UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,	:		
Plaintiff,	:	Civil Action No.:	14-1685 (RC)
v.	:	Re Documents No.:	14, 21
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,	:		
Defendants.	:		

MEMORANDUM OPINION

DENYING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AND GRANTING PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT.

I. INTRODUCTION

The Court previously vacated a Final Rule promulgated by the Secretary of the Department of Health and Human Services ("HHS") that addressed the circumstances in which an orphan drug must be offered at a discounted price pursuant to section 340B of the Public Health Service Act ("PHSA"). The Court concluded that HHS lacked the statutory authority to promulgate that rule. *See Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28, 42–45 (D.D.C. 2014) (hereinafter "*PhRMA*"). HHS has since issued an interpretive rule (the "Interpretive Rule") identical in substance to the vacated Final Rule that sets forth the "manner in which section 340B(e) of the PHSA will be interpreted and implemented by HHS." A.R. 680. The plaintiff, Pharmaceutical Research and Manufacturers of America ("PhRMA") again challenges HHS's action, contending that the Interpretive Rule contravenes section 340B's plain language. HHS has moved for summary judgment arguing that the Interpretive Rule does not constitute a final agency action sufficient to state a claim and that,

in any event, its reading of the statute is at least entitled to deference under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944) because it "reasonably balances Congress's concerns with maintaining incentives for the development of drugs for orphan diseases with providing the newly covered 340B entities with discounts sufficient to make participation in the program beneficial." Defs.' Mem. Supp. Summ. J. at 3, ECF No. 14–1. PhRMA has cross-moved for summary judgment and argues that the Interpretive Rule is a final agency action subject to immediate challenge and that the rule conflicts with the statute's plain language. Because the Court concludes that the Interpretive Rule is a final agency action and that the Interpretive Rule contravenes the plain language of section 340B(e), the Court will deny HHS's motion for summary judgment and grant PhRMA's motion for summary judgment.

II. FACTUAL & STATUTORY BACKGROUND

This case involves the intersection of two intricate statutory schemes: the Orphan Drug Act and the 340B Program. Both are designed, in large part, to ensure greater access to medications for certain populations. In its prior memorandum opinion in this dispute, the Court described the statutory schemes implicated in this case and the Court assumes familiarity with that discussion. *See PhRMA*, 43 F. Supp. 3d at 31–33.

A. The Orphan Drug Act

The Orphan Drug Act involves the designation and marketing of drugs—called orphan drugs—to treat rare diseases or conditions.[1] Orphan drugs are so-named because, absent the

[1] A rare disease or condition is defined by statute as:

> . . . [A]ny disease or condition which (A) affects less than 200,000 persons in the United States, or (B) affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making

financial and marketing incentives Congress has provided to pharmaceutical manufacturers for the development of such drugs, efforts to invest, research, and otherwise manufacture those drugs would likely be abandoned. Congress passed the Act after concluding that "because so few individuals are affected by any one rare disease or condition, a pharmaceutical company which develops an orphan drug may reasonably expect the drug to generate relatively small sales in comparison to the cost of developing the drug and consequently to incur a financial loss." Act of Jan. 4, 1983, Pub. L. No. 97-414, § 1(b)(4), 96 Stat. 2049, 2040. For that reason, the Orphan Drug Act provides several incentives to those pharmaceutical manufacturers that develop orphan drugs, including: a seven-year market exclusivity period during which no drugs, other than the designated orphan drug, can be licensed or approved "for such disease or condition," 21 U.S.C. § 360cc(a); a tax credit for the clinical testing expenses incurred during the orphan drug's development, *see* 26 U.S.C. § 45C; research grants for that clinical testing, *see* 21 U.S.C. § 360ee; and an exemption from the fees otherwise applicable to new drug applications, *see* 21 U.S.C. § 379h(a)(1)(F).

The Orphan Drug Act permits the Secretary of Health and Human Services (the "Secretary") to designate a drug as an orphan drug. According to statute, "[t]he manufacturer or the sponsor of a drug may request the Secretary to designate the drug as a drug for a rare disease or condition." 21 U.S.C. § 360bb(a)(1). The statute further instructs that, if the Secretary finds that the drug "is being or will be investigated for a rare disease or condition" and the approval, certification or licensure of that drug "would be for use for such a disease or condition," the Secretary "shall designate the drug as a drug for such disease or condition." *Id.* The Food and

---

> available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug . . . .

21 U.S.C. § 360bb(a)(2).

Drug Administration, an agency within HHS, oversees the designation and approval of orphan drugs. *See PhRMA*, 43 F. Supp. 3d at 41 n.11 (citing 21 C.F.R. § 316.1(a) (regulation promulgated by the FDA implementing the orphan-drug related sections of the Federal Food, Drug, and Cosmetic Act and providing "procedures to encourage and facilitate the development of drugs for rare diseases or conditions")); *see also* 21 U.S.C. § 393(d)(2).

A drug's designation as an orphan drug may not overlap entirely with its use. Drugs that carry an orphan designation "can also be used to treat non-rare diseases or conditions." *PhRMA*, 43 F. Supp. 3d at 30 (discussing, for example, Prozac, which commonly treats depression but is designated as an orphan drug to treat autism and body dysmorphic disorder). And a drug may be designated as an orphan drug even if that drug is also approved to treat a different disease or condition that does not qualify for orphan-drug designation. *See* 21 C.F.R. § 316.23(b). Nor does the designation of a drug as an orphan drug in and of itself afford a pharmaceutical manufacturer with the ability to market the drug in the United States. That a drug has been awarded an orphan designation "does not alter the standard regulatory requirements and process for obtaining marketing approval." Exclusion of Orphan Drugs for Certain Covered Entities Under 340B Program, 78 Fed. Reg. 44,016, 44,017 (July 23, 2013). Indeed, according to HHS "a large majority of drugs with orphan designations do not have approval to be marketed in the United States" at all. *Id.*

B. The 340B Program and the 2010 Extension

The second statutory scheme, section 340B of the Public Health Services Act, "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health facilities." *Astra U.S.A., Inc. v. Santa Clara Cnty., Cal.*, 131 S. Ct. 1342, 1345 (2011); *see generally* 42 U.S.C. § 256b. The program was first enacted as part of the Veterans Health Care

Act of 1992, *see PhRMA*, 43 F. Supp. 3d at 31, and is managed by the Health Resources Services Administration ("HRSA"), an agency within HHS, *see Astra*, 131 S. Ct. at 1345. In order for a pharmaceutical manufacturer's products to be covered under the 340B Program, and therefore eligible for reimbursement from Medicaid, manufacturers are required to enter into a Pharmaceutical Pricing Agreement with the Secretary calculating a specified ceiling price that covered entities must pay for the manufacturer's drugs. *See* 42 U.S.C. § 256b(a). A manufacturer must offer drugs "for purchase at or below the applicable ceiling price" to any entity covered by the 340B Program "if such drug is made available to any other purchaser at any price." *Id.*

In setting ceiling prices for covered drugs, section 340B is designed to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. 2, at 12 (1992). Many of the eligible health care facilities are "providers of safety net services to the poor." *Astra*, 131 S. Ct. at 1345. As initially enacted in 1992, the covered entities included health care facilities receiving certain federally-funded grants, state-operated AIDS drug purchasing assistance programs, black lung clinics, Native Hawaiian health centers, and urban Indian organizations, among other entities. *See* 42 U.S.C. § 256b(a)(4)(A)–(L); *see also* Veterans Health Care Act of 1991, Pub. L. No. 102-585, Title VI, § 602(a), 106 Stat. 4943, 4967–68. Disproportionate share hospitals (those hospitals that serve indigent populations) are also included as covered entities. *See* 42 U.S.C. § 256b(a)(4)(L).

As part of the Patient Protection and Affordable Care Act ("ACA") Congress added a significant number of new categories to the list of covered entities. Those entities are enumerated in what became subsections (M), (N), and (O) of section 340B(a)(4). Specifically, in

section 7101 of the ACA Congress added to the 340B Program children's hospitals that are excluded from the Medicare prospective payment system, free-standing cancer hospitals that are excluded from the Medicare prospective payment system, critical access hospitals, rural referral centers, and sole community hospitals. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7101(a), 124 Stat. 119, 821–22 (codified as amended at 42 U.S.C. § 256b(a)(4)(M)–(O)).

