

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MARYLAND

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MONIQUE D. ALMY, Chapter 7 Trustee for the Bankruptcy Estate of Bionicare Medical Technologies, Inc.,	*	
	*	
Plaintiff,	*	
v.	*	Civil Action Nos.: RDB-09-0255
	*	RDB-09-2617
	*	RDB-10-0131
KATHLEEN SEBELIUS, Secretary, United States Department of Health and Human Services	*	RDB-10-2755
	*	RDB-11-0598
	*	RDB-11-3691
	*	RDB-12-0856
Defendant.		
* * * * *		

**MEMORANDUM OPINION**

The Plaintiff Monique Almy, as Chapter 7 Trustee for the Bankruptcy Estate of Bionicare Medical Technologies, Inc., filed these seven lawsuits against Kathleen Sebelius, in her capacity as the Secretary of the United States Department of Health and Human Services (the “Secretary” or the “Defendant”), appealing the Secretary’s decisions to deny Medicare coverage for a medical device, pursuant to Title XVIII of the Social Security Act, 42 U.S.C. § 1395, *et seq.* (the “Medicare Act”), and the Administrative Procedure Act, 5 U.S.C. § 551, *et seq.* These filings followed an initial lawsuit in which this Court granted summary judgment in favor of the Secretary. *Almy v. Sebelius*, 749 F. Supp. 2d 315 (D. Md. 2010) (“*Almy I*”). The parties agreed to a stay in these seven cases pending an appeal to the United States Court of Appeals for the Fourth Circuit, which affirmed this Court’s opinion. *Almy v. Sebelius*, 679 F.3d 297 (4th Cir. 2012). Still pending are the Defendant’s Motions to Dismiss

filed in these seven remaining actions.<sup>1</sup> The parties' submissions have been reviewed and no hearing is deemed necessary. *See* Loc. R. 105.6 (D. Md. 2011). For the reasons that follow, the Defendant's Motions are GRANTED, and these remaining cases are DISMISSED WITH PREJUDICE.

### BACKGROUND

The Plaintiff Almy is the bankruptcy trustee of Bionicare Medical Technologies, Inc. ("Bionicare"), a company that sold a medical device, the Bionicare Stimulator System, Model 1000 (the "BIO-1000"), that purportedly treats osteoarthritis of the knee by electrical stimulation. The BIO-1000 is an item of Durable Medical Equipment as defined in 42 U.S.C. § 1395x(n). It was originally developed by Murray Electronics, which initially sought approval from the Food and Drug Administration ("FDA") under the stringent "Pre-Market Approval" standard, but eventually marketed the BIO-1000 pursuant to the less stringent "510(k) process." Under Section 510(k) of the Food, Drug, and Cosmetics Act, a device may be sold if it is "substantially equivalent to another device" that is already approved and on the market. 21 U.S.C. § 360c(f)(1)(A)(ii). In 1997, the FDA approved the BIO-1000 pursuant to the 510(k) process, concluding that it was equivalent to the Transcutaneous Electric Nerve Stimulator already approved for the market.<sup>2</sup> In 2003 and 2006, the FDA reaffirmed clearance of the BIO-1000.

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<sup>1</sup> The Motions to Dismiss filed in the seven pending cases are as follows: No. RDB-09-0255 ("*Almy IP*"), ECF No. 13; No. RDB-09-2617 ("*Almy IIP*"), ECF No. 10; No. RDB-10-0131 ("*Almy IV*"), ECF No. 10; No. RDB-10-2755 ("*Almy V*"), ECF No. 10; No. RDB-11-0598 ("*Almy VP*"), ECF No. 11; No. RDB-11-3691 ("*Almy VIP*"), ECF No. 11; and No. RDB-12-0856 ("*Almy VIIP*"), ECF No. 8.

<sup>2</sup> Because the Transcutaneous Electric Nerve Stimulator was marketed prior to the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, it did not itself pass Pre-Market Approval but was "grandfathered in."

Part B of the Medicare Act, 42 U.S.C. §§ 1395k(a), 1395x(s)(6), provides coverage for certain types of Durable Medical Equipment, but explicitly denies coverage for items that are “not reasonable and necessary,” 42 U.S.C. § 1395y(a)(1)(A). From 2004 until Bionicare filed for bankruptcy in 2007, the company was enrolled in Medicare as a supplier of Durable Medical Equipment. Since the BIO-1000’s approval in 1997, it was distributed to thousands of patients and Bionicare submitted thousands of claims to Medicare for the device. To facilitate administration of such claims, the Center for Medicare and Medicaid Services assigned the BIO-1000 a billing code in the Healthcare Common Procedure Coding System (“HCPCS”) and created a fee schedule for the device. Some Medicare contractors have covered the BIO-1000 while others have rejected Bionicare’s claims. Bionicare appealed many of its claims through the administrative process through adjudication by the Medical Appeals Council (“MAC”), which rendered a final decision of the Secretary covering, or rejecting coverage of, the BIO-1000.

