

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

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<b>HELOMICS CORPORATION,</b>	)	
	)	
<b>Plaintiff,</b>	)	
	)	
<b>v.</b>	)	<b>Civil Action No. 16-546 (RMC)</b>
	)	
<b>SYLVIA MATHEWS BURWELL,</b>	)	
<b>Secretary of the U.S. Department of</b>	)	
<b>Health and Human Services, <i>et al.</i>,</b>	)	
	)	
<b>Defendants.</b>	)	
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**OPINION**

This case involves the proverbial tension between form and function. Helomics Corporation is a health-care company that created a test called ChemoFx to measure the response of cancerous tumors to various chemotherapies. Novitas Solutions, Inc., a Medicare Administrative Contractor in Pennsylvania (where Helomics is located), issued a local coverage determination (LCD) on November 5, 2015 stating that Medicare would no longer cover ChemoFx treatments after December 31, 2015. This non-coverage LCD was issued after an earlier determination to the same effect in 2012 and then retired so that Novitas could consider more data from Helomics. The 2015 LCD followed a 45-day comment period, consideration and response to the comments by Novitas, and a notice period of 45 days before the LCD was to become effective. However, Helomics sued Novitas shortly before the effective date to challenge the LCD and enjoin its implementation. As a courtesy to Helomics and the court, Novitas agreed to place the LCD on hold during the pendency of the litigation and delay its

implementation. However, Novitas' database apparently did not contemplate this option; instead, Novitas checked that box that indicated that the LCD was "retired" to prevent it from coming into effect as previously scheduled.

Helomics' complaint challenging the substance of the 2015 LCD, filed in the Western District of Pennsylvania, was dismissed for lack of jurisdiction because the company had not exhausted its administrative remedies. At that point, Novitas re-issued the retired non-coverage LC after a 45-day notice period, to be effective on Monday April 11, 2016. No comment period was provided. Helomics filed suit in the District of Columbia on March 22, 2016, alleging that Novitas violated Medicare regulations when it re-issued the "retired" 2015 LCD without providing a new 45-day comment period. Helomics petitions for a writ of mandamus to order Sylvia Mathews Burwell, in her official capacity as Secretary of the Department of Health and Human Services (HHS), and Novitas to follow applicable Medicare regulations and guidance, which it insists requires a new 45-day comment period. Helomics asks the Court to enjoin implementation of the 2015 LCD before its scheduled effective date of April 11, 2016. *See* Compl. [Dkt. 1].

Helomics filed a Motion for Summary Judgment or, in the alternative, for a Preliminary Injunction. *See* Mot. for Summ. J. [Dkt. 4] (MSJ). Defendants opposed Helomics' Motion and filed a Motion to Dismiss under Federal Rule of Civil Procedure 12(b)(1). *See* Mot. to Dismiss [Dkt. 11] (MTD). Helomics also filed a reply. *See* Reply [Dkt. 14]. On April 7, 2016, the Court heard oral argument from both parties. For reasons stated on the record, the Court held that it had jurisdiction over Helomics' Complaint, but that Helomics failed to show that it was entitled to mandamus relief. With Helomics' consent, Defendants made an oral cross-motion for summary judgment. Given that time was of the essence due to the LCD's effective

date, the Court immediately entered an Order denying Helomics' Motion for Summary Judgment, denying Helomics' Motion for a Preliminary Injunction as moot, denying Defendants' Motion to Dismiss for Lack of Jurisdiction, and granting Defendants' Cross-Motion for Summary Judgment. *See* Order [Dkt. 15]. Helomics appealed and the D.C. Circuit Court of Appeals has set an abbreviated schedule. This Opinion provides the reasons for the April 7, 2016 Order.

## I. FACTS

### A. The Medicare Statute

The Medicare statute, located in Title XVIII of the Social Security Act, provides health insurance to the elderly and disabled. *See* 42 U.S.C. § 1395 *et seq.* The Medicare health insurance program is administered by the Centers for Medicare & Medicaid Services, which in turn operates through private entities known as Medicare Administrative Contractors. *See* 42 U.S.C. § 1395u(a), 1395kk-1(a)(4). These contractors are in charge of administering the program -- most particularly receiving, deciding the merit of, and paying claims for Medicare benefits -- in specific regions.

