UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CHARLES SEIFE and PETER LURIE,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, SECRETARY OF HEALTH AND HUMAN SERVICES, in his official capacity; NATIONAL INSTITUTES OF HEALTH; FRANCIS S. COLLINS, DIRECTOR OF THE NATIONAL INSTITUTES OF HEALTH, in his official capacity; U.S. FOOD AND DRUG ADMINISTRATION; and NORMAN SHARPLESS, ACTING COMMISSIONER OF FOOD AND DRUGS, in his official capacity,

Defendants.

Civil Action No. 18-cv-11462 (NRB)
ECF Case

ORAL ARGUMENT REQUESTED

September 13, 2019

REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF PLAINTIFFS' CROSS-MOTION FOR SUMMARY JUDGMENT

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PRELIMINARY STATEMENT

Defendants' opposition (D.I. 50) abandons many of the misplaced arguments initially advanced to challenge Plaintiffs' standing and merits case. None of their remaining arguments have merit, and this Court should enter summary judgment for Plaintiffs on their First and Second Claims.

To avoid summary judgment on Plaintiffs' First Claim, Defendants ask this Court to read out of the Food and Drug Administration Amendments Act (FDAAA) its *mandate* that information on clinical trials conducted on medical products be disclosed to patients, doctors, and the public via the ClinicalTrials.gov website. Their effort to rewrite the statute ignores the very problem that caused Congress to enact FDAAA in the first place: absent a universal disclosure mandate, the makers of prescription drugs and medical devices will selectively disclose clinical trial results, publishing favorable results and concealing unfavorable ones. To prevent this, FDAAA requires disclosure of Basic Results for *all* applicable clinical trials of *all* FDA-approved products. Yet Defendants' Final Rule purports to nullify this disclosure requirement and allow manufacturers to withhold from public disclosure the results from many clinical trials of FDA-approved products completed between FDAAA's enactment in 2007 and the Final Rule's effective date in 2017. Having no answer to the unambiguous text in FDAAA's Basic Results provision, Defendants advance a convoluted statutory interpretation based on a separate provision in FDAAA that was expressly designed to *expand*, not restrict, the scope of results reporting on ClinicalTrials.gov. The argument is entirely misdirected.

Defendants' opposition to Plaintiffs' Second Claim is likewise unavailing. FDAAA mandates that Defendant National Institutes of Health (NIH) inform the public whenever the Responsible Party for an Applicable Clinical Trial fails to report required information on

ClinicalTrials.gov. NIH must do so through readily searchable public notices containing statutorily prescribed language. Defendants do not meaningfully dispute NIH's mandatory duty to post these notices but wrongly ask the Court to render it discretionary by reading into the statute a nonexistent reference to a separate provision of FDAAA. And even if the duty to post public notices could somehow be viewed as discretionary, NIH has entirely abdicated that duty. It has yet to post a *single* public notice despite years of noncompliance—a fact Defendants do not dispute. Such clear abuse of discretion, frustrating Congress's objectives, itself constitutes grounds for granting summary judgment on Plaintiffs' Second Claim.

ARGUMENT

I. PLAINTIFFS HAVE ESTABLISHED THEIR STANDING

Plaintiffs' Combined Memorandum establishes their standing to bring this action. *See* Plaintiffs' Combined Memorandum of Law (Pls.' Com. Mem.) (D.I. 36) § III.A. Defendants no longer contest that Plaintiffs' injuries are fairly traceable to the challenged actions or that Plaintiffs' injuries would be redressed by a favorable decision of this Court. *See* Defendants' Memorandum of Law in Further Support of Defendants' Motions (Defs.' R. Mem.) (D.I. 50) § I. Defendants now dispute only Plaintiffs' injury-in-fact, but injury-in-fact plainly exists.

As the Supreme Court and Second Circuit have recognized, an "'inability to obtain information' that Congress ha[s] decided to make public is a sufficient injury in fact to satisfy Article III." *Strubel v. Comenity Bank*, 842 F.3d 181, 189-90 (2d Cir. 2016) (quoting *Fed. Election Comm'n v. Akins*, 524 U.S. 11, 20-25 (1998)). Defendants now concede that informational injury can confer standing but argue that Plaintiffs lack sufficient informational injuries-in-fact. They make two arguments—one legal, one factual, and both misplaced.

