UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MERCK & CO., INC., et al.,	)	
Plaintiffs,	)	
v.	)	**Case No. 19-cv-01738 (APM)**
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,	)	
Defendants.	)	

MEMORANDUM OPINION

I. INTRODUCTION

In May of 2019, the U.S. Department of Health and Human Services ("HHS") published a final rule that regulates the marketing of prescription drugs. The rule requires drug manufacturers to disclose in any television advertisement the list price—also known as the wholesale acquisition cost—of a 30-day supply of the drug ("WAC Disclosure Rule"). The cost of prescription drugs has been increasing for years, and because of its role as health insurer for millions of Americans through the Medicare and Medicaid programs, the United States government is the single largest payor of prescription drugs in the nation. HHS adopted the WAC Disclosure Rule to "introduce[ ] price transparency that will help improve the efficiency of the Medicare and Medicaid programs by reducing wasteful and abusive increases in drug and biological product list prices." HHS pointed to its general power under the Social Security Act to make rules necessary for the efficient administration of the Medicare and Medicaid programs as the source of its authority to issue the Rule. The WAC Disclosure Rule will go into effect on July 9, 2019.

Plaintiffs in this case are three drug manufacturers and a marketing trade association that contend that the WAC Disclosure Rule is unlawful. Plaintiffs advance two primary arguments. First, they argue that the Rule exceeds HHS's authority, because Congress neither expressly nor impliedly granted HHS the power under the Social Security Act to regulate drug marketing. Second, they maintain that the WAC Disclosure Rule is compelled speech that violates the First Amendment. Plaintiffs have asked the court to halt the WAC Disclosure Rule before it goes into effect.

Federal agencies typically enjoy expansive authority from Congress to formulate rules that have the force of law in areas germane to the statutes that they implement. But such authority is not unbounded. For a regulation to have the force of law, Congress must communicate through legislation, either expressly or impliedly, its intent for the agency to make rules in that specific area. When Congress has not communicated such intent, the agency has no power to act.

The court finds that HHS lacks the statutory authority under the Social Security Act to adopt the WAC Disclosure Rule. Neither the Act's text, structure, nor context evince an intent by Congress to empower HHS to issue a rule that compels drug manufacturers to disclose list prices. The Rule is therefore invalid. In view of this holding, the court does not reach Plaintiffs' First Amendment challenge.

To be clear, the court does not question HHS's motives in adopting the WAC Disclosure Rule. Nor does it take any view on the wisdom of requiring drug companies to disclose prices. That policy very well could be an effective tool in halting the rising cost of prescription drugs. But no matter how vexing the problem of spiraling drug costs may be, HHS cannot do more than what Congress has authorized. The responsibility rests with Congress to act in the first instance.

For the reasons addressed below, the court declares the WAC Disclosure Rule invalid and sets aside the Rule.

II. BACKGROUND

A. The Proposed Rule

In May 2018, the Department of Health and Human Services ("HHS") issued a policy statement titled "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" ("the Blueprint"). 83 Fed. Reg. 22,692 (May 16, 2018). The Blueprint's stated purpose was to halt rising drug prices and to lower out-of-pocket expenses that Americans pay for pharmaceutical products. *See id.* at 22,692. As one possible action, HHS announced that it would "[c]all on [the Food and Drug Administration ("FDA")] to evaluate the inclusion of list prices in direct-to-consumer advertising." *Id.* at 22,695. Direct-to-consumer advertising is one of the most important ways pharmaceutical manufacturers communicate with consumers to inform them of new products, raise disease awareness, and encourage consultation with health care providers. Compl., ECF No. 1 [hereinafter Compl.], ¶ 34.

Five months after issuing the Blueprint, in October 2018, HHS published a Notice of Proposed Rulemaking titled "Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency." 83 Fed. Reg. 52,789 (Oct. 18, 2018). The Notice announced a Proposed Rule that would require direct-to-consumer television advertisements for prescription drug and biological products to include the "list price" of the product for a 30-day supply, if the list price is more than $35 and the drug is covered under the Medicare or Medicaid program. *Id.* at 52,789, 52,799. The "list price" is a price that manufacturers set for sale to wholesalers before applying rebates or other price reductions. *See* Compl. ¶ 52. The "list price" is also known in the industry as the Wholesale Acquisition Cost ("WAC"). *See id.* at ¶¶ 4, 7. The Proposed Rule would require

covered television advertisements to contain the following statement: "The list price for a [30-day supply of] [typical course of treatment with] [name of prescription drug or biological product] is [insert list price]. If you have health insurance that covers drugs, your cost may be different." 83 Fed. Reg. at 52,799.

One of the unexpected features of the Proposed Rule was the HHS sub-agency that issued it. The Blueprint stated that HHS may "call on the FDA to evaluate the inclusion of list prices in direct-to-consumer advertising." 83 Fed. Reg. at 22,695. The issuing agency, however, turned out to be the Centers for Medicare & Medicaid Services ("CMS"), acting pursuant to its rulemaking authority under the Social Security Act ("SSA"). *See id.* at 52,791–92. HHS acknowledged that "Congress has not explicitly provided HHS with authority to compel the disclosure of list prices to the public." *Id.* at 52,791. Yet, it "concluded that the proposed rule has a clear nexus to the Social Security Act." *Id.* HHS explained that "Congress has explicitly directed HHS to operate Medicare and Medicaid programs efficiently," *see id.*, and that the Proposed Rule was designed to advance that directive by lowering the costs that public health insurance programs pay for prescription drug benefits, *see id.* at 52,791–92.

B. The Final Rule

On May 10, 2019, HHS announced that it had decided to finalize the Proposed Rule with minor modifications. *See Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency*, 84 Fed. Reg. 20,732 (May 10, 2019). The court will refer to the final rule as the "WAC Disclosure Rule." Consistent with the Proposed Rule, the WAC Disclosure Rule requires the disclosure of drug prices. *See id.* Specifically, direct-to-consumer television advertisements of drugs covered by the Medicare and Medicaid programs must communicate the list price, or

WAC, for a 30-day supply of the drug, if it costs more than $35 per month. *See id.* HHS set the effective date of the WAC Disclosure Rule as July 9, 2019. *See id.*

HHS adopted the WAC Disclosure Rule over numerous objections raised by the pharmaceutical industry. *See id.* at 20,735. Two primary objections are the focus of this action.

