JONES DAY

250 VESEY STREET • NEW YORK, NEW YORK 10281.1047

TELEPHONE: +1.212.326.3939 • FACSIMILE: +1.212.755.7306

DIRECT NUMBER: (212) 326-3658
JDELMEDICO@JONESDAY.COM

November 2, 2021

BY ECF & OVERNIGHT MAIL

Honorable Freda L. Wolfson
Chief United States District Judge
U.S. District Court for the District of New Jersey
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street Court, Room 5E
Trenton, New Jersey 08608

Re: *Sanofi-Aventis U.S., LLC v. U.S. Department of Health and Human Services, et al.*, Civil Action No. 3:21-cv-634

Dear Chief Judge Wolfson:

Plaintiff Sanofi-Aventis U.S., LLC ("Sanofi") respectfully notifies the Court that Judge Barker of the U.S. District Court for the Southern District of Indiana issued the enclosed decision on October 29, 2021, in *Eli Lilly and Company, et al. v. U.S. Department of Health and Human Services, et al.*, No. 1:21-cv-0081 (S.D. Ind.). The decision vacated two agency actions: Advisory Opinion 20-06, which Sanofi also challenges in this action, and HRSA's May 17 letter to Eli Lilly and Company ("Lilly"), which is similar to HRSA's May 17 letter to Sanofi at issue in this action. In particular, Judge Barker held that the Advisory Opinion was arbitrary and capricious. *Id.* at 34. As for HRSA's May 17 letter to Lilly, Judge Barker held that it too, although not contrary to law, was arbitrary and capricious. *Id.* at 58. In this case, Sanofi has challenged both the Advisory Opinion and HRSA's May 17 Letter to Sanofi as contrary to law and arbitrary and capricious.

In light of the ADR Panel's Initial Scheduling Order, which deferred Sanofi's deadline to respond to the ADR petition beyond November 5, *see* ECF 106, Sanofi respectfully requests the opportunity to provide the Court with supplemental briefing on Judge Barker's decision, including its applicability to the unique features of Sanofi's integrity initiative, *see* ECF 68-1, at 30-33; ECF 94, at 15-17. Sanofi proposes that the parties simultaneously file supplemental briefs limited to five pages on or before November 5.

Sanofi has conferred with the government about supplemental briefing. The government stated that "[w]e do not think it is necessary to provide supplemental briefing on the *Lilly* decision, given the thoroughness of the parties' existing briefing, and instead intend to file in each docket a short Notice of Supplemental Authority setting forth the government's position on the impact of that ruling."

Respectfully Submitted,

s/ Jennifer L. Del Medico

cc: All counsel of record

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, et al. Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al. Defendants.	)	No. 1:21-cv-00081-SEB-MJD

ORDER

This cause is before the Court on a virtual cornucopia of claims: Defendants' Motion to Dismiss, or in the alternative, for Summary Judgment [Dkt. 87], filed on April 19, 2021; and Plaintiffs' Cross Motion for Summary Judgment [Dkt. 89] and Motion for Preliminary Injunction [Dkt. 94], filed on May 10, 2021 and May 20, 2021, respectively. Plaintiffs Eli Lilly and Company and Lilly USA, LLC (collectively, "Plaintiffs" or "Lilly") have brought this action against Defendants United States Department of Health and Human Services ("HHS"), Health Resources and Services Administration ("HRSA"), Diana Espinoza, in her official capacity as Acting Administrator of HRSA, Xavier Becerra, in his official capacity as Secretary of HHS, and Daniel J. Barry, in his official capacity as Acting General Counsel of HHS (collectively, "Defendants") under the Administrative Procedures Act ("APA"), challenging various agency actions involving the 340B Drug Pricing Program ("340B Program"), which Congress created in 1992 to

expand low-income Americans' access to affordable prescription medicines. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967.

Currently before us for decision are Plaintiffs' various legal challenges to a December 30, 2020 Advisory Opinion ("Advisory Opinion") released by HHS's Office of the General Counsel and a May 17, 2021 enforcement letter ("May 17 Letter") from HRSA, both relating to drug manufacturers' obligations under the 340B statute when dealing with covered entities that dispense medications through contract pharmacy arrangements.[1] Plaintiffs seek a judgment declaring that in issuing the Advisory Opinion and the May 17 Letter Defendants violated the APA by having been issued without Defendants following the required procedures, exceeding the agency's statutory authority, violating the Constitution, and by being arbitrary and capricious or otherwise not in accordance with law. Plaintiffs seek to have their implementation and/or enforcement enjoined. Plaintiffs also seek a declaratory judgment holding that Defendants lack the lawful authority to require Lilly to offer or provide 340B discounts to contract pharmacies.

