IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Plaintiff, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	Civil Action No. 1:14-CV-01685 -RC

DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Defendants United States Department of Health and Human Services ("HHS"), et al, hereby move the Court to enter summary judgment in Defendants' favor pursuant to Rule 56(b) of the Federal Rules of Civil Procedure. Attached in support of this Motion is a Memorandum in Support of Defendants' Motion for Summary Judgment.

Dated: January 27, 2015

Respectfully submitted,

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MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

INTRODUCTION

This case presents a challenge to the legality of an interpretive rule issued by the Department of Health and Human Services (HHS) following this Court's decision in PhRMA v. HHS, No. 13-1501, 2014 WL 2171089 (D.D.C. May 23, 2014), which held that the agency lacked statutory authority to promulgate a legislative rule to implement subsection 340B(e) of the Public Health Service Act ("PHSA"). The legislative rule had provided that the drugs excluded from subsection 340B(e) for the newly-added covered entities are those that "are transferred, prescribed, sold, or otherwise used for the rare condition or disease for which that orphan drug was designated." Administrative Record ("AR") 676. In other words, the newly covered entities may purchase orphan-designated drugs at the discounted price when prescribing or using such drugs to treat a common

disease even if such drugs have also obtained a designation from FDA to treat a rare disease or condition.

Following this Court's vacatur of the legislative rule, HHS did not wish to leave program participants in the dark as to the agency's future interpretation of the statute. Since the Court did not address the validity of the agency's reading of the statute, uncertainty arose as to whether the agency intended to continue with that reading or planned to scuttle it notwithstanding that the Court had avoided addressing its validity. Thus, in accordance with the Administrative Procedure Act, HHS decided to issue the interpretive rule to provide guidance to interested parties that it is adopting essentially the same interpretation going forward, through an interpretive rule that does not have the binding legal effect that the legislative rule had.

Plaintiff Pharmaceutical Research and Manufacturers of America, an association of drug manufacturers, challenges the interpretive rule on the grounds that it incorrectly interprets subsection 340B(e) and runs afoul of the Administrative Procedure Act. Pl.'s Am. Comp. ¶ 5. These claims are without merit.

First, there is no final agency action to review. The interpretive rule merely reflects HHS's view of the meaning of the statutory provision, namely, that it applies only to an orphan-designated drug that is used or prescribed for the orphan indication for which the drug was designated. Granted, the interpretive rule marks the consummation of an agency's decision-making process; but it does not affect the legal rights and obligations of the program participants or have any *legal* effect to constitute a "final agency action" for the purpose of judicial review. The interpretive rule is non-binding; HHS could never bring an enforcement action against program participants to enforce the

rule. In an enforcement action against a drug manufacturer, the agency would enforce the 340B *statute*, not the interpretive rule.

Second, if the Court determines that there is a final agency action, the agency's sensible reading of the statute should be upheld on the merits. Subsection 340B(e) refers to "a drug designated . . . for a rare disease or condition," which is a specific procedure and classification under the Orphan Drug Act. The word "drug" is modified, and, limited, by the phrase "designated . . . for a rare disease or condition." The domain of "rare diseases and conditions" is therefore the critical focus of the statutory provision. Given the many different uses for drugs with an orphan designation and the 340B *statute*'s purpose to enable certain safety net providers to "stretch scare federal resources" to provide "comprehensive services" to their vulnerable patients, the agency's interpretation is consistent with the statute and its objectives. The statute does not compel the reading that plaintiff advances—that the subsection applies to all drugs with an orphan-drug designation even when such drugs are used in contexts unrelated to the orphan disease or condition for which they were designated. HHS's interpretation 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. At the very least, that interpretation merits respect as a cogent administrative interpretation that is entitled to deference under Skidmore v. Swift & Co., 323 U.S. 134 (1944). Consequently, the Court should dismiss plaintiff's Amended Complaint and grant summary judgment for defendants.

BACKGROUND

I. THE 340B PROGRAM

Section 602 of the Veterans Health Care Act of 1992, Pub. L. No. 102-585, 106 Stat. 4943, 4967, created a program under which certain safety net providers that serve the nation's vulnerable patient populations – "covered entities" – can purchase prescription drugs at a discount from drug manufacturers. This drug discounting program is commonly known as the "Section 340B Program," based on its codification within the Public Health Service Act. The program is managed by defendant Health Resources and Services Administration ("HRSA"), a subdivision of defendant HHS. See Health Resources and Services Administration; Statement of Organizations, Functions, and Delegations of Authority, 58 Fed. Reg. 19,137 (Apr. 12, 1993); Astra USA, Inc. v. Santa Clara Cnty., Cal., --- U.S. ---, 131 S. Ct. 1342, 1345 (2011).

Under this program, Congress instructs HHS to enter into pharmaceutical pricing agreements with drug manufacturers of covered outpatient drugs. 42 U.S.C. § 256b(a). The manufacturers must enter into such agreements as a condition of receiving reimbursement from Medicaid. Astra USA, Inc., 131 S. Ct. at 1346. Pursuant to these agreements, the drug manufacturers agree that the prices they charge for covered outpatient drugs to covered entities will not exceed defined "ceiling price[s]," calculated as determined in the statute. 42 U.S.C. § 256b(a)(1). Congress intended for covered entities to use the discount's benefit to provide more comprehensive services to "low-income patients." Univ. Med. Ctr. of S. Nev. Shalala, 173 F.3d 438, 439 (D.C. Cir. 1999).

