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 BRETT P. GIROIR, ACTING COMMISSIONER OF FOOD AND DRUGS, in his official capacity,[1]

Defendants.

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

ORAL ARGUMENT REQUESTED

December 6, 2019

PLAINTIFFS' SUPPLEMENTAL MEMORANDUM ON THE APPLICATION OF THE PRINCIPLES SET FORTH IN *AUER V. ROBBINS*

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[1] Pursuant to Fed. R. Civ. P. 25(d), Acting Commissioner Giroir is automatically substituted for former Acting Commissioner Norman Sharpless.

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PRELIMINARY STATEMENT

Plaintiffs submit this memorandum in response to the Court's request for supplemental briefing on *Auer v. Robbins*, 519 U.S. 452 (1997), *Kisor v. Wilkie*, 139 S. Ct. 2400 (2019), and their application to this case. *See* Letter of Nov. 19, 2019 (D.I. 59).

This case is fundamentally one of statutory interpretation, and Plaintiffs' First Claim is best decided as such. Defendants' interpretation of the Food and Drug Administration Amendments Act (FDAAA) in the Final Rule directly conflicts with their statutory mandate, and the Court therefore need not determine whether the Defendants' interpretation properly construes the text of the Final Rule. Rather, the Court can grant complete relief to Plaintiffs by setting that interpretation aside as contrary to the statute.

If the Court reaches Defendants' interpretation of the Final Rule's text, it deserves no deference because neither the regulation nor the statute it implements contains genuine ambiguity for the agency to interpret. Defendants' interpretation of the Final Rule conflicts with the plain language of both the statute and the Rule itself, and that plain language controls the meaning of the regulation. Moreover, Defendants' interpretation lacks persuasive power. It reverses Defendants' prior position without reasoned explanation, and it undermines the statutory and regulatory purposes. If the Final Rule is properly interpreted to require pre-Rule, pre-approval applicable clinical trials (ACTs) to report their results in the same manner as the statute, *see* Pls.' Opening Mem. (D.I. 36), §§ I.B.1, III.B, then Plaintiffs' First Claim will be resolved without striking down any of the Final Rule's text.

STATUTORY AND REGULATORY BACKGROUND

The interpretation of the Final Rule advanced by the Department of Health and Human Services (HHS)—that it creates an exemption for pre-Rule, pre-approval ACTs—is not found

within the text of the Final Rule itself. The Final Rule reiterates FDAAA's statutory reporting requirements for clinical trials completed before the Final Rule's effective date. The regulation simply bifurcates the requirement to submit results from trials of products "approved, licensed, or cleared by FDA" based on whether the ACT's primary completion date falls before or after the effective date of the Final Rule:

> (1) For ACTs completed *before* the Final Rule's effective date, "the responsible party must submit the clinical trial results information specified in section[] 402(j)(3)(C) . . . of the Public Health Service Act."
>
> (2) For ACTs completed *on or after* the Final Rule's effective date, "the responsible party must submit the clinical trial results information specified in [42 C.F.R.] § 11.48."

42 C.F.R. § 11.42(a) (emphasis added). Plaintiffs' First Claim only concerns trials completed *before* the effective date of the Final Rule, and therefore does not implicate the reporting requirements in 42 C.F.R. § 11.48. The relevant portion of the Final Rule, section 11.42(a)(1), restates FDAAA's statutory reporting requirements at (*inter alia*) 42 U.S.C. § 282(j)(3)(C). As Plaintiffs' Opening Memorandum of Law explains, section 282(j)(3)(C) defines the minimum set of clinical trial data, known as Basic Results, that Responsible Parties must submit to the ClinicalTrials.gov data bank. *See generally* Pls.' Opening Mem. § I.B.1.

Under FDAAA, whether a Responsible Party must submit these Basic Results data depends on the product's approval status. *See generally* Pls.' Opening Mem. §§ I.B.1.a, III.B. FDAAA does not differentiate among trials based on approval status at the time of trial completion; instead, it uses the present tense when referring to approval status. That is,

Responsible Parties must submit results for ACTs for approved products[2] regardless of when those products were approved.

