates and audited under PTO 2457, twenty-five were not payable – a failure rate of 83%. According to Wyeth, as of March 24, 2004, Petroff & Associates failed audit more than 70% of the time. In order to ameliorate the problem, the District Court ordered audits for all Matrix compensation claims. *See* PTO 2807 (Mar. 26, 2003).[5]

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significant proportion of the submissions came from a few law firms which carried out mass screening programs in which cardiologists retained by the firms "'made unreasonable judgments on a broad scale' concerning the existence, history, nature, and degree of heart-valve disease claimed." *Id.* (quoting *PTO 2640*, 236 F. Supp. 2d at 462).

[5]On October 15, 2002, the Trust notified Patterson that her claim was selected for audit. Accordingly, the Audit Policies and Procedures contained in PTO 2457 apply to Patterson's claim.

C.

In July 2002,[6] Mr. Petroff submitted Patterson's claim to the Trust. Patterson's Green Form relied on the certification of the attesting physician Reed Harris, D.O.[7] Based on a February 8, 2002 echocardiogram, Dr. Harris concluded that Patterson had a moderate mitral regurgitation ratio of 20% and that her left atrium was mildly enlarged.

The Trust selected Patterson's claim for audit. Under the Audit Policies and Procedures, Patterson had thirty days to submit "any additional credible medical information" for consideration by the Trust and the Independent Auditing Cardiologist. Patterson did not supplement her initial submission forms. On December 14, 2002, the auditing cardiologist, Keith B. Churchwell, M.D., concluded that there was no reasonable medical basis for Dr. Harris' finding of moderate mitral regurgitation because the echocardiogram demonstrated "trivial to mild" mitral regurgitation.

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[6]The Green Form reflects that Patterson signed the Green Form in March 2002. The Green Form, however, was marked as "received" in July 2002.

[7]Wyeth asserts that Dr. Harris has certified 105 Matrix claims under the Settlement Agreement. According to Wyeth, as of March 24, 2004, Dr. Harris' audited certifications resulted in a 82% failure rate (18 out of 22 were not payable).

"Eyeballing"[8] the echocardiogram, Dr. Churchwell determined that the "[mitral regurgitant] jet area [was] overestimated in comparison to [the left atrial] size. < 20%."

On January 6, 2003, the Trust informed Patterson that her claim had failed audit and attached Dr. Churchwell's findings. Patterson chose to dispute the Post-Audit Determination and proceed to the Show Cause Proceeding. The District Court granted the motion and referred the matter to a special master.[9]

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[8]The District Court has described "eyeballing" as visually inspecting an echocardiogram rather than retracing the regurgitant jet area or the left atrial area with a precise measuring device. *PTO 2640*, 236 F. Supp. 2d at 454. When conducting a visual assessment, the cardiologist reviews the entire echocardiogram to determine the existence and severity of the condition.

[9]Under the Audit Policies and Procedures approved in PTO 2457, the special master may assign a Technical Advisor to review the record and prepare a report to the Court "setting forth his/her opinions regarding the issue(s) in dispute in the audit." Audit Policies and Procedures, § VI.J. "Each Technical Advisor shall be a Board-Certified Cardiologist or Board-Certified Cardiothoracic Surgeon who has level 3 training in Echocardiography . . . ." *Id.* § VI.L. The claimant must pay the costs of the Technical Advisor in advance of the review. "If the Trust does not prevail on all aspects of its Application, the Trust