On July 30, 2021, the Court conducted a hearing at which oral arguments were made on the pending motion for preliminary injunctive relief, directed at enforcement of

[1] Lilly has also challenged in this lawsuit Defendants' December 14, 2020 Administrative Dispute Resolution Regulation published at 85 Fed. Reg. 80,632 and codified at 42 C.F.R. §§ 10.20-24 (the "ADR Rule"), which sets forth the administrative dispute resolution process for certain disputes regarding the 340B Program. Pursuant to our prior ruling, Defendants are currently enjoined from enforcing the ADR Rule as to Lilly. The parties have agreed that a final decision on the merits of this claim can be issued by separate order at a later date. Accordingly, we do not address the ADR Rule in this entry.

the May 17 Letter, and the cross-motions for summary judgment as to all Plaintiffs' claims related to the Advisory Opinion and the May 17 Letter. Pursuant to Federal Rule of Civil Procedure 65(a)(2), we now hereby consolidate our ruling on the preliminary injunction with our ruling on summary judgment. Having carefully reviewed and considered the parties' written briefs and oral arguments, the administrative record, and the applicable legal principles, we hold, for the reasons detailed below, that the Advisory Opinion is invalid under the APA as arbitrary and capricious, and that the May 17 Letter while not contrary to law, unconstitutional, or violative of notice and comment procedures, is likewise arbitrary and capricious and thus violative of the APA, warranting an order setting aside and vacating their findings and directives and remanding the May 17 Letter to the agency for further consideration/action consistent with the opinions explicated here.

Factual Background

Background of the 340B Drug Pricing Program

Plaintiffs' lawsuit arose under the 340B Drug Price Program ("340B Program"), a drug-pricing discount regime established by Congress in 1992 within the Public Health Service Act, *see* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71 (codified as amended at 42 U.S.C. § 256b), and administered by the Secretary of Health and Human Services ("HHS"), which requires, as a condition of Plaintiffs' participation in Medicaid and Medicare Part B,[2] that pharmaceutical

[2] Technically speaking, pharmaceutical manufacturers are free to opt out of participation in the 340B Program. However, if they do, they cannot receive coverage of or reimbursement for their

manufacturers such as Plaintiffs sell their outpatient drugs at a heavily discounted price to "covered entities," which are defined by statute to include 15 enumerated types of public and not-for-profit hospitals, community centers, and other federally funded clinics serving low-income patients. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967–71 (1992), *codified at* § 340B Public Health Service Act, 42 U.S.C. § 256b (1992). More specifically, all pharmaceutical manufacturers participating in the 340B Program must "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1). The resulting 340B "ceiling prices," which are calculated according to a prescribed statutory formula, *see id.* § 256b(a)(1), (a)(4), (b)(1), are significantly lower than the amount(s) other purchasers would pay and, in some cases, are as low as one penny per pill. These drug pricing discounts are intended to "enable [covered entities] to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. 2 at 12 (1992) (conf. report). Although not required, covered entities are permitted to pass the savings along to uninsured and underinsured patients to subsidize the costs of what would otherwise be cost prohibitive rates for medications.

---

products under Medicaid and Medicare Part B. If they opt out of participation in the 340B Program, they stand to lose "billions of dollars in revenue" annually from drug coverage in federal health-insurance programs. Am. Compl. ¶ 157.

To participate in the 340B Program, manufacturers are required to sign a form contract with HHS known as the Pharmaceutical Pricing Agreement ("PPA"), which incorporates the statutory obligations of the 340B Program and expresses the manufacturers' agreement to abide by those obligations. *See* 42 U.S.C. § 1396r-8(a)(1), (5). If at some point the government determines that a drug manufacturer has failed to comply with its 340B Program obligations, the manufacturer's PPA can be terminated, thereby preventing the manufacturer from receiving coverage for its drugs under Medicare and Medicaid. *See id.* § 1396r-8(b)(4)(B)(v); 61 Fed. Reg. 65,406, 65,412–65,413 (Dec. 12, 1996); PPA §§ IV(c), VI(c).