The Final Rule contains this same requirement; as described above, the reporting requirements of 42 C.F.R. § 11.42(a)(1) simply refer back to the statute. And while the Final Rule defines approval status, it does so with language nearly identical to FDAAA, including the same present-tense verbs:

- "*Approved drug* means a drug product that ***is*** approved for any use under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or a biological product licensed for any use under section 351 of the Public Health Service Act (42 U.S.C. 262)."

- "*Approved or cleared device* means a device product that ***is*** cleared for any use under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C[.] 360(k)) or approved for any use under sections 515 or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C[.] 360e, 360j(m))."

42 C.F.R. § 11.10(a) (bold emphasis added); *cf.* 42 U.S.C. § 282(j)(3)(C) (using nearly identical language). The Final Rule does not define "unapproved," "unlicensed," or "uncleared" products for its results reporting requirement. Nothing in the text of the Final Rule, therefore, explicitly alters or extinguishes the statutory reporting requirement for pre-Rule, pre-approval ACTs. *See* Pls.' Opening Mem. §§ I.B.1, III.B.

The purported exemption for reporting results from pre-Rule, pre-approval ACTs derives not from the text of the Final Rule, but from the "interpretation" HHS provided in its Preamble. Clinical Trials Registration and Results Information Submission, 81 Fed. Reg. 64,981, 65,120 (Sept. 21, 2016). HHS explained that "[f]or purposes of this final rule, the marketing status of a product will be determined based on its marketing status on the primary completion date." *Id.* As

[2] As before, Plaintiffs use the term "approved product" broadly to encompass drugs that are FDA-"approved" or "licensed" as well as devices that are FDA-"approved" or "cleared." *See* Pls.' Opening Mem. at 7 n.4.

a result, "if a drug product (including a biological product) or a device product is unapproved, unlicensed, or uncleared for any use as of the primary completion date, *regardless of whether it is later approved, licensed, or cleared*, we will consider that applicable clinical trial to be a trial of an unapproved, unlicensed, or uncleared product." *Id.* (emphasis added). If this interpretation of the approval status were permitted to stand, pre-Rule, pre-approval ACTs would be relieved of their submission requirements because FDAAA does not independently require results submission for trials of unapproved products. 42 U.S.C. § 282(j)(3)(D)(ii)(II) (permitting HHS to define results reporting obligations for trials of unapproved products). The Preamble of the Final Rule points to nothing in FDAAA that permits HHS to redefine the approval status of a product in this way.[3]

As HHS itself noted, this interpretation "differs from the proposal in the NPRM [Notice of Proposed Rulemaking]" in an "important way[]." 81 Fed. Reg. at 65,120; *cf.* Clinical Trials Registration and Results Submission, 79 Fed. Reg. 69,565, 69,593 (proposed Nov. 21, 2014). The NPRM had explained that HHS then "interpret[ed] the approval status of a product studied in an applicable clinical trial (i.e., either 'unapproved, unlicensed, or uncleared' or 'approved, licensed, or cleared') to be the approval status of the product on any given date." 79 Fed. Reg. at 69,593. That is, "if and when [a] study drug receives FDA approval," the NPRM would have treated a trial of that drug as a trial "of an approved product as of the date of FDA approval," even if the drug "was unapproved as of the [trial's] completion date." *Id*. The NPRM's approach

[3] Plaintiffs understand that the Preamble represents Defendants' official interpretation of the Final Rule. *See Halo v. Yale Health Plan, Dir. of Benefits & Records Yale Univ.*, 819 F.3d 42, 52 (2d Cir. 2016) (citing *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 158 n.13 (1982)) (explaining that a preamble offers the administrative construction of the regulation). Defendants have publicly reiterated their position that pre-Rule, pre-approval ACTs need not report any results in other guidance as well. *See, e.g.*, *Frequently Asked Questions (ClinicalTrials.gov)*, https://clinicaltrials.gov/ct2/manage-recs/faq#fr_6 (last visited Dec. 5, 2019).

would have comported with FDAAA. The Preamble to the Final Rule provides no reasoned explanation for HHS's abrupt reversal of course. *See* 81 Fed. Reg. at 65,120. While the Preamble makes cursory mention of comments received on the NPRM, such as potential "burden on small entities" and "retroactive effects," HHS did not clearly adopt any of these comments or articulate an explanation of its own to justify the reversal. *Id.*; *see also* Pls.' Opening Mem. § III.B.2.