Defendants first contend that Plaintiffs lack standing as a matter of law because "FDAAA creates no entitlement to this information and thus denial of it cannot constitute an 'informational injury,'" suggesting the Court must decide the merits of the claim as a prerequisite to finding that Plaintiffs have standing to raise it. Defs.' R. Mem. at 3. This is backwards. "[A] plaintiff suffers a sufficiently concrete injury to confer Article III standing when she is denied access to information that, *in the plaintiff's view*, must be disclosed pursuant to a statute and when there is 'no reason to doubt' that the information would help the plaintiff within the meaning of the statute." *McFarlane v. First Unum Life Ins. Co.*, 274 F. Supp. 3d 150, 161 (S.D.N.Y. 2017) (emphasis added) (quoting *Akins*, 524 U.S. at 21). But, in any event, Plaintiffs have demonstrated that their entitlement does indeed exist. *See* Pls.' Com. Mem. § III.B-C; *see also infra* §§ II & III.

Defendants also dispute as a matter of fact that Plaintiffs "have suffered the requisite harm to the[] concrete interest" alleged in their First Claim.[1] Defs.' R. Mem. at 4. The argument fails, as the record fully establishes the ways in which Plaintiffs' interests have been harmed by the Final Rule. *See* Pls.' Com. Mem. § III.A.1. *First*, Plaintiffs have shown that there are pre-Rule, pre-approval Applicable Clinical Trials (ACTs)[2] for which the Responsible Parties would have reported Basic Results to ClinicalTrials.gov but for the Final Rule. Pls.' *Id.* § I.D. *Second*, Plaintiffs Seife and Lurie have each documented their injuries arising from the absence on ClinicalTrials.gov of Basic Results for these trials.[3] Pls.' Com. Mem. § III.A.1; *see also* First Seife Decl. ¶¶ 10-25; Suppl. Seife Decl. ¶¶ 2-18; Lurie Decl. ¶ 13.

[1] Defendants no longer dispute Plaintiffs' injuries as to their Second Claim.

[2] As in their Opening Memorandum, Plaintiffs use the term "pre-Rule, pre-approval" ACT to refer to an Applicable Clinical Trial that (1) has a primary completion date before January 18, 2017 (the effective date of the Final Rule) and (2) was completed before the drug or device studied in the trial was approved by the FDA.

[3] Perplexingly, Defendants suggest that Plaintiffs have not been injured because Plaintiffs' injuries arise from a lack of "clinical data" and, in Defendants' view, "Basic Results" are not "clinical data." Defs.' R. Mem. at 5. Basic Results are a particular type of clinical trial data. As explained in Plaintiffs' Opening Memorandum, "Basic Results encompass the most important results of any given trial, the information critical to understand whether a tested drug

Defendants attempt to analogize Plaintiffs' injuries to the mere "procedural violation" in *Strubel.* Defs.' R. Mem. at 3. *Strubel* is important, as it confirms that the Second Circuit recognizes informational injury as sufficient to confer standing, 842 F.3d at 189-90, but its facts are distinguishable from the instant case. There, a "procedural violation" caused only a "'risk of real harm' to the [plaintiff's] concrete interest" rather than *actual* harm. *Id.* at 189. *Strubel* held that "an alleged procedural violation can by itself manifest concrete injury where Congress conferred the procedural right to protect a plaintiff's concrete interests and where the procedural violation presents a 'risk of real harm' to that concrete interest," *id.* at 190 (quoting *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1549 (2016)), and concluded that the plaintiff's risk of harm sufficed to confer standing, *id.* at 191. Plaintiffs have shown that the absence of Basic Results for pre-Rule, pre-approval ACTs constitutes not just a "procedural violation"—entailing some *risk* of future harm to their concrete interest in researching clinical trials—but also causes *actual*, ongoing harm. For example, Seife explains that the lack of Basic Results from a pre-Rule, pre-approval ACT, NCT00865280, has hampered and continues to hamper his investigation of the antibiotic drug omadacycline; without the full clinical trial record, he is unable to determine whether the FDA properly approved the drug on the basis of adequate evidence of safety and efficacy. Suppl. Seife Decl. ¶¶ 11-18; *see also* First Seife Decl. ¶¶ 10-25. As such, Plaintiffs easily surpass the *Strubel* standard, and *Akins* and *McFarlane* provide more apt analogies. In those cases, plaintiffs' standing arose from a lack of statutorily mandated information that actually harmed their concrete interests. *Akins*, 524 U.S. at 21 (plaintiffs harmed by lack of information "to evaluate candidates for public office, especially candidates who received

