UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,	:		
Plaintiff,	:	Civil Action No.:	13-1501 (RC)
v.	:	Re Document Nos.:	3, 24, 25, 26 29, 32
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*	:		
Defendants.	:		

MEMORANDUM OPINION

GRANTING PLAINTIFF'S MOTION FOR AN INJUNCTION; GRANTING PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT; AND DISPOSING OF ALL OTHER PENDING MOTIONS IN THIS CASE

I. INTRODUCTION

Orphan drugs are drugs that treat rare diseases or conditions, and are so-named because efforts to research, invest in, and produce them would otherwise be abandoned if not for the incentives Congress has provided pharmaceutical manufacturers to do so. While orphan drugs can only be *designated* as such to treat rare diseases or conditions, they can also be *used* to treat non-rare diseases or conditions.[1] For example, Prozac (generically named Fluoxetine) is designated an orphan drug for the treatment of autism and body dysmorphic disorder in children

[1] The timing of a request for orphan drug designation need not occur at a specific time in a drug's development. *See* 21 C.F.R. § 316.23(a) ("A sponsor may request orphan-drug designation at any time in its drug development process prior to the time that sponsor submits a marketing application for the drug for the same rare disease or condition."); 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.").

and adolescents, but is commonly prescribed for depression, a non-orphan condition. *See* Orphan Drug Designation and Approvals List as of March 3, 2014, at 72;[2] *see also* Amicus Curiae Brief of Safety Net Hospitals for Pharmaceutical Access, *et al*. 11, ECF No. 29-1 ("Safety Net Amicus Brief"). Rituxan,[3] designated an orphan drug for treatment of anti-neutrophil cytoplasmic antibody-associated vasculitis, non-Hodgkin's B-cell lymphoma, and immune thrombocytopenic purpura, is commonly prescribed to treat the non-orphan conditions of rheumatoid arthritis, multiple sclerosis, and autoimmune anemia. *See* Orphan Drug Designation and Approvals List as of March 3, 2014, at 254, *see also* Safety Net Amicus Brief at 9. The plaintiff in this case, Pharmaceutical Research and Manufacturers of America ("PhRMA"), challenges a final rule promulgated by the Secretary ("Secretary") of Health and Human Services ("HHS") addressing the uses for which an orphan drug must be offered at a discounted price, as specified in section 340B of the Public Health Service Act ("PHSA"). Because the Court concludes that HHS lacks the statutory authority to engage in such rulemaking, the Court will vacate the final rule, and grant the plaintiff's motion for an injunction and motion for summary judgment.

II. FACTUAL & STATUTORY BACKGROUND

A. The Orphan Drug Act

The Orphan Drug Act was passed in 1983 as an amendment to the Federal Food, Drug, and Cosmetic Act, "to facilitate the development of drugs for rare diseases and conditions . . . ." *See* Pub. L. 97-414, 96 Stat. 2049 (January 4, 1983). The Federal Food, Drug, and Cosmetic Act

[2] *available at* http://www.hrsa.gov/opa/programrequirements/orphandrugexclusion/orphandruglist.pdf.

[3] Rituxan brought in over $7 billion in revenue last year, the most of any orphan drug. *See* Michael J. Berens & Ken Armstrong, *Pharma's Windfall: The mining of rare diseases*, SEATTLE TIMES, Nov. 9, 2013, *available at* http://apps.seattletimes.com/reports/pharma-windfall/2013/nov/9/mining-rare-diseases/.

("FFDCA") defines a "rare disease or condition" as "any 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 available . . . a drug for such disease or condition will be recovered from sales . . . of such drug." 21 U.S.C. § 360bb(a)(2).

Congress passed the Orphan Drug Act in part because it found 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." 96 Stat. 2049 §1(b)(4). To encourage the development of such drugs, the Orphan Drug Act provides the following incentives to pharmaceutical manufacturers of those drugs: (1) a seven-year market exclusivity period for the orphan drug (as opposed to a two-year period for regular drugs), *see* 21 U.S.C. § 360cc(a); (2) a clinical tax credit for any expenses incurred in developing an orphan drug, *see* 26 U.S.C. § 45C; (3) research grants for clinical testing, *see* 21 U.S.C. § 360ee, and (4) an exemption from new drug application fees, *see* 21 U.S.C. § 379h(a)(1)(F).

B. 340B Program

The 340B Program began in 1992 when Congress enacted it as part of the Veterans Health Care Act, codified as section 340B of the Public Health Service Act ("PHSA") at 42 U.S.C. § 256b. Section 340B of the PHSA "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health care facilities." *Astra USA, Inc. v. Santa Clara Cnty., Cal.*, 131 S. Ct. 1342, 1345 (2011). Under this program, manufacturers are required, as a condition to Medicaid covering their products, to enter into a pricing agreement with the Secretary of HHS. *See* 42 U.S.C. § 256b(a). Under those pricing agreements, certain covered

entities, (*i.e.*, black lung clinics, hemophiliac diagnostic treatment centers, Native Hawaiian Health Centers, *see* 42 U.S.C. §§ 256b(a)(4)(F)–(H)) can get pharmaceutical medications at a discounted price "if such drug is made available to any other purchaser at any price." *Id.* § 256b(a)(1).

Under the original 340B statute, covered entities were generally disproportionate share hospitals—hospitals that serve indigent populations. *See id.* § 256b(a)(4)(L). However, as part of the Patient Protection and Affordable Care Act ("ACA"), Congress added several categories to the covered entities list that became (M), (N), and (O) under 42 U.S.C. § 256b(a)(4): children's hospitals excluded from the Medicare prospective payment system, free-standing cancer hospitals excluded from the Medicare prospective payment system, critical access hospitals, rural referral centers, and sole community hospitals. *See* Pub. L. 111-148 § 7101(a) (March 23, 2010), codified at 42 U.S.C. § 256b(a)(4)(M)–(O).

The Health Care and Education Reconciliation Act ("HCERA") also made several changes to the 340B Program, including excluding orphan drugs from 340B discount pricing available to the newly-added covered entities. This particular change is the critical statutory provision at issue in this case and goes as follows: "For 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*." Pub. L. 111-152 § 2302(4), codified at 42 U.S.C. § 256b(e) (emphasis added). Thus, under the new orphan drug exclusion, the newly-added covered entities can get their pharmaceutical medications at a discounted price, except for orphan drugs, for which they must pay full price. But, as set forth below, the parties take opposing

views as to whether these entities must pay full price for orphan drugs when used for a non-orphan indication.