Under the 340B Program, covered entities are prohibited from requesting "duplicate discounts or rebates," which means that covered entities may not request both a 340B discount and a Medicaid rebate for the same drug. 42 U.S.C. § 256b(a)(5)(A). Covered entities are also prohibited from engaging in "diversion," which is defined by statute as the practice of "resell[ing] or otherwise transfer[ring]" a covered outpatient drug "to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B).

HRSA's 1994 Final 340B Program Guidelines

In 1994, following a notice and comment period, HRSA issued "final program guidelines" for the 340B program which provided that "manufacturers must offer outpatient drugs at or below the section 340B discount prices," and "[i]f the manufacturer's drugs are available to covered entities through wholesalers, the discount must be made available through that avenue." 59 Fed. Reg. 25,113. The 1994 guidelines further provided that "[m]anufacturers may not single out covered entities from their

other customers for restrictive conditions that would undermine the statutory objective," (*id.* at 25,111–112), and "must not place limitations on the transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program." *Id.* at 25,113. In response to a comment urging the agency not to require manufacturers to honor contract-pharmacy sales, HRSA acknowledged that "[i]t is a customary business practice for manufacturers to sell to intermediaries as well as directly to the entity," that entities "often use … contract pharmacies," and that, "[b]y placing such limitations on sales transactions, manufacturers could be discouraging entities from participating in the program." *Id.* at 25,111.

HHS's 1996 Advisory Opinion Regarding Contract Pharmacies

During the first few years of operation of the 340B Program, it became clear that fewer than five percent of the covered entities who were statutorily eligible to participate in the 340B Program actually operated in-house pharmacies. Instead, the vast majority of such providers relied on distribution arrangements with outside pharmacies, called "contract pharmacies," to dispense prescriptions to patients. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549-01, 43,550 (Aug. 23, 1996) (hereinafter "1996 Guidance"). Covered entities participating in the 340B Program who did not operate in-house pharmacies thus began relying on contract pharmacies to take delivery from manufacturers of 340B drugs purchased by the covered entity in order to dispense those drugs to the covered entities' low-income patients. *Id.* at 43,549.

Acknowledging this practice, and recognizing that, because "covered entities provide medical care for many individuals and families with incomes well below 200% of the Federal poverty level and subsidize prescription drugs for many of their patients, it was essential for them to access 340B pricing," (*id.* at 43,549), HHS issued non-binding guidance in 1996, stating that "[i]t would defeat the purpose of the 340B program if these covered entities [without in-house pharmacies] could not use their affiliated pharmacies in order to participate," because "[o]therwise, they would be faced with the untenable dilemma of having either to expend precious resources to develop their own in-house pharmacies (which for many would be impossible) or forego participation in the program altogether." *Id.* at 43,550. This 1996 Guidance thus advised that "[i]t has been the Department's position that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price," regardless of whether the covered entity directs that the 340B drugs be shipped for handling and dispensing to a contract pharmacy. *Id.* at 43,549. In other words, "[i]f the [covered] entity directs the drug shipment to its contract pharmacy," that practice does not "exempt[] the manufacturer from statutory compliance." *Id.* at 43,549.

HHS further advised that limiting covered entities' access to 340B discounts only to those operating an in-house pharmacy would not be "within the interest of the covered entities, [or] the patients they serve, [or] consistent with the intent of the law." *Id.* at 43,550. The 1996 Guidance therefore explicitly provided that permitting the use of contract pharmacies does not constitute an unauthorized expansion of the 340B Program

because "[t]he statute is silent as to permissible drug distribution systems," and contains "no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself." *Id.* at 43,549. Instead, "[i]t is clear that Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities." *Id.* The 1996 Guidance counseled that covered entities could, if they chose, use "one pharmacy contractor per entity" to dispense 340B drugs. *Id.* at 43,555. The 1996 Guidance also clarified that it "create[d] no new rights or duties" under the 340B Program. *Id.* 43,550.

HHS's 2010 Advisory Opinion Regarding Contract Pharmacies

The 1996 Guidance addressed the use of only a single contract pharmacy. Fourteen years later, in 2010, HHS issued supplemental non-binding guidance specifying that covered entities were not necessarily limited to a single contract pharmacy, but were free to contract with as many pharmacies as they chose, even if they also operated an in-house pharmacy. *See* Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272-01 (Mar. 5, 2010) (hereinafter "2010 Guidance"). After issuing notice and soliciting comments, HHS opined that "[i]t would be a significant benefit to patients to allow the use of more easily accessible, multiple contract pharmacy arrangements by covered entities," and that, because "some patients currently face transportation barriers or other obstacles that limit their ability to fill their prescriptions," more widespread use of contract pharmacies "would permit covered entities to more effectively utilize the 340B program and create wider patient access." *Id.* at 10,273.

