UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CHARLES SEIFE and PETER LURIE,

Plaintiffs,

- against -

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

18 Civ. 11462 (NRB)

MEMORANDUM OF LAW IN FURTHER SUPPORT OF DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT, AND IN OPPOSITION TO PLAINTIFFS' CROSS-MOTION FOR SUMMARY JUDGMENT

GEOFFREY S. BERMAN
United States Attorney for the
Southern District of New York

By: JENNIFER JUDE
Assistant United States Attorney
86 Chambers Street
New York, New York 10007
Tel: (212) 637-2663
jennifer.jude@usdoj.gov

ROBERT P. CHARROW
General Counsel
U.S. Dept. of Health & Human Services

STACY CLINE AMIN
Chief Counsel
Food and Drug Administration
Deputy General Counsel
Department of Health and Human Services

ANNAMARIE KEMPIC
Deputy Chief Counsel, Litigation

MARCI B. NORTON
Senior Counsel
10903 New Hampshire Avenue
White Oak Bldg. 31, Rm. 4510
Silver Spring, MD 20993-0002
Tel: (301) 796-8580
marci.norton@fda.hhs.gov

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Defendants United States Department of Health and Human Services ("HHS"), Alex M. Azar II, Secretary of Health and Human Services (the "Secretary"), the National Institutes of Health ("NIH"), Francis S. Collins, Director of NIH, the Food and Drug Administration ("FDA"), and Norman E. Sharpless, Acting Commissioner of Food and Drugs (collectively, "Defendants"), respectfully submit this memorandum of law in further support of their motion to dismiss the complaint or, in the alternative, for summary judgment (Dkt. No. 30), and in opposition to Plaintiffs Charles Seife and Peter Lurie's ("Plaintiffs") cross-motion for summary judgment (Dkt. No. 35).

PRELIMINARY STATEMENT

Plaintiffs challenge two aspects of Defendants' implementation of the Food and Drug Administration Amendments Act of 2007 ("FDAAA")—(1) the Final Rule's requirement that Basic Results information ("Basic Results") for applicable clinical trials ("ACTs") involving unapproved products[1] be submitted to the ClinicalTrials.gov data bank only for those ACTs that reach their primary completion date after the effective date of the Rule, and (2) the fact that NIH has not yet posted any public notices regarding noncompliance with FDAAA's registration and results reporting requirements. Plaintiffs' claims must be dismissed for three reasons.

First, Plaintiffs lack standing to bring their claims because they have no legal entitlement to any of the information they seek and thus have not suffered any "informational injury." And even assuming that Plaintiffs were entitled to Basic Results

[1] For ease of reference, this memorandum will refer to drug products and biological products that have not been approved or licensed by FDA and device products that have not been approved or cleared by FDA as "unapproved products," and conversely, will refer to drug products and biological products that have been approved or licensed by FDA and devices that have been approved or cleared by FDA as "approved products."

for ACTs of unapproved products completed prior to the effective date of the Final Rule, which Plaintiffs refer to as "pre-Rule, pre-approval trials," the declarations Plaintiffs submitted fail to establish that they suffered any concrete harm as a result of not having these results.

Second, Plaintiffs' First Claim, that the Final Rule violates the Administrative Procedure Act ("APA") because it is contradicted by the plain language of FDAAA, or is an arbitrary and capricious interpretation of FDAAA, should be dismissed for failure to state a claim. Plaintiffs' interpretation of the statute does not comport with its plain language and is internally inconsistent. FDAAA unambiguously grants HHS discretion to determine by regulation whether or not to require Basic Results and Expanded Results information (hereafter, "Expanded Results") for ACTs for unapproved products, which includes "pre-approval" products. In the Final Rule, HHS used this discretion in a manner that was neither arbitrary nor capricious, but well-reasoned and supported and entitled to *Chevron* deference.

Third, Plaintiffs' Second Claim, which seeks to compel NIH to post public notices regarding noncompliance, must be dismissed because it is not reviewable under the APA. NIH's posting of notices regarding noncompliance is contingent upon FDA's exercise of its enforcement authority to make determinations of noncompliance, and under *Heckler v. Chaney*, such enforcement decisions are not subject to judicial review.