The first was that HHS lacks the legal authority to promulgate the Rule under the SSA. *See id.* at 20,735–36. In response to this criticism, HHS identified two provisions of the SSA, Sections 1102 and 1871, as the source of its rulemaking authority. *See id.* at 20,736. Section 1102(a) provides in pertinent part: The Secretary of HHS "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 [he] is charged under this chapter." 42 U.S.C. § 1302(a). Similarly, Section 1871(a) states that the Secretary of HHS "shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter." *Id.* § 1395hh(a)(1). HHS defended its reliance on these general rulemaking provisions on the ground that the WAC Disclosure Rule's objective was to lower drug costs, thereby promoting the "efficient administration of Medicare and Medicaid." *See* 84 Fed. Reg. at 20,736.

The second major objection concerned use of the WAC as the advertised price. The industry asserted that referring to the WAC risked misleading and confusing consumers, as the WAC rarely captures the actual out-of-pocket costs that most Americans pay for drug products due to, among other things, insurance coverage and patient assistance programs. *See id.* at 20,739–42. HHS responded that the WAC was a recognized benchmark of cost within the industry and correlated with out-of-pocket expenses, and that its disclosure would create an opportunity for patients to discuss the cost of drugs with their physicians. *See id.* at 20,739. HHS further stated that the second sentence of the disclosure—advising that if the buyer has health insurance, the cost

of the drug may be different—would mitigate any confusion. *See id.* at 20,741. It therefore dismissed the industry's concern. *Id.*

The industry's opposition to using the WAC also manifested itself as a First Amendment argument. *See id.* at 20,743–48. The challengers argued that the WAC Disclosure Rule was compelled speech that violated the First Amendment. *See id.* at 20,743–44. The forced disclosure, they maintained, did not pass muster under the intermediate scrutiny standard articulated by the Supreme Court in *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980), or the more relaxed standard used in *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626 (1985). *See id.* at 20,744. HHS rejected these arguments, finding that the WAC Disclosure Rule satisfied both tests. *See id.*

B. Procedural History

1. This Action and the Motion to Stay

Plaintiffs in this case are three pharmaceutical companies—Merck & Co., Inc.; Eli Lilly and Company; and Amgen Inc.—and the National Association of Advertisers, Inc., a membership organization focused on "promot[ing] and protect[ing] the well-being of the marketing community." Compl. ¶ 21. Plaintiffs filed their Complaint on June 14, 2019, approximately five weeks after the Final Rule's publication. *See* Compl. They named as defendants HHS; Alex M. Azar II, the Secretary of HHS in his official capacity; CMS; and Seema Verma, the Administrator of CMS in her official capacity (collectively "Defendants"). *Id.* ¶¶ 22–25.

The Complaint contains one count asserting that the WAC Disclosure Rule violates the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701–706. *Id.* ¶¶ 110–114. Plaintiffs allege three distinct theories of violation: (1) The WAC Disclosure Rule "exceeds the HHS's statutory authority, *see* 5 U.S.C. § 706(2)(C); (2) it is arbitrary, capricious, an abuse of discretion, and

otherwise not in accordance with law, *id*. § 706(2)(A); and (3) it is contrary to the First Amendment of the U.S. Constitution, *id.* § 706(2)(B)." *Id.* ¶ 111. Plaintiffs ask the court to declare the WAC Disclosure Rule invalid and to vacate the Rule. *Id.* at 36.

Contemporaneously with their Complaint, Plaintiffs filed a Motion to Stay the effective date of the WAC Disclosure Rule, set for July 9, 2019, *see* 5 U.S.C. § 705 (authorizing courts to "postpone the effective date" of agency action in order "to preserve status or rights pending conclusion of the review proceedings"). *See* Pls.' Mot. for a Stay Pending Judicial Review, ECF No. 12 [hereinafter Pls.' Mot.]; Pls.' Mem. of Law in Supp. of Pls.' Mot., ECF No. 12-1 [hereinafter Pls.' Mem.]. The Motion to Stay rests on two of the three theories advanced in the Complaint: (1) the WAC Disclosure Rule is not a valid exercise of HHS's and CMS's rulemaking authority under the SSA, *see* Pls.' Mem. at 21–28; and (2) the WAC Disclosure Rule compels speech in violation of the First Amendment, *see id.* at 28–43. The Motion to Stay did not advance the APA arbitrary and capricious claim. *See generally* Pls.' Mem. Plaintiffs asked the court to expedite consideration of their Motion. *See* Pls.' Mot. to Expedite Proceedings on Pls.' Mot., ECF No. 13. The court agreed to do so. *See* Order, ECF No. 17.

2. Consolidation on the Merits

The court held a hearing on the Motion to Stay on July 2, 2019. *See* July 2, 2019 Hr'g Tr., ECF No. 31 [hereinafter Hr'g Tr.]. At the hearing, the court inquired whether the parties would be amenable to consolidating the Motion to Stay with a motion on the merits, thereby treating the arguments before the court as seeking entry of final judgment. *See id.* at 4–7. The parties asked for time to consider the question. *See id.* at 6. After the hearing, Defendants consented to consolidating the two claims addressed in the Motion to Stay. *See* Notice of Defs.' Position, ECF No. 24. Plaintiffs, on the other hand, asked the court not to convert their motion to one on the

merits. *See* Notice of Pls.' Position, ECF No. 25. Plaintiffs' main concern was that, "if the [c]ourt converts Plaintiffs' motion into a motion for judgment on the merits, HHS may argue during any appeal of a judgment on the merits that it would be inappropriate for Plaintiffs (or this [c]ourt) to point to the declarations" they had filed with their Complaint. Notice of Pls.' Position, ECF No. 25, at 2 (referencing Compl., Exs., ECF Nos. 1-1–1-5). Plaintiffs wished to avoid any potential "procedural complications." *Id.*