In 2010, the Patient Protection and Affordable Care Act ("Affordable Care Act") and the Health Care and Education Reconciliation Act ("HCERA") made several changes to the 340B Program. Of relevance here, Section 7101(a) of the Affordable Care Act added several new categories of entities eligible for 340B Program participation. Pub. L. No. 111-148, 124 Stat. 119, 821 (2010). The entity types added to the list of eligible entities listed in Section 340B(a)(4) are children's hospitals and free-standing cancer hospitals (Section 340B(a)(4)(M)), critical access hospitals (340B(a)(4)(N)), and rural referral centers and sole community hospitals (340B(a)(4)(O)). See 42 U.S.C. § 256b(a)(4)(M), (N), (O).

HCERA then added subsection (e), entitled "Exclusion of Orphan Drugs for Certain Covered Entities," to Section 340B. See Pub. L. No. 111-152, § 2302(4), 124 Stat. 1029, 1083 (2010). This subsection excludes the newly covered entities from access to 340B drug pricing for "drug[s] designated by the Secretary under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition." Id. The Medicare and Medicaid Extenders Act of 2010 subsequently removed children's hospitals from this exclusion. See Pub L. No. 111-309, § 204(a)(1), 124 Stat. 3285, 3289 (2010).

As amended, new Subsection 340B(e) of the PHSA (42 U.S.C. § 256b(e)) now provides as follows:

> 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.

II. THE ORPHAN DRUG ACT AND ORPHAN-DRUG DESIGNATION

Congress passed the Orphan Drug Act of 1983 to stimulate the development of drugs for rare diseases, defined as diseases that affect fewer than 200,000 persons in the United States. See Pub. L. No. 97-414, 96 Stat. 2049 (1983). The Office of Orphan Products Development of the Food and Drug Administration ("FDA") administers the Orphan Drug Act and reviews requests for designations.

Pursuant to section 526 of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), which was added by the 1983 Orphan Drug Act, a drug will be designated by the FDA as a drug for a rare disease or condition if the FDA finds that the drug is being or will be investigated for a rare disease or condition and that, if approved by the FDA, the approval will be for that disease or condition. 21 U.S.C. § 360bb(a)(1). This designation is referred to as an "orphan-drug designation," 21 C.F.R. § 316.3(b)(11), and provides a number of incentives to encourage the development of the drug for the particular disease or condition.

These incentives include: (1) 7-year market exclusivity to sponsors of approved orphan products; (2) a tax credit of 50 percent of the cost of conducting qualified human clinical trials; (3) federal research grants for clinical testing of these new therapies to treat and/or diagnose rare diseases; and (4) an exemption from the usual drug application "user" fees charged by the FDA. See 21 U.S.C. §§ 360cc, 360ee, 379h(a)(1)(F); 26 U.S.C. § 45C. These incentives apply only when the drug is being investigated, marketed, or used for the rare disease or condition. In other words, "[n]one of the incentives associated with orphan drug designation applies to any indication for a disease

or condition that is not rare. For those non-rare disease or condition indications, the drug would not be considered to be an 'orphan drug."' AR683.

The award of orphan-drug designation does not alter the standard regulatory requirements and process for obtaining marketing approval for the drug, which is a separate process administered by the FDA. Declaration of Krista Pedley, Director of the Office of Pharmacy Affairs, Healthcare Systems Bureau, HRSA ("Pedley Decl."), ¶ 5, PhRMA v. HHS, No. 13-1501, ECF 24-3. In fact, a large majority of drugs that have received an orphan-drug designation do not have approval to be marketed in the United States, either for the orphan disease or for any other disease or condition. Id. In addition, the FDA can designate a drug as a drug for a rare disease or condition even where the drug is approved, either at that time or later, for marketing for a different disease or condition that does not qualify for orphan designation. 21 C.F.R. § 316.23(b); Pedley Decl. ¶ 6.

According to one recent study, drugs that have received orphan-drug designation may be used as much as 90% of the time for conditions or illnesses other than the designated orphan indication. Pedley Decl. ¶ 6. Indeed, a drug could have an orphan-drug designation even though it is approved for marketing only for non-orphan diseases or conditions. Pedley Decl. ¶6.

III. HHS'S VACATED LEGISLATIVE RULE IMPLEMENTING SUBSECTION 340B(e)

After Congress enacted subsection 340B(e), HHS received numerous requests from affected parties asking for clarification of the proper interpretation of that provision. See Pedley Decl. ¶ 12; AR312. Several drug manufacturers had concluded, and had so notified the newly eligible covered entities, that, under Subsection 340B(e), they were not

required to sell orphan-designated drugs at 340B pricing, even when the drugs are used for non-orphan indications. See, e.g., AR026, AR035, AR038, AR046, AR065, AR070. Some of the newly-added covered entities believed that this interpretation was incorrect and that they should be allowed to purchase these drugs at discounted price if the drugs were used for non-orphan indications. See, e.g., AR003-004, AR113. Without access to purchase these drugs at a discounted price when they are used for non-orphan indications, some of these entities indicated that they have chosen not to participate (or to defer or reconsider their participation) in the 340B Program. AR004, AR085, AR126. They explained that the high cost of orphan-designated drugs would not make participation sufficiently beneficial to them, given additional administrative costs and restrictions. Id.

To address this confusion, after formal notice-and-comment rulemaking procedures, HHS issued a legislative rule to implement subsection 340B(e). See Exclusion of Orphan Drugs for Certain Covered Entities Under 340B Program. AR665-AR677. HHS received 49 comments from Members of Congress, manufacturers, 340B entities and providers, and other 340B stakeholders. AR665-AR677; see Pedley Decl. ¶ 13. HHS stated that its purposes in issuing this regulation was to: (1) provide clarity in the marketplace; (2) maintain the 340B savings for newly-eligible covered entities; and (3) protect the financial incentives for manufacturing drugs designated for a rare disease or condition as indicated in the Affordable Care Act and intended by Congress. AR312.