ARGUMENT

I. This Action Should Be Dismissed for Lack of Subject Matter Jurisdiction Because Plaintiffs Lack Standing

This action should be dismissed because Plaintiffs lack Article III standing to bring it as they have suffered no injury-in-fact traceable to Defendants' conduct.

According to Plaintiffs, Defendants' actions have denied them two categories of information: (1) Basic Results for ACTs of unapproved products completed prior to the effective date of the Final Rule, and (2) public notices regarding noncompliance. Combined Memorandum of Law in Support of Plaintiffs' Cross-motion for Summary Judgment and in Opposition to Defendants' Motion to Dismiss or, in the Alternative, for Summary Judgment, Dkt. No. 34 ("Pls.' Mem.") at 18. However, as discussed in the Memorandum of Law in Support of Defendants' Motion to Dismiss or, in the Alternative, for Summary Judgment, Dkt. No. 31, ("Defs.' Mem.") and in Parts II and III below, FDAAA creates no entitlement to this information and thus denial of it cannot constitute an "informational injury." For that reason alone, Plaintiffs lack standing to bring their claims.

Even if Plaintiffs were entitled to such information, however, they have not shown that Defendants' alleged procedural violations of FDAAA constitute injuries for standing purposes. Plaintiffs argue that their inability to obtain information is *itself* an injury-in-fact because in *Strubel*, the Second Circuit "explicitly recognized *Akins*'s holding that an 'inability to obtain information that Congress had decided to make public is a sufficient injury in fact to satisfy Article III.'" Pls.' Mem. at 19 (quoting *Strubel v. Comenity Bank*, 842 F.3d 181, 190 (2d Cir. 2016) (internal quotation marks and citation omitted)). However, the *Strubel* court also noted that "a bare procedural violation with respect to the required notice to users of disseminated information *may not* demonstrate concrete injury." *Strubel*, 842 F.3d at 190 (emphasis added). Indeed, the court explained 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.* (internal quotation marks and citation omitted; emphasis added); *see also Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1549 (2016) ("Article III standing requires a concrete injury even in the context of a statutory violation.").

Along with their cross-motion, Plaintiffs submitted declarations to attempt to demonstrate that they have suffered the requisite harm to their concrete interest. But with respect to Plaintiffs' First Claim,[2] the declarations fall short. The Declaration of Peter Lurie, Dkt. No. 39 ("Lurie Decl."), fails to explain how Lurie has suffered any harm from being denied Basic Results for ACTs of unapproved products completed prior to the effective date of the Final Rule. Rather, it only vaguely asserts that with such results, Lurie "would have been able to make fuller, richer comparisons in a study, since abandoned, comparing result reporting on ClinicalTrials.gov to reporting on other online registries." Lurie Decl. ¶ 13. Lurie does not explain the purpose of such comparisons or how they could have been "fuller" or "richer" with the additional information. Such cursory allegations are not sufficient to show injury at the summary judgment stage. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992).

The Declaration of Charles Seife, Dkt. No. 40 ("Seife Decl."), asserts that Seife is harmed by the absence of "Basic Results or any raw clinical data" because he has been unable to obtain certain information about "Study 202," a clinical trial of the drug eteplirsen. Seife Decl. ¶¶ 10-25. However, Seife also states that "[t]o complete [his] investigation," he "need[s] access to *the clinical data* that [the study sponsor] submitted to FDA to support the approval of eteplirsen; the data that allegedly showed the drug to

[2] "[A] plaintiff must demonstrate standing separately for each form of relief sought." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 169, 185 (2000).

be effective in treating [Duchenne muscular dystrophy] . . . to confirm whether the data actually convincingly shows that eteplirsen is effective." *Id.* ¶ 15 (emphasis added); *see also id.* ¶ 21 ("The FDA has made some information from Study 202 available on its website . . . , but . . . not the *actual underlying data* that I need for my research") (emphasis added). It is unclear precisely what Seife means by the phrases "clinical data" and "raw clinical data from Study 202," but he distinguishes such data from "Basic Results" several times. *See id.* ¶¶ 21-22. Seife further explains that he filed a Freedom of Information Act ("FOIA") suit in 2017, but has not yet received "*the clinical data* that I seek (and that I am entitled to under FOIA)." *Id.* ¶ 23 (emphasis added). Even if Seife were correct that FDAAA entitles him to Basic Results for ACTs of unapproved products completed prior to the effective date of the Final Rule (and he is not, *see infra* Part III), FDAAA does not require either the submission or the posting of "raw clinical data."[3] *See* 42 U.S.C. § 282(j)(3)(C). Thus, Seife's alleged harms—the inability to complete his investigation without raw data and the "at least 100 hours" of time spent on his FOIA litigation pursuing raw data—are neither attributable to Defendants' conduct in promulgating the Final Rule nor could they be redressed by an order from this Court.