As part of the ACA, Congress also directed HHS to create an administrative dispute resolution process for the 340B Program. The ACA directed the Secretary to "promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged" for drugs or of "claims by manufacturers" following a statutorily-permitted audit of a covered entity. *Id.* at § 7102 (codified at 42 U.S.C. § 256b(d)(3)). Congress further instructed that the dispute resolution process should "includ[e] appropriate procedures for the provision of remedies and enforcement of determinations made pursuant" to that process—which could include sanctions of civil monetary penalties of up to $5,000 "for each instance of overcharging a covered entity that may have occurred." *Id.* (codified at 42 U.S.C. §§ 256b(d)(3), (d)(1)(B)(vi)(I)). Although the ACA directed the Secretary to promulgate those regulations within 180 days of the ACA's passage (March 23, 2010), and the Secretary did issue a notice of proposed rulemaking to establish that administrative dispute resolution process, HHS has not yet issued a final rule implementing the process. *See* 340B Drug Pricing Program Administrative Dispute Resolution Process, 75 Fed. Reg. 57,233 (Sept. 20, 2010). In omnibus guidance issued last month, HHS indicated only that "[f]uture rulemaking will address the administrative dispute resolution process." 340B Drug Pricing Omnibus Guidance, 80 Fed. Reg. 52,300, 52,301 (Aug. 28, 2015).

C. The Orphan Drug Exclusion and HHS's Interpretive Rule

At the same time that Congress added those new entities to the 340B Program, Congress also narrowed the categories of drugs to which the newly added entities would have access at reduced prices. In the Health Care and Education Reconciliation Act ("HCERA")—which amended the ACA—Congress added an additional subsection to the Act entitled "Exclusion of Orphan Drugs for Certain Covered Entities." That subsection ("section 340B(e)") provides that: "[f]or covered entities described in subparagraph (M), (N), or (O) of subsection (a)(4), the term 'covered outpatient drug' shall not include a drug designated by the Secretary under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition."[2] Health Care and Education Reconciliation Act, Pub. L. No. 111-152, § 2303, 124 Stat. 1029, 1083 (codified as amended at 42 U.S.C. § 256b(e)). As a result of section 340B(e), newly covered entities do not have access to "a drug designated . . . for a rare disease or condition" at a discounted price.

The parties contest the reach of the term "a drug designated . . . for a rare disease or condition." In addition, in the immediate aftermath of the ACA's passage covered entities expressed concern and confusion about the phrase's meaning, while pharmaceutical manufacturers contended that all orphan-designated drugs, whatever their particular use, were intended to be excluded from the 340B Program for the newly added covered entities. *See, e.g.*, A.R. 38–39, 65–68, 70, 85–87, 91–96. In part to eliminate that confusion and to provide "clarity

[2] Free-standing children's hospitals had previously been afforded access to the 340B Program in 2005. *See* Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 6004, 120 Stat. 4, 61. As a result, and because those entities had previously enjoyed access to orphan drugs at section 340B prices, an amendment was passed in 2010 to clarify section 340B(e)'s application to children's hospitals. *See* Medicare and Medicaid Extenders Act of 2010, Pub. L. No. 111-309, § 204, 124 Stat. 3285, 3289–90. As codified, section 340B(e) now specifies that it applies to "covered entities described in subparagraph (M) (*other than a children's hospital described in subparagraph (M)*)." 42 U.S.C. § 256b(e) (emphasis added).

in the marketplace," the Secretary issued a notice of proposed rulemaking. *See* Notice of Proposed Rulemaking, Exclusion of Orphan Drugs for Certain Covered Entities Under 340B Program, 76 Fed. Reg. 29,183, 29,184 (May 20, 2011).

HHS published its Final Rule on July 23, 2013. That Final Rule interpreted section 340B(e) to provide that, with respect to the newly covered entities, "a covered outpatient drug does not include orphan drugs that are transferred, prescribed, sold, or otherwise used for the rare condition or disease for which that orphan drug was designated under section 526 of the [Federal Food, Drug, and Cosmetics Act]." 42 C.F.R. § 10.21(a). The "practical effect" of that rule is that, while "the discounted 340B price is not available to newly-added covered entities when purchasing orphan drugs for their intended orphan use," when a covered entity instead purchases a drug for a non-orphan use, it "does receive the 340B discount price." *PhRMA*, 43 F. Supp. 2d at 32.

This Court previously found the Final Rule invalid because "HHS has not been granted broad rulemaking authority to carry out all the provisions of the 340B program" and the statutory provisions HHS relied on as authority to promulgate the rule were "specific grants of authority that do not authorize the orphan drug rule." *Id.* at 42, 39. Instead, the Court noted that Congress granted HHS only "a specific delegation of rulemaking authority to establish an adjudication procedure to resolve disputes between covered entities and manufacturers." *Id.* at 45. In an alternative, "half-hearted" argument HHS contended that the Final Rule could be upheld as an interpretive rule. *Id.* at 45–46. But the Court expressed some skepticism that the rule as expressed in the specific regulation before the court—which was promulgated by notice and comment and purported to have a binding legal effect—could properly be classified as an interpretive rule. *Id.* at 46. The Court invited HHS to offer further briefing on the issue,

including to address the question of whether "HHS must first promulgate the rule as interpretive for it to then be challenged under *Skidmore*." *Id.* at 46–47 & n.19 (citing *Kelley v. EPA*, 15 F.3d 1100 (D.C. Cir. 1994)). HHS declined the Court's invitation. *See* Defs.' Resp. to Court's May 23, 2014, Order, *PhRMA*, No. 1:13-cv-1501-RC (D.D.C. June 12, 2014), ECF No. 45.

Nevertheless, HHS has since issued the Interpretive Rule explaining "how HHS interprets section 340B(e)." *See* Availability of Interpretive Rule: Implementation of the Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program, 79 Fed. Reg. 42,801, 42,801 (July 23, 2014). That interpretation—effective as of July 21, 2014—restates, in substantively identical terms, the interpretation that HHS had reached in its prior Final Rule.[3] A.R. 680–86. According to HHS, "interpreting the statutory language to exclude all indications for a drug that has an orphan drug designation would be contrary to the Congressional intent of section 340B(e) to balance the interests of orphan drug development and the expansion of the 340B Program to new entities." A.R. 684. Thus, HHS again interpreted section 340B(e) as "excluding drugs with an orphan designation *only when those drugs are transferred, prescribed, sold, or otherwise used for the rare condition or disease for which the drug was designated*." A.R. 685 (emphasis added). For the same reason, HHS construed section 340B(e) to "not exclude drugs that are transferred, prescribed, sold, or otherwise used for conditions or diseases other than for which the drug was designated." A.R. 685–86.

In its notice, HHS acknowledged that its interpretation would require covered entities and manufacturers to identify those drugs that have an orphan designation and are used to treat that

[3] The Interpretive Rule is also available on HRSA's website. *See Interpretive Rule: Implementation of the Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program*, Health Resources & Services Administration, http://www.hrsa.gov/opa/programrequirements/interpretiverule/interpretiverule.pdf (last visited Oct. 13, 2015).

designation. To facilitate that process, HHS proposed to "publish a listing of orphan drug designations, providing the name of the drug and the designated indication" on "the first day of the month prior to the end of the calendar quarter." A.R. 685. Furthermore, HHS cautioned that "[i]f a covered entity lacks the ability to track drug use by indication, such entity would be unable to purchase drugs with orphan designations through the 340B Program." A.R. 685.

In line with its Interpretive Rule, HHS, through HRSA, has also sent letters to pharmaceutical manufacturers advising them that HRSA had been informed by one or more covered entities that "the 340B price is not available for at least one of [the manufacturers'] products with an orphan designation." *See* First Am. Compl. Ex. E, ECF No. 11–5. In those letters, HRSA set forth its interpretation of the statute and stated that the recipient manufacturer "*is out of compliance with statutory requirements* as described in HRSA's interpretive rule." *Id.* (emphasis added). HRSA further cautioned that "[m]anufacturers that do not offer the 340B price for drugs with an orphan designation when those drugs are used for an indication other than the rare condition or disease for which the drug was designated . . . *are violating section 340B(a)(1) of the PHSA* and the terms of their Pharmaceutical Pricing Agreement." *Id.* (emphasis added). Finally, HRSA noted that section 340B(d) requires manufacturers to "refund covered entities charged more than the statutory ceiling price for covered outpatient drugs" and requested the recipients to "respond within 30 days to notify HRSA of your plan to repay affected covered entities and to institute the offer of the discounted price in the future." *Id.* On its website, HRSA has also stated that "[a] manufacturer or covered entity's failure to comply with the statutory requirements could subject a manufacturer or covered entity to an enforcement action by HRSA, which could include refunds to covered entities in the case of overcharges, as

well as termination of a manufacturer's Pharmaceutical Pricing Agreement (PPA)." *See* First Am. Compl. Ex. D, ECF No. 11–4.[4]

PhRMA filed a complaint on October 9, 2014, challenging the Interpretive Rule under the Administrative Procedure Act ("APA") as "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *See* 5 U.S.C. § 706(2)(A); *see also* Compl., ECF No. 1; First Am. Compl., ECF No. 11. Pending before the Court are HHS's motion for summary judgment, *See* ECF No. 14, and PhRMA's cross-motion for summary judgment, *see* ECF No. 21.