The former legislative rule provided that the newly covered entities are generally eligible to purchase designated orphan drugs at a discounted price when these drugs are used or prescribed for common diseases. Specifically, the regulation provided as follows:

> For the covered entities described in paragraph (b) of this section, 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 FFDCA. A covered outpatient drug includes drugs that are designated under section 526 of the FFDCA when they are transferred, prescribed, sold, or otherwise used for any medically-accepted indication other than treating the rare disease or condition for which the drug was designated under section 526 of the FFDCA.

Thus, HHS's regulation mandated, in accordance with HHS's view of the statute, that the drugs excluded from 340B pricing, that is, from discount pricing, for the newly covered entities are only those drugs "used for the rare conditions or diseases for which that orphan drug was designated under section 526 of the FFDCA", i.e., designated under 21 U.S.C. § 360bb. AR676. Orphan-designated drugs that are prescribed or used for a non-rare condition or disease will be considered covered outpatient drugs and must be made available to all covered entities at the discounted 340B Program price. Id.

IV. DISTRICT COURT'S DECISION VACATING THE LEGISLATIVE RULE

Before HHS's legislative rule became effective on October 1, 2013, plaintiff filed a lawsuit seeking a declaratory judgment and injunctive relief to invalidate the regulation. PhRMA v. HHS, No. 13-1501, 2014 WL 2171089 (D.D.C. May 23, 2014). Plaintiff maintained that HHS acted *ultra vires* in promulgating the legislative rule to implement subsection 340B(e) because the statute did not authorize such rulemaking. PhRMA v. HHS, No. 13-1501, Pl.' Mot. Summ. J. 13-19, ECF No. 25-1. Plaintiff further argued that the legislative rule was substantively invalid because it contravened the plain language of the 340B statute. Id. at 19-33.

On May 23, 2014, this Court granted plaintiff's motion for summary judgment and issued a permanent injunction vacating the regulation, but only on the ground that

HHS had no statutory authority to promulgate a legislative rule in this area. PhRMA v. HHS, No. 13-1501, 2014 WL 2171089 (D.D.C. May 23, 2014). The Court declined to reach plaintiff's alternative challenge to the merits of the agency's interpretation of the statutory provision. Id. at *13. The Court then invited the government to submit a supplemental brief addressing whether the legislative rule could survive as an interpretive rule. Id. at 29. On June 12, 2014, the government informed the court that it would decline the invitation and that it was instead considering whether to propound a separate interpretive rule on this subject. PhRMA v. HHS, No. 13-1501, ECF No. 45.

V. INTERPRETIVE RULE

As a result of this Court's decision, many drug manufacturers stopped providing 340B discount prices for orphan drugs to the newly eligible entities. AR703, 704, 708, 712, 714. Many of the newly eligible entities have contacted HHS for guidance and expressed their concerns about the "significant drug price increases" that "threaten their ability to serve . . . the nation's most vulnerable patients." AR716, 719. These entities indicated that the financial impact of not getting access to 340B discounts on orphan-designated drugs when they are prescribed for non-orphan diseases would seriously undermine their ability to provide comprehensive services to their low-income patients. AR717, 719. They stated that eliminating access to these discounts would force them to "cut pharmacy staffing," provide fewer services to their "vulnerable patients," and "increase drug costs for patients." AR 719-721.

On July 21, 2014, HHS issued the interpretive rule, adopting essentially the same interpretation of the orphan-drug exclusion, but without the binding legal effect that a legislative rule would have had. AR 678-86. HHS explained that subsection 340B(e)

excludes 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." AR 679. HHS further indicated that the interpretive rule "is not binding on manufacturers and covered entities," because it "does not create or establish any binding norms." AR692. Although HHS recognized that this interpretive rule merely embodies the agency's view on the meaning of the statutory provision, the statute remains binding on the program participants. Id.

ARGUMENT

I. THE COURT LACKS JURISDICTION TO REVIEW THE INTERPRETIVE RULE BECAUSE IT IS NOT FINAL AGENCY ACTION.

Judicial review under the APA is limited to "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704. The Supreme Court has established a two-part test for determining whether an agency action is final. Bennett v. Spear, 520 U.S. 154, 177-78 (1997). First, the agency action must be the "consummation" of the agency's decision-making process; it cannot be tentative or interlocutory in nature. Id. (quotations and citations 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. It is uncontested that the interpretive rule at issue satisfies the first part of the Bennett test, as a consummation of the agency's decision-making process. This interpretive rule is the product of mature administrative judgment and was issued after extensive deliberation. It is not a preliminary or tentative agency conclusion on the meaning of subsection 340B(e). However, the second part of the Bennett test is not met, because the interpretive rule is non-binding and does not create

any rights and obligations or have any *legal* effect to constitute a "final agency action" for the purpose of judicial review.

The interpretive rule is not a final agency action under the APA. It itself does not affect any legal "rights or obligations" of the 340B Program participants. Nor does it have any legal consequence that is independent of the statute itself. Under the 340B Program, the drug manufacturers have a duty to extend 340B discounts on drugs dispensed to eligible patients of a covered entity, and, similarly, "covered entities" have an obligation to comply with the 340B Program requirements, including maintaining records of their compliance. 42 U.S.C. § 256b. Subsection 340B(e) excludes from the discount, for the newly added entities, drugs "designated . . . for a rare disease or condition." 42 U.S.C. § 256b(e). The agency interprets this provision to apply only when the drugs are "transferred, prescribed, sold, or otherwise used for the rare condition or disease for which [that orphan] drug was designated." AR685-86.

Although this interpretive rule "supplies crisper and more detailed lines" than the statutory provision being interpreted, it does not alter the legal obligations of the program participants. Am. Mining Cong. v. Mine Safety & Health Admin., 995 F.2d 1106, 1112 (D.C. Cir. 1993). The agency has inherent authority to issue an interpretive rule, a rule that "merely informs the public of the agency's views on the subject" but "does not, however, create 'adverse effects of a strictly legal kind' because it cannot 'command anyone to do anything or to refrain from doing anything.'" Am. Tort Reform Ass'n v. Occupational Safety & Health Admin., 738 F.3d 387, 393 (D.C. Cir. 2013) (citation omitted). Nothing in the interpretive rule purports to make HHS's interpretation of

subsection 340B(e) legally binding, nor does it have any force of law, independent of any binding effect that the statute itself may have.