[3] Indeed, the information on which FDA makes its approval decisions is more detailed than the Basic Results covered by FDAAA. C*ompare, e.g.*, 21 U.S.C. § 355(b)(1)(A) (new drug applications must contain "full reports of investigation which have been made to show whether or not such drug is safe for use and whether such drug is effective in use") *with* 42 U.S.C. § 282(j)(3)(C) (describing FDAAA's Basic Results). Even FDAAA's Expanded Results, 42 U.S.C. § 282(j)(3)(D)(iii), provide far less detail than the information reviewed by FDA when making approval decisions. *See* 81 Fed. Reg. 64,982, 65,066 ("[W]e did not propose to require the submission of detailed information about clinical trial results (such as required for inclusion in [a new drug application] submitted to FDA), but only summary results data typically found as tables or figures in journal articles, scientific abstracts, and press releases.").

Moreover, Seife's decision to spend his time and resources on his FOIA litigation is self-inflicted harm. *See* Defs.' Mem. at 22.[4]

II. Plaintiffs' First Claim Should Be Dismissed Because HHS's Final Rule Is Consistent with FDAAA

Plaintiffs' First Claim, that the Final Rule violates the APA because it is contrary to the statute, should also be dismissed for failure to state a claim upon which relief may be granted. Fed. R. Civ. P. 12(b)(6). FDAAA provides no statutory right to Basic Results for ACTs for products that are not approved by FDA, including "pre-approval" trials.

The parties agree that 42 U.S.C. § 282(j)(3)(C) requires Basic Results to be submitted to the ClinicalTrials.gov data bank for an ACT studying an *approved* product. Defs.' Mem. at 5-6, 20-21; Pls.' Mem. at 7. The parties disagree about whether an ACT studying a product that is not approved by FDA at the time of the trial but is approved by FDA after the trial ends is "an applicable clinical trial for a [product] that is approved" for which § 282(j)(3)(C) requires the submission of Basic Results. As explained below, it is not. FDAAA provides no statutory right to the Basic Results sought by Plaintiffs in this case.

A. "Pre-Approval" Trials Are Trials of Unapproved Products

Plaintiffs seek Basic Results for ACTs that were completed before the product studied in the trial was approved by FDA, which Plaintiffs refer to as "pre-approval" trials. Pls.' Mem. at 13. These ACTs are studying products that have not yet been approved by FDA, *i.e.*, products that are unapproved during the pendency of the trial.

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[4] Defendants note that all or most of the Basic Results information for "Study 202," which is discussed in the Seife Declaration, was posted on ClinicalTrials.gov on July 10, 2019. *See* https://clinicaltrials.gov/ct2/show/results/NCT01540409?term=NCT01540409&rank=1&view=results.

Plaintiffs attempt to re-characterize a "pre-approval" trial as an "applicable clinical trial for a product that is approved" within the meaning of § 282(j)(3)(C), by interpreting the term "is approved" to mean "is ever approved," even where the approval comes years after the clinical trial was completed. Specifically, Plaintiffs claim that § 282(j)(3)(C) "unambiguously," Pls.' Mem. at 29, "require[s] Basic Results reporting for all ACTs on products that are currently approved, without reference to the timing of those products' approval," *id.* at 8. Under Plaintiffs' view, then, 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." This interpretation is contrary to the law's plain language.

Defendants' interpretation, on the other hand, that § 282(j)(3)(C) requires Basic Results for an ACT studying a product that is approved by FDA before or while the trial is ongoing, 81 Fed. Reg. 64,982, 65,107, 65,120 (Sept. 21, 2016), is consistent with the statute. Under Defendants' interpretation, a product that is not approved while the trial is ongoing is an "unapproved" product, and ACTs for unapproved products are governed by 42 U.S.C. § 282(j)(3)(D)(ii)(II), which grants HHS discretion to determine by regulation "*whether or not*" Basic and Expanded Results must be submitted for such ACTs.