III. LEGAL STANDARD

A court may grant summary judgment when "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). When assessing a motion for summary judgment in an APA case, however, "the district judge sits as an appellate tribunal." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001). In such cases the complaint "actually presents no factual allegations, but rather only arguments about the legal conclusion to be drawn about the agency action." *Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993). Therefore, "[t]he entire case on review is a question of law, and only a question of law." *Id.* The Court's review "is based on the agency record and limited to determining whether the agency acted arbitrarily or capriciously," *Rempfer v. Sharfstein*, 583 F.3d 860, 865 (D.C. Cir. 2009), or in violation of another standard set out in section 10(e) of the APA, *see* 5 U.S.C. § 706.

[4] *See also FAQs*, Health Resources & Services Administration, http://www.hrsa.gov/opa/faqs/index.html (last visited Oct. 13, 2015).

IV. ANALYSIS

In support of its motion for summary judgment, HHS makes two principal arguments. First, HHS claims that the Interpretive Rule does not constitute a final agency action and, therefore, is not subject to judicial review. Second, HHS argues in the alternative that, even if the rule constitutes a final agency action, its interpretation is entitled to *Skidmore* deference. In opposition to the motion—and in support of its own motion for summary judgment—PhRMA contends that the Interpretive Rule is a final agency action and, further, that the rule conflicts with the plain language of section 340B(e).

At the outset, it is important to note what PhRMA has not challenged. Although the Court expressed some skepticism that the Final Rule could be sustained as an interpretive rule, it noted that more briefing was needed to determine whether, among other things, the rule could be challenged immediately, "or whether HHS must first promulgate the rule as interpretive for it to be challenged under *Skidmore*." *PhRMA*, 43 F. Supp. 3d at 46. Rather than continue to defend the original Final Rule, HHS did just that, and the Court entered final judgment because the new Interpretive Rule was "beyond the scope of the [original] action." *See* Order Entering Final Judgment, *PhRMA*, No. 1:13-cv-1501-RC (D.D.C. Aug. 27, 2014), ECF No. 55.

In this case, although PhRMA challenges the merits of the Interpretive Rule, the organization does not appear to challenge HHS's *authority* to issue an Interpretive Rule prospectively setting forth the agency's reading of the statute. In any event, it is clear that HHS has the authority to advise the public of its interpretation of the statute. *Cf. United States v. Mead Corp.*, 533 U.S. 218, 228 (2001) ("[W]hether or not they enjoy any express delegation of authority on a particular question, agencies charged with applying a statute necessarily make all sorts of interpretive choices."). In order to administer the dispute resolution process that

Congress has instructed HHS to establish, the agency necessarily will be obliged to set forth its understanding of a pharmaceutical manufacturer's obligations under the 340B Program. 42 U.S.C. § 256b(d)(3)(A). Moreover, Congress has instructed the Secretary to "designate or establish a decision-making official or decision-making body *within the Department of Health and Human Services* to be responsible for reviewing and finally resolving claims by covered entities . . . and claims by manufacturers." *Id.* § 256b(d)(3)(B)(i) (emphasis added). Quite obviously, then, to finally resolve those claims, HHS will be required to interpret the reach of section 340B(e). *See Gonzales v. Oregon*, 546 U.S. 243, 268 (2006) (after holding that the Attorney General lacked statutory authority to issue an "Interpretive Rule as a statement with the force of law," noting that "[i]f, in the course of exercising his authority, the Attorney General uses his analysis in the Interpretive Rule only for guidance in deciding whether to prosecute or deregister [a physician for violating the Controlled Substances Act], then the question remains whether his substantive interpretation is correct"). Accordingly, even though this Court concluded that HHS lacks the authority to promulgate the rule as a binding statement of law, HHS is not forbidden altogether from proffering its interpretation of the statute.

With that understanding in mind, the Court proceeds to address the issues the parties raise.

A. Whether the Interpretive Rule is a Final Order

The Court first considers whether the Interpretive Rule constitutes a final agency action. Under the APA, judicial review is available only of a "final agency action." 5 U.S.C. § 704. Therefore, if the Interpretive Rule does not constitute a final agency action, PhRMA lacks a

cause of action under the APA.[5] *See Reliable Automatic Sprinkler Co. v. Consumer Prod. Safety Comm'n*, 324 F.3d 726, 731 (D.C. Cir. 2003). The APA defines an "agency action" to include "an agency rule." 5 U.S.C. § 551(13). A "rule," in turn, is defined as including "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, *interpret*, or prescribe law or policy." *Id.* § 551(4) (emphasis added). Accordingly, HHS's Interpretive Rule falls within the ambit of an "agency action"; the question is whether that action is final for purposes of section 704. *See Sackett v. EPA*, 132 S. Ct. 1367, 1371 (2012) ("There is no doubt [the compliance order] is agency action, which the APA defines as including even a 'failure to act.' But is it *final*?" (citation omitted)).

In *Bennett v. Spear* the Supreme Court articulated a two-part test for determining whether an agency action is final. *See* 520 U.S. 154, 177–78 (1997). "First, the action must mark the 'consummation' of the agency's decision-making process—it must not be of a merely tentative or interlocutory nature." *Id.* (citation omitted). Second, "the action must be one by which rights or obligations have been determined or from which legal consequences will flow." *Id.* at 178 (internal quotation marks and citation omitted). Although "*Bennett* highlights the importance of avoiding disruption of the administrative decisionmaking process," *CSI Aviation Servs., Inc. v. U.S. Dep't of Transp.*, 637 F.3d 408, 411 (D.C. Cir. 2011), "the Supreme Court has instructed" that courts must nevertheless "apply the finality requirement in a 'flexible' and 'pragmatic'

[5] Although the D.C. Circuit has occasionally characterized the issue as "jurisdictional," *see Bark v. U.S. Forest Serv.*, 37 F. Supp. 3d 41, 50 (D.D.C. 2014) (citing *Cobell v. Norton*, 240 F.3d 1081, 1095 (D.C. Cir. 2001)), it is now "firmly established" that "the review provisions of the APA are not jurisdictional," *Viet. Veterans of Am. v. Shinseki*, 599 F.3d 654, 661 (D.C. Cir. 2010). Instead, section 704 simply "limits causes of action under the APA." *Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 452 F.3d 798, 806 (D.C. Cir. 2006); *see also Reliable Automatic Sprinkler*, 324 F.3d at 731 (noting that "[i]f there was no final agency action here, there is no doubt that [the party] would lack a cause of action under the APA").

way," *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430, 435 (D.C. Cir. 1986) (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 149–50 (1967)). In this case, HHS concedes that the Interpretive Rule "satisfies the first part of the *Bennett* test" because the rule "is the product of mature administrative judgment," "was issued after extensive deliberation," and is "not a preliminary or tentative agency conclusion on the meaning of subsection 340B(e)." Defs.' Mem. Supp. Summ. J. at 11. Accordingly, for purposes of the finality analysis the only remaining issue before this Court is whether the Interpretive Rule is an agency action by which "rights or obligations have been determined or from which legal consequences will flow." *Bennett*, 520 U.S. at 178 (internal quotation marks and citation omitted).

In support of its argument that the Interpretive Rule does not constitute a final agency action, HHS relies heavily on the fact that the rule is an interpretive one. In its motion for summary judgment, and particularly its reply,[6] HHS expends considerable energy arguing that the rule is not a legislative rule and, for that reason alone, is not yet subject to review under the APA. *See* Defs.' Mem. Supp. Summ. J. at 13; Defs.' Reply at 3–6, ECF No. 24. In doing so, HHS seems to suggest that the interpretive rule is categorically shielded from judicial review—and that "there is no final agency action"—"until HHS initiates an enforcement action against a drug manufacturer and imposes a penalty for not complying with the statutory provision." Defs.' Mem. Supp. Summ. J. at 15; *see also* Defs.' Reply at 5 (contending that PhRMA's argument "displays a fundamental misunderstanding of the difference between interpretive and legislative rules").

[6] On the same day, HHS separately filed two memoranda entitled "Memorandum in Opposition to Plaintiff's Motion for Summary Judgment and Reply to Plaintiff's Opposition to Defendants' Motion for Summary Judgment." *See* ECF Nos. 23, 24. The Court has reviewed both filings and they appear identical. With that understanding, the Court cites only to ECF No. 24.