ARGUMENT

I. BECAUSE PLAINTIFFS' FIRST CLAIM SHOULD BE DECIDED AS A QUESTION OF STATUTORY INTERPRETATION, THE COURT NEED NOT DECIDE WHETHER HHS'S INTERPRETATION OF THE FINAL RULE SHOULD RECEIVE DEFERENCE.

The Court need apply the principles of *Auer* to the Final Rule only if the statute is ambiguous. Otherwise, the statute controls, and the Final Rule and HHS's interpretation of it are invalid to the extent inconsistent with the statute. Here, because Congress has spoken clearly on the question at issue, there is no need to resolve the meaning of the Final Rule.

Where a party challenges an agency action as unlawful, the Court appropriately resolves the statutory interpretation question before construing any implementing regulations. *See, e.g.*, *Coeur Alaska, Inc. v. Se. Alaska Conservation Council*, 557 U.S. 261, 277-78 (2009) (concluding first that "the statute alone does not resolve the case" and only then deciding the disputed meaning of the implementing regulations); *Gen. Elec. Co. v. Comm'r*, 245 F.3d 149, 154 (2d Cir. 2001) (if a statute "clearly supplies . . . a rule of decision, we must apply that rule, regardless of what the regulations might otherwise dictate"). And as *Kisor* underscored, the *Chevron* Step One analysis is demanding: Courts "do not apply *Chevron* reflexively, and [they] find ambiguity only after exhausting ordinary tools of the judicial craft." *Mozilla Corp. v. F.C.C.*, 940 F.3d 1, 20 (D.C. Cir. 2019) (citing *Kisor*, 139 S. Ct. at 2414-15). The Court thus should first interpret FDAAA before examining the Final Rule.

FDAAA unambiguously requires reporting for pre-Rule, pre-approval ACTs. *See* Pls.' Opening Mem. § III.B.1; Pls.' R. Mem. (D.I. 55) § II.A. The Court therefore need not resolve whether the text of the Final Rule permits HHS's contrary interpretation. Section 282(j)(3)(C) itself forecloses that interpretation.

Congress chose to use the present tense "is approved" when creating the Basic Results reporting requirement, and "use of a verb tense is significant in construing statutes." *United States v. Wilson*, 503 U.S. 329, 333 (1992). If Congress had intended only to cover trials for products that were approved at the time of completion, it would have used the present perfect tense instead—referring, for example, to a product that *has been* approved, rather than one that *is* approved. As in *Carr v. United States*, "Congress could have phrased its requirement in language that looked to the past . . . , but it did not choose this readily available option." 560 U.S. 438, 448 (2010) (quoting *Gwaltney of Smithfield, Ltd. v. Chesapeake Bay Found., Inc.*, 484 U.S. 49, 57 (1987) (alteration in original)). Moreover, Congress has established a general rule of statutory construction that, absent evidence to the contrary, "words used in the present tense include the future as well as the present." 1 U.S.C. § 1. Construing "is approved" to include trials for products that ultimately are approved by the FDA gives effect to Congress's rule for statutory construction. Defendants' contrary interpretation denies effect to Congress's own words.

Plaintiffs First Claim is therefore properly resolved by construing the statute. Because FDAAA requires reporting of results, any contrary interpretation of the Final Rule—whether entitled to deference under *Auer* or not—cannot stand.

* * *

If the Court were to address the proper interpretation of the Final Rule, however, HHS's interpretation finds no support in the Rule's text or purpose, as explained below. The Court

should reject HHS's interpretation and hold that the Final Rule requires results reporting for pre-Rule, pre-approval ACTs.

II. THE ANTI-PARROTING DOCTRINE PRECLUDES DEFERENCE TO HHS'S INTERPRETATION OF THE FINAL RULE.

The Court owes HHS no *Auer* deference on its interpretation of the Final Rule because the regulation merely restates—or parrots—the statute. "An agency . . . gets no 'special authority to interpret its own words when, instead of using its expertise and experience to formulate a regulation, it has elected merely to paraphrase the statutory language.'" *Kisor*, 139 S. Ct. at 2417 n.5 (quoting *Gonzales v. Oregon*, 546 U.S. 243, 257 (2006)). That is precisely what the Final Rule does.