Other sections of the statute make this abundantly clear. Congress intended the phrase "that is approved" in the Basic Results section to be limiting, because it did not use that language in the registration section of FDAAA. Congress required registration information be submitted to the ClinicalTrial.gov data bank "for an applicable clinical trial," without limitation as to whether the clinical trial is for an approved or unapproved product. 42 U.S.C. § 282(j)(2)(A)(ii). But Congress took a markedly

different approach in the Basic Results section at issue here, requiring Basic Results only "for a [product] that is approved." 42 U.S.C. § 282(j)(3)(C); *see also id.* § 282(j)(3)(D)(ii)(I) (the regulation must require Basic and Expanded Results "for each applicable clinical trial for a [product] that is approved . . . ."). If Congress had wanted to require Basic Results for ACTs for products that were not yet approved but would be approved in the future, including "pre-approval" trials, it could have used the same language it used one subsection later, "an applicable clinical trial that is completed before the [product] is initially approved." *See* 42 U.S.C. § 282(j)(3)(E)(iv). Congress also could have said that Basic Results were required "for each applicable clinical trial for a [product] that is [approved], regardless of whether [approval] occurs prior to, during, or after the trial is completed." But Congress did not do this, instead requiring Basic Results only for each ACT of a product that "*is*" approved by FDA under the relevant statutory authorities.

Applying "[t]he interpretive canon that Congress acts intentionally when it omits language included elsewhere," *Dep't of Homeland Sec. v. MacLean*, 135 S. Ct. 913, 919 (2015), one can conclude that by omitting reference to the timing of product approval in the Basic Results provision, Congress acted intentionally to limit Basic Results to ACTs for products that are approved before the completion of the trial; otherwise, the phrases in §§ 282(j)(3)(C) and 282(j)(3)(E)(iv) would have the same interpretation despite their different language.

Section 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. This provision provides that, in the event that the Secretary requires the submission of

results information for ACTs for unapproved products, the Secretary shall determine by regulation the date by which the "information described in clause (iii) [*i.e.*, Basic and Expanded Results] is required to be submitted for the [ACTs] described in clause (ii)(II) [*i.e.*, for "Unapproved Products"] . . ., taking into account the certification process under *subparagraph (E)(iii)*." (Emphasis added). Subparagraph (E)(iii) permits a responsible party to submit a certification that clause (iv) applies in order to get an extension of the deadline to submit required results information until after the product is approved by FDA. 42 U.S.C.§ 282(j)(3)(E)(iii), (iv). Clause (iv), in turn, refers to "an [ACT] that is completed before the drug is initially approved," which is what Plaintiffs call an ACT of a "pre-approval" product. Therefore, FDAAA explicitly includes any ACT "that is completed before the drug is initially approved" within the scope of ACTs of unapproved products.

B. FDAAA Granted HHS Discretion to Determine by Regulation Whether or Not to Require Basic and Expanded Results for ACTs for Unapproved Products

Plaintiffs' attempt to fit "pre-approval" trials into the Basic Results provision fails under traditional rules of statutory construction. Contrary to Plaintiffs' assertions, FDAAA clearly grants discretion to HHS to establish by rulemaking whether to require *both* Basic and Expanded Results for ACTs for unapproved products. Plaintiffs claim that 42 U.S.C. § 282(j)(3)(D)(ii)(II), which requires HHS to establish by rulemaking "whether or not" to require "the results information described in clause (iii)" for ACTs for unapproved products, grants the Secretary discretion to decide by regulation whether only *Expanded* Results should be submitted for such ACTs. Pls.' Mem. at 26-29. But that interpretation completely ignores that the phrase "the results information described in clause (iii)" encompasses both Basic and Expanded Results. Specifically,

"clause (iii)," 42 U.S.C. § 282(j)(3)(D)(iii), states: "The regulations under this subparagraph shall require, *in addition to the elements described in subparagraph (C),*" certain Expanded Results. (Emphasis added.) Subparagraph (C) refers to 42 U.S.C. § 282(j)(3)(C), the provision that requires submission of Basic Results. Accordingly, 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.