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or device is safe and effective. Required Basic Results include both primary and secondary outcome data." Pls.' Com. Mem. at 6; *see also* Declaration of Charles Seife dated Jun. 8, 2019 (First Seife Decl.) (D.I. 40) ¶¶ 10-25, Supplemental Declaration of Charles Seife dated Sep. 11, 2019 (Suppl. Seife Decl.) ¶¶ 3-8, Declaration of Peter Lurie dated Jun. 4, 2019 (Lurie Decl.) (D.I. 39) ¶ 13.

assistance from AIPAC, and to evaluate the role that AIPAC's financial assistance might play in a specific election"); *McFarlane*, 274 F. Supp. 3d at 162 (plaintiff harmed by lack of information that would have helped her "in understanding and protecting her rights to disability benefits").

II. PURSUANT TO PLAINTIFFS' FIRST CLAIM, THE IMPROPER PORTION OF THE FINAL RULE SHOULD BE SET ASIDE AS CONTRARY TO LAW

As explained in Plaintiffs' Combined Memorandum, this Court should grant summary judgment on Plaintiffs' First Claim, and the improper portion of the Final Rule should be set aside as contrary to law. Pls.' Com. Mem. § III.B. Defendants do not contest the reviewability of the First Claim, and the parties agree that the central dispute it presents is whether pre-Rule, pre-approval ACTs of FDA-approved products are trials of "approved" products within the plain meaning of the Basic Results provision of FDAAA, 42 U.S.C. § 282(j)(3)(C).[4] Defs.' R. Mem. at 6. If the Court agrees with Plaintiffs that such trials are indeed trials of "approved" products, then the Final Rule contravenes FDAAA and Plaintiffs should prevail.

A. FDAAA Unambiguously Defines Pre-Rule, Pre-Approval Trials as Trials of "Approved" Products.

Since 2008, FDAAA has required publication of Basic Results in the ClinicalTrials.gov data bank "for each applicable clinical trial for a drug that *is* approved" by the FDA, regardless of when that product was approved. 42 U.S.C. § 282(j)(3)(C) (emphasis added); *see* Pls.' Com. Mem. §§ I.B.1, III.B.1. Pre-Rule, pre-approval ACTs are trials of FDA-approved products: on its face, section 282(j)(3)(C) makes no distinction between trials completed *before* a product is approved and those completed *after*. FDAAA is clear that both types of trials are trials of "approved" products subject to mandatory Basic Results reporting, and courts must give effect to Congress's unambiguous intent. *Nat. Res. Def. Council v. EPA*, 808 F.3d 556, 569 (2d Cir.

[4] As in their Combined Memorandum, Plaintiffs use the term "approved" product to encompass drugs that are FDA-"approved" or "licensed" as well as devices that are FDA-"approved" or "cleared."

2015). The portion of the Final Rule that purports to exempt pre-Rule, pre-approval ACTs from the Basic Results reporting requirement fails at *Chevron* step one because it contravenes the statute's text. *See* Pls.' Com. Mem. § III.B.