Notwithstanding Plaintiffs' objection, the court will consolidate on the merits on the sole claim that the court addresses in this opinion: Whether HHS's promulgation of the WAC Disclosure Rule was "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C). The court has not relied on any extra-record evidence submitted by Plaintiffs to rule on that question. Plaintiffs' concern regarding potential procedural complications arising from the reliance (or non-reliance) on the submitted declarations, so far as the court can tell, relates exclusively to their First Amendment claim. Because the court does not reach the First Amendment claim, Plaintiffs' expressed worry about consolidation is not germane. The court therefore will proceed on the merits of Plaintiffs' lack-of-authority claim under the APA.[1]

III. LEGAL FRAMEWORK

The parties disagree on the analytical framework the court must apply in deciding whether the WAC Disclosure Rule exceeds HHS's rulemaking authority. Plaintiffs contend that the question is controlled by the familiar two-step inquiry under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.* *See* Pls.' Reply in Supp. of Pls.' Mot., ECF No. 22, [hereinafter

[1] Because the court treats the Motion to Stay as a motion on the merits, the court need not evaluate the traditional injunction factors that apply to stay requests under the APA. *See Affinity Healthcare Servs., Inc. v. Sebelius*, 720 F. Supp. 2d 12, 15 n.4 (D.D.C. 2010).

Pls.' Reply], at 9–11. Under that construct, "applying the ordinary tools of statutory construction, the court must [first] determine '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.'" *City of Arlington v. FCC*, 569 U.S. 290, 296 (2013) (quoting *Chevron*, 467 U.S. 837, 842–43 (1984)). However, "if 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." *Chevron*, 467 U.S. at 843.

For their part, Defendants eschew the *Chevron* framework. Their brief does not even cite the case. *See* Defs.' Opp'n to Pls.' Mot., ECF No. 20 [hereinafter Defs.' Opp'n]; *see also* Hr'g Tr. at 55–56. Rather, they urge the court to follow the standard set forth in the pre-*Chevron* decision, *Mourning v. Family Publications Services, Inc.* *See* Defs.' Opp'n at 13–14. The Supreme Court in *Mourning* stated that, "[w]here the empowering provision of a statute states simply that the agency may 'make . . . such rules and regulations as may be necessary to carry out the provisions of this Act,' we have held that the validity of a regulation promulgated thereunder will be sustained so long as it is 'reasonably related to the purposes of the enabling legislation.'" 411 U.S. 356, 369 (1973) (quoting *Thorpe v. Hous. Auth. of City of Durham*, 393 U.S. 268, 280–81 (1969)). Applying this "reasonably related" standard is appropriate in this case, Defendants argue, because Congress granted the Secretary of HHS broad rulemaking authority to administer the Medicare and Medicaid programs. *See* Defs.' Opp'n at 12–13.

The court agrees with Plaintiffs that *Chevron* controls. The Supreme Court made clear in *City of Arlington* that questions such as the one before the court should be analyzed under *Chevron*. *See* 569 U.S. at 296–97. In that case, the Court rejected the notion that there were two distinct

classes of agency interpretations, some "jurisdictional" and others "nonjurisdictional." *Id.* at 291, 297. In every challenge to agency action, "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 297. Stated differently, "the question in every case is, simply, whether the statutory text forecloses the agency's assertion of authority, or not." *Id.* at 301. The answer to that question, the Court emphatically held, is determined by following the *Chevron* two-step framework. *See id.* at 307.

What then to make of the *Mourning* standard? Some courts have situated *Mourning* within *Chevron*'s second step, an inquiry made "only after a court has determined that Congress has indeed delegated interpretative powers to that agency." *Chamber of Commerce of U.S. v. N.L.R.B.*, 721 F.3d 152, 158 (4th Cir. 2013); *see also Int'l Swaps & Derivatives Ass'n v. U.S. Commodity Futures Trading Comm'n*, 887 F. Supp. 2d 259, 271 (D.D.C. 2012) (stating that "*Mourning* has been interpreted by courts in our Circuit to apply during the *Chevron* Step Two analysis, and that the Court's deference to the agency is still limited by the particular language of a statute at issue"). *Mourning* itself supports such a reading. *See Mourning*, 411 U.S. at 371–72 (stating that, "where reasonable minds may differ" about agency action, "courts should defer to the informed experience and judgment of the agency *to whom Congress delegated appropriate authority*") (emphasis added). And, although the D.C. Circuit has not expressly linked *Mourning* and *Chevron* Step Two, it has analyzed *Mourning* as part of a Step Two inquiry. *See Am. Fed'n of Labor & Cong. of Indus. Orgs. v. Chao*, 409 F.3d 377, 384 (D.C. Cir. 2005). In any event, the court's task here is clear: it must apply the *Chevron* framework and cannot, as Defendants insist, rely exclusively on the *Mourning* standard.

IV. ANALYSIS

There is no dispute here as to whether the SSA *expressly* grants HHS the authority to compel pharmaceutical companies to disclose the wholesale price of a marketed drug in television advertisements. It does not. The SSA contains no explicit delegation of authority to HHS to regulate the televised marketing of drugs. *See* 83 Fed. Reg. at 52,791 (stating in Proposed Rule that "Congress has not explicitly provided HHS with authority to compel the disclosure of list prices to the public").

Absent an express grant of authority to regulate, the court must determine whether Congress "would [have] expect[ed] [HHS] to be able to speak with the force of law" when it promulgated the WAC Disclosure Rule. *United States v. Mead Corp.*, 533 U.S. 218, 229 (2001). In other words, deference under *Chevron* is appropriate "*only* if the reviewing court finds an implicit delegation of authority to the agency." *Sea-Land Serv., Inc. v. Dep't of Transp.*, 137 F.3d 640, 645 (D.C. Cir. 1998) (emphasis added); *see also City of Arlington*, 569 U.S. at 306 (stating that *Mead* "requires that, for *Chevron* deference to apply, the agency must have received congressional authority to determine the particular matter at issue . . .").