Under the Audit Policies and Procedures, "[f]or audits based . . . on the grounds that no reasonable medical basis exists for specific answer(s) to the Audit Question(s), the Claimant shall have the burden of proving that there was a reasonable medical basis to support the material representation(s) made by the Attesting Physician in answering the Audit Question(s)." Audit Policies and Procedures, § VI.D, PTO 2457 (May 31, 2002). To support the attesting physician Dr. Harris's opinion, Patterson submitted the report of cardiologist Frank E. Silvestry, M.D. Dr. Silvestry reviewed the February 2, 2002 echocardiogram tape and "identified the maximum regurgitant jet . . . emanating from the mitral valve in systole." Based upon the maximal jet, drawn at 1:15:38:12 recording time, he concluded that Patterson had 20.57% mitral regurgitation. Further, Dr. Silvestry surmised that Dr. Churchwell, the auditing cardiologist, "may be expressing his . . . qualitative opinion of the degree of Mitral regurgitation; however, the Settlement documents specify a scientific and quantitative degree of mitral

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shall reimburse the Claimant for the Technical Advisor's costs." *Id.* § VI.K.

Both the Trust and the claimant have an opportunity to state a position as to whether a "Technical Advisor" should be appointed. The Trust requested the assistance of a Technical Advisor. Patterson noted that she did "not feel it [was] necessary to hire a Technical Advisor to review this case," but acknowledged that she would not object to such an appointment. The special master did not appoint a Technical Advisor.

regurgitation, a degree which is clearly substantiated by the echocardiogram, and my independent measurements."

The District Court concluded Patterson "has not met her burden in proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation" because she failed to rebut or challenge the conclusion that Dr. Harris' determination was based on improper measurements. *In re Diet Drugs*, No. 2:16 MD 1203, 2007 WL 674720, at *2, *4 (E.D. Pa. Feb. 26, 2007). The court noted that, notwithstanding Dr. Silvestry's report, Patterson had "failed to address the improper measurements underlying the finding of [Dr. Harris]." *Id.* at *3.

Furthermore, the court rejected Patterson's suggestion that she could recover Matrix Benefits by identifying a single maximum regurgitant jet at the required level of mitral regurgitation. "[Patterson] has not established that the 'maximum regurgitant jet' offered in support of her claim is representative of her level of mitral regurgitation, therefore, on this basis as well, [Patterson] has failed to establish a reasonable medical basis of her claim." *Id.* at *4.[10]

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[10]The District Court's order finally resolved the particular claim at issue. Accordingly, we treat the challenged order as final and exercise appellate jurisdiction under 28 U.S.C. § 1291. We review a District Court's exercise of its equitable authority to administer and implement a class action settlement for abuse of discretion. *See In re Cendant Corp. Prides Litig.*, 233 F.3d 188, 192 (3d Cir. 2000). "[T]o find an abuse of discretion the

II.

Patterson contends that the District Court erred in several respects when denying her claim. First, Patterson contends that, even in a borderline case, measuring a single frame to determine the severity of mitral regurgitation is an acceptable practice under the Settlement Agreement. Second, she asserts that the auditing cardiologist's visual assessment of the echocardiogram was insufficient to rebut her attesting physician's measurements. According to Patterson, the Settlement Agreement always requires a quantitative measurement of the regurgitant jets. Finally, Patterson contends that the District Court misapplied the reasonable medical basis standard by applying it to Dr. Silvestry's opinion, rather than the attesting physician Dr. Reed's opinion. Accordingly, Patterson asserts it was improper for the court to deny her claim based on its rejection of Dr. Silvestry's method of evaluating her echocardiogram. We disagree.

A.

Patterson contends that the identification, in her case, of

District Court's decision must rest on 'a clearly erroneous finding of fact, an errant conclusion of law or an improper application of law to fact.'" *In re Nutraquest, Inc.*, 434 F.3d 639, 645 (3d Cir. 2006) (quoting *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 246 F.3d 315, 320 (3d Cir. 2001)).

a single frame of an echocardiogram constitutes a reasonable medical basis because her doctor reviewed the entire echocardiogram. Patterson asserts that in order to find a "true" maximum jet, a cardiologist must review multiple loops and frames and compare regurgitant jets. Wyeth and the Trust contend that, even if Patterson's doctor reviewed the entire echocardiogram, he failed to indicate that the identified maximum jet was representative of her condition and not an isolated and non-recurring incident.