The statute provides that “no payment may be made . . . for any expenses incurred for items or services, which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . . .” *See* 42 U.S.C. §§ 1395y(a)(1)(A). Congress tasked HHS with important “discretionary functions,” such as deciding “whether a particular medical service is reasonable and necessary” and implementing said decision through rulemaking or individual adjudication. *Heckler v. Ringer*, 466 U.S. 602, 617 (1984) (internal quotation marks and citation omitted). The Secretary has a range of options for deciding whether a particular medical service is “reasonable and necessary,” by one of which

she has authorized Medicare Administrative Contractors to develop and implement local coverage determinations, which apply only in the area in which the contractor operates. *See* 42 C.F.R. § 400.202. Instead of reviewing claims individually, LCDs allow contractor staff to identify those items or services that will or will not be covered and under what circumstances, thus allowing them to deny a claim for coverage more readily. *See* 42 U.S.C. § 1395ff(2)(B).

LCDs must be developed and implemented in accord with detailed regulations and chapter 13 of the Medicare Program Integrity Manual (MPIM). *See* MPIM, Ch. 13, § 13.1.3.<sup>1</sup> New LCDs require “both a comment period and a notice period . . . .” *Id.* § 13.7.2. Specifically, Medicare Administrative Contractors must provide the public a minimum of 45 days to comment on the proposed LCD. *Id.* § 13.7.4. The contractor must then consider and respond to the comments, revise the LCD if appropriate, and, if it adopts a final LCD, provide a 45-day notice period before the LCD goes into effect. *Id.* Federal law and the MPIM provide for specific administrative procedures to challenge LCDs. *See, e.g.*, 42 U.S.C. § 1395ff(f)(5); 42 C.F.R. Part 498, Subparts B through E; MPIM § 13.11.

### **B. The ChemoFx Saga**

Since 2007, Novitas has paid only those claims for ChemoFx that it considered to be adequately supported by peer-reviewed literature. In September 2012, Novitas issued a draft LCD that would have refused coverage for chemoresponse tests, such as ChemoFx. However, the draft LCD did not go into effect because Helomics wanted additional time to submit evidence in support of ChemoFx. The truncated record is unclear as to whether Helomics submitted

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<sup>1</sup> Chapter 13 of the MPIM is available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c13.pdf>.

additional evidence. On May 14, 2015, Novitas issued a new draft LCD, which again would deny coverage for ChemoFx. The 45-day comment period ended on July 9, 2015. During the comment period, Novitas held an open public meeting to receive comments on the 2015 draft LCD. Helomics made an oral presentation and submitted written comments. In accord with the MPIM, Novitas responded to the comments and posted its responses on its website. On November 5, 2015, Novitas issued the non-coverage 2015 LCD with an effective date of December 31, 2015, thereby fulfilling the 45-day notice requirement.

On December 11, 2015, Helomics submitted a request for reconsideration to Novitas, which Novitas denied because “[t]he LCD Reconsideration Process is available only for final LCDs.” MPIM § 13.11(B). On December 17, 2015, Helomics sued Novitas in the Western District of Pennsylvania to enjoin the implementation of the 2015 LCD. *See Helomics, Inc. v. Novitas*, No. 2:15-cv-1667-CB (W.D. Penn. Filed Dec. 17, 2015) (*Helomics I*) (Bissoon, J.). In that litigation, Novitas “agreed to delay implementation of its non-coverage [2015] LCD until [January 22, 2016],” thereby allowing briefing and a ruling on Helomics’ Motion for Preliminary Injunction. *Id.*, Dkt. 11 (December 22, 2015 Minute Order). As a result, Novitas staff had to prevent the LCD from going into effect by an entry in the controlling database. With limited available options to check, Novitas staff checked the box indicating that the 2015 LCD was “retired,” which is a term of art in the regulatory scheme. Because Novitas intended only to delay the implementation of the 2015 LCD until Judge Bissoon could rule, it made several entries in the database and elsewhere to that effect. *See* MTD, Ex. 8 [Dkt. 10-12] (2015 LCD) (“This LCD has been placed on hold and may be reactivated at a future date.”); *see also* Ex. 14 [Dkt. 10-18] (Bennett Decl.), Ex. C (Medical Policy Update History page), Ex. D (Medicare New and Web Update pages), and Ex. E (E-mail Blast to Users). In essence, since Novitas did

not know how to change the effective date of the 2015 LCD in its database, it showed the LCD as retired to prevent it from coming into effect.