The Plaintiff alleges that, with regard to many claims, the Defendant Secretary of Health and Human Services improperly denied Medicare reimbursement for the BIO-1000. Almy first sued the Secretary in this Court in case No. RDB-08-1245 (“*Almy I*”). In *Almy I*, the Plaintiff sought judicial review and reversal of eight groups of Medicare Appeals Council decisions denying coverage. After *Almy I* was filed, the Plaintiff filed these other actions against the Secretary as more claims for the BIO-1000 were denied. It was agreed that because the resolution of *Almy I* might be dispositive of the issues at bar, these other cases regarding the denial of Medicare coverage for the BIO-1000 would be stayed. Accordingly,

these seven other suits (“*Almy II-VIII*”), addressing dozens of MAC decisions, were stayed pending resolution of *Almy I*.

In *Almy I*, this Court granted summary judgment for the Defendant and denied the Plaintiff’s motion for reconsideration. 749 F. Supp. 2d 315 (D. Md. 2010). First, this Court held that although some claims for the BIO-1000 were paid while others were denied, the Secretary’s decisions were not inconsistent and were therefore entitled to deference pursuant to 5 U.S.C. § 706, 42 U.S.C. § 405(g), and *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 843-45 (1984) (where a statute is silent or ambiguous as to a specific question, the administrative agency’s permissible construction of the statute is accorded deference by the court).<sup>3</sup> In particular, this Court noted that a certain amount of variation in coverage determinations is understandable, and that lower-level decisions by contractors and Administrative Law Judges (“ALJs”) are non-precedential. Under the deferential standard, this Court held that the Secretary properly considered the FDA’s clearance of the BIO-1000 under the Section 510(k) process in determining coverage, noting that FDA approval is necessary, but not sufficient for Medicare coverage. In addition, this Court upheld the Secretary’s negative determination of the BIO-1000’s medical efficacy and acceptance, holding that the Secretary properly considered and rejected evidence of peer-reviewed publications and case studies, statements and letters of medical necessity by physicians and experts, and the assignment of an HCPCS billing code and fee schedule for the device. The

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<sup>3</sup> The Plaintiff argued that the Secretary’s decisions are entitled to less deference because they were not preceded by any statute, regulation, or policy specifically addressing the BIO-1000. This Court rejected that argument, concluding that the Secretary properly announced the Department’s interpretation of coverage through individual decisions of the Medical Appeals Council, and was not required to issue a broad National or Local Coverage Decision.

Plaintiff's argument that the MAC improperly calculated the payment amount for BIO-1000 claims that were covered was also rejected. Finally, this Court found unpersuasive Bionicare's argument that it should not be liable for the non-covered cost of the BIO-1000 because it sent an Advance Beneficiary Notice ("ABN") pursuant to 42 U.S.C. § 1395pp to certain beneficiaries explaining that the device may not be covered. Specifically, this Court found that the ABN was too generic to shift liability to the beneficiary. The Plaintiff appealed the grant of summary judgment against her.

The United States Court of Appeals for the Fourth Circuit affirmed, and denied Almy's motion for rehearing and for rehearing en banc on June 25, 2012. 679 F.3d 297 (4th Cir. 2012). Almy's three challenges to this Court's ruling were rejected. Specifically, the Fourth Circuit held that the Secretary did not improperly implement policy by assessing coverage of the BIO-1000 through adjudication of individual claims rather than issuing broader National or Local Coverage Determinations. The Fourth Circuit noted that no policy is made by any single adjudication or by "the accretion of individual decisions finding that the BIO-1000 does not meet the statutory requirements for coverage," and that the Plaintiff's theory would "effectively require the Secretary to issue item-specific coverage rules for each and every item of [Durable Medical Equipment] before issuing case adjudications." *Id.* at 303-04 (quoting 679 F. Supp. 2d at 324 n.2). Furthermore, the Fourth Circuit held that Almy had not carried her burden to show coverage through "credible and credited evidence," while the Secretary's determination of coverage was supported by substantial evidence. The Fourth Circuit also held that the Secretary employed proper procedures pursuant to 5 U.S.C. § 706(2)(A), and adequately considered FDA Section 510(k)

approval,<sup>4</sup> the effect of precedent on Medicare Appeals Council decisions, HCPCS fee schedules, payment determinations, Advance Beneficiary Notices, and peer-reviewed studies in concluding that the BIO-1000 was not covered.