A. The Final Rule merely parrots FDAAA's reporting requirement for trials of approved products.

As described in the Statutory and Regulatory Background, *supra*, only two portions of the Final Rule are directly relevant to Plaintiffs' First Claim: *first*, the results reporting requirement in section 11.42(a)(1), and *second*, the definitions in section 11.10. While both sections address which clinical trials must report results, each "gives little or no instruction on [the] central issue" in Plaintiffs' First Claim. *Gonzales*, 546 U.S. at 257. That issue is whether a clinical trial for a product that is approved by the FDA after the trial's completion is a trial for a product that "is approved" under 42 U.S.C. § 282(j)(3)(C). The Final Rule provides no guidance because the differences between the regulatory language in these sections and the statutory language of FDAAA are insubstantial.

1. The reporting requirement.

For ACTs with primary completion dates prior to the Final Rule's effective date—the pre-Rule, pre-approval trials for which Plaintiffs seek Basic Results—the regulation neither modifies nor elucidates FDAAA's reporting requirement. The reporting requirement contained in

the Final Rule simply restates the statutory reporting requirement contained in FDAAA: for "[ACTs] for which the studied product is approved, licensed, or cleared by FDA," "the responsible party must submit the clinical trial results information specified in . . . 42 U.S.C. § 282(j)(3)(C)." 42 C.F.R. § 11.42(a)(1). As a result, the operative "language the [Final] Rule addresses comes from Congress, not" HHS. *Gonzales*, 546 U.S. at 257. The reporting requirement of 42 C.F.R. § 11.42(a)(1) parrots the statute and does not merit *Auer* deference.

2. The definitions section.

The Final Rule's definitions section borrows the statute's language wholesale when defining products that are "approved," "licensed," or "cleared." The regulation contains two relevant definitions, one for drugs and one for devices:

- "*Approved drug* means a drug product that is approved for any use under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or a biological product licensed for any use under section 351 of the Public Health Service Act (42 U.S.C. 262)."

- "*Approved or cleared device* means a device product that is cleared for any use under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C[.] 360(k)) or approved for any use under sections 515 or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C[.] 360e, 360j(m))."

42 C.F.R. § 11.10(a). These definitions use nearly identical language to FDAAA:

> "[T]he Secretary shall include in the registry and results data bank for each applicable clinical trial for a drug that is approved under section 355 of title 21 or licensed under section 262 of this title or a device that is cleared under section 360(k) of title 21 or approved under section 360e or 360j(m) of title 21, the following elements [of Basic Results] . . . ."

42 U.S.C. § 282(j)(3)(C). Both the regulation and statute cross-reference precisely the same sections of the Federal Food, Drug, and Cosmetic Act and Public Health Service Act. And, critically, both use the same present-tense verbs: "is approved" and "is cleared." Those two elements constitute the essence of FDAAA's reporting requirement for FDA-approved products.

3. The Final Rule's text concerning unapproved products does not alter the parroting analysis.

FDAAA grants HHS the authority to specify by rule what results must be reported for an ACT "for a drug that is not approved . . . and not licensed" or "a device that is not cleared . . . and not approved." 42 U.S.C. § 282(j)(3)(D)(ii)(II). Exercising this authority, the Final Rule requires results reporting for ACTs "for which the studied product is not approved, licensed, or cleared by FDA." 42 C.F.R. § 11.42(b). But this section of the Final Rule offers no further definition of when a product is "not approved, licensed, or cleared"; the Final Rule simply treats unapproved products as the logical complement to approved products, and in doing so, again parrots the statutory language. The Final Rule also defines the term, "Device Product Not Approved or Cleared by U.S. FDA," 42 C.F.R. § 11.10(b)(14), but this definition does not alter the parroting analysis before the Court. The definition, which has no counterpart for clinical trials of drugs, implements 42 U.S.C. § 282(j)(2)(D)(ii)(I)'s timeline for posting *registration*, not results, information for certain device clinical trials. *See* 42 C.F.R. § 11.35(b)(2); 81 Fed. Reg. at 64,993 (explaining how section 11.35(b)(2) implements the statute with respect to registration information). The results reporting provision, section 11.42, does not rely on, or even refer to, the definition in section 11.10(b)(14).