Novitas moved to dismiss the Pennsylvania complaint for lack of jurisdiction. Judge Bissoon dismissed Helomics' complaint because the court had no jurisdiction since Helomics had failed to exhaust administrative remedies. *See Helomics I*, Dkts. 23 (Order) and 24 (Mem. Op.). On February 25, 2016, Novitas issued the retired 2015 LCD under a new number and with a new notice period of 45 days (2016 LCD) so that it is scheduled to become effective on Monday, April 11, 2016. Because Novitas had told the database that the 2015 LCD was "retired," it needed to issue the identical LCD under a new number. *See* MPIM § 13.7.4.2; *see also* Bennett DeBcl. ¶ 11. The 2016 LCD is identical to the 2015 LCD as when it was challenged in *Helomics I*, with the exception of two new Current Procedural Terminology (CPT) code changes. Thus, the 2016 LCD is the same as the 2015 LCD, of which Helomics had full notice and opportunity to comment.

Helomics filed the instant suit to obtain an order to the Secretary that she adopt both a new 45-day comment period as well as a 45-day notice period for the "retired" but re-issued and re-numbered 2016 LCD. Defendants argued that this Court lacks jurisdiction over Helomics' mandamus petition. The Court ruled on the record that it had jurisdiction. After Helomics failed to show its entitlement to mandamus relief, Defendants cross-moved for summary judgment with Helomics' consent.

## **II. LEGAL STANDARDS**

### **A. Standard of Review**

Pursuant to Federal Rule of Civil Procedure 12(b)(1), a defendant may move to dismiss a complaint, or any portion thereof, for lack of subject matter jurisdiction. Fed. R. Civ.

P. 12(b)(1). No action of the parties can confer subject matter jurisdiction on a federal court because subject matter jurisdiction is both a statutory requirement and an Article III requirement. *Akinseye v. District of Columbia*, 339 F.3d 970, 971 (D.C. Cir. 2003). The party claiming subject matter jurisdiction bears the burden of demonstrating that such jurisdiction exists. *Khadr v. United States*, 529 F.3d 1112, 1115 (D.C. Cir. 2008); see *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994) (noting that federal courts are courts of limited jurisdiction and “[i]t is to be presumed that a cause lies outside this limited jurisdiction, and the burden of establishing the contrary rests upon the party asserting jurisdiction”) (internal citations omitted).

When reviewing a motion to dismiss for lack of jurisdiction under Rule 12(b)(1), a court should “assume the truth of all material factual allegations in the complaint and ‘construe the complaint liberally, granting the plaintiff the benefit of all inferences that can be derived from the facts alleged.’” *Am. Nat’l Ins. Co. v. FDIC*, 642 F.3d 1137, 1139 (D.C. Cir. 2011) (quoting *Thomas v. Principi*, 394 F.3d 970, 972 (D.C. Cir. 2005)). Nevertheless, “the court need not accept factual inferences drawn by plaintiffs if those inferences are not supported by facts alleged in the complaint, nor must the Court accept plaintiff’s legal conclusions.” *Speelman v. United States*, 461 F. Supp. 2d 71, 73 (D.D.C. 2006). A court may consider materials outside the pleadings to determine its jurisdiction. *Settles v. U.S. Parole Comm’n*, 429 F.3d 1098, 1107 (D.C. Cir. 2005); *Coal. for Underground Expansion v. Mineta*, 333 F.3d 193, 198 (D.C. Cir. 2003).

Under Rule 56 of the Federal Rules of Civil Procedure, summary judgment shall be granted “if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a); accord *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). Moreover, summary judgment is properly

granted against a party who “fails to make a showing sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). In ruling on a motion for summary judgment, the court must draw all justifiable inferences in the nonmoving party’s favor and accept the nonmoving party’s evidence as true. *Anderson*, 477 U.S. at 255. A nonmoving party, however, must establish more than “the mere existence of a scintilla of evidence” in support of its position. *Id.* at 252. In addition, the nonmoving party may not rely solely on allegations or conclusory statements. *Greene v. Dalton*, 164 F.3d 671, 675 (D.C. Cir. 1999). Rather, the nonmoving party must present specific facts that would enable a reasonable jury to find in its favor. *Id.* at 675. If the evidence “is merely colorable, or is not significantly probative, summary judgment may be granted.” *Anderson*, 477 U.S. at 249-50 (citations omitted).