The Supreme Court of the United States denied Almy's petition for certiorari on January 7, 2013. 133 S. Ct. 841 (2013). Upon the denial of certiorari, this Court then instructed the parties to address, via the pending Motions to Dismiss, whether the Fourth Circuit's decision in *Almy I* is controlling as to *Almy II-VIII*, compelling dismissal of the other seven cases. See Letter Order of Mar. 7, 2013, No. 09-0255, ECF No. 12. On April 30, 2013, the Defendant filed an identical Motion to Dismiss in all seven pending cases.

#### STANDARD OF REVIEW

Under Federal Rule of Civil Procedure 8(a)(2), a complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Rule 12(b)(6) authorizes the dismissal of a complaint if it fails to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). Therefore, "the purpose of Rule 12(b)(6) is to test the sufficiency of a complaint and not to resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses." *Presley v. City of Charlottesville*, 464 F.3d 480, 483 (4th Cir. 2006) (internal quotation marks and alterations omitted) (quoting *Edwards v. City of Goldsboro*, 178 F.3d 231, 243 (4th Cir. 1999)). When ruling on such a motion, the court must "accept the well-pled allegations of the complaint as true," and "construe the facts and reasonable inferences derived therefrom in the light most favorable to the plaintiff." *Ibarra v. United States*, 120 F.3d 472, 474 (4th Cir. 1997). However, this Court "need not accept the

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<sup>4</sup> The Fourth Circuit also declined to decide whether the more stringent Pre-Market Approval would per se satisfy the "reasonable and necessary" requirements. *Almy I*, 679 F.3d at 309.

legal conclusions drawn from the facts, and [this Court] need not accept as true unwarranted inferences, unreasonable conclusions or arguments.” *Nemet Chevrolet, Ltd. v. Consumeraffairs.com, Inc.*, 591 F.3d 250, 253 (4th Cir. 2009) (internal quotation marks and citation omitted).

The Supreme Court’s opinions in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), “require that complaints in civil actions be alleged with greater specificity than previously was required.” *Walters v. McMaben*, 684 F.3d 435, 439 (4th Cir. 2012) (citation omitted). The Supreme Court’s decision in *Twombly* articulated “[t]wo working principles” that courts must employ when ruling on Rule 12(b)(6) motions to dismiss. *Iqbal*, 556 U.S. at 678. First, while a court must accept as true all the factual allegations contained in the complaint, legal conclusions drawn from those facts are not afforded such deference. *Id.*; *Walters v. McMaben*, 684 F.3d 435, 439 (4th Cir. 2012) (“The mere recital of elements of a cause of action, supported only by conclusory statements, is not sufficient to survive a motion made pursuant to Rule 12(b)(6).” (citing *Iqbal*, 556 U.S. at 678.)). Second, a complaint must be dismissed if it does not allege “a plausible claim for relief.” *Iqbal*, 556 U.S. at 679.

Furthermore, as this Court has previously noted in *Almy I*, the Medicare Act provides that “the Secretary’s finding of fact, if supported by substantial evidence, shall be conclusive.” 749 F. Supp. 2d at 322 (quoting *McKenzie Med. Supply, Inc. v. Leavitt*, 506 F.3d 341, 346 (4th Cir. 2007) (citing 42 U.S.C. § 1395ff(b)(1)(A) and 42 U.S.C. § 405(g))). In addition, judicial review of the Secretary’s decision is governed by the Administrative Procedure Act, “which provides that final agency action shall be upheld absent a finding that

it is ‘arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.’” 749 F. Supp. 2d at 322 (quoting 5 U.S.C. § 706(2)(A)). As noted by the Fourth Circuit in its affirmance of *Almy I*, the Secretary’s interpretation of what is “reasonable and necessary” under the Medicare Act is entitled to judicial deference pursuant to *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 843-45 (1984). 679 F.3d at 302.

## DISCUSSION

The Defendant moves to dismiss *Almy II-VIII* on the grounds that the actions raise the same claims that were decided in *Almy I* and are therefore barred by principles of stare decisis, res judicata, and collateral estoppel. The Defendant further argues that although *Almy V-VIII* contain additional claims based on jurisdictional dismissals at the administrative level that were not raised in *Almy I*, this Court has no subject matter jurisdiction to hear such claims.