C. Orphan Drug Exclusion Rule

In response to numerous letters from drug manufacturers and covered entities alike asking for clarification on the orphan drug exclusion promulgated under the ACA/HCERA, the Secretary of HHS published a notice of proposed rulemaking to "(1) provid[e] clarity in the marketplace, (2) maintain[] the 340B savings and interests to the newly-eligible covered entities; and (3) protect[] the financial incentives for manufacturing orphan drugs designated for a rare disease or condition as indicated in the Affordable Care Act as intended by Congress." *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 provided a 60-day comment period and received 50 comment letters raising a variety of issues from members of Congress, manufacturers, 340B entities and providers, and other 340B stakeholders. *See* Final Rule, Exclusion of Orphan Drugs for Certain Covered Entities under 340B Program, 78 Fed. Reg. 44,016, 44,017 (July 23, 2013). HHS then published the final rule on July 23, 2013. *See id.*

The Final Rule establishes, *inter alia*, that with respect to the newly-designated 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 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." *See* 42 C.F.R. § 10.21(a) (emphasis added).

The practical effect of this rule is that 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 purchases the orphan drug for a non-orphan use, however, it does receive the 340B discount price. For instance, as explained by amicus Safety Net Hospitals for Pharmaceutical Access, in the case of Prozac, "an affected hospital could purchase the drug at 340B discounts if it were used to treat depression, its common purpose, but an affected hospital would have to purchase the drug outside the 340B program [and therefore, not at a discounted rate] if it were used to treat either of its two orphan indications." *See* Safety Net Amicus Brief at 11.

The Final Rule also imposes duties on the covered entities to maintain records of compliance. Specifically, the rule states that "[a] covered entity listed in paragraph (b) of this section is responsible for ensuring 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) (emphasis added). If the covered entity "cannot or does not wish to maintain auditable records sufficient to demonstrate compliance with this rule, [it] must notify HRSA[4] and purchase all orphan drugs outside of the 340B Program regardless of the indication for which the drug is used." *Id.* § 10.21(c)(3). The rule also explains that "[f]ailure to comply with this section shall be considered a violation of sections 340B(a)(5) and 340B(e) of the PHSA, as applicable." *Id.* § 10.21(f).

[4] HRSA is the Health Resources and Services Administration, the agency within the U.S. Department of Health and Human Services tasked with administering the 340B Program.

D. Preliminary Housekeeping issues

The plaintiff brought suit against HHS in this action, alleging that the rule contravenes the plain language of the statute, and is therefore invalid. Pending before the Court are the plaintiff's motion for a preliminary injunction and motion for summary judgment, *see* ECF Nos. 3 & 25, and the defendants' motion to dismiss, or in the alternative for summary judgment. *See* ECF No. 24. Also pending before the Court are: (1) the plaintiff's motion for judicial notice, *see* ECF No. 26, (2) an unopposed motion for leave to file an *Amicus Curiae* Brief by Safety Net Hospitals for Pharmaceutical Access ("Safety Net"), *see* ECF No. 29, and (3) the plaintiff's motion to strike the extra-record material included in the amicus brief submission, *see* ECF No. 32.

The Court will address the latter three issues first, as they can be quickly disposed of. With respect to the plaintiff's motion for judicial notice, the plaintiff asks this Court to take judicial notice of the "Frequently Asked Questions" page related to orphan drug designation and development posted on the U.S. Food and Drug Administration's ("FDA") website. *See* ECF No. 26. Federal Rule of Evidence 201 provides that "[t]he court may judicially notice a fact that is not subject to reasonable dispute because it can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." FED. R. EV. 201(b)(2). A court may also take judicial notice "at any stage of the proceeding." FED. R. EV. 201(d). Courts in this jurisdiction have frequently taken judicial notice of information posted on official public websites of government agencies. *See Cannon v. District of Columbia*, 717 F.3d 200, 205 n.2 (D.C. Cir. 2013) (taking judicial notice of document posted on the District of Columbia's Retirement Board website); *Carik v. Dep't Health & Human Svcs.*, No. 12-272(BAH), 2013 WL 6189313, *4 n.4 (D.D.C. Nov. 27, 2013) (taking judicial notice of information on the FDA's

website); *Hyson v. Architect of Capitol*, 802 F. Supp. 2d 84, 90–91 n. 4 (D.D.C. 2011) (taking judicial notice of description on U.S. Office of Personnel Management's website). As such, this Court will grant the plaintiff's motion and take judicial notice of the Frequently Asked Questions page for "Developing Products for Rare Diseases and Conditions."[5]

The Court will also grant Safety Net's unopposed motion for leave to file an Amicus Curiae Brief. *See* ECF No. 29. The Court notes that in resolving the motions for summary judgment pending in this case, it has considered Safety Net's Amicus Curiae brief.[6]

III. ANALYSIS

A. Legal Standard: Motion to Dismiss & Summary Judgment

The plaintiff originally filed a motion for a preliminary injunction in this case, asking this Court to enjoin HHS from implementing the final rule scheduled to take effect October 1, 2013. *See* ECF No. 3. However, the parties jointly requested that the Court grant a motion to consolidate the hearing on the merits of this action with the hearing on the plaintiff's application for a preliminary injunction under Federal Rule of Civil Procedure 65(a)(2). *See* ECF No. 16. The Court granted that motion on October 25, 2013. *See* ECF No. 17. Because the Court

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[5] *available at* http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseases Conditions/HowtoapplyforOrphanProductDesignation/ucm240819.htm (last accessed May 22, 2014).

[6] The plaintiff filed a motion to strike certain extra-record material attached as exhibits in Safety Net's Amicus Curiae brief. *See* ECF No. 32. Specifically, the plaintiff moved to strike the Declaration by Maureen Testoni, *see* ECF No. 29-2, survey results from a survey conducted by Safety Net, *see* ECF No. 29-3, and portions of Safety Net's brief that rely on those exhibits. Because the Court decides the merits of this case and not the preliminary injunction, the survey results and material showing harm to certain covered entities is not relevant to the Court's analysis of the statute. As such, the Court will find as moot the plaintiff's motion. And moreover, even if Safety Net provided those materials to supplement the administrative record, "it is black-letter administrative law that in an APA case, a reviewing court should have before it neither more nor less information than did the agency when it made its decision." *Hill Dermaceuticals, Inc., v. FDA*, 709 F.3d 44, 47 (D.C. Cir. 2013) (citations omitted). To the extent the materials were relevant to the Court's merits analysis, then, they would be stricken from the record.

decides that on the merits of the case, the plaintiff is entitled to a permanent injunction, it need not decide the preliminary injunction.