To figure out whether such an implicit delegation exists, at *Chevron* Step One courts must rely on the "traditional tools of statutory construction," including "the statute's text, legislative history, and structure, . . . as well as its purpose." *Bell Atlantic Tel. Cos. v. FCC*, 131 F.3d 1044, 1047 (D.C. Cir. 1997) (citations omitted); *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000) ("The meaning—or ambiguity—of certain words or phrases may only become evident when placed in context."). But those are not the only available tools. The court also may look to other legislative acts, "particularly where Congress has spoken subsequently and more specifically to the topic at hand." *Brown & Williamson*, 529 U.S. at 133. Additional factors

include "the interstitial nature of the legal question, the related expertise of the Agency, the importance of the question to administration of the statute, the complexity of that administration, and the careful consideration the Agency has given the question over a long period of time." *See Barnhart v. Walton*, 535 U.S. 212, 222 (2002). And, finally, "[t]he subject matter of the relevant provision—for instance, its distance from the agency's ordinary statutory duties or its falling within the scope of another agency's authority—has also proved relevant." *City of Arlington*, 569 U.S. at 309 (Breyer, J., concurring) (citing *Gonzales v. Oregon*, 546 U.S. 243, 265–66 (2006)). In the end, the court must decide "whether Congress delegated authority to the agency to provide interpretations of, or to enact rules pursuant to, the statute at issue . . ." *City of Arlington*, 569 U.S. at 308 (Breyer, J., concurring).

Having applied the tools of statutory interpretation here, the court finds that HHS's adoption of the WAC Disclosure Rule exceeds the rulemaking authority that Congress granted the agency under the SSA.

A. Statutory Text

The court begins, as it must, with the text of the statutes upon which the WAC Disclosure Rule rests. Defendants point to Sections 1102 and 1871 of the SSA as the source of their rulemaking authority. Those provisions provide: (1) The "Secretary of Health and Human Services . . . 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" he is charged by the SSA, which include the Medicare and Medicaid programs, 42 U.S.C. § 1302(a); and (2) "The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter," which establishes the Medicare program, *id.* § 1395hh(a)(1). These are broad grants of rulemaking authority. About that there is no real

dispute. But the words used by Congress matter. Plaintiffs focus on the word "necessary" contained in each provision to make their case. *See* Pls.' Mem. at 25. The more important word, in the court's view, however, is "administration."

The term "administration" means "[t]he process or activity of running a business, organization, etc.,"[2] or "[t]he management or performance of the executive duties of a government, institution, or business; collectively, all the actions that are involved in managing the work of an organization," BLACK'S LAW DICTIONARY (11th ed. 2019). The word thus conveys the types of actions that are directed toward controlling the operation of something over which a person has executive authority. The SSA reflects this meaning of "administration." It vests certain control in the Secretary of HHS, and it defines the objects of that control—i.e., what the Secretary is "administering"—as the Medicare and Medicaid programs. Thus, the basic power that Congress gave to the Secretary was to establish rules and regulations for "running" or "managing" the federal public health insurance programs through CMS.

HHS seeks to do more than that here. It has adopted a rule that regulates the conduct of market actors that are not direct participants in the Medicare or Medicaid programs. Pharmaceutical manufacturers are not health care providers, private plan carriers,[3] or beneficiaries—each of whom plays a direct role in the public health insurance programs. They do not receive payment for their products from CMS. Their pricing decisions, of course, affect the cost of pharmaceutical benefits offered under the Medicare and Medicaid programs. But those decisions impact program costs in an indirect way. The plain statutory text simply does not support

[2] Administration, OXFORD DICTIONARY OF ENGLISH, https://www.lexico.com/en/definition/administration.

[3] Prescription drug benefits under Medicare Part D are offered through private insurance companies. *See* 42 U.S.C. § 1395w-115; *see generally Action All. of Senior Citizens v. Johnson*, 607 F. Supp. 2d 33, 36 (D.D.C. 2009) (describing Medicare Part D program), aff'd sub nom. *Action All. of Senior Citizens v. Sebelius*, 607 F.3d 860 (D.C. Cir. 2010).

the notion—at least not in a way that is textually self-evident—that Congress intended for the Secretary to possess the far-reaching power to regulate the marketing of prescription drugs.

Other provisions of the SSA confirm the court's conclusion. In both the Final Rule and briefing here, HHS points to various sections of the SSA for the proposition that "[b]oth Titles XVIII and XIX of the Social Security Act reflect the importance of *administering* the Medicare and Medicaid programs in a manner that minimizes unreasonable expenditures." Defs.' Opp'n at 14 (quoting 84 Fed. Reg. at 20,735) (emphasis added). HHS cites SSA sections 1842(b)(8) and (9), 1860D-4(c)(3), 1860D-4(c)(5)(H), 1866(j)(2)(A), 1893(g), 1902(a)(64), 1902(a)(65), and 1936(b)(2). *See id.* HHS contends that these provisions show that, because Congress gave the agency power to make rules designed to control costs, the WAC Disclosure Rule fits comfortably within the agency's authority. *See* Defs.' Opp'n at 14 (arguing that compelling the disclosure of list prices "reasonably relates to that cost efficiency goal").