This Court's decision in PhRMA v. HHS, 2014 WL 2171089 (D.D.C. May 23, 2014), that HHS lacks statutory authority to issue legislative regulation to implement subsection 340B(e), provides additional support for the conclusion that the interpretive rule has no legal effect. If the agency lacks the authority to issue legislative rule, then the interpretive rule could not change plaintiff's legal obligations or generate legal consequences. See Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin., 452 F.3d 798, 810 (D.C. Cir. 2006). The agency's interpretation does not bind any "private parties or the agency itself with the 'force of law.'" Cement Kiln Recycling Coal. v. EPA, 493 F.3d 207, 216 (D.C. Cir. 2007) (citation omitted). Instead, its interpretation "is nothing more than a privileged viewpoint in the legal debate." Ctr. for Auto Safety, 452 F.3d at 808-09. In fact, the agency has proclaimed since its promulgation that the interpretive rule is non-binding. AR692. HHS's FAQs make clear that it understands that any requirements are imposed by the statute itself, but not by the interpretive rule. Id. An agency's characterization of a challenged agency action is also accorded "some weight." Brock v. Cathedral Bluffs Shale Oil Co., 796 F.2d 533, 537–38 (D.C. Cir. 1986); accord Nat'l Ass'n of Home Builders v. Norton, 415 F.3d 8, 14 (D.C. Cir. 2005) (agency's "characterization of its own action, while not decisive, is entitled to respect in a finality analysis.").

If and when the obligation to provide a discounted price in these circumstances is applied to a drug manufacturer in an enforcement action, it will be the statute, and not the interpretive rule, that will serve as the legal basis for adjudicating and resolving those

obligations. AT&T v. EEOC, 270 F.3d 973, 976 (D.C. Cir. 2001) (agency's expression of its view of what the law requires did not constitute final agency action because the view would have "force only to the extent the agency can persuade a court to the same conclusion."); Nat'l Ass'n of Home Builders, 415 F.3d at 16 (no final agency action because "the scope of a [regulated party's] liability under ... [the statute] remains exactly as it was before the [challenged] Protocols' publication").

The consequences suggested by plaintiff are that orphan drug manufacturers must either voluntarily comply with the agency's interpretation or face an enforcement action by the agency for violating the statutory requirements. Pl's. Am. Compl. ¶ 7. The flaw in this argument is that the consequences to which plaintiff alludes are practical, not legal. The D.C. Circuit made it clear that "if the practical effect of the agency action is not a certain change in the legal obligations of a party, the action is non-final for the purposes of judicial review" under the APA. Nat'l Ass'n of Home Builders, 415 F.3d at 15. "Practical consequences, such as the threat of having to defend itself in an administrative hearing should the agency actually decide to pursue enforcement, are insufficient to bring an agency's conduct under our purview." Indep. Equip. Dealers Ass'n v. EPA, 372 F.3d 420, 428 (D.C. Cir. 2004) (citation and internal quotation marks omitted). Even if some drug manufacturers have chosen to voluntarily comply with the interpretive rule to avoid possible enforcement action, their compliance does not establish the interpretive rule has *legal* consequences. Voluntary compliance is a practical effect, which is not enough to establish a final agency action. Ctr. for Auto Safety, 452 F.3d at 811.

Plaintiff further claims that HHS's pre-enforcement action is judicially reviewable because there is a possibility that plaintiff will incur "substantial monetary" penalties in case of non-compliance. Pl's. Am. Compl. ¶ 7. This argument is without merit. "[A] possible financial loss is not by itself a sufficient interest to sustain a judicial challenge to governmental action." Abbott Laboratories v. Gardner, 387 U.S. 136, 153 (1967); see also Am. Paper Inst.v. EPA, 882 F.2d 287, 289 (7th Cir. 1989) ("[u]ntil the EPA puts polluters under the gun, compelling them to do something they would rather not, the 'final' agency action lies ahead"); Bethlehem Steel Corp. v. EPA, 669 F.2d 903, 911 (3d Cir. 1982) (feeling coerced is not enough; the company may dispute liability, and appeal to the courts only if a final penalty is levied; the potential cost of such litigation does not render the action reviewable.). When an "agency has not yet made any determination or issued any order imposing any obligation..., denying any right..., or fixing any legal relationship," the agency action is not reviewable. Reliable Automatic Sprinkler Co., v. CPSC, 324 F.3d 726, 732 (D.C. Cir. 2003). Therefore, until HHS initiates an enforcement action against a drug manufacturer and imposes a penalty for not complying with the statutory provision, there is no final agency action subject to judicial review.