If that is HHS's position, it is contrary to D.C. Circuit and Supreme Court precedent. Although HHS's current rule is undoubtedly an interpretive rule in light of this Court's prior holding, the rule's particular classification is beside the point. The D.C. Circuit has instructed that *Bennett* "does not foreclose all pre-enforcement challenges." *CSI Aviation*, 637 F.3d at 411. Indeed, the Circuit has previously noted that an argument that "final agency action . . . requires the completion of a full enforcement action" is "mistaken." *Id.* at 413. And in a recent case the Supreme Court found that a pre-enforcement compliance order issued by the EPA was immediately subject to challenge under the APA even though the EPA had taken no steps to actually enforce that order. *See Sackett*, 132 S. Ct. at 1371; *see also Bimini Superfast Operations LLC v. Winkowski*, 994 F. Supp. 2d 106, 114 (D.D.C. 2014) (discussing *Sackett*). Admittedly, interpretive rules, guidance policies, and other general agency statements that lack the force of law "generally do not qualify" as a final agency action. *Am. Tort Reform Ass'n v. Occupational Safety & Health Admin.*, 738 F.3d 387, 395 (D.C. Cir. 2013). But, "an agency's other pronouncements"—beyond legislative rules—"can, as a practical matter, have a binding effect" which contributes to a finding that the action is "final." *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1021, 1022 (D.C. Cir. 2000); *cf. Barrick Goldstrike Mines Inc. v. Browner*, 215 F.3d 45, 48 (D.C. Cir. 2000) ("That the issuance of a guideline or guidance may constitute final agency action has been settled in this circuit for many years."). Indeed, the D.C. Circuit and this Court have identified exceptions—and have done so specifically in cases, like the one here, where the agency issued a rule, guidance document, or letter setting forth its view of the law and threatening enforcement if the regulated entity did not comply. *See, e.g.*, *Barrick*, 215 F.3d at 49; *CSI Aviation*, 637 F.3d at 412; *Bimini Superfast*, 994 F. Supp. 2d at 114–18; *cf. Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 452 F.3d 798, 807 (D.C. Cir. 2006) (noting that

finality can exist "when an agency merely threatens enforcement of a [policy guideline], if the guideline is binding on its face or in practice").

To be sure, in some cases, including those that HHS relies upon, an agency's pre-enforcement activity will be deemed non-final. *See* Defs.' Mem. Supp. Summ. J. at 15–16 (citing, *e.g.*, *Reliable Automatic Sprinkler*, 324 F.3d at 732). These conflicting decisions merely confirm that whether an agency's pre-enforcement action is subject to judicial review "varies based on the circumstances." *CSI Aviation*, 637 F.3d at 414 n.2. Contrary to the agency's position, however, interpretive rules or other pronouncements setting forth an agency's reading of a statute are not categorically insulated from review before a specific enforcement proceeding has commenced. *See, e.g.*, *Appalachian Power Co.*, 208 F.3d at 1023 ("[T]he Guidance, insofar as relevant here, is final agency action, reflecting a settled agency position which has legal consequences both for State agencies administering their permit programs and for companies."); *see also Sackett*, 132 S. Ct. at 1371.

One recent D.C. Circuit case concluding that an agency's pre-enforcement resolution of a question of statutory interpretation constituted a final agency action is particularly instructive here. In *CSI Aviation Services, Inc. v. United States Department of Transportation*, the Circuit considered whether a Department of Transportation ("DOT") cease-and-desist letter, issued in advance of any enforcement action, was subject to judicial review. *See* 637 F.3d at 410. The petitioner, CSI Aviation Services, Inc., had contracted with the General Services Administration ("GSA") to provide air-charter services for federal agencies. *Id.* Shortly before CSI prevailed in a bid to renew its contract with the GSA, the DOT requested information from CSI "to determine whether the company was engaging in 'indirect air transportation' without the certificate of authority required by the Federal Aviation Act." *Id.* (citing 49 U.S.C. § 41101(a)). After

considering the information CSI had presented, DOT informed CSI that "CSI has been acting as an unauthorized indirect air carrier in violation of section 41101," that the company faced "civil penalties of up to $27,500 per violation," that "[e]ach day such violation continues is a separate violation," and, finally, that the DOT would "refrain from taking enforcement action" if CSI "cease[d] and desist[ed] from any further activity that would result in it engaging in indirect air transportation." *Id.* Although six other companies had received similar letters, only CSI chose not to comply with the letter and challenged the agency's interpretation of the Federal Aviation Act. *Id.* At the time the case was before the D.C. Circuit, DOT had granted CSI a temporary, time-limited exemption from the certification requirement and had not yet pursued an enforcement action. *Id.* at 411.

The Circuit began its analysis by noting that the Supreme Court's decision in *Bennett* "does not foreclose all pre-enforcement challenges." *Id.* Instead, and relying on earlier Circuit precedent, the Circuit set forth three specific factors that a court should consider when determining whether a pre-enforcement action constitutes final agency action.[7] *Id.* at 412 (citing

[7] That earlier precedent, *Ciba-Geigy Corp. v. EPA*, was framed in terms of ripeness. *See* 801 F.2d at 434. The D.C. Circuit has since held that the question of whether an agency's action is a final one requires an analysis "complementary" to a ripeness inquiry. *See, e.g.*, *Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131, 1137 (D.C. Cir. 2010); *CSI Aviation*, 637 F.3d at 411. For that reason, and as the Circuit has done, the Court uses the caselaw relative to both issues to inform its analysis. *See, e.g.*, *Reckitt Benckiser*, 613 F.3d at 1137.

At the same time, and although finality and ripeness overlap considerably, the questions remain distinct. *See, e.g.*, *Barrick*, 215 F.3d at 47–49 (analyzing "final agency action" and "ripeness" separately). For example, even if an agency action is "'final' for purposes of the APA . . . issues still may not be fit for review where the agency retains considerable discretion to apply the new rule on a case-by-case basis, particularly where there is a complex statutory scheme or there are other difficult legal issues that are implicated by the agency action." *Sprint Corp. v. FCC*, 331 F.3d 952, 956 (D.C. Cir. 2003). In this case, the government has not argued that the issues are not ripe for adjudication even if the Court concludes that the Interpretive Rule is a final one. To the extent that ripeness is a jurisdictional requirement, however—and the Court therefore has a duty to consider it *sua sponte*, *cf. Nat'l Park Hospitality Ass'n v. Dep't of Interior*, 538 U.S. 803, 808 (2003) (noting that "the question of ripeness may be considered on a

Ciba-Geigy Corp., 801 F.2d at 435–37). First, a court should ask whether "the agency had taken a 'definitive' legal position concerning its statutory authority." *Id.* (quoting *Ciba-Geigy Corp.*, 801 F.2d at 436). Second the court should consider whether "the case present[s] 'a purely legal' question of 'statutory interpretation.'" *Id.* (quoting *Ciba-Geigy Corp.*, 801 F.2d at 435). Finally, a court should determine whether the agency's action "impose[s] an immediate and significant practical burden on [the regulated entity]." *Id.* (citing *Ciba-Geigy Corp.*, 801 F.2d at 437); *see also Bimini Superfast*, 994 F. Supp. 2d at 118 (invoking the *CSI Aviation* test).

The D.C. Circuit concluded that all three factors were present. DOT's initial warning letter had "declared in no uncertain terms" that CSI was not in compliance with the Federal Aviation Act, and "gave no indication that it was subject to further agency consideration or possible modification." *Id.* at 412 (internal quotation marks and citation omitted). The issue also presented a "purely legal question of statutory interpretation" without the existence of any "disputed facts that would bear on [the] question." *Id.* (internal quotation marks and citation omitted). Finally, the Circuit held that DOT had "effectively declared the company's operations unlawful" which, "[a]t the very least . . . cast a cloud of uncertainty over the viability of CSI's ongoing business." *Id.* DOT's cease and desist letter "put the company to the painful choice between costly compliance and the risk of prosecution at an uncertain point in the future." *Id.* As the Circuit explained, that "conundrum" is "'the very dilemma [the Supreme Court has

---

court's own motion")—the Court concludes that HHS's Interpretive Rule is ripe for review, and that judicial intervention would not "inappropriately interfere with further administrative action," *Ohio Forestry Ass'n, Inc. v. Sierra Club*, 523 U.S. 726, 733 (1998). This challenge is ripe both because the Interpretive Rule presents a purely legal question of statutory interpretation, and would therefore not benefit from a more concrete setting, and, as explained below, because the rule also poses a "hardship to the parties of withholding court consideration." *See Nat'l Park Hospitality Ass'n*, 538 U.S. at 808; *see also Reckitt Benckiser*, 613 F.3d at 1137; *Barrick*, 215 F.3d at 49.

found] sufficient to warrant judicial review.'" *Id.* (alteration in original) (quoting *Ciba-Geigy*, 801 F.2d at 439).

In this case, the Court concludes that all three *CSI Aviation* factors are met and that HHS's Interpretive Rule similarly represents a definitive and purely legal determination that puts pharmaceutical manufacturers to the painful choice of complying with HHS's interpretation or risking the possibility of an enforcement action at an uncertain point in the future.

First, given HHS's concession that the Interpretive Rule represents the consummation of the agency's decisionmaking process, the Court has no trouble concluding that the agency has "taken a 'definitive' legal position." *Id.* at 412. The Interpretive Rule itself admits to "no ambiguity" and provides no indication that it is "subject to further agency consideration." *Id.* (quoting *Ciba-Geigy*, 801 F.2d at 436–37); *see also* A.R. 680–86. The enforcement letters sent to manufacturers also indicate as much. Those letters state that a manufacturer who has not offered orphan-designated drugs at the 340B price when those drugs are not used to treat a rare condition or disease "*is out of compliance with statutory requirements*" and "*[is] violating* section 340B(a)(1) of the PHSA." First Am. Compl. Ex. E (emphasis added). The D.C. Circuit has found similar wording in pre-enforcement letters definitive. *See, e.g.*, *CSI Aviation*, 637 F.3d at 412; *Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131, 1138 (D.C. Cir. 2010) (holding that EPA's interpretation of statute, as contained in a pre-enforcement letter, was sufficiently final where the letter "unequivocally informed" the party that its products "*would be considered misbranded*" under the statute (emphasis in original)).