But a close inspection of these provisions tells a different story. Sections 1842(b)(8) and (b)(9) require HHS to promulgate regulations describing the factors that it will use in determining reimbursement requests that are "grossly excessive" or "grossly deficient" and thus not "inherently reasonable," and to consult with health care providers who submit such requests. *See* 42 U.S.C. §§ 1395u(b)(8), (b)(9). Section 1860D-4(c)(3) directs HHS to require prescription drug plan sponsors to dispense covered Part D drugs in a manner that reduces waste associated with 30-day fills. *Id.* § 1395w-104(c)(3). Similarly, Section 1860D-4(c)(5)(H) commands HHS to establish rules and procedures to identify at-risk beneficiaries who are using prescription drugs "outside normal patterns," which "may indicate fraudulent, medically unnecessary, or unsafe use." *Id.* § 1395w-104(c)(5)(H)(ii). Section 1866(j)(2)(A) concerns procedures for enrolling and screening new providers and suppliers. *Id.* § 1395cc(j)(2)(A). And Sections 1893(g), 1902(a)(64), and

1936(b)(2) are all directed to programs or practices designed to prevent and combat fraud, waste, and abuse. *Id.* §§ 1395ddd(g) (establishing Medicare-Medicaid Data Match Program); 1396a(a)(64) (requiring state programs to have a mechanism for beneficiaries and others to report, and compile data concerning, waste, fraud, and abuse); 1396u-6(b)(2) (describing activities of the Medicaid Integrity Program). Other parts of the SSA that expressly address the "administration" of the programs are to the same effect. *See, e.g.*, SSA §§ 1808, 42 U.S.C. § 1395b-9 ("Provisions relating to administration"); 1816, 42 U.S.C. § 1395h (Provisions relating to the administration of Part A); 1842, 42 U.S.C. § 1395u (Provisions relating to the administration of Part B); 1866B, 42 U.S.C. § 1395cc-2 (Provisions for administration of demonstration program); and 1874, 42 U.S.C. § 1395kk (Administration).

What these provisions have in common is this: each contains a congressional directive that concerns the day-to-day running and operation of Medicare and Medicaid as public health insurance programs, and each is directed in some way to a program participant or the program itself. None authorize HHS, in the name of attempting to reduce the costs, to regulate the health care market itself or market actors that are not direct participants in the insurance programs. Simply put, the delegation of authority that HHS says allows it "to speak with the force of law" on the marketing of prescription drugs is nowhere to be found in the vast statute that is the SSA. *Mead*, 533 U.S. at 229. Thus, when viewed as a whole, the SSA unambiguously does not delegate to HHS the power to promulgate the WAC Disclosure Rule.

Defendants contend that Congress's delegation of general rulemaking power under the SSA, combined with the absence of a clear statutory restriction, demonstrate that Congress intended for HHS to regulate broadly on subjects affecting the costs of the Medicare and Medicaid programs. As Defendants put it: "[N]either the statutory scheme as a whole nor any specific

provision precludes the Secretary from ensuring the efficient administration of the Medicaid and Medicare programs through a CMS regulation that would provide more information to consumers about drug prices." Defs.' Opp'n at 16. HHS advanced the same rationale in the Final Rule. *See* 84 Fed. Reg. at 20,736 ("These statutes do not impose a limit on the means, other than to say, in the case of section 1102, that they not be inconsistent with the [SSA]"; "Viewing the Medicare and Medicaid schemes as a whole, nothing prohibits the requirements we are finalizing in this rule.").

An agency's general rulemaking authority plus statutory silence does not, however, equal congressional authorization. "An agency's general rulemaking authority does not mean that the specific rule the agency promulgates is a valid exercise of that authority." *Colo. River Indian Tribes v. Nat'l Gaming Comm'n*, 466 F.3d 134, 139 (D.C. Cir. 2006). Indeed, "[r]egardless of how serious the problem an administrative agency seeks to address, . . . [an agency] may not exercise its authority in a manner that is inconsistent with the administrative structure that Congress enacted into law." *Brown & Williamson*, 529 U.S. at 125 (internal quotation marks and citation omitted). The D.C. Circuit has echoed these principles in multiple settings, stating that provisions like those at issue here do not supply an agency "[c]arte blanche authority" to promulgate rules on any matter relating to its enabling statute. *Citizens to Save Spencer Cty v. EPA*, 600 F.2d 844, 873 (D.C. Cir. 1979); *see also Nat'l Mining Ass'n v. U.S. Dep't of Interior*, 105 F.3d 691, 694 (D.C. Cir. 1997); *Am. Petrol. Inst. v. EPA*, 52 F.3d 1113, 1119–20 (D.C. Cir. 1995). Even broad rulemaking power must be exercised within the bounds set by Congress. *See Ragsdale v. Wolverine World Wide, Inc.*, 535 U.S. 81, 92 (2002) ("Our previous decisions, *Mourning* included, do not authorize agencies to contravene Congress'[s] will . . ."); *Aid Ass'n for Lutherans v. U.S. Postal Serv.*, 321 F.3d 1166, 1174 (D.C. Cir. 2003) ("An agency construction of

a statute cannot survive judicial review if a contested regulation reflects an action that exceeds the agency's authority."). Here, as discussed, Congress empowered HHS to "administer" the public health insurance programs. That grant of rulemaking authority does not sweep so broadly as to authorize HHS to regulate the marketing of prescription drugs.

Nor does the absence of an express limitation of authority establish HHS's capacity to act. "Agency authority may not be lightly presumed. Were courts to *presume* a delegation of power absent an express *withholding* of such power, agencies would enjoy virtually limitless hegemony, a result plainly out of keeping with *Chevron, Mead*, and quite likely with the Constitution as well." *Atlantic City Elec. Co. v. FERC*, 295 F.3d 1, 9 (D.C. Cir. 2002) (cleaned up). To that end, the D.C. Circuit has long "refuse[d] . . . to presume a delegation of power merely because Congress has not expressly withheld such power." *Ethyl Corp. v. EPA*, 51 F.3d 1053, 1060 (D.C. Cir. 1995); *see also Motion Picture Ass'n of Am., Inc. v. FCC*, 309 F.3d 796, 805 (D.C. Cir. 2003) (rejecting as "entirely untenable" the agency's position that the adoption of a regulation "is permissible because Congress did not expressly foreclose the possibility"); *Am. Bus Ass'n v. Slater*, 231 F.3d 1, 9 (D.C. Cir. 2000) ("Hence if Congress wishes to deny an agency a given power, it need not expressly restrict the agency; it is enough for Congress simply to decline to delegate power."). Instead, "it is only legislative intent to delegate such authority that entitles an agency to advance its own statutory construction for review under the deferential second prong of *Chevron*." *Nat. Res. Def. Council v. Reilly*, 983 F.2d 259, 266 (D.C. Cir. 1993) (quoting *Kansas City v. Dep't of Hous. & Urban Dev.*, 923 F.2d 188, 191–92 (D.C. Cir. 1991)); *see also Am. Bus Ass'n*, 231 F.3d at 9 ("In order for there to be an ambiguous grant of power, there must be a grant of power in the first instance."). In this matter, there is nothing in the SSA that reflects congressional intent to vest in HHS the power to compel pharmaceutical companies to disclose the WAC in direct-to-