Defendants somehow question that "an ACT with a primary completion date in 2012 that studied a product that was not approved by FDA until 2016 is a 'clinical trial for a product that is approved.'" Defs.' R. Mem. at 7. Defendants obscure the simple fact that a hypothetical product approved in 2016 *is approved* today, and might currently be used by thousands or millions of Americans. FDAAA's disclosure requirement applies to clinical trials for any product that "is approved," 42 U.S.C. § 282(j)(3)(C), and reflects Congress' clear intent to make public all relevant information about medical products approved for use in the United States. Defendants' contrary approach exempts an entire *decade* of trials of approved products from disclosure to scrutiny by researchers, physicians, patients, and the general public just because the trials were completed before FDA approval of the products and before the promulgation of the Final Rule.

Defendants do not meaningfully address the clear text of section 282(j)(3)(C). Defendants insist that Plaintiffs' interpretation "is contrary to the law's plain language," but their arguments refer not to the language of section 282(j)(3)(C) but instead to other parts of FDAAA. Even those provisions, in context, fail to support Defendants' position and instead confirm Plaintiffs'.

1. The "Submission of results information" Subparagraph, Section 282(j)(3)(E), Confirms Plaintiffs' Interpretation of Section 282(j)(3)(C).

Plaintiffs' Combined Memorandum explains that 42 U.S.C. § 282(j)(3)(E)(iv) is an "initial approval" extension provision that mandates "[s]ubmission of results information" from ACTs conducted by Responsible Parties "[s]eeking initial approval of a [tested] drug or device" within a statutorily mandated deadline. Pls.' Com. Mem. §§ I.B.1, III.B.1. The initial approval extension provision provides a Responsible Party for a pre-Rule, pre-approval ACT—"an

applicable clinical trial that is completed before the drug is initially approved"—with extra time to submit Basic Results, but still *mandates* submission: "[T]he responsible party *shall* submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described *in subparagraphs (C)* [defining Basic Results] and (D) not later than 30 days after the drug or device is approved . . . ." 42 U.S.C. § 282(j)(3)(E)(iv) (emphasis added).

The text of section 282(j)(3)(E)(iv) therefore confirms Plaintiffs' view that Congress deemed pre-Rule, pre-approval ACTs to be a special *subset* of the broader set of trials subject to mandatory Basic Result reporting, namely *all* ACTs of *all* FDA-approved products. Contrary to Defendants' suggestion, Defs.' R. Mem. at 8, Congress had no reason to import the narrowing term it used in section 282(j)(3)(E)(iv) to define the subset of pre-Rule, pre-approval ACTs ("an applicable clinical trial that is completed before the [product] is initially approved") into the broad Basic Results provision, 42 U.S.C. § 282(j)(3)(C), covering approved products generally.

Defendants propose that "[section] 282(j)(3)(E)(iv) does not independently require submission of any results information; it simply prescribes the timeframes for submitting the results information required elsewhere in the statute or the regulations." Defs.' R. Mem. at 11. Yet the subparagraph as a whole is entitled "Submission of results information," and it establishes rules requiring Responsible Parties to submit Basic Results to ClinicalTrials.gov. 42 U.S.C. § 282(j)(3)(E)(i) ("Except as provided in clauses (iii), (iv), (v), and (vi) the responsible party for an applicable clinical trial that is described in clause (ii) *shall submit* to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraph (C) . . . ." (emphasis added)). Subparagraph 282(j)(3)(E) thus works hand-in-hand with section 282(j)(3)(C) to effectuate Congress's disclosure mandate: section 282(j)(3)(C) creates a public entitlement to Basic Results, which NIH must publish on ClinicalTrials.gov, and

section 282(j)(3)(E) mandates when and how Responsible Parties must submit those results to NIH so that NIH can publish them.

2. The Expanded Results Subparagraph, Section 282(j)(3)(D), Does Not Restrict the Meaning of the Basic Results Subparagraph, Section 282(j)(3)(C)

FDAAA separately defines a second category of clinical trial results, "Expanded Results." 42 U.S.C. § 282(j)(3)(D); *see* Pls.' Com. Mem. §§ I.B.1.b, III.B.1. Congress used clear, explicit language: Expanded Results "expand the registry and results data bank" "[t]o provide more complete results information and to enhance patient access to and understanding of the results of clinical trials." 42 U.S.C. § 282(j)(3)(D)(i). Yet Defendants argue that various provisions of section 282(j)(3)(D) should be construed not to expand ClinicalTrials.gov but instead to *restrict* the scope of section 282(j)(3)(C). Defendants contend that "[s]ection 282(j)(3)(D)(iv)(III)(aa) further demonstrates that Congress explicitly intended to treat an ACT conducted on a product prior to its approval as an ACT of an unapproved product, regardless of whether the product is later approved." Defs.' R. Mem. at 8. It does not.