### **A. The Identical Causes of Action in *Almy II-VIII* Are Precluded by *Almy I***

In its Motions, the Defendant argues that the principle of stare decisis and the affirmative defenses of res judicata and collateral estoppel preclude the Plaintiff from bringing the causes of action asserted in *Almy II-VIII*. The Defendant bears the burden of establishing an affirmative defense such as res judicata or collateral estoppel. *Theune v. U.S. Bank, N.A.*, No. MJG-13-1015, 2013 WL 5934114, at \*3 (D. Md. Nov. 1, 2013) (citing *Goodman v. Praxair, Inc.*, 494 F.3d 458, 464 (4th Cir. 2007)). As stated by the Fourth Circuit in *Goodman*:

It follows therefore, that a motion to dismiss filed under Federal Rule of Civil Procedure 12(b)(6), which tests the sufficiency of the complaint, generally cannot reach the merits of an affirmative defense . . . . But in the relatively rare circumstances where facts sufficient to rule on an affirmative defense are



alleged in the complaint, the defense may be reached by a motion to dismiss filed under Rule 12(b)(6). This principle only applies, however, if all facts necessary to the affirmative defense clearly appear *on the face of the complaint*.

494 F.3d at 464 (citations and internal quotation marks omitted; emphasis in original).

The seven cases pending here form such a “relatively rare circumstance” where facts sufficient to rule on affirmative defenses clearly appear on the face of the complaint. In

*Almy II-VIII*, the Plaintiff alleges in the respective Complaints in those actions that:

- i. Marketing clearance by the FDA foreclosed the Secretary’s Medicare coverage denials for the BIO-1000;
- ii. Certain studies established that the BIO-1000 was safe and effective;
- iii. Physician prescriptions and payments made by commercial insurers established that the BIO-1000 was generally accepted in the medical community as reasonable and necessary;<sup>5</sup>
- iv. The establishment of a Healthcare Common Procedure Coding System (“HCPCS”) billing code and inclusion of the payment amount in the fee schedule show that the BIO-1000 is covered;
- v. The Secretary’s final denials of coverage were arbitrary and capricious because the denials by the Medicare Appeals Council (“MAC”) are inconsistent with Medicare’s payment of numerous claims for the BIO-1000;
- vi. Because Bionicare gave Advance Beneficiary Notices indicating the possibility of non-coverage, the Secretary unlawfully refused to waive Bionicare’s liability for denied claims, and should have shifted liability to the Department or to the beneficiaries;
- vii. The Secretary unlawfully determined the payment amount for BIO-1000 claims that were covered.<sup>6</sup>

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<sup>5</sup> The Plaintiff also argues that the Secretary improperly failed to apply the “treating physician rule.” The rule, wherein the opinion of a treating physician of a Social Security claimant is given controlling weight if it is supported by, and not inconsistent with, the medical evidence in the record, *Mastro v. Apfel*, 270 F.3d 171, 178 (4th Cir. 2001), applies only to Social Security cases and not to Medicare cases. *Almy I*, 749 F. Supp. 2d at 332 n.10.

<sup>6</sup> Additionally, in *Almy IV* only, the Plaintiff alleges that it was unlawful for the MAC to review the issue of coverage where the decision of the Administrative Law Judge (“ALJ”) only addressed the payment amount. In *Almy I*, however, the Plaintiff argued the opposite—that the MAC had the authority to review coverage in cases where the ALJ only addressed payment. In any event, in *Almy I*, the Fourth Circuit held that the MAC’s authority to review an ALJ’s decision *de novo* “is incompatible with the notion that the MAC is somehow obligated to defer to the outcomes of prior decisions below.” 679 F.3d at 310. Therefore, the Plaintiff is prohibited by *Almy I* from relitigating this issue in *Almy IV*.

Because each of these allegations was considered in depth and rejected both by this Court and by the Fourth Circuit, all of the facts necessary to decide the merits of an affirmative defense are stated in the Complaints in *Almy II-VIII*. Therefore, it is proper at this stage to consider the merits of the affirmative defenses raised by the Defendant, as well as the overarching principle of stare decisis.

### 1. Stare Decisis

Stare decisis is the general concept of precedent: “when a point or principle of law has been once officially decided or settled by the ruling of a competent court in which it is directly and necessarily involved, it will no longer be considered as open to examination or to a new ruling by the same tribunal, or by those which are bound to follow its adjudications.” Black’s Law Dictionary 1414 (7th ed. 1999). Accordingly, published opinions of the United States Court of Appeals for the Fourth Circuit are binding precedent on this Court. *See United States ex rel. Palmieri v. Alpharma, Inc.*, 928 F. Supp. 2d 840, 857 (D. Md. 2013) (“In sum, [*United States ex rel Nathan v. Takeda Pharms. N. Am., Inc.* 707 F.3d 451 (4th Cir. 2013)] is binding circuit precedent that is clearly dispositive of the issue. It dictates that the Amended Complaint must be dismissed for failure to state a claim upon which relief can be granted.”).