The results reporting provisions of the Final Rule are therefore paradigmatic parroting regulations, merely "repeat[ing] two statutory phrases." *Gonzales*, 546 U.S. at 257. *Kisor* and *Gonzales* therefore preclude the government from receiving *Auer* deference on its "interpretation" of the regulatory language.

B. When an agency promulgates a parroting regulation, the Court must determine the meaning of the statute, not the regulation.

When a regulation merely parrots a statute, the Court must interpret the underlying statute. "Simply put, the existence of a parroting regulation does not change the fact that the

question here is not the meaning of the regulation but the meaning of the statute." *Gonzales*, 546 U.S. at 257. *Auer* deference simply has no application when the parties dispute the meaning of a statute, not a regulation. *Id.* at 256. Plaintiffs' briefing has shown why FDAAA unambiguously requires results reporting for pre-Rule, pre-approval ACTs, and Defendants' strained arguments are unsupported by the plain text, structure, or purpose of FDAAA. *See supra* § I; Pls.' Opening Mem. § III.B.1; Pls.' R. Mem. § II.A. The Court must set aside any contrary regulation or agency interpretation.

III. BECAUSE THE TEXT OF THE FINAL RULE COVERS PRE-RULE, PRE-APPROVAL ACTS, HHS CANNOT ADOPT A CONTRADICTORY INTERPRETATION.

Even if the Final Rule did not merely parrot the statute, HHS's interpretation would still not be entitled to *Auer* deference. In *Kisor*, the Supreme Court clarified that *Auer* deference has four essential prerequisites:

1. The regulation must be "genuinely ambiguous." *Kisor*, 139 S. Ct. at 2414.

2. The interpretation "must be the agency's 'authoritative' or 'official position,' rather than any more ad hoc statement not reflecting the agency's views." *Id.* at 2416.

3. "The agency's interpretation must in some way implicate its substantive expertise." *Id.* at 2417.

4. "An agency's reading of a rule must reflect 'fair and considered judgment' to receive *Auer* deference." *Id.*

Most importantly here, the Final Rule is not "genuinely ambiguous." Without ambiguity, HHS has no room to offer its interpretation. *Id.* at 2415 ("The regulation then just means what it means—and the court must give it effect, as the court would any law.").

A. The Preamble does not control interpretation of the Final Rule's regulatory text.

The Preamble of the Final Rule does not control the interpretation of the regulatory text. While a preamble can aid in the interpretation of a regulation, "language in the preamble of a regulation is not controlling over the regulation itself." *Halo v. Yale Health Plan, Dir. of Benefits & Records Yale Univ.*, 819 F.3d 42, 52-53 (2d Cir. 2016) (quoting *Wyo. Outdoor Council v. U.S. Forest Serv.*, 165 F.3d 43, 53 (D.C. Cir. 1999)). Employing all the traditional tools of construction, as required by *Kisor*, makes clear that the Final Rule unambiguously requires results reporting for pre-Rule, pre-approval ACTs. HHS's contrary interpretation in the Preamble therefore cannot control the Final Rule's meaning.

B. Like FDAAA itself, the text of the Final Rule is not ambiguous as to the scope of its coverage.

In *Kisor*, the Supreme Court unanimously agreed on the importance of *genuine* ambiguity. Justice Kagan, writing for the Court, emphasized that "when we use that term, we mean it—genuinely ambiguous, even after a court has resorted to *all* the standard tools of interpretation." *Kisor*, 139 S. Ct. at 2414 (emphasis added). The three concurrences all underscored this same point. *Id.* at 2424 (Roberts, C.J., concurring); *id.* at 2448 (Gorsuch, J., concurring); *id.* (Kavanaugh, J., concurring). Few regulations contain genuine ambiguity because courts using all the traditional tools of interpretation "will resolve many seeming ambiguities out of the box, without resort to *Auer* deference." *Id.* at 2415 (majority op.). Employing those traditional tools here, the regulation—like the statute that it closely mirrors—requires results reporting for pre-Rule, pre-approval ACTs.