Plaintiff's allegation that HHS attempted to enforce subsection 340B(e) is without merit because the drug manufacturers' voluntary compliance with the statutory provision does not transform the interpretive guidance into a binding rule. See Pl. Am. Compl. ¶¶ 44-45. After issuing the interpretive rule, HHS sent a letter to several drug manufacturers that stopped providing the discounts on orphan drugs to the newly-added covered entities, conveying its desire that they comply with otherwise non-binding policies within the interpretive rule, as well as its view that the manufacturers were required to comply with

the *statute*. See Ex. E (attached to Pl. Amend. Compl.). An interpretive rule "may signal potential future enforcement trends within [an agency]." Sec. Indus. & Fin. Ass'n v. U.S. Commodity Futures Trading Comm'n, No. 13-1916, 2014 WL 4629567, at *31 (D.D.C. Sept. 16, 2014). Plaintiff's members therefore understandably "may feel pressure to voluntarily conform their behavior because the writing is on the wall" on how HHS intends to interpret subsection 340B(e) in future enforcement actions, but there has been no order compelling a drug manufacturer to do anything. Nat'l Mining Ass'n v. McCarthy, 758 F.3d 243, 253 (D.C. Cir. 2014) (quoting Indep. Equip. Dealers Ass'n v. EPA, 372 F.3d 420, 428 (D.C. Cir. 2004)). Therefore, "the industry's apparent *de facto* compliance" with the interpretive rule is insufficient to "convert guidance into a binding rule." Securities Industry and Financial Ass'n, 2014 WL 4629567 at *31; Nat'l Ass'n of Home Builders, 415 F.3d at 15; see Ctr. for Auto Safety, 452 F.3d at 809 ("[I]t does not matter that agency officials have *encouraged* automakers to comply with the guidelines." (emphasis in original)).

Indeed, the "pressure to voluntarily conform," National Mining Ass'n, 758 F.3d at 253, is part and parcel of many interpretive rules. Interpretive guidance provides a "formal method by which an agency can express its views" about its "policies prior to their actual application in particular circumstances." Pac. Gas & Elec. Co. v. Fed. Power Conm'n, 506 F.2d 33, 38 (D.C. Cir. 1974). This advance-notice function "facilitates long range planning within the regulated industry," Pacific Gas, 506 F.2d at 38, and allows "the public a chance to contemplate an agency's views before those views are applied to particular factual [circumstances]." Panhandle E. Pipe Line Co. v. FERC, 198 F.3d 266, 269 (D.C. Cir. 1999); see also Cmty. Nutrition Inst. v. Young, 818 F.2d 943, 949 (D.C.

Cir. 1987) (noting the "not inconsiderable benefits of apprising the regulated community of the agency's intentions"). "[T]he case law is clear that [courts] lack authority to review claims under the APA 'where an agency merely expresses its view of what the law requires of a party, even if that view is adverse to the party.'" Ctr. for Auto Safety, 452 F.3d at 808 (quoting Indep. Equip. Dealers Ass'n, 372 F.3d at 427); AT&T, 270 F.3d at 975.

II. HHS'S INTERPRETATION OF SUBSECTION 340B(E) IS CONSISTENT WITH THE 340B STATUTE AND IS ENTITLED TO DEFERENCE UNDER SKIDMORE.

If the Court determines that there is a final agency action, the interpretive rule should be upheld on the merits because it is a correct interpretation of the statute. Contrary to plaintiff's view, the regulation does not conflict with the 340B statute. It merely explains the meaning of subsection 340B(e) in a manner that is consistent with the statute's language and purpose.

A. Standard of Review

HHS's interpretive rule should be upheld unless the court finds the agency's action to be "arbitrary, capricious, or otherwise inconsistent with law." 5 U.S.C. § 706. This standard of review is "highly deferential" and presumes the agency's action to be valid. See Fla. Power & Light Co. v. Lorion, 470 U.S. 729, 743 (1985); Camp v. Pitts, 411 U.S. 138, 142 (1973). A court may not substitute its judgment for that of the agency. Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co., 463 U.S. 29, 43 (1983). Instead, the reviewing court must defer to the agency's rational judgment. See Peabody Coal Co. v. Watt, 454 U.S. 822 (1981). Deference to the administering agency "is particularly appropriate" when dealing with a "complex regulatory statute." In re

Permanent Surface Mining Regulation Litig., 653 F.2d 514, 522 (D.C. Cir. 1981). Such deference is warranted, when, as here, the interpretive rule implicates significant agency's expertise and the "'exercise of judgment grounded in policy concerns.'" Pauley v. BethEnergy Mines, Inc., 501 U.S. 680, 697 (1991).

In Skidmore, the Supreme Court held that "[t]he rulings, interpretations and opinions [of the agency], while not controlling upon the courts by reason of their authority, do constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance."[1] Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944). Under the Skidmore standard, "the persuasiveness of an agency's interpretation is determined by the thoroughness in its consideration, the validity of its reasoning, and its consistency with earlier pronouncements." Ctr. for Biological Diversity v. Jackson, 815 F. Supp. 2d 85, 93 (D.D.C. 2011) (citing Skidmore, 323 U.S. at 140). The Supreme Court has characterized Skidmore as requiring courts to defer to an agency's interpretations of statutes it administers to the extent those interpretations have the "power to persuade." Christensen v. Harris Cnty., 529 U.S. 576, 587 (2000). Applying the Skidmore standard, the interpretive rule at issue in this case easily meets this test.

[1] The agency's interpretive rule is "at least" entitled to Skidmore deference. Indeed, but for the fact that it has no legal effect, it would be clearly entitled to Chevron deference. See Mead, 533 U.S. at 234. But the view that the regulation has no legal effect is *defendants'* argument on the threshold question whether there is final agency action that, by hypothesis, will have been rejected before the Court addresses the question of deference. *Plaintiff* cannot have it both ways: if the regulation has enough legal effect to be final agency action, then it has enough effect to be entitled to Chevron deference as well.