### 2. Res Judicata

Res judicata, also known as claim preclusion, “bars a party from relitigating a claim that was decided or could have been decided in an original suit,” *Laurel Sand & Gravel, Inc. v. Wilson*, 519 F.3d 156, 161 (4th Cir. 2008), and “bars a cause of action adjudicated between the same parties or their privies in a prior case.” *Jones v. SEC*, 115 F.3d 1173, 1178 (4th Cir.

1997) (citation omitted). The elements of a res judicata defense are: “(1) a final judgment on the merits in a prior suit, (2) an identity of the cause of action in both the earlier and later suit, and (3) an identity of parties or their privies in the two suits.” *Id.*

### 3. Collateral Estoppel

Collateral estoppel, a subset of res judicata also known as issue preclusion, “bars the relitigation of issues that were actually determined in a prior action.” *Sartin v. Maciek*, 535 F.3d 284, 287 (4th Cir. 2008). A collateral estoppel defense is available if: (1) the issue sought to be precluded is identical to one previously litigated; (2) the issue was actually determined in the prior proceeding; (3) the determination of the issue was a critical and necessary part of the decision in the prior proceeding; (4) the prior judgment is final and valid; and (5) the party against whom estoppel is asserted had a full and fair opportunity to litigate the issue in the previous forum. *Sedlack v. Brawell Servs. Group, Inc.*, 134 F.3d 219, 224 (4th Cir. 1998).

### 4. Preclusive Effect of *Almy I*

These cases involve the same parties, the same subject device, and the same arguments as to why the Secretary’s denials of coverage in *Almy I* were contrary to law. The Fourth Circuit, in a published opinion, has clearly rejected each of the arguments once again raised in *Almy II-VIII*. Therefore, stare decisis bars the causes of action asserted in *Almy II-VIII* that are identical to those in *Almy I*.<sup>7</sup>

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<sup>7</sup> The Defendant also argues that *Almy II-VIII* are barred by a variant of stare decisis known as the “law of the circuit” doctrine. The law of the circuit doctrine is the statutorily-based rule that a “decision of a division [of a Circuit Court of Appeals] is the decision of the court,” and that “[o]ne three-judge panel, therefore, does not have authority to overrule another three-judge panel of the court.” *LaShawn A. v. Barry*, 87 F.3d 1389, 1395 (D.C. Cir. 1996); *United States v. Valencia*, 645 F.2d

As to the affirmative defenses raised by the Defendant, although *Almy II-VIII* involve the same parties and subject medical device, separate denials of coverage are different transactions. See *Laurel Sand & Gravel, Inc.*, 519 F.3d at 162 (res judicata applies to a claim that “arises out of the same transaction or series of transactions as the claim resolved by the prior judgment,” or “could have been brought in the earlier action”). To the extent that *Almy* now seeks coverage for different beneficiaries at different time periods than those decided in *Almy I*, those claims are a different series of transactions. Moreover, because this Court stayed *Almy II-VIII* rather than consolidating them with *Almy I*, the Plaintiff could not have brought the claims, which accrued at a later time, in the earlier action. Thus, because *Almy II-VIII* do not advance the same claims as in *Almy I*, res judicata does not apply.<sup>8</sup>

However, while res judicata does not apply, the issue in all the claims is exactly the same, and therefore collateral estoppel precludes the actions in *Almy II-VIII*. As noted above, the issues surrounding the Secretary’s denial of coverage for the BIO-1000 are identical. The Plaintiff argues unconvincingly that new and material evidence in *Almy II-VIII* makes those seven cases distinct from *Almy I*. Specifically, the Plaintiff states that the

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1158, 1176 (2d Cir. 1980) (Van Graafeiland, J., dissenting) (the law of the circuit doctrine is “the commonly accepted doctrine that one Court of Appeals panel cannot overrule the decision of a prior panel but that such disregard of stare decisis requires action by an en banc court.”). As such, under the law of the circuit doctrine, “the same issue presented in a later case in the same court should lead to the same result.” *In re Grant*, 635 F.3d 1227, 1232 (D.C. Cir. 2011) (citation omitted). Here, the Plaintiff correctly notes that because she does not ask one panel of Fourth Circuit judges to overrule a decision of another panel, the law of the circuit doctrine is not implicated at this stage in *Almy II-VIII*. Nevertheless, the fact remains that the Fourth Circuit’s decision in *Almy I* is binding precedent on this Court. Therefore, general stare decisis principles mandate dismissal.