In determining whether a single frame of an echocardiogram constitutes a reasonable medical basis for finding moderate mitral regurgitation, the parties agree that the District Court's prior decisions are instructive.[11] These decisions indicate that the Settlement Agreement requires a cardiologist to review the echocardiogram for a regurgitant jet that is representative of the severity of the claimant's medical condition. The identification of a single jet without any explanation or indication of its representativeness will not satisfy the claimant's burden.

In *PTO 2640*, the District Court examined seventy-eight claims determined by the Trust to be medically unreasonable because the echocardiograms showed no significant levels of

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[11] *See, e.g.*, Patterson Reply Br. at 5 ("One appropriate place to look for guidance in evaluating a Diet Drug Claim includes the Orders that the District Court has issued thus far in this lengthy litigation.").

mitral regurgitation. The court noted that "[f]or moderate mitral regurgitation to be present, the size of the reverse flowing jet of blood at its most expansive point must encompass between twenty percent and forty percent of the area of the left atrium," *PTO 2640*, 236 F. Supp. 2d at 450, and discussed the Settlement Agreement's "protocol" for measuring regurgitation. "Only after reviewing multiple loops and still frames can a cardiologist reach a medically reasonable assessment as to whether the twenty percent threshold for moderate mitral regurgitation has been achieved." *Id.* at 451.[12] The District Court held that each of the disputed claims lacked a reasonable medical basis, and in most cases, the measured jet was not a true regurgitant jet but rather a phantom jet or a backflow. *Id.* at 454, 458.

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[12] *See also id.* at 452 ("To confirm mitral regurgitation, a cardiologist will have to review numerous frames and loops."); *id.* at 454 (accepting the "analysis, conclusions, and opinions" of an expert witness, Dr. Dent, because "[h]e did not simply look at one frame of an echocardiogram and reach an opinion about the severity of mitral regurgitation"); *id.* at 457 (noting that an attesting physician "frequently mistook backflow and mild mitral regurgitation for moderate or more severe regurgitation" because "[u]nlike Dr. Dent who based this assessment on reviews of both the digitized images and the videotapes, [the attesting physician] did not analyze the videotapes for all of the echocardiograms to which she attested").

Since *PTO 2640*, the District Court has repeatedly criticized the use of a single frame of an echocardiogram as the sole basis for a claim of mitral regurgitation. "[F]or a reasonable medical basis to exist, a claimant must demonstrate that a finding of the requisite level of regurgitation is representative of the level of regurgitation throughout an echocardiogram." *In re Diet Drugs*, No. 2:16 MD 1203, 2007 WL 1461441, at *5 (E.D. Pa. May 16, 2007); *In re Diet Drugs*, No. 2:16 MD 1203, 2007 WL 1462407, at *4 (E.D. Pa. May 16, 2007). "Nothing in the Settlement Agreement suggests that it is permissible for a claimant to rely on isolated instances of what appears to be the requisite level of regurgitation to meet this definition." *In re Diet Drugs*, 2007 WL 1461441, at *5 n.12. Even though "one of the endnotes in the Green Form refers to obtaining the regurgitant jet area from a 'maximum or average [of] three planes,' this does not mean that a claim is compensable based only on the maximum or average regurgitant jet measured." *In re Diet Drugs*, 2007 WL 1462407, at *4. "To conclude otherwise would allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement." *Id.*