B. HHS's Interpretive Rule Is Consistent With the 340B Statute and the Orphan Drug Act

Congress has assigned the Secretary of HHS the duties of administering the 340B Program, 42 U.S.C. § 256b, and the Orphan Drug Act, 21 U.S.C. § 360bb. These programs are "complex and highly technical," and the Secretary has acquired substantial expertise in administering them over several decades. See Thomas Jefferson Univ. Shalala, 512 U.S. 504, 512 (1994). In carrying out these duties, the Secretary must necessarily interpret the statutory language concerning the 340B Program requirements. HHS exercised its expert judgment and rationally concluded, based on its careful and deliberate examination of the statutory language and purpose, that orphan designated-drugs when used to treat common diseases are not excluded from the drug discount program for the newly-added covered entities. HHS's interpretation is entirely consistent with the 340B *statute* and its "basic objectives," Barnhart v. Walton, 535 U.S. 212, 219 (2002), as reflected in the statutory language at issue and its legislative purpose. See, e.g., Pilot Life Ins. Co. v. Dedeaux, 481 U.S. 41, 51 (1987)("[I]n expounding a statute, we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy."). Even if the interpretive rule does not "carry the force of law," United States v. Mead Corp., 533 U.S. 218, 221 (2001), the particular interpretation that it embodied reflects the agency's expert judgment and thus warrants respect. See Wis. Dep't of Health & Family Servs. v. Blumer, 534 U.S. 473, 497 (2002) (Secretary's interpretation of Medicaid statute set forth in letters and proposed rule "warrants respectful consideration").

HHS's interpretation of subsection 340B(e) is consistent with the plain language of the statute, which highlights the "rare disease or condition" for which an orphan drug

has been designated. By its terms, subsection 340B(e) provides that "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). This provision refers to a specific procedure and classification under the Orphan Drug Act. In the statute, the word "drug" is modified, and limited, by the phrase "designated . . . for a rare disease or condition." The domain of "rare diseases and conditions" is therefore the critical focus of subsection 340B(e), and that focus naturally leads to the conclusion that the exclusion applies only to drugs that are actually being used or prescribed for their designated rare disease or condition.

In other words, the phrase "for a rare disease or condition" defines and delimits the "designation." This means that a multi-disease drug gains no further benefit from the designation outside the circumscribed designation of the rare-condition domain. In Mid-Con Freight Systems v. Michigan Public Service Commission, the Supreme Court interpreted "State Registration requirement" not to apply to "*every* State Registration requirement," but only to those requirements that "concern" the subject of the federal statute at issue. 545 U.S. 440, 447 (2005). Here too, the drugs may be "designated," but the designation is for a particular disease, and does not make them a drug designated for treatment of common diseases. Thus, HHS's interpretation that the statutory phrase restricts the limitation on the discount finds clear support in the statutory text.

HHS's interpretation is also consistent with the general statutory and regulatory treatment of the incentives for orphan-designated drugs. As HHS noted, each incentive associated with the orphan-designated drug applies only to the orphan indication, and not to non-orphan indications. First, the marketing exclusivity only applies to the use of the

drug that has been approved by FDA to treat an orphan rare disease or condition." Second, "the tax credit must relate to testing of the drug for the rare disease or condition underlying the orphan designation and not for the testing for other diseases or conditions (non-rare uses)." Finally, "the exemption from FDA user fees payments only applies to user fees charged when seeking marketing approval for the use to treat the orphan designated rare disease or condition. The exemption does not apply to user fees charged for applications that seek marketing approval for non-rare uses." AR682-83.

This conclusion is strongly buttressed by FDA's longstanding interpretation that the incentives for orphan-designated drugs are applicable only when the drugs are being investigated, marketed, or used for their rare diseases or conditions. AR683. The use of the drug for the particular orphan indication is distinguished from its use for other (non-orphan) indications. Id. In other words, a drug with an orphan designation is subject to the same general rules and requirements under the 340B Program as all other covered outpatient drugs, when the orphan-designated drug is being used for a common disease or condition.

HHS's interpretation reasonably takes into account that many drugs with orphan designations are not approved or used for their orphan indications but, rather, are prescribed to treat common diseases. As Commander Pedley explains in her Declaration submitted in PhRMA v. HHS, No. 13-1501, ECF 24-3, drugs that have received an orphan-drug designation are not used exclusively for (and, in fact, may not even be approved for) the designated orphan indication but often are used or prescribed for common diseases or conditions. Pedley Decl. ¶¶ 5-7; 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."). Indeed, according to a recent study, "drugs that have received orphan-drug designation may be used as much as 90% of the time for conditions or illnesses other than the designated orphan indication." Pedley Decl. ¶ 6. And, when used in the latter contexts, such drugs are not formally categorized or considered "orphan-designated drugs" and it would be anomalous to refer to them as such.

The U.S. Supreme Court has often said that "'every clause and word of a statute'" should, "'if possible,'" be given "'effect.'" United States v. Menasche, 348 U.S. 528, 538–39 (1955) (quoting Inhabitants of Montclair Tnp. v. Ramsdell, 107 U.S. 147, 152 (1883)). Plaintiff's interpretation that the exclusion in subsection 340B(e) applies to the "drug. . . regardless of how it is used" would deprive the words "designated . . . for a rare disease or condition" of any effect. Plaintiff's suggested reading would render these terms surplusage; they do not do any work not already performed "by the Secretary under section 360bb of Title 21." The better view (and at least a permissible one) is that the phrase "for a rare disease or condition" strongly suggests that a precise and narrow application was intended in subsection 340B(e).

Moreover, Congress should not lightly be presumed to have intended to force the newly-added covered entities, serving low-income patients, to pay higher prices for their outpatient orphan drugs when these drugs are used to treat common diseases. It is one thing (and something Congress evidently did intend) to provide for the higher price and the manufacturer incentive when the drugs are used for the orphan indications. But it would be quite another to have the newly covered entities intended to benefit from participation in the 340B Program to pay higher prices up to 90% of the time (particularly

when, as it turns out, such a requirement may cause newly eligible entities to forfeit their participation in the 340B Program).

While a congressional purpose consistent with the Secretary's common-sense construction of the statute is easy to discern, plaintiff's reading of the statute attributes to Congress an unlikely intent indeed. Even though it has provided, in the orphan drug provision itself, for incentives to develop drugs for rare conditions and diseases, plaintiff's reason supposes that Congress wanted to add an extra incentive bonus for such drugs based on the happenstance of whether they also are used to treat common conditions. It is even less likely that Congress would choose to provide such an unlikely extra-bonus windfall incentive, not in the Orphan Drug Act itself, but as an exception to the 340B Program that undermines the central purposes of that program.