Furthermore, if Plaintiffs were correct that the phrase "applicable clinical trial of a [product] that is approved" in § 282(j)(3)(C) unambiguously includes "pre-approval trials," then that same language in § 282(j)(3)(D)(ii)(I), which pertains to ACTs of "approved products," would require Expanded Results for "pre-approval" trials, because where "Congress uses similar statutory language and similar statutory structure in two adjoining provisions, it normally intends similar interpretations." *Nijhawan v. Holder*, 557 U.S. 29, 39 (2009) (citing *IBP, Inc. v. Alvarez*, 546 U.S. 21, 34 (2005)). Yet Plaintiffs do not claim to be entitled to Expanded Results for "pre-approval" trials and, in fact, explicitly state that they are not seeking Expanded Results information for such trials. Pls.' Mem. at 6 n.3 ("Expanded Results are not the focus of Plaintiffs' concerns; Plaintiffs seek Basic Results."). Plaintiffs' interpretation of the statute fails because it is internally inconsistent.

C. The Timing Provision on Which Plaintiffs Rely Does Not Create a Right to Basic Results for Trials of Unapproved Products, Including "Pre-Approval" Trials

Plaintiffs' other argument to support an interpretation that Basic Results are required for "pre-approval" trials is based on their interpretation of 42 U.S.C. § 282(j)(3)(E)(iv), which they claim "mandate[s] submission of results information."

Pls.' Mem. at 8; *see also id.* at 6-7. As Defendants explained in their opening brief, 42 U.S.C. § 282(j)(3)(E) simply prescribes the timing for submitting results information that is otherwise "described in subparagraphs (C) and (D)"; it does not create a right to results information. Defs.' Mem. at 7-10. "[S]ubparagraphs (C) and (D)" refers to those statutory sections that require Basic Results for ACTs for approved products, 42 U.S.C. § 282(j)(3)(C), and a rulemaking to include both Basic and Expanded Results for ACTs for approved products and, should HHS in its discretion decide to require it, Basic and Expanded Results for ACTs of unapproved products, 42 U.S.C. § 282(j)(3)(D).

As a matter of statutory construction, if 42 U.S.C. § 282(j)(3)(E) created a right to Basic Results for "pre-approval" trials, as Plaintiffs argue, then it must also create a right to Expanded Results for "pre-approval" trials, which again, Plaintiffs do not claim is the case. Plaintiffs' attempt to parse the statutory requirements regarding Basic and Expanded Results to find some statutory basis requiring Basic Results—but not Expanded Results—for "pre-approval" trials, fails on the statute's plain language. But again, for the reasons explained above and in Defendants' opening brief, § 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.

D. Even if FDAAA's Language Is Ambiguous, HHS's Interpretation Is Reasonable and Entitled To Deference

Even if the Court finds FDAAA to be ambiguous, HHS properly interpreted 42 U.S.C. § 282(j)(3)(C) to set the date on which a product's approval status is determined as the primary completion date of the trial. FDAAA describes results information submission requirements for "approved products" and "unapproved products." 42

U.S.C. § 282(j)(3)(D). But FDAAA does not expressly state at what point a clinical trial should be categorized as an ACT for an approved product or an ACT for an unapproved product, notwithstanding Plaintiffs' insistence to the contrary, *see* Pls.' Mem. at 21, 29. Left without a statutory edict, one could theoretically set this date as the date the protocol for an ACT is approved by a human subject protection review board, the date on which the first participant is enrolled, the completion date of the trial, or a handful of other dates relevant to clinical trials.

In promulgating the Final Rule, HHS considered the appropriate time for determining a product's status for purposes of the registration and results submission requirements and chose a "framework [that] provides a logical approach to registering and submitting results information, in that it relies on what are, in the simplest terms . . . , the start date and the primary completion date of a trial." 81 Fed. Reg. at 65,120. Because HHS has authority to implement the ClinicalTrials.gov provisions by rulemaking, and because its interpretations of the statutory provisions at issue were reached through careful administrative processes and were entirely consistent with the statute, HHS's interpretations are not arbitrary and capricious and are entitled to *Chevron* deference. *See Cmty. Health Ctr. v. Wilson-Coker*, 311 F.3d 132, 138 (2d Cir. 2002).