To illustrate, the District Court has, in disagreement with the auditing cardiologist, awarded Matrix compensation when the evidence shows a representative regurgitant jet of sufficient magnitude. In *In re Diet Drugs*, No. 99-20593, 2007 WL 320407 (E.D. Pa. Jan. 29, 2007), the attesting physician found

a regurgitation ratio of 24 percent and concluded the claimant suffered from moderate mitral regurgitation. Upon review, the auditing cardiologist concluded that the attesting physician's opinion lacked a reasonable medical basis. During the show cause proceedings, a technical advisor concluded the echocardiogram demonstrated moderate mitral regurgitation. Importantly, the technical advisor found an average of 22 percent mitral regurgitation over four cardiac cycles. *Id.* at *3. "Under these circumstances, claimant has met her burden in establishing a reasonable medical basis for her claim." *Id.*; *see also In re Diet Drugs*, No. 2:16 MD 1203, 2007 WL 1118379, at *3-4 (E.D. Pa. Apr. 12, 2007) (holding that claimant demonstrated reasonable medical basis for moderate mitral regurgitation and an abnormal left atrial dimension based on Technical Advisor's opinion, which examined three different views of the heart).

In addition to the District Court's instructions on what is medically reasonable, the Auditing Cardiologist Training Course is instructive.[13] The training course states:

> **Importance of Viewing Multiple Heartbeats and Frames**
>
> As you are aware from your clinical practice, an echo reader cannot focus on a single frame

[13]The District Court approved the training course in PTO 2825 (E.D. Pa. Apr. 7, 2003).

> without reference to the overall level of regurgitation as assessed using multiple frames and heartbeats. Only after reviewing multiple loops and still frames can a cardiologist reach a Medically Reasonable assessment as to whether any of the various thresholds established by the Settlement for the different severity levels of regurgitation have been achieved, such as the 20% threshold for moderate mitral regurgitation.
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> The interpreter or auditor thus must properly appreciate the level of regurgitation where a single frame may not appropriately represent the true volume of the regurgitation during systole.

PTO 2825 (E.D. Pa. Apr. 7, 2003).[14]

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[14]On the same page, the course cites an authoritative medical text, A.E. Weyman, Principles and Practice of Echocardiography 436 (1994):

> When the duration of systole changes (changing heart rate) or when regurgitant flow is confined to only a portion of systole (i.e., mitral valve prolapse), the relationship of the peak area to the regurgitant volume will vary. In patients with premature beats or atrial fibrillation, the color jet area may vary from cycle to cycle as the duration of systole and ventricular pressure change. In such cases, it is important to average the color jet

As noted, Patterson contends that the Settlement Agreement allows a cardiologist to measure a single maximum jet. Furthermore, Patterson asserts that "[t]here is no factual basis for concluding that the maximum regurgitant jet is *not* representative of the regurgitation throughout the echocardiogram or that [Dr. Silvestry] did not review all the loops and frames." Patterson Br. at 7.

Dr. Silvestry's report indicated: "On May 7, 2003, I reviewed and analyzed Ms. Patterson's echocardiographic study . . . and performed my own measurements of the left atrial and regurgitant jet area. I identified the maximum regurgitant jet and measured its area using EchoAnalysis software." Based on this statement, Patterson contends that Dr. Silvestry could not have identified the maximum regurgitant jet without reviewing multiple loops and comparing regurgitant jets. But even if we were to assume that Dr. Silvestry reviewed multiple loops, the question of representativeness remains. Under the Settlement Agreement, Patterson has the burden of proof to demonstrate her entitlement to benefits. A general statement that a doctor reviewed an echocardiogram does not necessarily mean the measured jet is representative of the claimant's true level of mitral regurgitation.

We cannot agree with Patterson's argument that, in a

> area from a number of beats to attain a representative measure of regurgitant flow.

PTO 2825 (E.D. Pa. Apr. 7, 2003).

borderline case such as this, the measurement of a single frame in an echocardiogram, without evidence showing that the depicted jet is a true regurgitant jet, i.e., representative of the claimant's actual level of mitral regurgitation, constitutes a reasonable medical basis for recovering Matrix compensation.[15] To hold otherwise would permit claimants whose echocardiograms show an aberrant jet in a single frame to recover payment from the Trust.[16]

B.