Plaintiff relies on other statutory provisions that reference drugs that have received an orphan-drug designation and that contain use-based limiting language not present in subsection 340B(e). Pl's. Am. Compl. ¶ 48. Subsection 340B(e) may not be as clear here – one reason why the agency's policy-laden resolution of that ambiguity matters – but plaintiff's policy preference makes no more sense here. That HHS is reaching the same conclusion that Congress has itself repeatedly enacted in those other provisions is all the more reason to uphold HHS's reading. The language in the other provisions is not consistent enough to suggest that omission of particular language in an entirely different statute has any significance. Merely different language does not compel the conclusion that Congress deviated here from the consistent and sensible approach it has adopted in those other statutes that the incentive given to orphan-designated drugs in the 340B Program is limited to their orphan indications.

HHS's interpretation reasonably balances the goal of the 340B Program, which is to provide cost savings for newly-eligible covered entities, with that of the Orphan Drug Act, which is to create the financial incentives for developing drugs for rare diseases or conditions. AR678. In issuing the interpretive rule, HHS concluded that, "to exclude all uses of drugs with an orphan designation, including indications for other diseases and conditions, would nullify the benefits of the expansion of the 340B Program for those entities," which would be "contrary to Congressional intent to balance the interests of orphan drug research and the expansion of the 340B Program to new entities." AR684. Therefore, HHS determined that its interpretation "reflects the intent of Congress to expand eligible entities and restrict purchases of certain orphan drugs by both providing 340B savings for newly-eligible covered entities including commonly prescribed uses of orphan drugs and protecting the financial incentives for manufacturing orphan drugs designated for a rare disease or condition." AR666.

On the other hand, plaintiff's interpretation to exclude all drugs that have received an orphan-drug designation even when they are only approved and prescribed to treat common diseases would frustrate Congressional intent. When Congress created the 340B drug discount program in 1992, it said its purpose was to enable clinics and hospitals to "stretch scare federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 7-8 (1992); Cnty. of Santa Clara v. Astra USA, Inc., 588 F.3d 1237, 1246 (9th Cir. 2009). Congress required drug manufacturers to enter into pricing agreements with HHS "to extend the same price reduction to a covered entity for a drug or biological as is provided under the Medicaid outpatient drug rebate program." Joint Explanatory Statement on

H.R. 5193, 138 Cong. Rec. S17890, 1992 U.S.C.C.A.N. 4186, 4211. Thus, the 340B program enables covered entities to obtain lower prices on the drugs that they provide to their patients who are mostly poor or uninsured in order to "stretch federal resources."

In the Affordable Care Act, by increasing the number of safety-net providers eligible for the 340B Program, Congress reaffirmed its commitment to eligible entities' access to price reductions on covered drugs. Plaintiff's interpretation of Subsection 340B(e) would nullify this benefit as to the newly eligible entities and accordingly should be rejected. A "statute should ordinarily be read to effectuate its purposes rather than frustrate them." United States v. Barnes, 295 F.3d 1354, 1364 (D.C. Cir. 2002) (rejecting interpretation that would "render[] the law a nullity in a majority of the states as well as at the Federal level")(citations omitted). "'The cardinal principle of statutory construction is to save and not to destroy.'" United States v. Menasche, 348 U.S. 528, 538 (1955) (quoting NRLB v. Jones & Laughlin Steel Corp., 301 U.S. 1, 30 (1937)). Plaintiff's reading of Subsection 340B(e) would so limit the cost savings of the 340B program to the entities affected by that subsection that some of them would simply decline to participate in the program. See AR004, AR085, AR126, AR684. It cannot realistically have been Congress's intent in enacting Subsection 340B(e) to nullify the very changes it had made to Section 340B earlier in 2010. See United States v. Brown, 333 U.S. 18, 23, 27 (1948) (rejecting interpretation of statute that would result "in patently absurd consequences" and "nullify the statutory purpose"); Halverson v. Slater, 129 F.3d 180, 185 (D.C. Cir. 1997) (invoking "the familiar doctrine that the Congress cannot be presumed to do a futile thing").

In any event, the interpretive rule has many of the characteristics that the Supreme Court has identified as favoring deference under Skidmore. First, HHS's interpretation of subsection 340B(e) represents an agency-wide position; "it is not an interpretation that was made at a low level within the agency." Cathedral Candle Co. v. U.S. Int'l. Trade Comm'n, 400 F.3d 1352, 1367 (Fed. Cir. 2005). HHS' interpretation was "contemporaneous" with the enactment of subsection 340B(e) in 2010 and has been "adhered to consistently by the agency since that time. It is not a position formulated belatedly in response to litigation in this case or others, nor is it inconsistent with positions the [agency] has previously taken." Id. (citing Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 212–13 (1988)). Third, HHS has explained its reason for the interpretation which is grounded in the statute and its purpose. Finally, HHS is responsible for administering the 340B Program and the Orphan Drug Act, and is in a perfect position to take the goals of *both* statutes into account and to make sure they mesh. Thus, the interpretation is the product of HHS's "specialized expertise" in administering the 340B program over two decades; it is informed by the "information available to the agency" and reflects a single uniform interpretation on the part of the agency. Nat'l Org. of Veterans' Advocates, Inc. v. Secretary of Veterans Affairs, 260 F.3d 1365, 1379 (Fed. Cir. 2001). Under these circumstances, HHS's interpretation of the statute it administers is entitled to "considerable weight." Cathedral Candle Co., 400 F.3d at 1367. Because HHS's interpretation reflects a reasonable effort to resolve the confusion in the marketplace regarding the scope of subsection 340B(e) and to provide clarify to the program participants, that interpretation is entitled to deference.