1. Motion to Dismiss

The Federal Rules of Civil Procedure require that a complaint contain "a short and plain statement of the claim" in order to give the defendant fair notice of the claim and the grounds upon which it rests. FED. R. CIV. P. 8(a)(2); *accord Erickson v. Pardus*, 551 U.S. 89, 93 (2007) (per curiam). A motion to dismiss under Rule 12(b)(6) does not test a plaintiff's ultimate likelihood of success on the merits; rather, it tests whether a plaintiff has properly stated a claim. *See Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974). A court considering such a motion presumes that the complaint's factual allegations are true and construes them liberally in the plaintiff's favor. *See, e.g.*, *United States v. Philip Morris, Inc.*, 116 F. Supp. 2d 131, 135 (D.D.C. 2000).

Nevertheless, "[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). This means that a plaintiff's factual allegations "must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555–56 (2007) (citations omitted) (parenthetical in original). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements," are therefore insufficient to withstand a motion to dismiss. *Iqbal*, 556 U.S. at 678. A court need not accept a plaintiff's legal conclusions as true, *see id.*, nor must a court presume the veracity of the legal conclusions that are couched as factual allegations. *See Twombly*, 550 U.S. at 555.

2. Summary Judgment

Typically, 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). But when assessing a summary judgment motion in an APA case, "the district judge sits as an appellate tribunal." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001). In a case such as this, the "complaint, properly read, 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). "The entire case on review is a question of law, and only a question of law." *Id.* The district 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 (2012).

B. APA Standard of Review

Under the APA, a reviewing court "shall hold unlawful and set aside agency action, findings, and conclusions found to be in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C). "It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988); *see also Atl. City Elec. Co. v. FERC.*, 295 F.3d 1, 8 (D.C. Cir. 2002) ("In the absence of statutory authorization for its act, an agency's action is plainly contrary to law and cannot stand.") (internal quotation marks and citations omitted). "To determine whether the agency's action is contrary to law, we look first to determine whether Congress has delegated to the agency the legal authority to take the

action that is under dispute." *Michigan v. EPA*, 268 F.3d 1075, 1081 (D.C. Cir. 2001); *see also id.* at 1082 ("Agency authority may not be lightly presumed.").

Judicial review of an agency's interpretation of its guiding statute usually follows a two-step process. The familiar *Chevron* two-step goes as follows: "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 on 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.* At this stage of the analysis, "a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency." *Id.* at 844.

In *United States v. Mead*, the Supreme Court elaborated on when *Chevron* deference applies, holding that "administrative implementation of a particular statutory provision qualifies for *Chevron* deference *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*." 533 U.S. 218, 226–227 (2001) (emphasis added). Scholars coined this inquiry "Chevron Step Zero—" a threshold question as to whether *Chevron* deference even applies at all. *See generally* Cass R. Sunstein, *Chevron Step*

Zero, 92 VA. L. REV. 187 (2006). The question of whether *Chevron* applied to an agency's interpretation of the scope of its regulatory authority—its jurisdiction—was left unanswered by the Supreme Court. Or, to the extent that question was answered, it resulted in confusion in the lower courts about what the standard of review should be. *See id.* at 234–236.

Last year, however, the Supreme Court clarified the standard of review that governs "an agency's interpretation of a statutory ambiguity that concerns the scope of its regulatory authority (that is, its jurisdiction) . . . ." *City of Arlington, Tex. v. F.C.C.*, 133 S. Ct. 1863, 1866 (2013) (parenthetical in original). The Court explained that whatever the inquiry, *Chevron* deference applies: "the distinction between 'jurisdictional' and 'nonjurisdictional' interpretations is a mirage. No matter how it is framed, the question a court faces when confronted with an agency's interpretation of a statute it administers is always, simply, *whether the agency has stayed within the bounds of its statutory authority*." *Id.* at 1868 (emphasis in original). It went on to explain:

> [J]udges should not waste their time in the mental acrobatics needed to decide whether an agency's interpretation of a statutory provision is 'jurisdictional' or 'nonjurisdictional.' Once those labels are sheared away, it becomes clear that the question in every case is, simply, whether the statutory text forecloses the agency's assertion of authority, or not.

Id. at 1870–71; *accord Verizon v. FCC*, 740 F.3d 623, 635 (D.C. Cir. 2014) ("As the Supreme Court has recently made clear, *Chevron* deference is warranted even if the Commission has interpreted a statutory provision that could be said to delineate the scope of the agency's jurisdiction.") (citing *City of Arlington*, 133 S. Ct. at 1874).

However, not all agency interpretations are accorded *Chevron* deference. Where an agency's interpretation lacks the force of law, it is "beyond the *Chevron* pale." *Mead*, 533 U.S. at 234; *accord Christensen v. Harris Cnty.*, 529 U.S. 576, 587 (2000). Instead, courts may

afford some deference to a non-binding agency interpretation of its guiding statute to the extent the interpretation has the "power to persuade." *See Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944) ("We consider that the rulings, interpretations and opinions of the Administrator under this Act, 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."). "[I]nterpretive rules . . . enjoy no *Chevron* status as a class." *Mead*, 533 U.S. at 232; *see also Bamonte v. City of Mesa*, 598 F.3d 1217, 1228 (9th Cir. 2010) (explaining that "*Chevron* deference is reserved for legislative rules that an agency issues within the ambit of the authority entrusted to it by Congress," whereas an agency rule or decision "not within an area of express delegation of authority or [that] does not purport to have the force of law" is entitled to *Skidmore* deference).[7]

C. HHS's rulemaking authority under the PHSA

The plaintiff's first argument, and ultimately the dispositive one in this case, is that HHS lacks statutory rulemaking authority to promulgate the orphan drug rule at issue here. *See* Pl.'s Mot. Summ. J. 13–18, ECF No. 25-1. As articulated above, "the question a court faces when confronted with an agency's interpretation of a statute it administers is always, simply, *whether the agency has stayed within the bounds of its statutory authority*." *City of Arlington*, 133 S. Ct.