Next, Patterson contends that an auditing cardiologist must make quantitative measurements in order to determine the

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[15]Because the measurements by Dr. Harris and Dr. Silvestry were at or slightly above the 20 percent threshold, we need not address whether indications of representativeness are required in a more clear-cut case of mitral regurgitation.

[16]In her brief, Patterson also appears to suggest that she was denied procedural fairness, asserting that the District Court has not concretely defined "reasonable medical basis" and decides the merit of claims on a case-by-case basis. However, at the time of Patterson's briefs and Dr. Silvestry's report in May 2003, the District Court had clearly announced the requirements for reading an echocardiogram, *see PTO 2640*, and had approved the Auditing Cardiologist Training Course, *see* PTO 2825. Thus, Patterson and her attorneys had sufficient notice of the reasonable medical basis standard.

percentage of mitral regurgitation. She argues that a visual assessment is not precise enough to compute the minimum 20% regurgitation required by the Settlement Agreement. Patterson asserts because her case is a close one – Dr. Harris measured 20% regurgitation and Dr. Silvestry measured 20.57% regurgitation – the District Court should not have relied upon the auditing cardiologist's visual assessment to reject Patterson's claim. Wyeth and the Trust demur, contending that an auditing cardiologist may visually determine whether a qualifying condition exists. That is, an auditing cardiologist need not make a quantitative measurement when the echocardiogram clearly shows an amount of mitral regurgitation consistent with the general population. According to Wyeth and the Trust, since Dr. Churchwell found only trivial to mild mitral regurgitation,[17]

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[17]The Settlement Agreement incorporates the definitions of mitral regurgitation described in J.P. Singh, et al., *Prevalence of Clinical Determinants of Mitral, Tricuspid and Aortic Regurgitation (The Framingham Heart Study)*, 83 Am J. Cardiology 897 (1999). "Mild Mitral Regurgitation" is defined in the Settlement Agreement 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%)." As noted, RJA in the numerator of the fraction represents Regurgitant Jet Area while LAA in the denominator stands for Left Atrial Area. Singh describes "trace" or trivial mitral regurgitation as a mitral regurgitant jet that remains "within 1 cm from the valve orifice"

it was unnecessary to take quantitative measurements.

While conducting the audit of Patterson's claim, Dr. Churchwell reviewed the echocardiogram tape, a copy of the Green Form, and Patterson's medical records. Dr. Churchwell conducted a visual assessment of the echocardiogram and concluded there was no reasonable basis for Dr. Harris' determination. Dr. Churchwell noted that Dr. Harris "overestimated" the mitral regurgitant jet area in relation to the left atrial size. Furthermore, Dr. Churchwell determined that Patterson's mitral regurgitation was "trivial to mild" and "< 20%."

The purpose of the auditing cardiologist review is to examine the claimant's medical condition using normal clinical judgment and accepted medical standards to determine whether the attesting physician's conclusions had a reasonable medical basis. The District Court has, on numerous occasions, accepted an auditing cardiologist's medical opinion when based upon a visual assessment of an echocardiogram and still frames. In doing so, the District Court observed that "'[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiology." *PTO 2640,* 236 F. Supp. 2d at 454. We agree and understand that "eyeballing" is proper when an echocardiogram clearly indicates that the claimant's level of mitral regurgitation is consistent with the general population.

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and occupies less than five percent of the left atrial area.

In order to diagnose a patient, a cardiologist will visually review an echocardiogram tape to determine whether a condition is present. As noted, mild and trace regurgitation occur normally in 90% of the population. Accordingly, if an echocardiogram shows a normal amount of regurgitation – i.e., clearly below the qualifying threshold – an auditing cardiologist need not measure the maximum jet. But if the amount of regurgitation is at or near the threshold, in this case 20%, it would appear to be necessary to measure particular frames to quantify the severity of the condition. After reviewing the echocardiogram, Dr. Churchwell visually determined that Dr. Harris' measurement – 20% mitral regurgitation – "overestimated" Patterson's level of regurgitation and Dr. Churchwell characterized her symptoms as "trivial to mild." Although Dr. Churchwell could have been more precise, it appears that his language – "overestimated" and "trivial to mild" – indicates he found regurgitation well below the 20% threshold, making a quantitative measurement unnecessary in this case.