CONCLUSION

Because HHS's interpretive rule is not a final agency action for the purpose of judicial review under the APA and because, in any event, the rule is consistent with the 340B statute and is entitled to deference under Skidmore, summary judgment should be granted for defendants. Plaintiff's Amended Complaint should be dismissed.

Dated: January 27, 2015

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Plaintiff, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	Civil Action No. 1:14-CV-01685 -RC

[PROPOSED] ORDER GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Upon Consideration of Defendants' Motion for Summary Judgment, the opposition thereto, and the entire administrative record herein, it is hereby ORDERED that the Defendants' Motion be GRANTED, and it is further ORDERED that Plaintiff's Amended Complaint be DISMISSED.

SO ORDERED.

_____ _____

Date Hon. Rudolph Contreras
United States District Judge

Updated Administrative Record Index in PhMAR v. HHS, Civ #14CV01685

Page	Date	Document Description
AR678	Jul-23-14	Table 1 - New Draft Product-Specific be Recommendations for Drug Products-Continued
AR680	Jul-21-14	Interpretive Rule: Implementation of the Exclusion of Orphan Drugs for Certain Covered Entities Under the 340-B Program
AR687	May-23-14	Orphan Drugs Exclusion-340B Drug Pricing Program
AR695	June-28-14	340B Prime Vendor Program-Search Results
AR698	May-23-14	Orphan Drugs Exclusion-340B Drug Pricing Program
AR700	May-25-14	Email from Curran to vacated or invalidated final rule on the treatment of orphan drugs under the 340B program
AR703	June-03-14	Email Genentech is going to stop providing 340B discounts on orphan drug when purchased by NEE hospitals today
AR704	June-9-14	Email As of roughly 12 am this morning, we have removed 340B pricing for Orphan Drugs for CAN, CAH, RRC, and SCH 340B accounts
AR707	June-6-14	Email NEE hospital regarding Genentech's decision to stop providing 340B discount on orphan products
AR708	June-6-14	Discontinuation of 340B Pricing for Orphan Drugs purchased by Newly Eligible Entities
AR710	June-9-14	Email Notice of orphan drug exclusion
AR712	June-6-14	Novartis Pharmaceuticals will no longer make 340B pricing available on it orphan drugs to the new covered entity types added to the 340B program
AR714	June-9-14	340B Contract pricing removel for orphan Drugs-340 Orphan Drug Regulation Update
AR715	June-10-14	Email 340B Orphan Drug List-Orphan status of on our products Vemurafinib/Zelboraf
AR717	Jul-2-14	RRC and CAH recent court decision regarding the HRSA regulation related to orphan durgs
AE718	Jul-2-14	Department of Health & Human Services thank you for the letter from AEH, NRHA, and SNHFP 340B Drug Pricing Program orphan durg policy
AR719	June-19-14	Maintaining HRSA's Orphan Drug Policy
AR722		Orhan Drug Lawsuit Survey
AR756	Oct-8-13	Explanation of SNHPA Survey on Orphan Drug Regulation
AR758	Jul-3-14	Email 340B pricing not being supplied
AR759		HRSA Notification Template
AR761	Jul-3-14	Email Prime vendor model for pharmacy distribution (Cardinal) with few pruchases made directly for manufacturers
AR763	Jul-7-14	Email Amgen directed us to block pricing on orphan drug for otp-in entities effective July 1st
AR768	Jul-7-14	Email OPA approved our request to purchase orphan drugs on 340B contracts on April 1, 2014
AR771	Jul-9-14	Inablility to purchase orphan drugs for no-orphan diagnoses for covered entity: MRH RRC-440073-00 and MRH d/b/a MRCC RRC-440073-01
AR772	Aug-1-14	Email regarding the availablitiy of orphan drugs at 340B prices

AR773	Jul-11-14	Email Union Hospital notification regarding our inability to receive 340B pricing for Neulasta
AR775		HRSA Notification Template for the purpose of HRSA when a 340B price is unavailable for a product
AR776	Jul-11-14	Email from Cardinal Health-Daniel Neal Sr. Product Manager, 340B-Innovative Delivery Solutions
AR778	Jul-21-14	Bayer Healthcare Pharmacenticals effective immediately BHP will no longer offer its orphan drugs at PHS340B discounted prices
AR779	Jul-22-14	Email from Rebecca Harmon, 340B Coordinator, CPhT
AR780	Jul-24-14	Email fromDawn McClellan CPhT
AR782		340B Price Unavailable HRSA Notification Template
AR784	Aug-1-14	Email from Tammy M. Darnell
AR788		

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Plaintiff, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., Defendants	Civil Action No. 1:14-cv-1685

DESIGNATION AND CERTIFICATION OF ADMINISTRATIVE RECORD

I, Krista Pedley, PharmD, MS, Commander, U.S. Public Health Service, hereby declare and certify as follows:

I. I am the Director of the Office of Pharmacy Affairs, Healthcare Systems Bureau, Health Resources and Services Administration ("HRSA"), U.S. Department of Health and Human Services ("Department"). The Office of Pharmacy Affairs is the Departmental component responsible for overseeing the 340B Drug Pricing Program.

2. The attached pages identified in the accompanying index constitute a true and complete copy of the agency record underlying the Orphan Drug Interpretive Rule issued by HRSA, 79 Fed. Reg. 42801 (July 23, 2014), which is at issue in the present litigation.

In accordance with 28 U.S.C. § 1746, I hereby certify and declare under penalty of perjury that the foregoing is true and correct.

Executed on: 12/5/14

Krista Pedley
PharmD, MS, Commander, U.S. Health Service
Director, Office of Pharmacy Affairs
Health Systems Bureau
Health Resources and Services Administration