consumer television advertising. Therefore, the SSA's absence of an express limitation does not enable HHS to arrogate to itself the power to regulate drug marketing as a means of improving the efficiency of public health insurance programs.

The cases on which Defendants primarily rely are different. *Thorpe*, *Mourning*, and the D.C. Circuit's recent decision in *Doe 1 v. FEC* all involve instances in which the agency's authority to make the challenged rule under a broad delegation of authority was not seriously in doubt. In *Thorpe*, the Department of Housing and Urban Development required that housing authorities provide tenants of federally assisted housing projects the reasons for eviction and an opportunity to respond before the start of eviction proceedings. *See* 393 U.S. at 269–70. This rule, the Court held, was reasonably related to "[o]ne of the specific purposes of the federal housing acts" "to provide 'a decent home and a suitable living environment for every American family' that lacks the financial means of providing such a home without governmental aid." *Id.* at 281. In *Mourning*, the Federal Reserve Board subjected a magazine subscription service to the Truth in Lending Act under a regulation that triggered the Act's disclosure requirements whenever a consumer is offered credit payable in more than four installments. 411 U.S. at 362. The Court found the rule to be consistent with Congress's delegation of authority to make rules that would prevent merchants from structuring transactions to conceal credit charges. *See id.* at 371–72. And, in *Doe 1*, the question simply concerned the extent of the Federal Election Commission's ability to disclose its investigative files. 920 F.3d 866, 870–71 (D.C. Cir. 2019). The court held that the Commission's disclosure policy, though broader than statutorily required, was consistent with the statutory objectives of deterring future violations of the federal election laws and promoting Commission accountability. *See id.* In each of these cases, the agency aimed its rule at either the very actors that Congress empowered the agency to regulate (local housing authorities receiving federal funds

in *Thorpe* and merchants who extend credit in *Mourning*) or the agency's own operations (public release of the agency's records in *Doe 1*). Here, by contrast, HHS has not directed the WAC Disclosure Rule at program participants or program operations. Instead, the Rule, as Plaintiffs put it, "regulates primary conduct several steps removed from the heartland of HHS's authority under the Social Security Act." Pls.' Reply at 13. *Thorpe*, *Mourning*, and *Doe 1*, therefore, do not support what HHS has done here.

The more apt comparison is to *Colorado River Indian Tribes v. National Gaming Commission*. There, the National Indian Gaming Commission issued regulations for both Class II gaming, as expressly permitted by the Indian Gaming Regulatory Act, and Class III gaming, as to which the statute granted no explicit authority. 466 F.3d 134, 135–37 (D.C. Cir. 2006). The Commission claimed it could regulate Class III gaming based on its general rulemaking authority and the Act's declaration of policy to "promote integrity in Indian gaming." *Id.* at 139. The court rejected the agency's rationale. The court observed that "[a]ll questions of government are ultimately questions of ends and means." *Id.* (quoting *Nat'l Fed'n of Fed. Emps. v. Greenberg*, 983 F.2d 286, 290 (D.C. Cir. 1993)). Thus, agencies are "bound, not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes." *Id.* (quoting *MCI Telecomms. Corp. v. AT&T*, 512 U.S. 218, 231 n.4 (1994)). Congress wanted to ensure the integrity of Indian gaming, the court explained, but only by the means it had chosen. *Id.* This observation led the court "back to the opening question—what is the statutory basis empowering the Commission to regulate Class III gaming operations?" *Id.* at 140. It found none. *Id.* The same is true here. There is no statutory basis in the SSA that empowers HHS to regulate the television marketing of prescription drugs.

Defendants attempt to distinguish *Colorado River* from this case by arguing that the structure of the Indian Gaming Regulatory Act revealed Congress's intent not to subject Class III gaming to federal regulation. *See* Defs.' Opp'n at 15. Defendants say that there is no comparable restriction on HHS's authority. *See id.* at 16. But Defendants' proposed mode of statutory interpretation has it precisely backwards. As discussed, the mere absence of an express statutory restriction is not a blank check to regulate on any subject matter that might conceivably advance a legislative purpose. The means chosen by Congress to effectuate legislation matters. Here, there is nothing in the text or structure of the SSA that conveys Congress's intent to permit HHS to accomplish the efficient administration of the Medicare and Medicaid programs through the compelled disclosure of wholesale drug prices in television advertisements. Therefore, HHS cannot rely upon the mere absence of the kind of statutory structural feature that was present in *Colorado River* to establish congressional intent to allow it to make rules in the area of drug marketing. An agency cannot appropriate the power to regulate simply because Congress has not explicitly taken that power away.

B. Other Statutes

In *Brown & Williamson*, the Supreme Court instructed that when "determining whether Congress has specifically addressed the question at issue, a reviewing court should not confine itself to examining a particular statutory provision in isolation." 529 U.S. at 132. Other statutes may bear on Congress's intent. "[T]he meaning of one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand." *Id.* at 133. That principle applies in this case.