[7] *See also* Harry Edwards, *et al.*, FEDERAL STANDARDS OF REVIEW XIII.D ("If an administrative action is within the area in which Congress has authorized an agency to act, a question may arise as to whether it was taken pursuant to congressionally delegated authority to . . . make rules carrying the force of law and in the exercise of that authority, or, alternatively, whether it was simply one of the many sorts of interpretative choices that an agency charged with applying a statute necessarily must make in the course of administering it. If an action falls within the former category, it will be reviewed under the *Chevron* framework. If the action falls within the latter category, the agency's interpretation will be entitled only to a level of deference commensurate with its inherent power to persuade") (internal quotation marks and citations omitted).

at 1868 (emphasis in original); *see id.* at 1874 ("for *Chevron* deference to apply, the agency must have received congressional authority to determine the particular matter at issue in the particular manner adopted."); *see also Adams Fruit Co., Inc. v. Barrett*, 494 U.S. 638, 649–50 (1990) ("A precondition to deference under *Chevron* is a congressional delegation of administrative authority.") (citation omitted).

The plaintiff argues that HHS lacks the statutory authority to implement 340B(e) rulemaking, relying largely on *Gonzales v. Oregon*, 546 U.S. 243 (2006). *Gonzales* involved a challenge to an Interpretive Rule implemented by the Attorney General under the Controlled Substances Act ("CSA"), which he issued in response to Oregon passing the "Death with Dignity Act," which exempted from civil or criminal liability state-licensed physicians who prescribed a lethal dose of drugs upon request of a terminally ill patient. *See id.* at 249. Congress had given the Attorney General rulemaking power to fulfill his or her duties in two specific areas: (1) "to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to listed chemicals [under 21 U.S.C. § 821]" and (2) "[to] promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter." *Id.* at 259. Congress did not delegate authority to the Attorney General "to carry out or effect all provisions of the CSA." *Id.* Invoking those two specific provisions for rulemaking authority, the Attorney General implemented an Interpretive Rule concerning physician assisted suicide explaining that "[a]ssisting suicide is not a legitimate medical purpose within the meaning of 21 CFR 1306.04 (2001), and [] prescribing, dispensing, or administering federally controlled substances to assist suicide violates the Controlled Substances Act." *Id.* at 254. The Supreme Court found that the Attorney General's rule

exceeded his statutory rulemaking authority because, *inter alia*, "[t]he CSA does not grant the Attorney General this broad authority to promulgate rules." *Id.* at 259. The Court elaborated that the two specific grants of rulemaking authority could not be stretched to include such broad, expansive rulemaking authority. *Id.* at 267 ("The idea that Congress gave the Attorney General such broad and unusual authority through an implicit delegation in the CSA's registration provision is not sustainable."). The Court went on to find that even under the *Skidmore* standard of deference,[8] the Attorney General's position did not pass muster. *Id*. at 268–69.

The D.C. Circuit has similarly taken the position that "[w]here Congress prescribes the form in which an agency may exercise its authority . . . [the court] cannot elevate the goals of an agency's action, however reasonable, over that prescribed form." *Amalgamated Transit Union v. Skinner*, 894 F.2d 1362, 1364 (D.C. Cir. 1990). In *Amalgamated Transit Union*, the Urban Mass Transportation Administration ("UMTA") "issued regulations to require recipients of federal mass transit funds to implement an anti-drug program for [federal] employees who perform sensitive safety functions." *Id.* at 1363. In promulgating the rule, UMTA relied on § 22 of the Urban Mass Transportation Act which authorized the Secretary of Transportation to "investigate conditions in any facility, equipment, or manner of operation financed under this chapter which the Secretary *believes creates a serious hazard of death or injury*." *Id.* at 1365 (emphasis added). If the Secretary determines that such conditions create a hazard, "he shall require the local public body which has received funds . . . to submit a plan for correcting or eliminating such condition" and may even withhold funding from that local public body. *Id.* "Based on the premise that the use of any controlled substance has the potential to degrade safety performance, UMTA proposed regulations that would detect and deter drug use among mass transportation

[8] The Court went on to analyze the case under *Skidmore* because the rule at issue was an interpretive rule, and not a legislative rule.

workers performing sensitive-safety functions." *Id.* The court found that the language of § 22 "does not . . . confer authority upon UMTA to define initially through rulemaking the precise terms of that [local] plan and condition receipt of federal money on compliance with those specific terms, prior to any dialogue with local agencies (and their unions) that must begin by the submission of a locally-developed plan." *Id.* at 1369 (parenthetical in original). Importantly, the court noted, Congress had given UMTA specifically delegated authority "to investigate safety hazards . . . in a manner that requires *case-by-case development* of local solutions to those hazards." *Id.* (emphasis added). Accordingly, UMTA's "prophylactic rulemaking," *see id.* at 1368, was unauthorized agency action, and the court reversed and remanded the case to the district court to vacate the anti-drug program rule. *Id.* at 1372.

The D.C. Circuit did the same in *Motion Picture Ass'n of America v. FCC,* 309 F.3d 796 (D.C. Cir. 2002). That case involved Congress's enactment of the Telecommunications Act of 1996, which amended the Communications Act, and the provision that specifically dealt with closed captioning and video description technologies employed to enhance television watching for hearing and visually impaired individuals. *Id.* at 798. The Telecommunications Act required the FCC to "complete a closed captioning inquiry and to report its findings to Congress," and "to prescribe closed captioning regulations and establish[] compliance deadlines." *Id.* With respect to video descriptions, however, Congress only "required the FCC to prepare a report to Congress." *Id.* The FCC nevertheless implemented rules mandating television programming with video descriptions, and the court vacated the rules because "the FCC can point to no statutory provision that gives the agency authority to mandate visual description rules." *Id.* at 807; *see also Am. Library Ass'n v. FCC*, 406 F.3d 689, 708 (D.C. Cir. 2005) ("categorically" rejecting the FCC's argument that "it possesses *plenary* authority to act within a given area

simply because Congress has endowed it with *some* authority to act in that area") (emphasis in original); *Cal. Indep. Sys. Op. Corp. v. FERC*, 372 F.3d 395, 396, 401 (D.C. Cir. 2004) (vacating a FERC order replacing the governing board of a public benefit corporation because "Congress's specific and limited enumeration of FERC's power over corporate governance in section 305 [of the Federal Power Act] is strong evidence that section 206(a) confers no such authority on FERC" to resolve conflicts of interest among the directors of public utilities by altering the corporate governance structure of public utilities.); *United Mine Workers of America v. Mine Safety & Health Admin.*, 823 F.2d 608, 617–19 (D.C. Cir. 1987) (invalidating a regulation implemented by the Secretary of Labor regarding interim relief for mining companies because there was no statutory grant of authority for the Secretary to do so, and there was strong evidence that "Congress did not intend to authorize the Secretary to grant temporary relief from mandatory health and safety standards as a matter of course under section 101(c)"); *cf. Sutton v. United Air lines, Inc.*, 527 U.S. 471, 479 (1999), *overturned due to legislative action by* Pub. L. 110-325 (2009) (finding that various agencies' interpretations of the word "disability" under the ADA did not deserve deference for various reasons, including that "no agency has been delegated authority to interpret the term 'disability.'").