Plaintiffs argue that "Defendants have failed to provide a reasoned explanation for the Final Rule." Pls.' Mem. at 30. But as Defendants stated in their opening brief, HHS explained that its decision not to require Basic and Expanded Results submissions for ACTs studying unapproved products that reached their primary completion date before the Final Rule's date was a response to some of the nearly 900 comments that HHS received during the notice and comment process. *See* Defs.' Mem. 14-15. Those

included comments related to the burden that requiring such information would impose, particularly on smaller entities, and retroactivity concerns. *See id*. (citing 81 Fed. Reg. at 64,982-85, 65,018-20)). This is far beyond what is necessary to support HHS's decision as the APA's arbitrary and capricious standard is "narrow and particularly deferential." *Envtl. Def. v. U.S. E.P.A.*, 369 F.3d 193, 201 (2d Cir. 2004); *see also Int'l Fabricare Inst. v. EPA*, 972 F.2d 384, 389 (D.C. Cir. 1992) (stating that this "highly deferential standard of review 'presumes agency action to be valid'"). Indeed, courts have "no license to substitute [their] policy judgment for that of the agency." *Bellevue Hosp. Center v. Leavitt*, 443 F.3d 163, 174 (2d Cir. 2006) (citing *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971)). Rather, the court's task is to determine whether the agency's decision is "within the bounds of reasoned decisionmaking." *Baltimore Gas & Elec. Co. v. Natural Resources Defense Council*, 462 U.S. 87, 105 (1983). HHS's decision easily meets this standard.

III. Plaintiffs' Second Claim Should Be Dismissed Because It Seeks To Challenge Non-Reviewable Agency Enforcement Decisions

Plaintiffs' Second Claim should be dismissed because it seeks to challenge decisions that are committed to agency discretion and not judicially reviewable under the APA.[5]

A. NIH's Posting of Public Notices Is Contingent Upon FDA's Discretionary Determination of Noncompliance

In their brief, Plaintiffs try to distance themselves from FDAAA's Notice of Noncompliance provision, authority over which has been delegated to the FDA, Joint Stipulation, Dkt. No. 29 ("Stip.") ¶ 2. That provision states that:

[5] Plaintiffs are no longer pursuing their Third Claim. Pls.' Mem. at 16.

> If the Secretary determines that any clinical trial information was not submitted as required under this subsection, or was submitted but is false or misleading in any particular, the Secretary shall notify the responsible party and give such party an opportunity to remedy such noncompliance by submitting the required revised clinical trial information not later than 30 days after such notification.

42 U.S.C. § 282(j)(5)(C)(ii). The delegation vests FDA with the authority to determine that there has been a failure to submit required clinical trial information and to provide notice of that determination to the violator. *See* 77 Fed. Reg. 59,196 (Sept. 26, 2012). Plaintiffs instead focus almost entirely on 42 U.S.C. § 282(j)(5)(E), FDAAA's provision requiring NIH to post public notices regarding noncompliance on the ClinicalTrials.gov data bank. But FDAAA's requirement that NIH post public notices regarding noncompliance does not apply until *after* FDA makes a threshold determination of noncompliance under 42 U.S.C. § 282(j)(5)(C)(ii), as the statute does not impose any obligation on NIH to identify noncompliance. Defs.' Mem. at 23-28.

Plaintiffs argue that these two provisions are not linked and that "FDAAA creates two distinct monitoring regimes: it imposes on NIH certain non-discretionary ministerial duties to notify the public whenever Responsible Parties fail to comply with FDAAA, and it separately grants certain *discretionary* enforcement powers to FDA and to HHS (which HHS subsequently delegated to FDA in the Final Rule)." Pls.' Mem. at 9-11 (emphasis added).[6] Plaintiffs are incorrect for several reasons.