<sup>8</sup> On a related note, it is of no moment that the MAC remanded a separate case involving the BIO-1000 to an Administrative Law Judge who dismissed on res judicata grounds without holding a hearing. See Pl.’s Opp. Ex B, ECF No. 14-1. This Court is in a different position than an ALJ. The Defendant is arguing that this Court is bound not by the MAC decision, but by the decision of the Fourth Circuit. While proper deference is owed to the MAC because it states the decision of the Secretary, this Court is bound by the published opinion of the Fourth Circuit.

administrative records are “likely” to contain evidence of, among other things, affidavits of physicians and experts, journal articles and studies, Internet articles, video recordings, and insurance and treatment guidelines that will establish that the Secretary’s denial of coverage in those cases was arbitrary and capricious. *See* Pl.’s Opp. Ex. A, ECF No. 14-1. This evidence, Almy argues, will show that: Bionicare’s peer-reviewed studies should be given more weight than case studies; the BIO-1000 is widely accepted in the medical community; the BIO-1000 is considered part of the standard of care; the device is not experimental or investigational; and physicians and experts generally support coverage of the device. Thus, the Plaintiff argues that the claims in *Almy II-VIII* cannot be ruled upon until the administrative records purportedly containing this new evidence are filed in this Court.

The Plaintiff’s citation to this “new” evidence carries no weight for a number of reasons. First, Almy argues only that the administrative records are “likely” to contain this evidence. Such speculation is unwarranted and insufficient to survive a motion to dismiss. Furthermore, the evidence is not “new.” Almost all of this evidence was in administrative record in *Almy I*, or in the Plaintiff’s possession, or accessible by her, during the pendency of *Almy I*. Additionally, all but four of the listed documents were submitted to the court by Plaintiff’s counsel Debra Parrish in *International Rehabilitative Sciences, Inc. v. Sebelius*, 737 F. Supp. 2d 1281 (W.D. Wash. 2010), *rev’d*, 688 F.3d 994 (9th Cir. 2012), another case where coverage for the BIO-1000 was ultimately rejected, in which Almy was not a party. Finally, and most critically, the evidence is not “material.” The Plaintiff fails to articulate how this additional evidence would affect the outcome of a coverage decision regarding the same product. Nothing establishes that any of the documents that may be contained in the

administrative records of *Almy II-VIII* would have any effect on the previous holdings of this Court or the Fourth Circuit in *Almy I*. Indeed, the precise types of evidence cited by Almy as “new” were already considered and rejected. A few additional form affidavits about the BIO-1000 will have no bearing on the determination of whether the decisions of the Secretary were supported by substantial evidence. Likewise, “it is not [the court’s] office to tender an independent judgment on the value and validity of various [additional] scientific studies submitted.” *Almy I*, 679 F.3d at 305. Despite her arguments to the contrary, there is no new and material evidence that makes Almy’s claims in *Almy II-VIII* any different than those finally decided in *Almy I*.

Thus, the Plaintiff raises the same arguments in support of coverage that were critical and necessary to the decision in *Almy I*.<sup>9</sup> After a full and fair opportunity to litigate these identical issues, the Fourth Circuit actually rendered a final judgment on those issues. Because the same causes of action that are at issue in *Almy II-VIII* were decided in a final and valid opinion on the merits in *Almy I*, the Defendant has established that those claims are barred by the affirmative defense of collateral estoppel. The causes of action raised in *Almy II-VIII* that were already decided in *Almy I* are precluded based on the principle of stare decisis and the affirmative defense of collateral estoppel. Therefore, the Plaintiff has

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<sup>9</sup> The Plaintiff also argues that in a redacted Medical Appeals Council decision attached to the Plaintiff’s Opposition, dated October 11, 2012 and unrelated in any way to the BIO-1000, the Secretary changed her position with regard to the medical documentation required at the Qualified Independent Contractor level, showing that the Secretary is not bound by *Almy I*. It is irrelevant whether the Secretary “acted as if *Almy I* was not binding” because this Court is in fact bound by that decision with regard to the issues in *Almy II-VIII*. The unrelated MAC decision is not at issue here, and this Court expresses no opinion on its validity. To the extent that that single MAC decision represents a different interpretation of the requirements for medical documentation, this cannot be considered a general change in the Secretary’s policy. *Almy I*, 679 F.3d at 303 (“The Secretary’s own regulations make clear that any policy implications in an adjudication do not have precedential effect.” (citing 24 C.F.R. § 405.1062)).

failed to state a plausible claim for relief. Accordingly, the Defendant's Motions to Dismiss are granted.