Second, the Interpretive Rule clearly raises a pure question of statutory interpretation. The rule supplies HHS's reading of the statute as applied to all manufacturers that produce drugs

with an orphan designation.[8] There is nothing to indicate that the administrative record produced during a specific enforcement proceeding would change HHS's legal interpretation. *See Bimini Superfast*, 994 F. Supp. 2d at 117 (holding that a Customs and Border Protection letter detailing the agency's interpretation of the Immigration and Nationality Act constituted final agency action where "[t]here is no indication that any such enforcement process would change CBP's legal position or require that an agency record be developed given the purely legal nature of CBP's position").

Third—and most vigorously contested by the parties—the Court finds that the Interpretive Rule imposes a significant burden on pharmaceutical manufacturers and other regulated entities alike. As an initial matter, HHS claims that the Interpretive Rule, itself, "does not alter the legal obligations of the program participants" and that the rule has no legal force "independent of any binding effect that the statute itself may have." Defs.' Mem. Supp. Summ. J. at 12–13. HHS repeatedly argues that the *statute*—and not the Interpretive Rule, itself—is binding on the parties. But this purported distinction is a hollow one without any meaningful difference. By virtue of the definitive interpretation the agency has settled on, as far as the agency is concerned the Interpretive Rule and the statutory requirements are one in the same. Indeed, the agency's letters to manufacturers indicate that HHS believes entities are "out of

[8] For this reason the Interpretive Rule and HHS's follow-on letters here are also distinct from those in the cases HHS cites in its reply, in which courts found no final agency action. *See* Defs.' Reply at 10–11. For example, in *Center for Auto Safety*, the D.C. Circuit noted that the agency's guidelines regarding the legality of regional automobile recalls was "conditional" and that the "agency remain[ed] free to exercise discretion in assessing proposed recalls" on a case-by-case basis. 452 F.3d at 809; *see also Reliable Automatic Sprinkler*, 324 F.3d at 734 (finding nonfinal action where "the agency has made it clear that the interpretation of 'consumer product' with respect to sprinkler heads *remains to be determined*" (emphasis added)). By contrast here, as in *CSI Aviation*, HHS's Interpretive Rule concerns only the meaning of section 340B(e), "which is antecedent to and distinct from whether [any manufacturer] has violated the law." 637 F.3d at 412.

compliance *with statutory requirements* as described in HRSA's interpretive rule" when they fail to offer orphan-designated drugs used to treat other conditions at section 340B prices. First Am. Compl. Ex. E (emphasis added). And on its website HRSA further notes that "[a] manufacturer or covered entity's failure to comply *with the statutory requirements* could subject a manufacturer or covered entity to an enforcement action by HRSA, which could include refunds to covered entities in the case of overcharges, as well as termination of a manufacturer's Pharmaceutical Pricing Agreement (PPA)." *See* First Am. Compl. Ex. D (emphasis added).

Accordingly, HHS's reliance on those cases in which "an agency merely expresses its view of what the law requires of a party" is misplaced. *See* Defs.' Mem. Supp. Summ. J. at 17 (quoting *Ctr. for Auto Safety*, 452 F.3d at 808); *see also id.* at 13–14. Even those cases acknowledge that there are "particular circumstances in which an agency's taking a legal position itself inflicts injury or forces a party to change its behavior, such that taking that position may be deemed final agency action." *AT&T Co. v. EEOC*, 270 F.3d 973, 975–76 (D.C. Cir. 2006); *see also Ctr. for Auto Safety*, 452 F.3d at 808. The Interpretive Rule very clearly requires pharmaceutical manufacturers and covered entities alike to change their behavior in a not insignificant way.

HHS's claim that the rule "does not independently impose any obligations on the program participants," Defs.' Reply at 6, is particularly unpersuasive in light of the new tracking and monitoring obligations that the Interpretive Rule explicitly mandates. As the Court previously acknowledged, HHS's rule "imposes duties on the covered entities to maintain records of compliance." *PhRMA*, 43 F. Supp. 3d at 33. The vacated final rule specifically required covered entities to "ensur[e] that any orphan drugs purchased through the 340B Program are not transferred, prescribed, sold, or otherwise used for the rare condition or disease

for which the orphan drugs are designated under section 526 of the FFDCA." 42 C.F.R. § 10.21(c)(1). Pursuant to its Interpretive Rule, HHS has now imposed identical duties. HHS explained that it "will publish a listing of orphan drug designations, providing the name of the drug and the designation indication" on "the first day of the month prior to the end of the calendar quarter." A.R. 685. The Rule further cautions that, "[i]f a covered entity lacks the ability to track drug use by indication, such entity would be unable to purchase drugs with orphan designations through the 350B program." *Id.*

Whether to comply with the Interpretive Rule presents pharmaceutical manufacturers, too, with a "painful choice between costly compliance and the risk of prosecution at an uncertain point in the future" similar to the choice faced by the petitioner in *CSI Aviation*. 637 F.3d at 412. That choice is "costly" in at least three ways. First, and quite obviously, under the agency's interpretation of the statute, pharmaceutical manufacturers will be required to sell orphan drugs at reduced prices when covered entities use those drugs to treat ailments other than the rare disease or condition for which they have been designated. Those losses themselves impose a financial cost.

There is also evidence that implementing the Interpretive Rule will have a "direct effect" on pharmaceutical manufacturers' "day-to-day business." *Reckitt Benckiser*, 613 F.3d at 1138 (quoting *Abbott Labs*, 387 U.S. at 152). Various pharmaceutical company officials have submitted sworn declarations representing that, to determine whether covered entities are in fact using orphan-designated drugs to treat non-rare conditions, their companies must "make changes to [their] own accounting, contracting and government price reporting systems and require the wholesaler[s] through whom [they] sell [their] 340B drugs to make changes to their tracking system." *See* Am. Decl. of Derek L. Asay ¶ 9, *PhRMA*, No. 1:13-cv-1501-RC (D.D.C. Oct. 22,

2013), ECF No. 15; *see also* Decl. of Paul Maillet, ¶¶ 8–9, *PhRMA*, No. 1:13-cv-1501-RC (D.D.C. Sept. 30, 2013), ECF. No. 3–6; Decl. of Pfizer Inc. ¶ 9, *PhRMA*, No. 1:13-cv-1501-RC (D.D.C. Oct. 1, 2013), ECF. No. 11. Those officials have further alleged that they will be forced to increase their auditing and monitoring expenditures to implement those changes.[9] *See, e.g.*, Decl. of Paul Maillet ¶¶ 8–9. The D.C. Circuit has found similar requirements that a regulated entity track its business activities sufficient to constitute an immediate and significant burden on a regulated entity. *See, e.g.*, *Reckitt Benckiser*, 613 F.3d at 1138 (finding hardship where "sworn declarations by company officials" showed that "the company has been forced to spend hundreds of thousands of dollars on research and development of []compliant products" and expected to incur "an additional one million dollars to conclude development"); *Barrick Goldstrike*, 215 F.3d at 48 (noting that agency's guidance extending application of the Emergency Planning and Community Right-to-Know Act to the metal mining industry had "legal consequences" because the plaintiff was now "bound to keep track of its movements of waste rock and report the movements as releases of toxic substances").

Most tellingly, however, is the fact that HHS contends that failure to comply with the statutory requirements—as interpreted by its Interpretive Rule—will expose manufacturers to significant penalties in future enforcement proceedings. *Sackett*, 132 S. Ct. at 1372 (noting that pre-enforcement compliance order exposed the petitioners "to double penalties in a future enforcement proceeding"). Under section 340B, manufacturers must refund covered entities if

[9] These declarations refute HHS's claim that "Plaintiff has not offered any detail of the 'significant changes' they are required to make in their daily 'business practices.'" Defs.' Reply at 6. Moreover, they refute HHS's comparison to the Department of Labor's compliance letters in *Rhea Lana, Inc. v. U.S. Dep't of Labor*, which another judge on this Court concluded did not constitute final agency action because the letters "[did] not affirmatively compel Rhea Lana to do anything." 74 F. Supp. 3d 240, 245 (D.D.C. 2014), *appeal docketed*, No. 15-5014 (D.C. Cir. Jan. 21, 2015); *see* Defs.' Reply at 10–11.

they have charged more than the ceiling price and HHS has instructed manufacturers to "notify HRSA of [their] plan[s] to repay affected covered entities." First Am. Compl. Ex. E. In addition, the statute provides for a civil monetary penalty of up to $5,000 "for each instance of overcharging a covered entity that may have occurred." 42 U.S.C. § 256b(d)(1)(B)(vi)(II). A manufacturer's Pharmaceutical Pricing Agreement may also be cancelled altogether, which PhRMA represents, and HHS has not refuted, would result in a "loss of Medicaid and Medicare Part B reimbursement for all of the manufacturer's products." Pl.'s Mem. Opp. Summ. J. at 16; *see also* Def.'s Mem. Summ. J. at 4 ("The manufacturers must enter into such agreements as a condition of receiving reimbursement from Medicaid."); *Astra*, 131 S. Ct. at 1345 ("Manufacturers' eligibility to participate in state Medicaid programs is conditioned on their entry into PPAs for covered drugs purchased by 340B entities.").