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[6] Because Plaintiffs concede that all of FDA's responsibilities under FDAAA are discretionary, and only argue that "the public notices of noncompliance that FDAAA requires NIH to post are not discretionary," they have failed to state any claim against FDA. Plaintiffs do argue that "to the extent the Court agrees that NIH cannot post public notices until FDA makes [a] threshold decision [regarding noncompliance], then Plaintiffs [sic] injuries as to the public notices are traceable to FDA as well as NIH." Pls.' Mem. at 23 n.16. But as explained in Defendants' opening brief, because FDA's threshold determinations regarding noncompliance are committed to that agency's discretion, they are not reviewable under 5 U.S.C. § 701(a)(2), *Heckler v. Chaney*, 470

First, FDA has the authority to make determinations of noncompliance and send Notices of Noncompliance that request correction within 30 days, 42 U.S.C. § 282(j)(5)(C)(ii), and the authority to bring civil money penalty actions for failures to comply with the registration and results submission requirements and seek enhanced daily penalties if violations are not corrected within the 30 day period set forth in the Notice, 21 U.S.C. § 333(f)(3).[7] It follows logically, therefore, that NIH cannot post notices regarding noncompliance, whether penalties have been imposed, and whether the information has been corrected until *after* FDA makes a threshold determination regarding noncompliance.

Second, Plaintiffs point to no statutory language that requires NIH to "identify" noncompliant trials; the "Public Notice" provision they invoke, 42 U.S.C. § 282(j)(5)(E), focuses solely on NIH's responsibility to include notices regarding noncompliance in the data bank. And as explained, NIH does not have the authority to make the threshold determination regarding noncompliance, FDA does. Although it may be a ministerial

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U.S. 821, 830 (1985), regardless of whether they are causing injury to Plaintiffs. Defs.' Mem. at 23-27.

[7] Indeed, it makes perfect sense that authority to make such determinations and issue Notices of Noncompliance was delegated to FDA. All functions vested in the Secretary under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, are delegated to the Commissioner of Food and Drugs. *See* Staff Manual Guide 1410.10, available at https://www.fda.gov/media/81983/download. FDAAA amended the FDCA by making it a prohibited act to fail to submit required clinical trial information or to submit false or misleading information, 21 U.S.C. § 331(jj), and by authorizing civil money penalties for violations of these prohibited acts, 21 U.S.C. § 333(f)(3). Thus, because FDA has the authority to bring enforcement actions regarding violations of the registration and results reporting requirements, the Secretary delegated to FDA the authority to determine whether there are such violations and to provide the statutory Notice of Noncompliance. Moreover, it would also make no sense for Congress to create "two distinct monitoring regimes" for the same conduct, as Plaintiffs argue, Pls.' Mem. at 9-11, which could create conflicts where FDA and NIH reach different conclusions.

duty to post a public notice regarding noncompliance after NIH is notified by FDA about a noncompliance determination, it is FDA's job to determine whether there has been a noncompliance, 42 U.S.C. § 282(j)(5)(C)(ii), and FDA's decisions are not reviewable under the APA because they are quintessential enforcement decisions that are "committed to agency discretion by law." 5 U.S.C. § 701(a)(2).

Plaintiffs argue that the presumption that agency enforcement decisions are non-reviewable does not apply here because the "identification of noncompliant trials and posting of public notices fall on the non-discretionary, non-enforcement side of *Heckler*." Pls.' Mem. at 34; *see id.* at 35 (describing duty to post notices as "mandatory, ministerial"). Plaintiffs are wrong. FDA's determination that there has been a failure to comply with the requirements of FDAAA, including its implementing regulations, and FDA's response to that noncompliance, including issuing a notice giving the party 30 days to come into compliance, determining whether the party has come into compliance, and in its discretion, deciding whether to take an enforcement action such as pursuing civil money penalties, involves "a complicated balancing of a number of factors which are peculiarly within its expertise." *Heckler*, 470 U.S. at 831. These decisions are neither mandatory nor ministerial.

The absence of public notices regarding noncompliance to date does not mean that Defendants have "abdicated their responsibility to enforce FDAAA," as Plaintiffs argue. Pls' Mem. at 37. NIH has not abdicated its responsibility to post notices because it can only do so after FDA has identified instances of noncompliance, which FDA has not yet done. *See* Stip. ¶ 3. In fact, Defendants have taken significant efforts to assist Responsible Parties in understanding and complying with law by, among other things: thoroughly considering the voluminous comments received and addressing them in the

Final Rule; regularly answering questions about the requirements of FDAAA and the Final Rule; and making such answers public for the regulated community, *see* https://clinicaltrials.gov/ct2/manage-recs/faq; and publishing a draft guidance regarding FDA's compliance and enforcement program, *see* 83 Fed. Reg. 47,926.[8] Defendants' efforts to date can hardly be seen as "'consciously and expressly adopt[ing] a general policy that is so extreme as to amount to an abdication of its statutory responsibilities'" such that an action otherwise committed to agency discretion is reviewable. *See* Pls.' Mem. at 37 (quoting *Heckler*, 470 U.S. at 833 n.4).