Section 282(j)(3)(D)(iv)(III)(aa) is simply a narrow timing provision that permits the Responsible Parties for ACTs of a certain subset of unapproved products—products that are *not yet approved* by the FDA but for which the Responsible Party is actively seeking FDA approval—to delay submission of trial results to ClinicalTrials.gov until after the FDA grants approval. In section 282(j)(3)(D)(iv)(III), Congress contemplated the possibility that "the clinical trial information described in clause (iii) [i.e., Expanded Results] is required to be submitted for the applicable clinical trials described in clause (ii)(II) [i.e., trials of unapproved products]." 42 U.S.C. § 282(j)(3)(D)(iv)(III). This possibility has come to pass: the Department of Health and Human Services (HHS) decided, in its Final Rule, to require Responsible Parties to submit Expanded Results for "[a]pplicable clinical trials for which the studied product is not approved,

licensed, or cleared by FDA" completed since the effective date of the Rule, 42 C.F.R. § 11.42(b), and, in general, to require Responsible Parties to submit those results "no later than 1 year after the primary completion date of the" ACT, 42 C.F.R. § 11.44(a). Thus, absent a provision like section 282(j)(3)(D)(iv)(III)(aa), the Final Rule would generally require Responsible Parties for ACTs of not-yet-approved (and thus "unapproved") products to report Expanded Results within a year of trial completion, even if the FDA were still deciding whether to approve the product.[5] To require submission and public disclosure of trial results while the Responsible Party pursues FDA approval would undermine FDA's practice of keeping clinical trial results for not-yet-approved products secret until those products are approved or finally rejected by the FDA. *See, e.g.*, 21 C.F.R. § 314.430(c) ("If the existence of an unapproved application or abbreviated application has not been publicly disclosed or acknowledged, no data or information in the application or abbreviated application is available for public disclosure.").

Section 282(j)(3)(D)(iv)(III)(aa) protects FDA's practice. It allows HHS to determine "by regulation" "the date by which such clinical trial information shall be required to be submitted, taking into account . . . the certification process under subparagraph (E)(iii) when approval, licensure, or clearance is sought." Section 282(j)(3)(E)(iii), in turn, permits "[d]elayed submission of results with certification" under section 282(j)(3)(E)(iv) for a Responsible Party "[s]eeking initial approval of a drug or device."[6] Section 282(j)(3)(D)(iv)(III)(aa) thus permits

[5] It is common for ACTs of unapproved products to be completed more than one year before the FDA renders an approval decision. *See, e.g.*, Morten Decl. (D.I. 41), Ex. 8, at 13 (FDA's median time from submission of a new drug application to approval averaged approximately 6.0-13.0 months between FY2007 and FY2016).

[6] Clause (iii) includes a reference to Basic Results ("the clinical trial information described in subparagraph[] (C)") because clause (iii) permits delayed submission of trial results upon certification under either the aforementioned initial approval extension provision (section 282(j)(3)(E)(iv)) *or* under a separate extension provision for Responsible Parties that seek FDA approval for a new use of an already approved product (section 282(j)(3)(E)(v) ("Seeking approval of a new use for the drug or device")). 42 U.S.C. § 282(j)(3)(E)(iii). The latter category of trial results are subject to mandatory Basic Results reporting because they are trials of FDA-approved products.