### **B. Mandamus Relief**

This Court has “original jurisdiction of any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff.” 28 U.S.C. § 1361. “To show entitlement to mandamus, plaintiffs must demonstrate (1) a clear and indisputable right to relief; (2) that the government agency or official is violating a clear duty to act, and (3) that no adequate alternative remedy exists.” *Am. Hosp. Ass’n v. Burwell*, 812 F.3d 183, 189 (D.C. Cir. 2016) (citation omitted). “Even when the legal requirements for mandamus jurisdiction have been satisfied, however, a court may grant relief only when its finds ‘compelling . . . equitable grounds.’” *In re Medicare Reimb. Litig.*, 414 F.3d 7, 10 (D.C. Cir. 2005) (quoting *13th Reg’l Corp. v. U.S. Dep’t of Interior*, 654 F.2d 758, 760 (D.C. Cir. 1980)).

### III. ANALYSIS

#### A. Exhaustion of Administrative Remedies

Defendants first argue that this Court lacks jurisdiction over the instant case because Helomics failed to exhaust its administrative remedies. In essence, Defendants reassert their successful argument in *Helomics I*. Defendants contend that Helomics' claim arises under the Medicare statute and must be channeled through the administrative process. In light of Helomics' failure to exhaust, Defendants argue that mandamus relief is unavailable. However, unlike *Helomics I*, this case does not involve a challenge to the substance of Novitas' non-coverage LCD. Instead, it involves a challenge to Novitas' alleged failure to follow the required regulatory process when it issued the 2016 LCD on February 25, 2016 with only a notice period and no new 45-day comment period. Therefore, this Court must decide whether said procedural challenge is also subject to Medicare's broad channeling (administrative exhaustion) requirement.

Exhaustion of the administrative process is a statutory requirement imposed by Congress in the Medicare statute as a condition of the waiver of sovereign immunity. *See Weinberger v. Salfi*, 422 U.S. 749, 764, 766 (1975). Section 405(h) provides:

No findings of fact or decision of [the Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against [the Secretary] or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28, United States Code, to recover on any claim arising under this subchapter.

42 U.S.C. § 405(h).<sup>2</sup> The prohibition articulated in § 405(h) applies to all actions arising under the Medicare statute — namely, any action “inextricably intertwined” with a claim for Medicare benefits. *Heckler*, 466 U.S. at 614-15. This statutory requirement “demands the ‘channeling’ of virtually all legal attacks through the agency,” see *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000), thereby prohibiting an action in federal court that has not been first addressed by the agency, see *Salfi*, 422 U.S. at 757. One example of such action subject to the channeling requirement is a challenge to the substance of an LCD. See, e.g., *Popkin v. Burwell*, No.16-cv-141 (RMC), 2016 WL 1170939, at \*5-6 (D.D.C. Mar. 24, 2016); *Helomics I*, No. 15-cv-1667 (CB), 2016 WL 374314 (W.D. Pa. Feb. 1, 2016); *Cal. Clinical Lab. Ass’n v. Sec’y of HHS*, 104 F. Supp. 3d 66 (D.D.C. 2015).

The Court concludes that § 405(h) does not preclude mandamus relief in the circumstances presented here. The D.C. Circuit has “join[ed] the virtual unanimity of circuit courts” in holding “that § 1361 jurisdiction is not barred [by § 405(h)].” *Monmouth Med. Ctr. v. Thompson*, 257 F.3d 807, 813 (D.C. Cir. 2001) (citation omitted); see also *Heckler*, 466 U.S. at 616 (assuming without deciding that “§ 405(h) does not foreclose mandamus jurisdiction in all . . . cases”). In fact, “[t]here is nearly unanimous consensus among the . . . circuits that 28 U.S.C. § 1361 ‘provides jurisdiction in cases challenging the procedures used in administering . . . benefits but unrelated to the merits’ of the benefits claim.” *Wolcott v. Sebelius*, 635 F.3d 757, 764-65 (5th Cir. 2011) (quoting *Burnett v. Bowen*, 830 F.2d 731, 737-38 (7th Cir. 1987)) (citing several decisions from other circuits, including *Monmouth Med. Ctr.*, 257 F.3d at 813).

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<sup>2</sup> This section was incorporated into the Medicare statute by 42 U.S.C. § 1395ii.