The traditional tools of construction include the regulatory text and purpose, as well as the purpose and meaning of the authorizing statute. *Id.* (requiring the reviewing court to consider the "text, structure, history, and purpose of a regulation, in all the ways it would if it had no

agency to fall back on"); *Fernandez v. Zoni Language Ctrs., Inc.*, 858 F.3d 45, 50 (2d Cir. 2017) (requiring the reviewing court to consider "the plain language of the regulatory text . . . in light of its purpose, as stated in the regulation's preamble . . . as well as the purpose of the regulation's authorizing statute." (internal quotation marks and citation omitted)). Employing these tools confirms that the Final Rule requires pre-Rule, pre-approval ACTs to report their results.

Plain text. The plain text of the Final Rule encompasses pre-Rule, pre-approval ACTs in its reporting requirement. The text of the Final Rule is materially indistinguishable from FDAAA. *See supra* § II.A. And the text of FDAAA requires results reporting for pre-Rule, pre-approval ACTs once the products studied are approved. *See generally* Pls.' Opening Mem. § III.B.1; Pls.' R. Mem. § II.A. For all the same reasons, the plain text of the regulation requires pre-Rule, pre-approval ACTs to report their results.

Like Congress, HHS chose to use the present tense to refer to the class of approved products for which Responsible Parties must report results. If a product "is approved," the Responsible Party must report results. 42 C.F.R. §§ 11.10, 11.42. The present-tense verb used in the regulation must be given meaning and effect. *See supra* § I. Like Congress, HHS had readily available alternative language it might have used to achieve an alternative result (though, of course, such a result would be contrary to the statute). For example, HHS might have defined an approved product as one that *was* approved, licensed, or cleared by FDA for any use *before* the primary completion date of the trial. *Cf.* 42 C.F.R. § 11.44(c)(1) (permitting delayed results submission for "an FDA-regulated drug product . . . or device product that *was not* approved, licensed, or cleared by FDA for any use *before* the primary completion date of the trial" (emphasis added)). HHS declined to do so in the regulatory text, instead placing its interpretation

in the non-binding Preamble of the Final Rule.[4] The plain meaning of the regulation, determined through the rules of ordinary usage and grammar, requires reporting.

Regulatory purpose. The HHS interpretation undermines the statutory and regulatory purposes by limiting the class of clinical trials that must report results. The Final Rule explains its purpose as "implement[ing] section 402(j) of the Public Health Service Act (42 U.S.C. 282(j))," which is the relevant subsection of FDAAA. 42 C.F.R. § 11.2. As the Preamble explains, FDAAA "[was] intended to improve public access to information about certain clinical trials of U.S. FDA-regulated drugs, biological products, and devices." 81 Fed. Reg. at 64,982. But the HHS interpretation achieves the opposite effect. It diminishes the public entitlement to clinical trial results under FDAAA, and undermines "[o]ne of the aims of the statute and of the rule"—"to 'provide more complete results information,' which [HHS] believe[s] complements the goals of increased transparency and accountability." 81 Fed. Reg. at 64,987 (quoting 42 U.S.C. § 282(j)(3)(D)(i)). These goals are particularly important for approved products. Regardless of when a product received FDA approval, the fact that it is currently approved means patients across the country likely currently use the product. Those patients, their prescribing physicians, and researchers need the clinical trial information to accurately evaluate

[4] Plaintiffs do not know why HHS chose to place its interpretation in the Preamble instead of changing the regulatory text. Nothing in the proposed rule suggested that Defendants might exempt pre-Rule, pre-approval ACTs from their reporting requirements; the proposed rule's preamble stated that HHS would adopt precisely the opposite approach. *See supra* Statutory and Regulatory Background. Modifying the regulatory text to exempt pre-Rule, pre-approval ACTs might therefore have violated the "logical outgrowth" requirement for notice-and-comment rulemaking because the notice of proposed rulemaking would not have "described the range of alternatives being considered with reasonable specificity." *Time Warner Cable Inc. v. F.C.C.*, 729 F.3d 137, 170 (2d Cir. 2013) (citation omitted). If HHS attempted to avoid the strictures of notice-and-comment rulemaking, its interpretation would not reflect the "fair and considered judgment" necessary to receive *Auer* deference. *See Kisor*, 139 S. Ct. at 2417-18; *see also Wyeth v. Levine*, 555 U.S. 555, 577 (2009) (describing FDA's views as "inherently suspect in light of [its] procedural failure" where FDA reversed its position from the preamble of a proposed rule to the preamble of a final rule "without offering . . . interested parties notice or opportunity for comment").

the safety and efficacy of those products. In light of these goals, the regulatory text should require results for trials where a product "is approved," regardless of the timing of that approval.