In promulgating the final rule at issue here, HHS relied upon five statutory authorizations of rulemaking authority. Specifically, HHS relied upon: (1) Section 340B of the PHSA, 42 U.S.C. § 256b, as amended, (2) Section 215 of the PHSA, 42 U.S.C. § 216, as amended, (3) Section 526 of the FFDCA, 21 U.S.C. § 360bb, as amended, (4) Section 701(a) of the FFDCA, 21 U.S.C. § 371(a); and (5) Section 1927 of the Social Security Act, 42 U.S.C. § 1396r-8, as amended. *See* 78 Fed. Reg. at 44,027. Ultimately, the Court finds that the statutory provisions HHS has strung together to give it rulemaking authority are much like the provisions in *Gonzales*

and *Amalgamated Transit Union*, in that they are specific grants of authority that do not authorize the orphan drug rule implemented here. As such, the Court "must give effect to the unambiguously expressed intent of Congress," and vacate the final rule under *Chevron* step one. *See City of Arlington*, 133 S. Ct. at 1868.

1. Non-section 340B rulemaking authority

The last four statutory provisions relied upon by HHS clearly do not confer any rulemaking authority upon HHS for the orphan drug rule issued here, because they do not arise under the PHSA or the 340B program. As such, HHS has acted beyond "the bounds of its statutory authority," *see id*., and is not entitled to *Chevron* deference. 42 U.S.C. § 216(b) gives the Surgeon General, with the approval of the Secretary, authority to "promulgate all other regulations necessary to the administration of the [Public Health] Service, including regulations with respect to uniforms for employees, and regulations with respect to the custody, use, and preservation of the records, papers, and property of the Service." While such a section does confer general rulemaking authority on the Secretary, the statute is clear that the regulations she may issue pursuant to that grant must pertain to the "administration of the [Public Health] Service,"[9] not the *implementation* of the Public Health Service *Act*. Though the Health Resources and Services Administration ("HRSA") is considered a component of the U.S. Public Health Service,[10] the rulemaking authority clearly applies to administrative issues such as regulations regarding uniforms, record-keeping, etc.—not *implementation* of any and all statutes

[9] "Overseen by the Surgeon General, the U.S. Public Health Service Commissioned Corps is a diverse team of more than 6,500 highly qualified, public health professionals." *See* http://www.usphs.gov/ (last accessed May 22, 2014).

[10] *See* U.S. Department of Health and Human Services Organization Chart, *available at* http://www.hhs.gov/about/orgchart/.

related to the public health. That statutory provision thus cannot be read to grant the Secretary the authority to issue the orphan drug rule at issue here.

The second rulemaking provision upon which HHS relies also does not confer rulemaking authority on the Secretary to issue the rule under the 340B Program. 21 U.S.C. § 360bb(d) provides that "[t]he Secretary shall by regulation promulgate procedures for the implementation of subsection (a) of this section." Subsection (a), meanwhile, provides for orphan drug designation by the Secretary, specifying that "[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). The procedures for implementation therefore, clearly refer to the process for *orphan drug designation* in the first instance—which is handled by the FDA—not the HRSA under the 340B Program.[11] Importantly, Title 21 of the United States Code pertains to the FFDCA; the 340B Program, meanwhile is part of Title 42 and the PHSA—an entirely different statute. A limited grant of rulemaking authority in *an entirely different statute*, therefore, cannot carry the day for the rulemaking here. *Cf. Sutton*, 527 U.S. at 478–79 (explaining that the EEOC's authority to issue regulations under Title I of the ADA did not give it the authority to then interpret the term "disability," which fell outside Title I of the ADA); *Kelley v. EPA*, 15 F.3d 1100, 1105 (D.C. Cir. 1994) (explaining that "[a]lthough the mandate of section 105 [of CERCLA] does provide the EPA with broad rulemaking authority . . . it is hardly a specific delegation of authority to EPA to interpret section 107.") (internal citation omitted).

[11] Indeed, the FDA has promulgated rules regarding orphan designation pursuant to this very delegation of rulemaking power. *See, e.g.*, 21 C.F.R. § 316.1(a) ("This part implements sections 525, 526, 527, and 528 of the [Federal Food, Drug, and Cosmetic A]ct and provides procedures to encourage and facilitate the development of drugs for rare disease or conditions . . . .").

HHS also relies on another provision within Title 21 (again, the FFDCA), 21 U.S.C. § 371(a), which states that "[t]he authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary." The chapter referred to is Chapter 9 of the Federal Food, Drug, and Cosmetic Act. The rule issued here is found in Chapter 6 of the Public Health Service Act—again, an entirely different statute altogether.

Finally, HHS also relies upon 42 U.S.C. §1396r-8, which pertains to Medicaid payment for covered outpatient drugs, and authorizes the Secretary to "*by regulation, periodically update the list of drugs or classes of drugs described in paragraph (2) or their medical uses, which the Secretary has determined*, based on data collected by surveillance and utilization review programs of State medical assistance programs, to be subject to clinical abuse or inappropriate use." 42 U.S.C. § 1396r-8(d)(3) (emphasis added). Paragraph (2), meanwhile, lists the drugs that may be excluded from Medicaid coverage, or otherwise restricted, such as drugs used for anorexia, weight loss, or weight gain, drugs used to promote fertility, and several other categories of which orphan drugs are not a part. 42 U.S.C. § 1396r-8(d)(2).[12] Again, this limited, specific, grant of rulemaking authority does not confer upon HHS authority to issue the rule here, which arises under section 340B of the PHSA.[13]

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[12] While "covered outpatient drug" does appear under paragraph (2), it is qualified: *See* 42 U.S.C. § 1396r-8(d)(2)(G) ("Covered outpatient drugs *which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee*.") (emphasis added).