Under ordinary circumstances, a visual review by the auditing cardiologist indicating mitral regurgitation at or near the threshold would appear to call for more than "eyeballing" by the auditing cardiologist. Nevertheless, even if this case is, as Patterson asserts, close to the threshold, Dr. Churchwell's determination does not preclude recovery of Matrix compensation – it merely shifts the burden back to Patterson. Audit Policies & Procedures § VI.D., PTO 2457 (May 31, 2002). If the auditing doctor's visual assessment is wrong, the

claimant has the opportunity to offer a rebuttal and present additional evidence. As noted, Patterson submitted a report by Dr. Silvestry identifying and measuring the maximum regurgitant jet. However, a report based upon a single frame measurement does not rebut an auditing cardiologist's assessment of the entire echocardiogram. Because Dr. Silvestry's report does not include any indication of the maximum regurgitant jet's representativeness, Patterson has failed to meet her burden.[18] Accordingly, we reject Patterson's argument that Dr. Churchwell's method of reviewing her echocardiogram was insufficient to support the Trust's denial of her claim.

C.

Finally, Patterson contends that the District Court erred because it rejected the medical report submitted during the show cause proceedings rather than that of the original attesting doctor. She argues that "the standard is whether there is a reasonable medical basis for the *attesting* physician's opinion, not the *reviewing* physician's opinion." Patterson Br. at 7.

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[18]It appears that Dr. Silvestry was instructed by Patterson's counsel to review the echocardiogram according to their interpretation of the Settlement Agreement. Dr. Silvestry's report indicates that his opinion was "intended to provide legal consultation" and should not be relied upon "for the diagnosis, prognosis, or treatment" of the claimant's medical condition.

Once the Trust denies a claim and the claim advances to a show cause proceeding, the claimant has the burden of proving there was a reasonable medical basis for the attesting physician's representations. Audit Policies & Procedures § VI.D., PTO 2457 (May 31, 2002). The District Court acknowledged and applied the correct standard under the Settlement Agreement. According to the District Court, "[t]he issue presented for resolution of this claim is whether [Patterson] has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation." *In re Diet Drugs*, 2007 WL 674720, at *2. The court concluded that "the attesting physician's answer lacks a reasonable medical basis . . . because the attesting physician's finding failed to reflect the actual level of [Patterson's] mitral regurgitation." *Id.* at *3. It faulted Patterson for failing to "address the improper measurements underlying the finding of her attesting physician." *Id.*

As noted, in an attempt to support her claim, Patterson submitted a certification prepared by Dr. Silvestry. But because Dr. Silvestry's report identified the maximum regurgitant jet without any discussion of its representativeness, the court concluded that the report did not support Patterson's contention that Dr. Harris' opinion had a reasonable medical basis. *Id.* at *4 ("Claimant has not established that the 'maximum regurgitant jet' offered in support of her claim is representative of her level of mitral regurgitation . . . .").

Dr. Churchwell found trivial to mild mitral regurgitation

in Patterson's echocardiogram. Under the Audit Policies and Procedures, Patterson had the burden to prove that Dr. Harris' opinion had a reasonable medical basis. Patterson had the opportunity to show that Dr. Harris' finding represented the actual level of Patterson's mitral regurgitation. But Dr. Silvestry's report failed to satisfy Patterson's burden because it only identified a single maximum regurgitant jet without any indication of the jet's representativeness. Accordingly, the District Court properly rejected Dr. Silvestry's report because it failed to rebut Dr. Churchwell's conclusion that Dr. Harris' report lacked a reasonable medical basis.

III.

For the foregoing reasons, we will affirm.