B. FDAAA's Notice of Noncompliance Provision Is Separate from FDAAA's Pilot Quality Control Project

Plaintiffs also attempt to diminish the significance of the statutory Notice of Noncompliance provision, 42 U.S.C. § 282(j)(5)(C)(ii), by arguing that it applied only during the course of the limited Pilot Quality Control Project. Pls.' Mem. at 11, 41-42. Plaintiffs' reading of the statute is incorrect. The section in which the Notice of Noncompliance provision is located, 42 U.S.C. § 282(j)(5)(C), is entitled "Quality Control," and it provides *two different* quality control provisions: the "Pilot Quality Control Project" provision and the "Notice of [Non-]Compliance" provision. The Pilot Quality Control Project was to be conducted "[u]ntil the effective date of the regulations issued under paragraph (3)(D) [the Final Rule]" and for purposes of "determin[ing] the optimal method of verification to help ensure that the clinical trial information submitted under paragraph (3)(C) [Basic Results for ACTs for approved products] is non-promotional and is not false or misleading in any particular." 42 U.S.C.

[8] *See* 83 Fed. Reg. 47,926 (discussing Civil Monetary Penalties Relating to the ClinicalTrials.gov Data Bank (Draft Guidance), *available at* https://www.fda.gov/media/113361/download).

§ 282(j)(5)(C)(i). The Notice of Noncompliance provision, on the other hand, is not time-limited, it requires such notice be sent if there is a determination that clinical trial information was not submitted as required, or was submitted, but was false or misleading in any particular, and it further requires that such notice give the responsible party 30 days to remedy the violation. 42 U.S.C. § 282(j)(5)(C)(ii).

Nothing in FDAAA supports Plaintiffs' interpretation that the Notice of Noncompliance provision, 42 U.S.C. § 282(j)(5)(C)(ii), applies *only* during the Pilot Quality Control Project described in § 282(j)(5)(C)(i). Indeed, were Plaintiffs' interpretation correct, after the issuance of the Final Rule, FDA could never assess the enhanced civil money penalties for each day a violation continues after the 30-day correction period following receipt of a Notice of Noncompliance, *see* 21 U.S.C. § 333(f)(3)(b), because the correction period would cease to apply after the Pilot Quality Control Project. Clearly, this is not what Congress intended. The only possible interpretation of 42 U.S.C. § 282(j)(5)(C) is that the Pilot Quality Control Project and the Notice of Noncompliance are *two separate* quality control provisions: the former applying until the Final Rule went into effect and relating only to the statutory requirements, and the latter applying on an ongoing basis to (1) encourage voluntary compliance; and (2) provide a mechanism to enforce the requirements of the statute and the regulations.

CONCLUSION

For all of the reasons set forth above and in Defendants' opening brief, the Complaint should be dismissed or, in the alternative, summary judgment should be granted in favor of Defendants.

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Respectfully submitted

GEOFFREY S. BERMAN
United States Attorney for the
Southern District of New York

By: */s/ Jennifer Jude*
JENNIFER JUDE
Assistant United States Attorney
86 Chambers Street
New York, New York 10007
Tel: (212) 637-2663
jennifer.jude@usdoj.gov

ROBERT P. CHARROW
General Counsel
U.S. Dept. of Health & Human Services

STACY CLINE AMIN
Chief Counsel
Food and Drug Administration
Deputy General Counsel
Department of Health and Human Services

ANNAMARIE KEMPIC
Deputy Chief Counsel, Litigation

MARCI B. NORTON
Senior Counsel
10903 New Hampshire Avenue
White Oak Bldg. 31, Rm. 4510
Silver Spring, MD 20993-0002
Tel: (301) 796-8580
marci.norton@fda.hhs.gov