Responsible Parties to wait until *after* FDA approval to submit trial results to ClinicalTrials.gov and thereby disclose them to the public.[7]

Defendants' arguments about discretion are misplaced. Defs.' R. Mem. at 7, 9. FDAAA indeed grants HHS discretion to determine, by regulation, "whether or not the results information described in clause (iii) [Expanded Results]" must be submitted for ACTs of *unapproved* products. 42 U.S.C. § 282(j)(3)(D)(ii)(II). But Defendants mistakenly suggest that "the phrase 'the results information described in clause (iii)' encompasses both Basic and Expanded Results" and that, therefore, "42 U.S.C. § 282(j)(3)(D)(ii)(II) grants HHS discretion to determine whether or not to require the submission of both Basic Results and Expanded Results for ACTs for unapproved products." Defs. R. Mem. at 9-10. It does not. HHS's discretion extends *only* to Expanded Results. Clause (iii) "encompasses" Basic Results only insofar as it demands that HHS define Expanded Results broadly, to include *all* the data "elements described in subparagraph (C) [defining Basic Results]" *plus* certain additional "Required elements." 42 U.S.C. § 282(j)(3)(D)(iii). Clause (iii) references the Basic Results subparagraph, section 282(j)(3)(C), merely to define the minimum scope of Expanded Results; it does not grant HHS discretion to define the scope of Basic Results. In this sense, clause (iii) comports with FDAAA's broader mandate that *Expanded* Results disclose more to the public than *Basic* Results.

B. Even if FDAAA Were Ambiguous, the Final Rule Is an Unreasonable Interpretation.

Even if FDAAA's mandate to disclose Basic Results for pre-Rule, pre-approval ACTs were ambiguous, the portion of the Final Rule that purports to exempt these trials from Basic Results reporting is unreasonable and should be set aside. Pls.' Com. Mem. § III.B.2.

[7] The Final Rule implements 42 U.S.C. § 282(j)(3)(D)(iv)(III)(aa) as described by Plaintiffs. *See* 42 C.F.R. § 11.44(c) ("Delayed submission of results with certification if seeking initial approval, licensure, or clearance").

III. PURSUANT TO PLAINTIFFS' SECOND CLAIM, THE COURT SHOULD COMPEL DEFENDANTS TO PROVIDE PUBLIC NOTICES OF NONCOMPLIANCE AND SEARCH FUNCTIONALITY ON CLINICALTRIALS.GOV

A. Plaintiffs Are Entitled to Judicial Review on Their Second Claim under the Administrative Procedure Act (APA).

Plaintiffs' Second Claim is reviewable under the APA because (1) nothing in FDAAA grants the government discretion with respect to posting public notices of noncompliance, and (2) even if there were a discretionary duty, Defendants have completely abdicated their statutory responsibilities. Because Defendants have failed to overcome their "heavy burden" to rebut reviewability, *Mach Mining, LLC v. EEOC*, 135 S. Ct. 1645, 1651 (2015), Plaintiffs are entitled to judicial review of Defendants' inaction pursuant to their Second Claim.

1. Nothing in FDAAA provides Defendants with discretion to identify noncompliance and post public notices of noncompliance.

The text of FDAAA is clear: NIH has a mandatory duty to post public notices of noncompliance. 42 U.S.C. § 282(j)(5)(E). Defendants do not dispute this point. *See* Defs.' R. Mem. at 15-16 (posting notices is a nondiscretionary, ministerial task). Instead, Defendants insist those notices become discretionary because FDAAA *separately* confers some discretion on HHS or FDA to make their own findings of noncompliance. But any separate grant of authority to HHS or FDA is a red herring; the APA permits judicial review of Plaintiffs' Second Claim because NIH has a nondiscretionary duty to post public notices. *See* Pls.' Com. Mem. § III.C.2.

Defendants assert that NIH's duty to post public notices of noncompliance is contingent on a prior finding of noncompliance by FDA. Defs.' R. Mem. at 14. To support this argument, Defendants point to a delegation of authority by HHS pursuant to 42 U.S.C. § 282(j)(5)(C)(ii), a provision that permits HHS to privately notify Responsible Parties of noncompliance. *Id.* But Defendants simply assume, without any textual or other support, that the Court should read a

cross-reference to section 282(j)(5)(C)(ii) into section 282(j)(5)(E) when Congress declined to create one. *See* 42 U.S.C. § 282(j)(5)(E)(i) (cross-referencing section 282(j)(2) and (3), but not section 282(j)(5)(C)(ii)).