[13] 42 U.S.C. § 1302(a) states that "[t]he Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services, respectively, shall make and publish such rules and regulations, not inconsistent with this chapter, as may be necessary to the efficient administration of the functions with which each is charged under this chapter." Importantly, this general grant of rulemaking authority is limited to "this chapter," which is Chapter 7 of the Social Security Act, codified within Title 42 of the United States Code. The PHSA is part of Chapter 6 of Title 42, and thus, any general grant of rulemaking authority conferred to the

2. Section 340B rulemaking authority

The provisions within section 340B of the PHSA upon which HHS rely for its authority require more analysis. Within section 340B, Congress specifically authorized rulemaking in three places: (1) the establishment of an administrative dispute resolution process, (2) the "regulatory issuance" of precisely defined standards of methodology for calculation of ceiling prices, and (3) the imposition of monetary civil sanctions. The Court analyzes each in turn.

HHS first relied on the following provision regarding the establishment of an administrative dispute resolution process in promulgating the final rule here:

> the Secretary *shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section*, and claims by manufacturers . . . of violations of subsections (a)(5)(A) or (a)(5)(B) . . . .
>
> 42 U.S.C. § 256b(d)(3)(A) (emphasis added).

HHS argues that it "promulgated the present regulation to clarify the law in advance instead of waiting for an adjudicatory proceeding," and "[b]ecause of the confusion in the marketplace, the agency's jurisdiction to adjudicate would necessitate its deciding—at least in adjudications—to what drugs the exception applies." Fed.-Def.'s Mot. Summ. J. 16, ECF No. 24-1. HHS relies on *National Petroleum Refiners Association v. FTC* for the proposition that "courts are recognizing that use of rule-making to make innovations in agency policy may actually be fairer to regulated parties than total reliance on case-by-case adjudication." 482 F.2d 672, 681 (D.C. Cir. 1973). While that court recognized rulemaking as preferable to "adjudication for development of new agency policy," *see id.* at 683, it did so in the context of a statute that conferred *broad* rulemaking authority on the agency to carry out its adjudicatory and

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Secretary of HHS under the Social Security Act is clearly limited to Chapter 7 and not applicable to Chapter 6 of the Public Health Service Act.

other functions. For instance, section 5(b) of the Trade Commission Act (which established the Federal Trade Commission) directed the Commission to accomplish its statutory goal of preventing unfair methods of competition "by means of issuance of a complaint, a hearing, findings as to the facts, and issuance of a cease and desist order." *Id.* at 675. Meanwhile, section 6(g) of the Trade Commission Act empowered the Commission to "make rules and regulations for the purpose of carrying out the provisions of [*inter alia*], Section 5 [of the Act]." *Id.* at 676–77, 676 n.7. The court therefore found that "under the terms of its governing statute *and* under section 6(g) . . . in particular, the Federal Trade Commission is authorized to promulgate rules defining the meaning of the statutory standards of the illegality the Commission is empowered to prevent." *Id.* at 698 (citations omitted) (emphasis added).

Unfortunately for HHS, the Court's holding in *National Petroleum* turned on the fact that the FTC had a grant of broad rulemaking authority "to carry out" the provisions of its adjudicatory power, as well as broad rulemaking authority in its governing statute, that are absent here. Here, Congress has given HHS rulemaking power *specifically for purposes of administering a dispute resolution process* "for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section, and claims by manufacturers . . . of violations of [the prohibition on duplicate discounts and/or resales] . . . ." 42 U.S.C. § 256b(d)(3)(A). Congress has specifically delineated the scope of HHS's rulemaking authority in that regard to: (1) designating or establishing a decision-making official or decision-making body within the HHS for reviewing and resolving claims by covered entities that they have been overcharged; *see id.* § 256b(d)(3)(B)(i); (2) establishing deadlines and procedures to make sure claims are resolved fairly, *see id.* § 256b(d)(3)(B)(ii); (3) establishing discovery procedures for covered entities, *see id.* § 256b(d)(3)(B)(iii); (4) requiring manufacturers to conduct audits, *see*

id. § 256b(d)(3)(B)(iv); (5) allowing consolidation of claims by more than one manufacturer against the same covered entity, *see id.* § 256b(d)(3)(B)(v); and (6) allowing joint claims by multiple covered entities against the same manufacturer, *see id.* § 256b(d)(3)(B)(vi). The rulemaking authority granted HHS by Congress under the 340B program has thus been specifically limited, and HHS has not been granted broad rulemaking authority to carry out all the provisions of the 340B program. Instead, Congress has limited HHS's rulemaking authority to creating a system for resolving disputes between covered entities and manufacturers—not to engaging in prophylactic non-adjudicatory rulemaking regarding the 340B program altogether. While the Court agrees that a prophylactic rule like this seems like the most reasonable way for implementing the orphan drug exclusion, unfortunately, Congress did not delegate to HHS broad rulemaking authority as a means of doing so.[14]

Tied into the regulations HHS is allowed to promulgate for the administrative dispute resolution process is the following language regarding improvements in 340B program integrity, codified at 42 U.S.C. § 256b(d), and referenced in the grant of specific rulemaking authority: "the Secretary shall promulgate regulations to establish and implement an administrative process . . . including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraphs (1)(B) and (2)(B)". *See id.* § 256(d)(3)(A). Paragraphs (1)(B) and (2)(B), meanwhile, discuss improvements in compliance by manufacturers and covered entities,

[14] Importantly, HHS issued a notice of proposed rulemaking for the purpose of establishing this very adjudicative power delegated by Congress. *See* 340B Drug Pricing Program Administrative Dispute Resolution Process, 75 Fed. Reg. 57,233 (Sept. 20, 2010). In that notice, HHS explained that it was soliciting comments as to how best to implement the system contemplated by Congress—noting this very section of the statute and all of its requirements. HHS never issued the final rule, and as of briefing, the administrative dispute resolution process has not been implemented by HHS.