The Court also notes that, by its own terms, § 405(h) does not bar Helomics' lawsuit. It is a well-known canon of statutory construction that "the mention of one thing means the exclusion of another." *Black's Law Dictionary* 661 (9th ed. 2009) (defining the canon of *expressio unius est exclusio alterius*); see *EchoStar Satellite L.L.C. v. F.C.C.*, 704 F.3d 992, 1000 (D.C. Cir. 2013). Section 405(h) only bars actions "brought under section 1331 or 1346," as well as substantive challenges to LCDs (*i.e.*, review of a "finding[] of fact or decision"). There is no reference to actions invoking mandamus jurisdiction under § 1361 or to procedural challenges to an LCD. Consequently, the statute's channeling requirement does not bar Helomics' procedural challenge.

#### **B. Entitlement to Mandamus Relief**

The critical question is whether Helomics demonstrated that it was entitled to mandamus relief. Helomics argues that, regardless of Novitas' intention to put the 2015 LCD "on hold," its selection of "retired" from the limited options in the database is dispositive. Helomics contends that, notwithstanding Novitas' efforts to make clear that it was merely delaying the LCD's implementation during the pendency of the *Helomics I* litigation, the notation that the 2015 LCD was "retired" rendered it "invalid and unreasonable." MSJ at 3. Consequently, the argument goes, Novitas was precluded from re-issuing the 2015 LCD without providing Helomics and the public with a new 45-day comment period. On these precise facts, the Court disagrees.

Helomics' argument, while creative, is a red herring. To support the proposition that the 2015 LCD was "invalid and unreasonable," see MSJ at 3, Helomics relies on MPIM § 13.13.9. Section 13.13.9 of the MPIM, titled "Contractor Options," provides that "[a] contractor has the discretion to retire an LCD under review any time before the date the [Administrative

Law Judge (ALJ)] issues a decision regarding the LCD.” MPIM § 13.13.9(A). It further states, “Retiring an LCD under review has the same effect as a decision under [42 C.F.R.] § 426.460(b) . . . .” *Id.* Section 426.460(b) describes the effect of an ALJ decision invalidating one or more provisions of a challenged LCD under the necessary and reasonable standard. *See* 42 C.F.R. § 426.460(b); *see also* MPIM § 13.13.11. When read in tandem, Helomics correctly asserts that a retired LCD is the equivalent of an LCD declared invalid under the necessary and reasonable standard.

The problem is that these sections apply only to substantive challenges to an LCD in the administrative process. All of the provisions that fall under MPIM § 13.13, “The Challenge of an LCD,” describe the careful procedures and rules governing the administrative process from an ALJ’s decision on a substantive challenge to an LCD through to an appeal to the Departmental Appeals Board. *See* MPIM §§ 13.13.1-13.13.15. None of these provisions applies to litigation in federal court. It follows that, contrary to Helomics’ assertion, Novitas did not retire an LCD that was under substantive review, as the regulations contemplate. Judge Bissoon’s dismissal of Helomics’ lawsuit in Pennsylvania recognized that federal courts do not have original jurisdiction over substantive challenges to LCDs. Therefore, it would be unreasonable to hold that the fact that Novitas checked the box “retired” -- only and clearly to prevent the 2015 LCD from becoming effective on December 31 as the parties and judge agreed -- rendered its substantive provisions void under 42 C.F.R. § 426.460(b) and Chapter 13 of the MPIM.

Although Helomics limited its request at oral argument to a mere 45-day comment period, it argued in brief that a contractor cannot reinstate a retired LCD unless the contractor identifies a different rationale for it. MSJ at 3 (citing MPIM § 13.13.15); *see also* 42

C.F.R. § 426.463 (“The contractor may not reinstate an LCD provision found to be unreasonable unless the contractor has a different basis (such as additional evidence) than what the ALJ evaluated.”). This regulation only makes sense in the context of an LCD under substantive review as part of the administrative process. If this Court were to accept Helomics’ argument, the effect of granting mandamus relief in this instance would go beyond requiring a new 45-day period for the 2016 LCD: Novitas would be precluded from reissuing any LCD covering ChemoFx until it articulates a different reason for an LCD despite the fact that the substantive provisions of the 2015 and 2016 LCD were never properly challenged.

Helomics also argues that Novitas issued a *new* LCD in 2016 to replace the invalid and unreasonable 2015 LCD (whose status is proved by its retirement). It is true that contractors must “provide for both a comment period and a notice period” for: (1) “all new LCDs;” (2) “revised LCDs that restrict existing LCDs;” and (3) “revised LCDs that make a substantive correction.” MPIM § 13.7.2. However, the 2016 LCD did not revise an existing LCD. The relevant question is whether the 2016 LCD was a “new” LCD requiring a new 45-day comment period. Helomics engages in straight-line reasoning: since Novitas “retired” the 2015 LCD, it clearly follows that the 2016 LCD was a new LCD. This logic would be persuasive had the 2015 LCD been retired while it was under substantive review. *See* 42 C.F.R. § 426.460(b); MPIM §§ 13.13.9, 13.13.11. Because the facts are clearly to the contrary, the Court fails to see how Novitas’ systems limitations must, as a matter of law, render the 2016 LCD a new LCD.