In fact, Defendants' own arguments prove Plaintiffs' point. As Defendants note, Congress is presumed to "act[] intentionally when it omits language included elsewhere" in a statute. Defs.' R. Mem. at 8 (quoting *Dep't of Homeland Sec. v. MacLean*, 135 S. Ct. 913, 919 (2015)). And Defendants themselves observe that a penalty provision, 21 U.S.C. § 333(f)(3)(B), includes an *explicit* cross-reference to section 282(j)(5)(C)(ii) to make notice under section 282(j)(5)(C)(ii) a precondition for other agency action. Defs.' R. Mem. at 15, 18. In section 333(f)(3)(B), Congress authorizes enhanced civil monetary penalties "[i]f a violation [of FDAAA's registration and reporting requirements] . . . is not corrected within the 30-day period following notification under section 282(j)(5)(C)(ii)." Similarly, in section 282(j)(5)(A), the subparagraph of FDAAA requiring withholding of federal grants to noncompliant parties, Congress includes an *explicit* statutory cross-reference to make one agency action a precondition for other agency action. 42 U.S.C. § 282(j)(5)(A)(iii) ("If the head of an agency . . . verifies that a grantee has not submitted clinical trial information *as described in clause (ii)*, such agency head shall provide notice to such grantee of such non-compliance . . . ." (emphasis added)).

Congress made no cross-reference to section 282(j)(5)(C)(ii) in subparagraph 282(j)(5)(E), the statutory provision critical to Plaintiffs' Second Claim. Instead, Congress simply mandated that "[i]f the responsible party for an applicable clinical trial fails to submit clinical trial information for such clinical trial as required under paragraphs (2) or (3), the Director of NIH shall include" the required public notices on ClinicalTrials.gov. 42 U.S.C. § 282(j)(5)(E)(i). If Congress wished to precondition NIH's mandatory duty to post public

notices on an initial notification step under section 282(j)(5)(C)(ii), it would have *explicitly* cross-referenced section 282(j)(5)(C)(ii)—just as it did in section 333(f)(3)(B). But Congress chose not to. The lack of an explicit cross-reference in section 282(j)(5)(E) must be given effect. Defendants' "reading denies effect to Congress'[s] textual shift," and thereby violates the canons of statutory interpretation. *Roberts v. Sea-Land Servs., Inc.*, 566 U.S. 93, 102 n.5 (2012).

Finally, Defendants resort to an agency efficiency argument, suggesting that FDA's determinations must precede NIH's public notices because "it would . . . make no sense for Congress to create 'two distinct monitoring regimes' for the same conduct." Defs.' R. Mem. at 15 n.7. This argument rests on a mistaken factual premise. Congress *did* establish multiple monitoring regimes for the same conduct, in the context of government grants that fund clinical trials. *See* 42 U.S.C. § 282(j)(5)(A) (each grant-making agency, including both NIH and FDA, must separately verify submission of clinical trial information required under FDAAA). But even if the argument had a sound factual basis, it was *Defendants'* decision to delegate responsibility under section 282(j)(5)(C)(ii) to FDA, not Congress's. Joint Stip. (D.I. 29) ¶ 2. HHS might have delegated the same authority to NIH instead—and thereby simplified the entire notice regime. Defendants cannot credibly claim that their own post-FDAAA decision about how to allocate authority between FDA and NIH reflects Congressional intent.

2. Even if Plaintiffs' claim were otherwise unreviewable, Defendants' abdication of their statutory responsibilities renders the claim reviewable.

Attempting to defend the complete failure to ever post a single non-compliance notice, Defendants argue that they have been undertaking "significant efforts to assist Responsible Parties in understanding and complying with law." Defs.' R. Mem. at 16-17. The argument is entirely irrelevant. Notwithstanding other regulatory efforts, however laudable, the posting of notices is mandatory under section 282(j)(5)(E).