respectively. With respect to manufacturer compliance, those sections call on the Secretary to "provide for improvements in compliance" by, *inter alia*, "[t]he development of a system to enable the Secretary to verify the accuracy of ceiling prices," including "[d]eveloping and publishing *through an appropriate policy or regulatory issuance*, precisely defined standards and methodology for calculation of ceiling prices under [subsection (a)(1)]." *Id.* § 256b(d)(1)(B)(i)(I) (emphasis added). The Secretary is also tasked with, *inter alia*, "[p]erforming spot checks of sales transactions," "[c]omparing regularly the ceiling prices calculated by the Secretary with the quarterly pricing data," and "[e]stablish[ing] procedures for . . . issu[ing] refunds." *See id.* § 256b(d)(1)(B)(i)–(ii). With respect to covered entity compliance, the Secretary is authorized to provide for improvements such as "[t]he development of more detailed guidance describing methodologies and options available to covered entities for billing covered outpatient drugs," and "[t]he establishment of a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers . . . for purposes of facilitating the ordering . . . ." *Id.* § 256b(d)(2)(B)(iii)–(iv). Finally, the Secretary is also authorized to establish regulations for imposing civil monetary sanctions. *See id.* § 256b(d)(1)(B)(vi)(I) ("The imposition of sanctions in the form of civil monetary penalties . . . shall be assessed according to standards established in regulations to be promulgated by the Secretary not later than 180 days after March 23, 2010.").

Of all of those compliance improvements delineated above, only two mention the Secretary's ability to issue regulations. One section authorizes the Secretary to develop "through an appropriate policy or *regulatory issuance*, precisely defined standards and methodology for the calculation of ceiling prices" under subsection (a)(1). *See id.* § 256b(d)(1)(B)(i)(I) (emphasis added). The government argues that "[i]n order for HHS to define these standards precisely,

HHS must define which drugs are 'covered outpatient drugs' for purposes of the 340B Program," citing Krista Pedley's declaration as authority. *See* Def.'s Opp'n Mot. 18, ECF No. 24-1. However, that does not follow from the text of the statute. The discount price offered to a covered entity—the ceiling price—is set by determining the average manufacturer price ("AMP"), which is then reduced by the rebate percentage described in 42 U.S.C. § 1396r-8(c).[15] *See* 42 U.S.C. § 256b(a)(1). 42 U.S.C. § 256b(a)(1) specifies that the Secretary shall require "that the manufacturer offer each covered entity covered outpatient drugs at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." Thus, the only relevance the ceiling price has to the definition of "covered outpatient drugs" is that a covered entity either will get the discount or it will not. Whether the covered outpatient drug gets a discount at all, in other words, is an entirely separate process from the complex calculation involved in determining the ceiling price and the average manufacturer price in the first instance. *See Astra*, 131 S. Ct. at 1345–46 (explaining that the ceiling price calculation is derived from the average and best prices and rebates calculated under the Medicaid Drug Rebate Program and that "[c]alculation of a manufacturer's 'average' and 'best' prices, undertaken by the pharmaceutical company, is a complex enterprise requiring recourse to detailed information about the company's sales and pricing.") (citing 42 U.S.C. § 1396r-8(c) & (k)).

Specifically, the Social Security Act defines average manufacturer price as follows: "[subject to certain exclusions], the term 'average manufacturer price' means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by (i) wholesalers for drugs distributed to retail

[15] The rebate percentage is defined in the Social Security Act and its definition is unrelated to whether or not a drug is classified as an orphan drug. *See* 42 U.S.C. § 1396r-8(c)(1)(B)(i) (setting the minimum rebate percentage as between 12.5% and 23.1%, depending on the year).

community pharmacies; and (ii) retail community pharmacies that purchase drugs directly from the manufacturer." 42 U.S.C. § 1396r-8(k)(1)(A). The statute goes on to list what discounts and payments are excluded from the calculation of the average manufacturer price. *See id.* §§ 1396r-8(k)(1)(B)(i)-(ii) (excluding, for example, customary prompt pay discounts extended to wholesalers, bona fide service fees paid by manufacturers to wholesalers, and certain reimbursements). Moreover, HHS guidance documents enacted as part of the 340B Program explain how the drug price of a covered outpatient drug is calculated:

> To determine the price for a covered outpatient drug, the manufacturer shall calculate the average manufacturer price (AMP) for the drug and reduce it by the rebate percentage. Average manufacturer price is the average price paid to the manufacturer for the drug in the United States by wholesalers for the drug distributed to the retail pharmacy class of trade in the calendar quarter . . . . The Medicaid rebate calculation utilizes the Best Price information which considers the lowest price available at which the manufacturer sells the covered outpatient drug to any wholesaler, retailer, nonprofit entity, or governmental entity . . . .

See Guidance Regarding Section 602 of the Veterans Health Care Act of 1992; Limitation on Prices of Drugs Purchased by Covered Entities, 58 Fed. Reg. 27,289, 27,291 (May 7, 1993). Meanwhile, as to the "best price" figure, the text of the Social Security Act reveals that whether a discount is applied to a covered entity is irrelevant to the "best price," and in turn, the ceiling price calculation. *See* 42 U.S.C. § 1396r-8(c)(1)(C)(i)(I) ("The term 'best price' means . . . the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider . . . *excluding any prices charged . . . to . . . a covered entity described in subsection (a)(5)(B) of this section . . . .*"). The text of all the statutory provisions that determine ceiling price thus show that the classification of a drug as a "covered outpatient drug" is not part of the equation for ceiling price determination. Thus, a drug's classification is not required, "in order

for [HHS] to define these standards [for calculating ceiling price] precisely." Pedley Decl. ¶ 16, ECF No. 24-3.[16]

Finally, the specific delineation for regulation regarding civil monetary sanctions also cannot be interpreted to allow for the expansive rule at issue in this case. This specific grant of rulemaking authority is not enough to sustain rulemaking for an entirely different purpose under the statute. *See Gonzales*, 546 U.S. at 267; *Amalgamated Transit Union*, 894 F.2d at 1369.

Under *Chevron* step one, then, all of the foregoing statutory provisions are clear that they do not confer orphan drug rulemaking authority upon the agency. In other words, the agency did not receive congressional authority "to determine the particular matter at issue in the particular manner adopted." *City of Arlington*, 133 S. Ct. at 1874. Rather, Congress gave HHS a specific delegation of rulemaking authority to establish an adjudication procedure to resolve disputes between covered entities and manufacturers. Though the Court finds the agency's proactive, prophylactic rule to be the most reasonable way of administering the statute, Congress has not given HHS the broad rulemaking authority to do so, and "[w]here Congress has established a clear line, the agency cannot go beyond it . . . ." *Id.* As such, the Court must vacate the final rule, and grant the plaintiff's motions.