Congress enacted the general rulemaking provisions of the SSA, Sections 1102 and 1871, respectively, as part of the original Act in 1935 and as part of the Social Security Amendments of

1965. *See* Pub. L. No. 74-271, 49 Stat. 620; Pub. L. No. 89-97, 79 Stat. 331. During this time and after, Congress has legislated on the subject of direct-to-consumer advertising of pharmaceutical products multiple times under a different statute—the Food, Drug, and Cosmetic Act ("FDCA"). Under the FDCA, Congress has vested in HHS the power to regulate drug advertising to ensure that direct-to-consumer advertisements are truthful and communicate relevant information concerning a drug's benefits and risks. *See* 21 U.S.C. § 321(n) (concerning the "misbranding" of products, including "advertising [that is] misleading"). The Secretary, in turn, has delegated this authority to the FDA. So, for instance, as part of the Drug Amendments of 1962, Congress amended Section 502 of the FDCA to impose content requirements for prescription drug advertisements. *See* Pub. L. No. 87-781, § 131(a), 76 Stat. 791–92 (Oct. 10, 1962) (codified at 21 U.S.C. § 352(n)). Among other things, Congress required advertisements to contain the established name of the drug, the drug's ingredients, and "such other information in brief summary related to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary" of HHS. *Id.* Later, as part of the Food and Drug Administration Amendments of 2007, Congress added to Section 503 in two ways. First, Congress mandated that published direct-to-consumer prescription drug advertisements contain contact information for the FDA so consumers can report adverse side effects. *See* Pub. L. No. 110-85, § 906(a), 121 Stat. 949–50 (Sept. 27, 2007) (codified at 21 U.S.C. § 352(n)). Second, Congress prescribed the minimum content for television advertisements of a particularly toxic category of drugs that must be administered by physicians. *See* Pub. L. No. 110-85, § 901(d)(3)(A), 121 Stat. 940. As these amendments to the FDCA demonstrate, Congress knows how to prescribe the content of drug advertising when it chooses to do so.

Congress also has enacted specific legislation pertaining to television advertising of drug products. As part of the Amendments of 2007, Congress added Section 503B to the FDCA (later renumbered as Section 503C), titled "Prereview of Television Advertisements." *See* Pub. L. No. 110-85, § 901(d)(2), 121 Stat. 939–40 (presently codified at 21 U.S.C. § 353c). That provision states that the Secretary "may require the submission of any television advertisement for a drug . . . for review under this section not later than 45 days before dissemination of the television advertisement." 21 U.S.C. § 353c(a). The Secretary may make recommendations about the advertisement's contents as it relates to consumer protection, the drug's prescribing information, and the drug's efficacy as to certain population groups. *Id.* § 353c(b). But Congress prohibited the Secretary from ordering direct changes, except in one instance. *Id.* § 353c(c). The lone exception is where "the Secretary determines that the advertisement would be false or misleading without a specific disclosure about a serious risk listed in the labeling of the drug involved, the Secretary may require inclusion of such disclosure in the advertisement." *Id.* § 353c(e)(1). As these passages demonstrate, Congress has directly addressed the subject of television drug advertising and pre-review of such advertisements. Yet, for decades Congress has not addressed the disclosure of drug prices.[4]

Defendants acknowledge these congressional actions but dismiss them as irrelevant. They contend that the FDCA "serves purposes distinct from the Social Security Act and does not occupy the field when it comes to drug advertising." Defs.' Opp'n at 17. According to Defendants, the

[4] Congress appears in one instance to have spoken on the disclosure of drug prices. In 1971, the United States signed the Convention on Psychotropic Substances. The Convention is a United Nations treaty whose purpose is to establish an international control system for psychotropic substances. Congress passed enabling legislation in 1978. *See* Pub. L. No. 95-633, 92 Stat. 3768 (Nov. 10, 1978). As part of that legislation, Congress amended Section 503 of the FDCA to include the following: "Nothing in the Convention on Psychotropic Substances . . . shall be construed to prevent drug price communications to consumers." *Id.*, § 111, 92 Stat. 3773–74 (codified at 21 U.S.C. 352(n)). The legislative history offers no clue as to why Congress made that amendment. *See* H.R. No. 95-1193 (1978); S. Rep. No. 95-959 (1978). Therefore, Congress's purpose in ensuring that the Convention would not be construed to interfere with conveying drug prices to consumers is unclear.

FDCA is designed primarily to protect the health and safety of the public at large, whereas the SSA "governs government benefit programs and is concerned with expenditures," thereby allowing HHS to regulate under the latter but not the former. *Id.* Additionally, Defendants maintain, "nothing in the FDCA reflects a deliberate choice by Congress to give the FDA the authority to regulate [direct-to-consumer] advertising to the exclusion of all other agencies," thus leaving the door open to CMS to do so. *Id.*

Defendants are correct that the FDCA and the SSA have different purposes, but that distinction misses the larger point. Congress deliberately and precisely legislated in the area of drug marketing under the FDCA. Such purposeful action demonstrates that Congress knows how to speak on that subject when it wants to. It is therefore telling that the SSA contains no provisions concerning drug marketing. The SSA's different purpose cannot overcome the statute's silence. *Cf. Brown & Williamson*, 529 U.S. at 155–56 (finding that the FDA lacked authority to regulate tobacco products where "Congress has enacted several statutes addressing the particular subject of tobacco and health," but had not expressly granted the FDA the power to regulate); *Am. Petroleum Inst.*, 52 F.3d at 1119 ("EPA cannot rely on its general authority to make rules necessary to carry out its functions when a specific statutory directive defines the relevant functions of EPA in a particular area.").

C. Subject Matter of the WAC Disclosure Rule

The subject matter of the WAC Disclosure Rule also leads to the conclusion that Congress did not delegate authority under the SSA to compel drug price disclosures. Courts "must be guided to a degree by common sense as to the manner in which Congress is likely to delegate a policy decision of such economic and political magnitude to an administrative agency." *Brown &*

Williamson, 529 U.S. at 133. In these types of cases, the Supreme Court has said, "[w]e expect Congress to speak clearly . . . ." *Util. Air. Regulatory Grp. v. EPA*, 573 U.S. 302, 324 (2014).