**B. This Court Lacks Subject Matter Jurisdiction Over the Challenges to Jurisdictional Dismissals in *Almy V-VIII***

In *Almy V-VIII*, the Plaintiff asserts one type of claim that was not at issue in *Almy I*. Specifically, in *Almy V-VIII*, the Plaintiff challenges the dismissal of Bionicare's administrative appeals that were dismissed for lack of jurisdiction. For example, in *Almy VI*, the Plaintiff argues that Bionicare timely filed requests for reconsideration of the ALJ's determination, but that the challenges were rejected out of hand at each administrative level based on untimeliness, without a hearing on the merits. The Plaintiff alleges that the Durable Medical Equipment Medicare Administrative Contractor acknowledged receipt of Bionicare's "letter dated March 7, 2007, requesting a redetermination." Later, the Qualified Independent Contractor upheld the dismissal because Bionicare's request "should have been received on or before May 28, 2007." Pl.'s Opp. 21, ECF No. 14. The Medical Appeals Council, the final administrative level, eventually concluded that there was no subject matter jurisdiction and the claim was not subject to further review. The Defendant argues that this Court lacks subject matter jurisdiction over the Plaintiff's challenges to dismissals based on jurisdiction.

Pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure, a claim must be dismissed when the district court lacks subject matter jurisdiction. The Plaintiff has the burden to establish the existence of subject matter jurisdiction. *Piney Run Pres. Ass'n v. Cnty. Comm'rs of Carroll Cnty.*, 523 F.3d 453, 459 (4th Cir. 2008). Even accepting her factual

allegations that the reconsideration requests were timely filed, the Plaintiff has failed to carry her burden to show that subject matter jurisdiction exists.

The Medicare Act limits judicial review to the “final decision of the [Secretary]<sup>10</sup> made after a hearing.” 42 U.S.C. § 405(g) (incorporated in the Medicare Act by 42 U.S.C. § 1395ff(b)(1)(A)). In the Fourth Circuit, the dismissal of an administrative appeal for untimely filing is not a final decision of the Secretary made after a hearing, and thus such administrative dismissals are not subject to judicial review under 42 U.S.C. § 405(g). *Adams v. Heckler*, 799 F.2d 131, 133 (4th Cir. 1986) (collecting cases and noting that each circuit to have addressed the issue, except one, has held that administrative dismissals for untimely filing are not final decisions subject to judicial review under 42 U.S.C. § 405(g)); *Brandtner v. Dep’t of Health & Human Servs.*, 150 F.3d 1306, 1307 (10th Cir. 1998) (same). In *Adams*, the Fourth Circuit agreed with the reasoning of the Eighth Circuit that an administrative dismissal for untimely filing “does not address the merits of the claim, and thus cannot be considered appealable . . . . If the claimant may avoid the timely exhaustion of remedies requirement, any claimant could belatedly appeal his claim at any time and always obtain district court review of an ALJ’s decision.” 799 F.3d at 133 (quoting *Smith v. Heckler*, 761 F.2d 516, 518 (8th Cir. 1985)).

In *Almy V-VIII*, the Plaintiff alleges that certain claims were dismissed for lack of jurisdiction. Even assuming, as this Court must at this stage, that the Plaintiff’s allegation that the requests for reconsideration were in fact timely filed, there was no hearing and no

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<sup>10</sup> Although 42 U.S.C. § 405(g) refers to the Commissioner of Social Security, the Medicare Act explicitly states that references to the Commissioner in § 405(g) are considered references to the Secretary of Health and Human Services. 41 U.S.C. § 1395ff(b)(1)(A).



decision on the merits. Therefore, there has been no exhaustion of administrative remedies and no final, appealable decision.<sup>11</sup> Accordingly, because there has been no final decision by the Secretary, the Medicare Act does not confer to this Court subject matter jurisdiction over claims dismissed for lack of jurisdiction.

The Plaintiff argues in the alternative that this Court has general federal question jurisdiction pursuant to 28 U.S.C. § 1331. However, the Medicare Act explicitly provides that no action against the Secretary may be brought under § 1331. 42 U.S.C. §§ 405(h), 1395ii. The Supreme Court has established that § 405(h)'s bar of federal question jurisdiction applies if the Medicare Act provides “the standing and the substantive basis” for a plaintiff's claims.<sup>12</sup> *Heckler v. Ringer*, 466 U.S. 602, 615 (1984). Because *Almy II-VIII* are brought pursuant to the Medicare Act, this Court has no federal question jurisdiction over her challenges to jurisdictional dismissal.

Finally, the Plaintiff argues that this Court should exercise mandamus jurisdiction over the jurisdictional dismissal claims in *Almy V-VIII*. The “remedy of mandamus is a drastic one, to be invoked only in extraordinary situations.” *Kerr v. United States Dist. Court*, 426 U.S. 394, 402 (1976). Mandamus relief is an appropriate remedy “only if [a plaintiff] has

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<sup>11</sup> The Plaintiff cites *Auburn Regional Medical Center v. Sebelius*, a decision of the District of Columbia Circuit, for the proposition that jurisdictional dismissal is a final decision that is appealable. 642 F.3d 1145 (D.D.C. 2011). That decision was reversed by the Supreme Court, 133 S. Ct. 817 (2013), and on remand the D.C. Circuit affirmed the district court's judgment providing that a jurisdictional dismissal is not appealable, as well as rejecting jurisdiction on the alternative bases of the federal question statute and mandamus. 686 F. Supp. 2d 55 (D.D.C. 2010), *judgment aff'd*, 509 F. App'x 1 (D.C. Cir. 2013).