The argument is also misleading, as Defendants' supposedly "significant efforts" are insubstantial. Reviewing and responding to comments on a notice of proposed rulemaking is nothing more than a minimum duty under the APA. *Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1203 (2015) ("An agency must consider and respond to significant comments received during the period for public comment.").[8] And publishing general, nonbinding guidance—whether in the form of an online "FAQ" or draft guidance on possible FDA enforcement guidelines—fails even to meet the test for final agency action. *See U.S. Army Corps of Engineers v. Hawkes Co.*, 136 S. Ct. 1807, 1813 (2016). Defendants conspicuously fail to note that no legal consequences flow from FDA's guidance.[9]

Defendants provide no evidence that they have taken any steps to enforce FDAAA that carry any legal consequences for regulated parties. Defendants have abdicated their statutory duties and, as already shown, that abdication is reviewable. Pls.' Com. Mem. § III.C.1.b.ii.

B. Defendants Have Abandoned Any Arguments (Other Than Reviewability) Contesting the Merits of Plaintiffs' Second Claim with Respect to Notices.

In briefing the cross-motions before the Court, Defendants have declined to present any argument that their failure to act is consistent with FDAAA; they argue *only* that Plaintiffs' Second Claim is unreviewable. Defs.' Mem. (D.I. 31) at 23-28; Defs.' R. Mem. at 13-18. There is no factual dispute that public notices of noncompliance are missing from the ClinicalTrials.gov database, Joint Stip. ¶ 4, and Plaintiffs are entitled to summary judgment for the reasons set forth in their opening memorandum. Pls.' Com. Mem. § III.C.2-3. If the Court

[8] Plaintiffs again note that the rulemaking resulting in the Final Rule was separately and explicitly required by FDAAA as a nondiscretionary action. 42 U.S.C. § 282(j)(3)(D)(i). Defendants cannot use their (untimely) compliance with that subsection to defend their noncompliance with their other statutory duties under section 282(j)(5)(E).

[9] *Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank: Draft Guidance for FDA Staff, Responsible Parties, and Submitters of Certain Applications and Submissions to FDA*, 83 Fed. Reg. 47,926, 47,927 (The draft guidance "does not establish any rights for any person and is not binding on FDA or the public.").

finds the Second Claim reviewable, it should grant Plaintiffs' motion for summary judgment and compel Defendants to post the public notices of noncompliance.

C. Defendants Do Not Contest at All the Merits of Plaintiffs' Second Claim with Respect to the Search Functionality of ClinicalTrials.gov.

Plaintiffs have established, and Defendants do not dispute, that FDAAA imposes a clear, nondiscretionary duty on NIH to permits "the public [to] easily search" the ClinicalTrials.gov database "for entries that include notices required under" subsection (j)(5)(E). 42 U.S.C. § 282(j)(5)(E)(vi).[10] The ClinicalTrials.gov website lacks any search functionality that would permit the public to easily search for entries containing public notices, as required by ClinicalTrials.gov. *See* Joint Stip. ¶ 6. The website currently lacks even search functionality to permit the public to confirm that NIH has not posted any public notices. *Id.*[11] Because Defendants have unlawfully withheld or unreasonably delayed providing this mandated search function, Plaintiffs should prevail on the search function portion of their Second Claim.

CONCLUSION

For the reasons stated above and in Plaintiffs' Combined Memorandum, Plaintiffs' motion for summary judgment should be granted.

Dated: September 13, 2019
New York, NY

Respectfully submitted,[12]

[10] Plaintiffs do not understand Defendants' briefing to contest the reviewability of this portion of Plaintiffs' Second Claim. Nothing about the website design of ClinicalTrials.gov—including the search functionality required by statute—could reasonably be construed as a discretionary enforcement decision.

[11] *See also* Advanced Search, ClinicalTrials.gov, https://clinicaltrials.gov/ct2/search/advanced (last accessed September 13, 2019).

[12] This memorandum was prepared by the Media Freedom & Information Access Clinic, a program of the Abrams Institute for Freedom of Expression at Yale Law School, and the Technology Law & Policy Clinic at New York University School of Law, with the Collaboration for Research Integrity and Transparency at Yale University. Nothing in this memorandum should be construed to represent the institutional view of any of these organizations, if any.

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