Congress has not spoken clearly here. HHS estimates that in 2015 Americans spent $457 billion on prescription drugs. 84 Fed. Reg. at 20,733. Of that amount, $328 billion was for retail drugs (those typically obtained at a pharmacy) and $128 billion was for non-retail drugs (those typically administered at a hospital or clinic). *See id.* CMS is the single largest payor of prescription drugs in the nation. *See id.* In 2016, CMS and its beneficiaries spent $238 billion on prescription drugs, which represents approximately 53 percent of the $448.2 billion expended on retail and non-retail drugs in that year. *See id.* The magnitude of the pharmaceutical industry is thus apparent, and it is clear that the WAC Disclosure Rule moves HHS and CMS into regulating the marketing of products that comprise "a significant portion of the American economy." *Brown & Williamson*, 529 U.S. at 159. Common sense dictates that Congress would not have authorized such a dramatic seizure of regulatory power based solely on general rulemaking authority under the SSA.

Further, it is not lost on the court that HHS has never before attempted to use the SSA to directly regulate the market for pharmaceuticals. *See* Hr'g Tr. at 59–60 (admitting no prior efforts to regulate the marketing of drugs outside of the FDCA). Sure, there is a first time for everything. But when, as here, an agency "claims to discover in a long-extant statute an unheralded power to regulate 'a significant portion of the American economy,'" courts should "greet its announcement with a measure of skepticism." *Util. Air Regulatory Grp.*, 573 U.S. at 324. The Medicare program came into existence over a half-century ago, in 1965. Yet, it would appear that HHS did not discover its purported authority to regulate drug marketing under the SSA until soon before HHS proposed the WAC Disclosure Rule in October 2018. *See* 83 Fed. Reg. at 52,791–92. Indeed,

when it released the Blueprint in May 2018, HHS said that it may "[c]all on the *FDA* to evaluate the inclusion of list prices in direct-to-consumer advertising." *Id.* at 22,695 (emphasis added). Yet, a mere five months later, CMS became the issuing sub-agency. It thus would seem that HHS at first believed that the FDA, presumably under the FDCA, would be the proper sub-agency through which to promulgate the WAC Disclosure Rule, as opposed to CMS under the SSA. To be fair, the Blueprint also says that HHS may direct CMS to "make Medicare and Medicaid prices more transparent" and "hold drug makers accountable for their price increases." *Id.* It is telling, however, that HHS first announced the specific action in dispute here as falling within the purview of a different sub-agency. The WAC Disclosure Rule feels like agency action in search of a statutory home. *Cf. Barnhart*, 535 U.S. at 222 (weighing "the careful consideration the Agency has given the question over a long period of time" as favoring deferring to the agency's action). It cannot find one in the SSA.

Finally, as the court already has intimated, the WAC Disclosure Rule is far afield of any other type of rulemaking authority HHS has previously exercised under the SSA. This is not a case of interstitial rulemaking. *See Barnhart*, 535 U.S. at 222. Instead, the Rule's "distance from the agency's ordinary statutory duties" is considerable. *City of Arlington*, 569 U.S. at 308 (Breyer, J., concurring). This factor, too, counsels against according deference to HHS's action here.

Defendants respond to these points as follows. They argue that, unlike *Brown & Williamson* and *Utility Air Regulatory Group*, this is not a case in which the agency has made a decision "of vast economic or political impact." Defs.' Opp'n at 20. The WAC Disclosure Rule is not like the FDA announcing its regulation of the tobacco industry (*Brown & Williamson*) or the EPA expanding licensing requirements tenfold (*Utility Air*). Instead, Defendants say, the rule here imposes only an "exceedingly modest" disclosure requirement that will cost the industry a "relative

pittance." *Id.* at 21 (estimating an annualized cost of $2.45 million, a "relative pittance compared to the $4.2 billion spent on [direct-to-consumer] television advertising in 2017") (citing 84 Fed. Reg. at 20,755). Therefore, they insist, the WAC Disclosure Rule is entirely compatible with the statutory scheme.

To be sure, the costs imposed by the WAC Disclosure Rule amount to a rounding error for the pharmaceutical industry. But that argument misses the point. It is the agency's incursion into a brand-new regulatory environment, and the rationale for it, that make the Rule so consequential. To accept the agency's justification here would swing the doors wide open to any regulation, rule, or policy that might reasonably result in cost savings to the Medicare and Medicaid programs, unless expressly prohibited by Congress. Indeed, the agency identifies no limiting principle, aside from an express statutory withholding of authority. So, this case is not just about whether HHS can force drug companies to disclose their list prices in the name of lowering costs. Rather, the WAC Disclosure Rule represents a significant shift in HHS's ability to regulate the health care marketplace. Congress surely did not envision such an expansion of regulatory authority when it granted HHS the power to issue regulations necessary to carry out the "efficient administration" of the Medicare and Medicaid programs.[5]

D. Remedy

Because the court finds that HHS exceeded its authority under the SSA, the court vacates the WAC Disclosure Rule. *See* 5 U.S.C. § 706(2)(C) (stating that courts must "set aside [that]

[5] One tool of construction that the court has not considered is legislative history. Neither side has cited any. That Congress would have intended for CMS to compel drug price disclosures, yet not said a word about such power, strikes the court as unlikely. Nevertheless, the court is mindful of the Circuit's admonition that "[d]rawing inferences as to congressional intent from silence in legislative history is always a precarious business." *Symons v. Chrysler Corp. Loan Guarantee Bd.*, 670 F.2d 238, 242 (D.C. Cir. 1981). Accordingly, the court does not draw any inference from the absence of legislative history in this case.

agency action" if found "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right"); *Nat. Res. Def. Council v. EPA*, 777 F.3d 456, 464 (D.C. Cir. 2014).

V. CONCLUSION

For the foregoing reasons, the court grants Plaintiffs' Motion to Stay, as consolidated on the merits of their APA claim under 5 U.S.C. § 706(2)(C). A final, appealable Order accompanies this Memorandum Opinion.

Dated: July 8, 2019

Amit P. Mehta
United States District Court Judge