These penalties impose a particularly acute burden in this case because, at present, manufacturers have no meaningful recourse to dispute HHS's reading of section 340B(e) or to avoid the continued accumulation of potential liability. HHS is now five years overdue in complying with Congress's mandate that it set up an administrative dispute resolution process within 180 days of the ACA's passage. HHS has maintained only that "[f]uture rulemaking" will address the dispute resolution process. 340B Drug Pricing Omnibus Guidance, 80 Fed. Reg. at 52,301. And although that process, as envisioned by Congress, would appear to allow a manufacturer to initiate proceedings, *see* 42 U.S.C. § 256b(d)(3)(A) (instructing HHS to develop a process to resolve "claims by manufacturers"), until that system is implemented manufacturers

are left without any remedy. "[E]ach day they wait for the agency to drop the hammer, they accrue" significant penalties. *Sackett*, 132 S. Ct. at 1372.[10]

In an effort to brush aside these very real consequences, HHS claims that they represent merely *practical*, not *legal*, effects and obligations. But the concept of "[f]inality resulting from the practical effect of an ostensibly non-binding agency proclamation is a concept" the D.C. Circuit "ha[s] recognized." *Nat'l Ass'n of Home Builders v. Norton*, 415 F.3d 9, 15 (D.C. Cir. 2005). Indeed, *CSI Aviation* spoke only of whether the DOT's action there "imposed an immediate and significant *practical burden*" on the regulated entity. 637 F.3d at 412 (emphasis added). Therefore, regardless of classification, the burdens posed by HHS's Interpretive Rule here are sufficiently significant to rise to the level of a final agency action.[11]

Ultimately, the Court finds that this case is in line with *CSI Aviation* and far afield from those cases in which an agency's guidance was "conditional," had not "commanded, required, ordered, or dictated" any specific action, or merely presented entities with the option of

---

[10] To state a claim the APA also requires that the party seeking review have "no other adequate remedy in a court." 5 U.S.C. § 704; *see also Sackett*, 132 S. Ct. at 1372. HHS has not argued that PhRMA's claim is non-actionable on this ground; in fact, neither party addresses the point. In any event, because there is currently no other mechanism—following an enforcement proceeding or otherwise—for PhRMA to seek review of the Interpretive Rule, the Court concludes that PhRMA and the pharmaceutical manufacturers it represents lack an adequate alternative remedy. *Cf. Sackett*, 132 S. Ct. at 1372; *accord Bimini Superfast*, 994 F. Supp. 2d at 117 n.4.

[11] At least one D.C. Circuit case seems to reject unequivocally, as inconsistent with *Bennett*, the argument that practical consequences suffice to present a final agency action. *See Ctr. for Auto Safety*, 452 F.3d at 811. As an initial matter, the Court has some doubt that the civil monetary penalties and the threat of the pricing agreement cancelation that manufacturers face here could be properly classified as "practical" and not "legal" burdens. But, regardless, more recent D.C. Circuit caselaw speaks of practical burdens, alone. Moreover, as an astute decision by another member of this Court recently pointed out, *Bennett* in fact speaks in the alternative and states that final agency actions are those from which "'rights or obligations have been determined' *or* from which 'legal consequences flow.'" *Bimini Superfast*, 994 F. Supp. 2d at 114 n.3 (emphasis in original) (quoting *Bennett*, 520 U.S. at 177–78). Therefore, this Court does not view the consideration of practical burdens as conflicting with *Bennett*'s holding.

voluntary compliance. *See Ctr. for Auto Safety*, 452 F.3d at 809. Thus, HHS's attempt to distinguish *CSI Aviation* by arguing that its action "lacks the legal consequences that the order in *CSI Aviation Services* had," is unpersuasive.[12] Defs.' Reply at 7–8. "'[A]n agency may not avoid judicial review merely by choosing the form of a letter," or a purportedly non-binding Interpretive Rule, "to express its definitive position on a general question of statutory interpretation.'" *CSI Aviation*, 637 F.3d at 412 (quoting *Ciba-Geigy*, 801 F.2d at 438 n.9). Instead, a constellation of factors counsels in favor of finding a final agency action here: HHS's Interpretive Rule presents a pure question of statutory interpretation; the Interpretive Rule requires both covered entities and pharmaceutical manufacturers alike to make significant changes to their business practices; despite HHS's urging that manufacturers' wait until a formal enforcement proceeding is initiated to challenge the Interpretive Rule, there currently exists no formal dispute resolution mechanism and the timing of future rulemaking remains undetermined; and HHS has informed manufacturers that it considers those who do not adopt its Interpretive Rule out of compliance with the statute—accruing potential penalties until such time as HHS chooses to take action. "Having thus flexed its regulatory muscle, [HHS] cannot now evade judicial review." *CSI Aviation*, 637 F.3d at 413. Accordingly, the Court concludes that the Interpretive Rule constitutes final agency action within the ambit of 5 U.S.C. § 704.

[12] HHS also argues that *Ciba-Geigy* is distinguishable because it involved a process-based injury (the EPA there had contended that it could cancel the petitioner's pesticide registration without notice and a hearing, *see* 801 F.2d at 433) and that, unlike the petitioner there, pharmaceutical manufacturers here can make their case in a future enforcement proceeding. *See* Defs.' Reply at 8. As just explained, however, the possibility of an enforcement proceeding is currently a hollow one. And, in any event, in *CSI Aviation* the Circuit did not find the substantive, non-procedural-based ground for review raised there any less final at a pre-enforcement stage. *See* 637 F.3d at 412.

B. The Validity of HHS's Interpretive Rule

The Court thus proceeds to determine whether HHS's Interpretive Rule is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *See* 5 U.S.C. § 706(2)(A). Resolution of this question turns on the interpretation of section 340B(e). The interpretation of an administrative agency's guiding statute typically "follows a two-step process." *PhRMA*, 43 F. Supp. 3d at 35. "First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984). However, if "Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction of the statute, as would be necessary in the absence of an administrative interpretation." *Id.* at 843 (footnote omitted). In this latter situation, a court instead proceeds to step two of the *Chevron* framework: "[I]f the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id.* "[A] court may not substitute its own construction of a statutory provision for a reasonable interpretation by the administrator of an agency." *Id.* at 844.

Yet, deference in the face of a silent or ambiguous statute under *Chevron* "is warranted *only* 'when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority.'" *Gonzales*, 546 U.S. at 255–56 (emphasis in original) (quoting *Mead Corp.*, 533 U.S. at 226–27). As this Court previously held, HHS was not delegated authority to make binding rules that carry the force of law related to section 340B(e). *See*

PhRMA, 43 F. Supp. 3d at 45. Thus, if the Court does find an ambiguity, HHS's interpretation "does not receive *Chevron* deference," but instead "receives deference only in accordance with *Skidmore*" and the Court will "follow [the] agency's rule only to the extent it is persuasive." *Gonzales*, 546 U.S. at 268, 269. In either event, however, "it is elementary that 'no deference is due to agency interpretations at odds with the plain language of the statute itself.'" *Smith v. City of Jackson, Miss.*, 544 U.S. 228, 266 (2005) (quoting *Pub. Emps. Ret. Sys. of Ohio v. Betts*, 492 U.S. 158, 171 (1989)). As explained below, the Court concludes that HHS's interpretation here is contrary to the plain language of section 340B(e).[13]

The Court starts, as it must, with the text of section 340B(e) which provides:

> (e) Exclusion of orphan drugs for certain covered entities
>
> For covered entities described in subparagraph (M) (other than a children's hospital described in subparagraph (M)), (N), or (O) of subsection (a)(4), the term "covered outpatient drug" *shall not include a drug designated by the Secretary under section 360bb of Title 21 for a rare disease or condition.*

42 U.S.C. § 256b(e) (emphasis added). By its plain terms, the orphan drug exclusion applies to a drug that is "designated . . . for a rare disease or condition." The section refers only to the *designation* of that drug, and makes no mention of whether the so-designated drug is in fact *used* by the covered entity to treat the rare disease or condition for which it was designated. This choice of language is informative; as HHS, itself notes, and as FDA regulations make clear, a drug can be *designated* as an orphan drug even if that drug has uses—or has previously been

[13] HHS argues that if the Interpretive Rule "has enough legal effect to be final agency action, then it has enough effect to be entitled to *Chevron* deference as well." Defs.' Mem. Supp. Summ. J. at 18 n.1. Not so. As explained above, even non-legislative rules like interpretive rules or guidance policies may be classified as a final agency action in circumstances like these. But that conclusion does not alter Congress's delegation of authority. In any event, even were *Chevron* deference appropriate here, because the Court's conclusion rests on the plain language of section 340B(e), HHS's interpretation would nevertheless fail at *Chevron* step one. *Smith*, 544 U.S. at 266.

approved and marketed—to treat conditions that are not rare ones. *See* Exclusion of Orphan Drugs, 78 Fed. Reg. at 44,017 ("FDA will designate a drug for a rare disease or condition as an orphan drug in situations where the drug is also approved for a different disease or condition that does not qualify for such a designation."); 21 C.F.R. § 316.23(b) ("A sponsor may request orphan-drug designation of an already approved drug for an unapproved use without regard to whether the prior marketing approval was for a rare disease or condition").