There is no definition of “new LCD” in the regulations or Chapter 13 of the MPIM. However, the MPIM identifies those circumstances in which a contractor shall or may develop a new LCD or revise an existing LCD. *See* MPIM § 13.4. None of these circumstances fits the facts of this case. But the MPIM does allow a contractor to delay the effective date of an

LCD by extending the notice period. *See* MPIM § 13.7.4.3 (“The notice period ends 45 calendar days after the notice period begins *unless extended by the contractor*. If the notice period is not extended by the contractor, the effective date of the LCD is the 46th calendar date after the notice period began.”) (emphasis added). Novitas intended to extend the notice period as a matter of courtesy to Judge Bissoon and Helomics and the realities of litigation. *See* December 22, 2015 Minute Order (indicating that Novitas “agreed to delay implementation of its non-coverage LCD until [January 22, 2016]”). Defendant argues that Novitas did not find any way in its database to extend the notice period and prevent the LCD from coming into effect on December 31, 2015. In order to delay the effective date, Novitas did the only thing that the system provided for, which was to “retire” the LCD. *See* Bennett Decl. ¶ 11; MPIM § 13.7.4.2 (listing the available LCD status indicators for contractors to post to their Web sites and databases).<sup>3</sup>

Novitas made significant efforts to alert interested parties that, while it checked “retired” for the 2015 LCD, the LCD may be effective in the future (*i.e.*, extending the notice period, which is precisely what MPIM § 13.7.4.3 authorizes). For example, Novitas used the “sticky note” function in its database to indicate that the “LCD has been placed on hold and may be reactivated at a future date.” *See* MTD, Ex. 8. Novitas included similar messages on its

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<sup>3</sup> Helomics questions Novitas’ “technological-deficiency story” because Novitas placed the 2012 ChemoFx non-coverage LCD on hold without retiring it. Reply at 11; *id.*, Ex. 5 (2012 LCD). Helomics contends that this history demonstrates that Novitas knew how to extend the notice period without retiring the 2015 LCD. These facts are muddy in the record and the timing of the delay (and eventual retirement) of the 2012 LCD is too uncertain. What is un rebutted is that the regulations allow an extension of a notice period but Novitas personnel did not how to reflect this extension. In any event, the argument does not show that Novitas’ action was improper under the regulations or the MPIM.

website (Bennett Decl., Ex. C), the Medicare website (*id.*, Ex. D), and in a blast e-mail to users (*id.*, Ex. E). Having been part of the Pennsylvania litigation, and beneficiary of the Novitas agreement to extend the effective date (much less its later notices clarifying its intent), Helomics was well aware that Novitas intended only to delay the LCD's implementation but not "retire" it within the lexicon of Medicare.

Finally, it is unclear why Novitas should be prevented from reinstating the identical LCD in 2016 (albeit under a different number) without a second comment period inasmuch as Helomics actively commented (orally and in writing) in 2015. Without any specificity or detail, Helomics argues that it has amassed new evidence to challenge the validity or wisdom of the non-coverage 2015 LCD. This may well be true and the lawyers spared themselves (and the Court) from the scientific details. Two things are clear: Helomics has had ample opportunities to submit evidence to Novitas since 2012 and Helomics can use any new scientific evidence on the efficacy of ChemoFx in an administrative challenge to the LCD pursuant to MPIM § 13.13.8.

It is uncontested that Novitas agreed to delay the effective date of the 2015 LCD as a matter of courtesy to Judge Bissoon and Helomics to give time to litigate the Pennsylvania lawsuit. The human error on entering this delay in a computer system cannot overcome the reality of what all parties knew and the professionalism of the lawyers involved. The Court is quite conscious of the expansive nature of the Medicare system and the necessity to have clear rules for Medicare Administrative Contractors, who are the Secretary's agents and exercise her authority in a complex administrative regime. Holding such administrators to the letter of the law is often necessary to protect all interests. In these circumstances, however, Helomics is not entitled to mandamus relief as a matter of the Court's exercise of its equitable jurisdiction.