<sup>12</sup> The Plaintiff cites the Supreme Court's statement that jurisdiction would be available under § 1331 if application of the provisions of the Medicare Act limiting jurisdiction “would mean no review at all.” *Shalala v. Ill. Council of Long Term Care, Inc.*, 529 U.S. 1, 17 (2000). However, that statement is in reference to review of constitutional claims, where application of § 405(h) as a bar would potentially be unconstitutional. No such claims are at issue in *Almy V-VIII*.

exhausted all other avenues of relief and only if the defendant owes him a clear nondiscretionary duty.” *Ringer*, 466 U.S. at 616 (citing 28 U.S.C. § 1361). “To establish the necessary conditions for issuance of a writ of mandamus, the party seeking the writ must show that (1) he has a clear and indisputable right to the relief sought; (2) the responding party has a clear duty to do the specific act requested; (3) the act requested is an official act or duty; (4) there is no other adequate means to attain the relief he desires; and (5) the issuance of the writ will effect right and justice in the circumstances.” *Montgomery Cnty, Md. v. Leavitt*, 445 F. Supp. 2d 505, 514 (D. Md. 2006) (denying petition for mandamus in the Medicare context) (citations and internal quotation marks omitted). The Fourth Circuit has not squarely addressed whether 42 U.S.C. § 405(h) categorically bars mandamus jurisdiction. Even so, the Plaintiff has not shown that this is such an “extraordinary” situation to meet the high bar to invoke mandamus jurisdiction. The Plaintiff argues that a writ of mandamus is necessary “to correct Medicare payment determinations that are clearly incorrect.” Pl.’s Opp. 25, ECF No. 14. The Plaintiff has not shown that she has a clear and indisputable right to coverage for the BIO-1000. Unlike in the context of a motion to dismiss for failure to state a claim, for mandamus jurisdiction purposes, Almy’s factual allegations that the requests for reconsideration were filed on time are insufficient to establish a clear and indisputable right to a further administrative hearing,<sup>13</sup> let alone for the outcome to be in her favor. To be sure, the Secretary has an official, nondiscretionary duty to hear the merits of

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<sup>13</sup> This Court notes that the Plaintiff did not provide any supporting evidence for the argument that the jurisdictionally dismissed claims were timely filed. *See Metzgar v. KBR, Inc.*, \_\_\_ F. 3d \_\_\_, No. 13-1430, slip op. at 10 (4th Cir. Mar. 6, 2014). As recently noted by the Fourth Circuit, on a motion to dismiss under Rule 12(b)(1), the district court may consider evidence beyond the scope of the pleadings without converting the motion to one for summary judgment. *Id.* (citing *Velasco v. Gov’t of Indon.*, 370 F.3d 392, 398 (4th Cir. 2004)).

timely filed requests for reconsideration. However, the Plaintiff asks this Court for more—to conclude that the BIO-1000 is covered in those cases. That determination, subject to the applicable statutes and regulations, is squarely within the province of the Secretary’s discretion.<sup>14</sup> *See Montgomery Cnty., Md.*, 445 F. Supp. 2d at 514 (Secretary had no duty to certify Canadian prescription drug for importation). For those reasons, the issuance of a writ of mandamus will not effect right and justice in these cases, and the Plaintiff’s petition is accordingly denied.<sup>15</sup>

### CONCLUSION

For the reasons stated above, the Defendant’s Motions to Dismiss are GRANTED, and these remaining seven cases (*Almy II-VIII*) are DISMISSED WITH PREJUDICE.

Dated: March 7th, 2014

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/s/  
Richard D. Bennett  
United States District Judge

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<sup>14</sup> Also, as noted above in Part A of this Memorandum Opinion, the Plaintiff has failed to state a claim upon which relief can be granted with respect to the coverage determination of the BIO-1000 and identifies no facts setting the jurisdictionally dismissed claims apart from those dozens of others decided on the merits.

<sup>15</sup> It is also of note that, although there is no further administrative avenue for the claims that were jurisdictionally dismissed, the Plaintiff had other means of obtaining relief for the denial of a hearing as to these specific coverage decisions. *See Brandtner v. Dep’t of Health & Human Servs.*, 150 F.3d 1306, 1307 n.3 (10th Cir. 1998) (noting that denial of hearing on the merits for an untimely request for review could be considered a final decision of the Secretary for purposes of a constitutional due process claim).