To support its reading of the exclusion as tied to the drug's *use*, HHS places controlling weight on the phrase "for a rare disease or condition." According to HHS, that phrase "effectively limits the scope of the exclusion," because it modifies the word "drug" and therefore already "convey[s] [a] meaning" cabined to a drug's particular "uses or indications." Defs.' Reply at 12–13; *see also* Defs.' Mem. Supp. Summ. J. at 19–20.

While HHS's reading might appear plausible at first glance, and when confined solely to section 340B(e), "[w]hen interpreting a statute, we examine related provisions in other parts of the U.S. Code." *Boumediene v. Bush*, 553 U.S. 723, 776 (2008). When one reads the statute in the context of its related provisions, it becomes clear that HHS's interpretation runs counter to the way Congress has used the phrase "a drug designated . . . for a rare disease or condition" or similar wording throughout the U.S. Code. In each case, although Congress refers to a drug "for a rare disease or condition" or a drug so "designated," Congress has added *additional* language to specify that the provision's applicability is limited to occasions when that designated drug is actually used to treat the rare disease or condition.

A typical example is 42 U.S.C. § 1395*l*(t)(6)(A)(i). That statute, part of the Medicaid program, provides for prospective, pass-through payments of certain drugs and medical devices. The statute limits the payments for "[c]urrent orphan drugs," however, to "[a] drug or biological

that is used for a rare disease or condition with respect to which the drug or biological *has been designated as an orphan drug* under section 360bb of Title 21 . . . ." 42 U.S.C. § 1395*l*(t)(6)(A)(i). Like section 340B(e), this section specifies that it applies only to a drug that has been designated under 21 U.S.C. § 360bb. *Compare id.* (applying to a "drug or biological . . . designated as an orphan drug under section 360bb of Title 21"), *with* 42 U.S.C. § 256b(e) (applying to "a drug designated by the Secretary under section 360bb of Title 21 for a rare disease or condition"). Unlike section 340B(e), however, the section *further specifies* that the benefit is only available for those drugs when "*used* for a rare disease or condition" for which it has been designated. 42 U.S.C. § 1395*l*(t)(6)(A)(i) (emphasis added).

It is a "cardinal principle of statutory construction that we must give effect, if possible, to every clause and word of a statute." *Williams v. Taylor*, 529 U.S. 362, 404 (2000) (internal quotation marks and citation omitted). In section 1395*l*, the negative implication from Congress's use of further qualifying language is that Congress's use of the phrase "designated as an orphan drug under section 360bb of Title 21," alone, would have not have cabined the provision's scope to *only* those pass-through payments for drugs when used to treat the rare disease or condition but would have applied, more generally, to all of the "designated" orphan drug's uses—rare or otherwise. Otherwise, the additional language providing that the provision applies to a drug "that is used for a rare disease or condition" for which it has been designated is unnecessary surplusage.

Other examples abound. Consider 21 U.S.C. § 379h(a)(1)(F), which exempts a "human drug application for a prescription drug product that has been designated *as a drug for a rare disease or condition*" from the fees typically assessed for such applications. (Emphasis added). According to the subsection, the exception applies "*unless* the human drug application *includes*

an indication for other than a rare disease or condition." 21 U.S.C. § 379h(a)(1)(F) (emphasis added). This subsection includes both the language "designated as a drug for a rare disease or condition" and the further qualification that the application must pertain solely to indications for that rare disease or condition. Again, if a prescription drug product "designated as a drug for a rare disease or condition" by definition only described that drug product when used to treat those rare diseases or conditions, Congress would not have needed to specify that the provision does not apply when that drug product's alternative indications are included.

Similar in scope is 26 U.S.C. § 45C—entitled "Clinical testing expense for certain drugs for rare disease or conditions"—which provides a tax credit for the clinical testing expenses incurred during the orphan drug's development. The statute specifies that the credit applies to clinical testing "for a drug being tested for a rare disease or condition" and must occur "after the date such drug is designated under section 526 of [the Federal Food, Drug, and Cosmetic Act]." 26 U.S.C. §§ 45C(b)(2)(A)(i), (ii)(I). But the statute goes on to specify that clinical testing should be taken into account "only to the extent such testing is related to *the use of a drug for the rare disease or condition for which it was designated* under section 526 of the Federal Food, Drug, and Cosmetic Act." *Id.* § 45C(b)(2)(B) (emphasis added).[14]

[14] Another section of the ACA, in which section 340B(e) was enacted, is also informative. Although the Supreme Court has cautioned that the ACA "does not reflect the type of care and deliberation that one might expect of such significant legislation," *King v. Burwell*, 135 S. Ct. 2480, 2492 (2015), it is nevertheless telling that Congress *did* add use- or indication-limiting language elsewhere in the ACA when referring to certain benefits that apply to orphan-designated drugs. Section 9008(b), which applies an excise tax to branded prescription drugs, exempts orphan drugs until "the date on which such drug or biological product is approved . . . for marketing for *any indication other than the treatment of the rare disease or condition* with respect to which [the section 45C tax credit] was allowed." *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 9008(e)(3), 124 Stat. 119, 860 (Mar. 23, 2010) (emphasis added). Generally, Congress "acts intentionally when it uses particular language in one section of a statute but omits it in another." *Dep't of Homeland Sec. v. MacLean*, 135 S. Ct. 913, 919 (2015) (citing *Russello v. United States*, 464 U.S. 16, 23 (1983)).

To be sure, each of these statutes varies slightly in its exact wording; some refer to drugs "designated . . . for a rare disease or condition" while others refer to drugs "designated as an orphan drug." Yet, together, these provisions indicate that Congress knows how to add an additional use- or indication-based limitation when referring to a drug that has received an orphan designation. *Cf. Dep't of Homeland Sec. v. MacLean*, 135 S. Ct. 913, 921 (2015) (referencing other federal statutes demonstrating that Congress "knew how to distinguish between regulations that had the force and effect of law and those that did not"); *Dole Food Co. v. Patrickson*, 538 U.S. 468, 476 (2003) (finding it instructive that the statute at issue referred only to "ownership" while "[v]arious federal statutes refer to 'direct and indirect ownership'" as demonstrating that "[w]here Congress intends to refer to ownership in other than the formal sense, it knows how to do so"). Each provision contains use- or indication-limiting language, suggesting that Congress must typically intend for the term "designated . . . for a rare disease or condition" to have a more general meaning when used alone. That Congress by contrast used only the general phrase "designated . . . to treat a rare condition or disease" in section 340B(e), implies that it must have meant to refer to that designated drug in all of its uses and indications.

HHS has not pointed the Court to a single provision in the U.S. Code that appears to use the language "designated . . . for a rare disease or condition," alone, in the use-limiting way that it argues section 340B(e) should be read. And HHS's response that the comparison provisions just discussed "are too remote in time and location to cast any illuminating light on the congressional intent behind the language chosen for" section 340B(e) simply does not withstand scrutiny. Defs.' Reply at 17. These related provisions are some of the *very same* benefit-providing provisions with which HHS claims its own interpretation is meant to accord. *See* A.R. 682–83 (citing 21 U.S.C. § 379h(a)(1)(F); 26 U.S.C. § 45C) Defs.' Mem. Sup. Summ. J. at 20–

21. But, far from evidencing consistency, the differing language of those related provisions demonstrates that Congress must have had a different intent in mind when it drafted section 340B(e).[15] These provisions, moreover, refute HHS's contention that when "drugs are used for common diseases, they are not formally categorized or considered 'orphan-designated drugs' and it would be a mistake to classify them as such." Defs.' Reply at 12. Congress's addition of qualifying language indicates that it believes reference to a drug's orphan designation, alone, would refer to the drug, generally, irrespective of the specific use.[16]

HHS is correct to note that the general statutory "incentive[s] associated with the orphan-designated drug applies only to the orphan indication, and not to non-orphan indications." Defs.' Mem. Support. Summ. J. at 20. But, the language of section 340B(e) does not indicate whether the newly added entities' inability to access orphan-designated drugs at 340B Program prices was intended to serve as an additional benefit meant to flow to the manufacturers of those drugs, or simply as a compromised-limitation on the reach of the newly expanded program. Indeed, the Court takes notes that the orphan-drug exclusion pertains *only* to the newly added entities. Section 340B(e) continues to allow pre-existing entities—or those enumerated in subsections (A) through (L) plus children's hospitals—to access orphan-designated drugs at section 340B prices

[15] PhRMA also points to section 340B(e)'s heading. While "section headings are tools available for the resolution of a doubt about the meaning of the statute," *Fla. Dep't of Revenue v. Piccadilly Cafeterias, Inc.*, 554 U.S. 33, 47 (2008) (internal quotation marks and citation omitted), the Court does not find section 340B(e)'s heading particularly informative here. The section's heading refers generally to "orphan drugs." Contrary to PhRMA's argument, however, other subsections in the U.S. Code similarly refer generally to an "orphan drug" without specifying usage, even when the actual text of that provision includes a use-based limitation. *See* 21 U.S.C. § 379h(a)(1)(F) ("Exception for designated orphan drug or indication").