[16] To the extent a pharmaceutical company's sales figures involved in the calculation of average manufacturer price are affected, either directly or indirectly by a drug's classification as a covered outpatient drug (*i.e.*, a certain drug's sales increase or decrease and the sales price in turn is affected by that fluctuation, based on whether it is characterized as a covered outpatient drug), that is neither accounted for in the statutory text, nor raised by the parties as a reason for regulation. And the government has cited no legal authority for that proposition. Regardless, Congress "does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman v. Am. Trucking Assoc.*, 531 U.S. 457, 468 (2001) (citing *MCI Telecomms. Corp. v. AT&T*, 512 U.S. 218, 231 (1994)). If Congress had meant the scope of HHS's rulemaking authority to reach as far as what may be an indirect connection, it would have said so.

D. Interpretive Rule Theory

In the alternative, HHS asks this Court to uphold the rule as an interpretive, as opposed to a legislative, rule. *See* Def.'s Opp'n Mot. 21, ECF No. 24-1. HHS relegates one paragraph of its opposition brief to this issue; however, such relief poses a much more nuanced and complicated question than suggested by the parties. As the D.C. Circuit has explained, there are many different formulations for determining whether a rule is legislative as opposed to interpretive. *See Community Nutrition Institute v. Young*, 818 F.2d 943, 946 (D.C. Cir. 1987) ("The distinction between legislative rules and interpretive rules or policy statements has been described at various times as 'tenuous,' 'fuzzy,' 'blurred,' and perhaps most picturesquely, 'enshrouded in considerable smog.'") (per curiam) (citations omitted). Nevertheless, the D.C. Circuit has formulated a well-known four-factor test for determining whether a rule is legislative, and in turn, subject to *Chevron* deference. *Am. Min. Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106 (D.C. Cir. 1993). In *American Mining Congress*, the Court stated the test as follows:

> Accordingly, insofar as our cases can be reconciled at all, we think it almost exclusively on the basis of whether the purported interpretive rule has "legal effect," which in turn is best ascertained by asking (1) whether in the absence of the rule there would not be an adequate legislative basis for enforcement action or other agency action to confer benefits or ensure the performance of duties, (2) whether the agency has published the rule in the Code of Federal Regulations, (3) whether the agency has explicitly invoked its general legislative authority, or (4) whether the rule effectively amends a prior legislative rule. If the answer to any of these questions is affirmative, we have a legislative, not an interpretive rule.

Id. at 1112.[17]

[17] Over the years, certain of those factors have been de-emphasized. *See Health Ins. Ass'n of America, Inc. v. Shalala*, 23 F.3d 412, 423 (D.C. Cir. 1994) (explaining that while courts have suggested that publication in the Code of Federal Regulations is dispositive of a rule being legislative as opposed to interpretive, in that case, publication was "[nothing] more than a snippet of evidence of agency intent" that was "not enough" to render the rule legislative).

The government's argument is half-hearted, and the Court is inclined to think it is wrong because the rule (1) underwent notice and comment rulemaking—the hallmark of a legislative rule[18]—and (2) it has a "legal effect" on the parties so regulated because the interpretation of "covered outpatient drug," as well as the compliance procedures impose obligations on covered entities and manufacturers alike. *See Elec. Privacy Info. Ctr. v. U.S. Dep't of Homeland Sec.*, 653 F.3d 1, 6–7 (D.C. Cir. 2011) ("The practical question inherent in the distinction between legislative and interpretive regulations is whether the new rule effects a substantive regulatory change to the statutory or regulatory regime.") (internal citation omitted); *Gen. Motors Corp. v. Ruckelshaus*, 742 F.2d 1561, 1565 (D.C. Cir. 1984) ("If by its action the agency intends to create new law, rights or duties, the rule is properly considered to be a legislative rule.").

However, if HHS wishes to pursue the interpretive rule theory further, the Court needs more briefing on why the rule is interpretive, the implications of it being found interpretive, whether parts of the rule can be vacated and others upheld as interpretive, and whether it can be challenged now, or whether HHS must first promulgate the rule as interpretive for it to then be challenged under *Skidmore*.[19] On the issue before the Court today—whether HHS has

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[18] Indeed, HHS noted that it was—for the first time—promulgating a regulation and not a mere guidance document in enacting the orphan drug rule. *See* 78 Fed. Reg. 44,016, 44,017 (July 23, 2013) ("The 340B Program generally has relied on published program guidance documents, which are typically finalized after a notice and comment period. However, we have determined that a regulation is necessary to implement these changes."). While HHS's position is not binding on the court, it does shed light on the agency's intent in engaging in the rulemaking. *See, e.g.*, *Truckers United for Safety v. Fed. Highway Admin.*, 139 F.3d 934, 939 (D.C. Cir. 1998) ("Although the label an agency places on a rule is not dispositive, the label, as indicative of intent, does carry some weight in our consideration whether the underlying rule is legislative or interpretative.") (citing *Action for Children's Television v. FCC*, 59 F.3d 1249, 1257 (D.C. Cir. 1995)).

[19] *Kelley v. EPA*, 15 F.3d 1100 (D.C. Cir. 1994) is instructive on this murky issue. In *Kelley*, the EPA promulgated a regulation under CERCLA that the D.C. Circuit found it did not have the statutory authority to promulgate. *Id.* at 1106–07. EPA argued in the alternative that the rule should be upheld as an interpretive rule. *Id.* at 1108. The court similarly struggled

substantive rulemaking authority under section 340B of the PHSA to promulgate the orphan drug rule—the Court concludes that HHS does not, and that the final rule must be vacated.

IV. CONCLUSION

For the foregoing reasons, the plaintiff's motion for an injunction and motion for summary judgment are GRANTED, and the defendants' motion for summary judgment is DENIED. An order consistent with this Memorandum Opinion is separately and contemporaneously issued.

Dated: May 23, 2014

RUDOLPH CONTRERAS
United States District Judge

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with the question of whether the rule could even be considered interpretive, but ultimately concluded that the rule was in fact legislative, and vacated the final rule. *Id.* at 1108–09. However, the court noted that EPA was free to then implement some sort of guidance policy on the same issue because the petitioners had conceded that the regulation could be sustained as a policy statement. The court explained: "[g]iven our uncertainty as to EPA's wishes, we think the proper course is to vacate the rule and leave EPA free to take whatever steps it thinks appropriate." *Id.* at 1109.