Avoidance of conflict with the statute. Under the traditional constitutional avoidance canon, courts interpret statutes in ways that would avoid potential constitutional infirmities. *See, e.g.*, *Jennings v. Rodriguez*, 138 S. Ct. 830, 842 (2018). The same principle applies to interpretation of regulations: where an agency interpretation of a regulation would cause the regulation to conflict with a statute, the court should avoid that construction. *See Zuniga v. Barr*, 934 F.3d 1083, 1088 (9th Cir. 2019) (per curiam) ("We 'need not accept an agency's interpretation of its own regulations if that interpretation is inconsistent with the statute under which the regulations were promulgated.'" (citation omitted)). Plaintiffs' Opening and Reply Memoranda describe why the plain text of FDAAA requires results reporting for pre-Rule, pre-approval ACTs. *See* Pls.' Opening Mem. § III.B.1; Pls.' R. Mem. § II.A. Since accepting HHS's interpretation of the Final Rule would create conflict between the statute and the regulation, requiring the regulation to be set aside under 5 U.S.C. § 706(2)(A), the Court should construe the Final Rule as faithful to the statute.

C. Because the regulation covers pre-Rule, pre-approval ACTs, the HHS interpretation cannot control the Final Rule's meaning, regardless of the deference regime applied.

When an agency interpretation does not receive *Auer* deference, courts need only grant it so-called *Skidmore* deference "to the extent it has the 'power to persuade.'" *Kisor*, 139 S. Ct. at 2414 (citation omitted). HHS's interpretation cannot survive regardless of the deference regime applied because it contradicts the text of the regulation. The agency "is not entitled to either *Auer* deference or *Skidmore* deference . . . [when] the language of the regulation is not ambiguous." *City Club of N.Y. v. U.S. Army Corps of Eng'rs*, 246 F. Supp. 3d 860, 869 (S.D.N.Y. 2017) (citing *Halo*, 819 F.3d at 53; *Catskill Mountains Ch. of Trout Unlimited, Inc. v. EPA*, 846 F.3d

492, 509 (2d Cir. 2017)). The Court should reject the HHS interpretation because it is "plainly erroneous or inconsistent with the regulation." *Auer*, 519 U.S. at 461.

But even if not flatly contradictory to the regulatory text, the HHS interpretation has minimal power to persuade. The interpretation lacks indicia of persuasiveness, including "thoroughness evident in [the agency's] consideration, . . . validity of its reasoning, [and] . . . consistency with earlier and later pronouncements." *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 159 (2012) (internal quotation marks and citations omitted). Defendants articulated no justification for their interpretation (beyond vague reference to comments received on the NPRM) and manifested complete inconsistency with their earlier pronouncement in the NPRM. *See supra* Statutory and Regulatory Background; *see also* Pls.' Opening Mem. § III.B.2. Courts have declined to extend even minimal *Skidmore* deference under similar circumstances. *See*, *e.g.*, *Wyeth v. Levine*, 555 U.S. 555, 577 (2009) (extending no deference to FDA interpretation announced in preamble of final rule that directly contradicted interpretation proffered in the initial NPRM, and observing that the preamble was "inherently suspect in light of this procedural failure"); *In re Vioxx Prods. Liab. Litig.*, 501 F. Supp. 2d 776, 788 (E.D. La. 2007) (earlier decision extending no deference to the same FDA interpretation because of this procedural failure along with FDA's failure to provide any reasoned explanation). Plaintiffs' interpretation of the Final Rule should therefore prevail.

CONCLUSION

For the foregoing reasons, the Court should declare HHS's interpretation of the Final Rule unlawful, and enjoin that interpretation, to the extent it purports to exempt pre-Rule, pre-approval ACTs from reporting Basic Results to ClinicalTrials.gov as required by FDAAA.

Respectfully submitted,[5]

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