[16] The Court does agree with HHS that the statute's cross reference to section 360bb (regarding the designation process) rather than section 360cc (regarding the marking process) is not conclusive. As HHS points out, "use" is not synonymous with "marketing" and drugs may be lawfully prescribed to treat conditions for which they have not been approved for marketing. Defs.' Reply. at 13–14.

even when used to treat a rare disease or condition. That result is an odd one if Congress intended for the orphan drug exclusion to operate as an additional incentive for drug manufacturers to develop orphan drugs, and therefore conflicts to some extent with HHS's characterization of section 340B(e) as intended in some way to preserve the Orphan Drug Act's incentives.

Neither party has identified any contemporaneous legislative history that bears on the purpose behind, or rationale for, section 340B(e).[17] After undertaking its own review, the Court has found none, either. HHS cites only to the *general* stated purpose for the 340B Program: "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." *See* H.R. Rep. No. 102-384, pt. 2, at 12 (1992). But that legislative history is drawn from the program's initial passage *in 1992*. That far earlier proclamation sheds little light on the specific reasoning of Congress *in 2010* when it passed section 340B(e). The Court fails to see how it persuasively supports HHS's contention that in 2010 Congress specifically intended for "section 340B(e) to balance the interests of orphan drug development and the expansion of the 340B Program to new entities." A.R. 684. Moreover, while it is beyond dispute that the 340B Program is intended to ensure access to drugs at a reduced cost for certain entities and in certain circumstances, the acknowledgement that the

[17] Both of the amicus briefs filed in this case point to a post-enactment letter from Congressman Henry Waxman and Congressman Tom Harkin which states that "HRSA's interpretation of [section 340B(e)] is consistent with legislative intent." *See* A.R. 335–36; *see also* Brief of the American Hospital Association as Amicus Curiae at 17, ECF No. 19; Amicus Curiae Brief of the Safety Net Hospitals for Pharmaceutical Access, *et al.* at 17–18, ECF No. 20. Neither brief identifies any contemporaneous statements made to that effect while Congress was considering the ACA, however, and such "post-enactment legislative history" is "inherently entitled to little weight." *Cobell v. Norton*, 428 F.3d 1070, 1075 (D.C. Cir. 2005). Because that letter was written well after the ACA was enacted, the letter is unhelpful here as it "by definition could have had no effect on the congressional vote." *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 242 (2011) (internal quotation marks and citation omitted).

program was meant to "stretch scarce Federal resources" at a general level is of little use in assessing the parties' competing interpretations of the exact balance Congress ultimately settled upon when extending the 340B Program to new entities.[18] It is worth noting that, notwithstanding section 340B(e)'s orphan drug exclusion, by making the newly covered entities eligible to purchase all non-orphan designated drugs at a lower cost, Congress has still placed those entities in a better position than they were in prior to the addition of section 340B(e).

The Court readily acknowledges that the plain meaning of the broad, unqualified language that Congress chose to employ in section 340B(e) is somewhat curious, and might be more difficult to reconcile with the generally-stated goal of the 340B Program.[19] The Court appreciates the views of amici explaining how many orphan-designated drugs have common non-orphan uses and explaining why construing section 340B(e) to apply to all orphan-designated drugs, whatever their uses in a particular case, would make the 340B Program less attractive for many newly covered entities. The Court further concedes that, "[c]ertainly, there

---

[18] For their part, PhRMA points to Congress's decision not to amend the language "designated . . . for a rare disease or condition" in section 340B(e) when it amended that section to remove children's hospitals from the list of excluded entities. Pl.'s Mem. Opp. Summ. J. at 28; *see also* note 2, *supra*. The Court does not find Congress's failure to act conclusive in either direction. Congress's refusal to act may indicate that members of Congress definitively read the statute as the Court does and simply intended to "le[ave] the matter where it was." *Kucana v. Holder*, 558 U.S. 223, 250 (2010). But it may also infer that members of Congress, contrary to what the text seems to indicate but in line with HHS's reading, believed "that the existing legislation already incorporated the offered change." *Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 650 (1990). Given these differing interpretations of Congress's inaction, the Court gleans little from Congress's failure to amend the statute.

[19] At the same time—and cautioning, again, that the parties have not identified and the Court has not found any contemporaneous legislative history directly on point—it is worth pointing out that the 2010 ACA amendment was the first addition of new specifically-enumerated covered entities since the 340B Program's inception in 1992. Congress may have chosen to exclude all orphan-designated drugs from the program for those new entities in an effort to balance the program's significant extension to new covered entities with the impact that extension would have on the prices that pharmaceutical manufacturers' could charge to a large number of newly eligible entities.

may be compelling policy reasons," *Hall v. United States*, 132 S. Ct. 1882, 1893 (2012), for excluding orphan-designated drugs from the section 340B pricing program only when they are used to treat those diseases, particularly in light of Congress's clear effort to expand the 340B Program. "But if Congress intended that result, it did not so provide in the statute." *Id.* Congress's chosen statutory language evidences that it struck a different balance and it is simply "not for [this Court] to rewrite the statute." *Id.* Congress remains free to amend section 340B(e) if it determines that, in practice, the scheme it has set up is not a workable one or does not provide the hoped-for benefits to the extent envisioned. But until Congress does so "this court is bound by the language that Congress has so far provided."[20] *United States v. Singleton*, 182 F.3d 7, 15 (D.C. Cir. 1999); *see also Jerman v. Carlisle, McNellie, Rini, Kramer & Ulrich LPA*, 559 U.S. 573, 604 (2010) (noting that "[t]o the extent Congress is persuaded that the policy concerns identified by the dissent require a recalibration of the [statutory] scheme, it is, of course, free to amend the statute accordingly").

[20] HHS also argues that adopting PhRMA's reading of the statute would "create perverse incentives" and would encourage pharmaceutical manufacturers to seek to designate their best-selling drugs as orphan drugs. Defs.' Reply at 18–19. The Court finds this fear unfounded. FDA regulations already specify that the agency will "refuse to grant a request for orphan-drug designation" if "[t]here is *insufficient information* about the drug, or the disease or condition for which it is intended, *to establish a medically plausible basis for expecting the drug to be effective in the prevention, diagnosis, or treatment of that disease or condition*." 21 C.F.R. § 316.25(a)(2) (emphasis added). Nor does the administrative record appear to support some of the negative consequences that HHS portends. As PhRMA points out, an informal survey undertaken by several advocacy organizations representing hospitals that participate in the 340B Program showed that only 17.2% of entities responding to the survey were "somewhat" or "very" likely to withdraw from the 340B Program if they were unable to access orphan-designated drugs when used to treat non-rare conditions, while 72.9% were "unlikely" to withdraw. A.R. 727. Similarly, only 7.1% of entities that responded to the survey stated that they would not have registered for the program if they had known they were unable to access those drugs at reduced prices; 92.9% responded that they would have registered for the program nonetheless. *Id.*

Because the term "a drug designated . . . for a rare disease or condition" in section 340B(e), as construed with reference to related statutory provisions, unambiguously indicates that Congress intended to exclude all drugs carrying an orphan-designation from 340B Program eligibility for the newly added entities, the Court concludes that HHS's Interpretive Rule is contrary to the plain language of the statute. Accordingly, the Court grants plaintiff's motion for summary judgment and vacates the Interpretive Rule as "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

V. CONCLUSION

For the foregoing reasons, the defendants' motion for summary judgment (ECF No. 14) is **DENIED**, and the plaintiff's motion for summary judgment (ECF No. 21) is **GRANTED**. An order consistent with this Memorandum Opinion is separately and contemporaneously issued.

Dated: October 14, 2015

RUDOLPH CONTRERAS
United States District Judge