The 2010 Guidance, in an effort to prevent unlawful duplicate discounts and the diversion of 340B drugs, included the following "essential elements" for transactions involving contract pharmacies: the "covered entity will purchase the drug, maintain title to the drug and assume responsibility for establishing its price"; "[a] 'ship to, bill to' procedure [will be] used in which the covered entity purchases the drug; the manufacturer/wholesaler must bill the covered entity … but ship[] the drug directly to the contract pharmacy"; "[b]oth the covered entity and the contract pharmacy are aware of the potential for civil or criminal penalties" for violations; and both the covered entity and contract pharmacy must maintain auditable records, track prescriptions, and verify patient eligibility. *Id.* at 10,278. The 2010 Guidance further stated that the covered entity was responsible for ensuring adherence to the 340B Program requirements and could lose eligibility if violations were to occur. *Id.*

The 2010 Guidance also provided that, "if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price," regardless of whether the covered entity "directs the drug shipment to its contract pharmacy." *Id.* HHS represented that the 2010 Guidance did not constitute "substantive rulemaking under the APA" because it merely interpreted the 340B statute "to create a working framework for its interpretation" and imposed no "additional burdens upon manufacturers, nor create[d] any new rights for covered entities under the law." *Id.*

Following issuance of the 2010 Guidance, no pharmaceutical manufacturer, trade association, or other similar entity filed suit to challenge its requirements or effect.

Defendants' Claimed Lack of Authority to Enforce Contract Pharmacy Arrangements

According to Lilly, at no time between 1992, when the 340B program began, and 2020, did Defendants initiate any enforcement action against any manufacturer that declined to deliver discounted drugs to contract pharmacies or refused to deal with an unlimited number of contract pharmacy arrangements.[3] In fact, in 2020, Defendants represented on several occasions that the agency did not possess legal authority to undertake such enforcement action. For example, on June 11, 2020, HRSA informed Lilly that the 1996 and 2010 "contract pharmacy advice" was not "binding" on manufacturers. VLTR_7590. HRSA also represented in a 340B-focused article in July 2020 that "[t]he 2010 guidance … is not legally enforceable" and that it could not "compel[]" manufacturers "to provide 340B discounts on drugs dispensed by contract pharmacies." Tom Mirga, *HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable*, 340B Report (July 9, 2020). On more than a few occasions during 2020, Defendants also informed covered entities that, although "HRSA continues to strongly encourage all manufacturers to sell 340B priced drugs to covered entities directly and through contract pharmacies," it "has only limited ability to issue enforceable regulations" in light of what was described as a lack of "authority" to make such a

[3] We note, however, that it is not clear how many, if any, drug manufacturers might have taken such actions prior to 2020.

demand. VLTR_3272, VLTR_3285, VLTR_4194. Accordingly, prior to late 2020, covered entities and contract pharmacies would have "underst[ood]" that HRSA "cannot require manufacturers to offer drugs at the 340B ceiling price to be shipped to contract pharmacies because the 2010 contract pharmacy guidance … is not legally enforceable." VLTR_3283.

Lilly's Decision to Restrict Shipment of 340B Drugs to Contract Pharmacies

For approximately ten years, Lilly (and apparently every other pharmaceutical manufacturer participating in the 340B Program) followed the guidance set forth in the HHS's 2010 Advisory Opinion by shipping 340B drugs purchased by covered entities to the covered entities' designated contract pharmacies when and as requested to do so. However, in July 2020, Lilly determined, and so notified HHS, that with certain caveats it would no longer offer 340B pricing throughout contract pharmacy arrangements for one of its drugs—Cialis, a drug prescribed to treat erectile dysfunction. In that communication to HHS, Lilly also proposed that HHS rescind its 2010 Guidance on the use of contract pharmacies to dispense drugs purchased by 340B covered entities, even though Lilly had never filed a legal challenge to the 2010 Guidance and had been complying with its requirements for approximately ten years.

Approximately one month thereafter, on August 19, 2020, in response to what Lilly maintains were documented and widespread abuses of the 340B Program that had been increasing over the years since HHS issued its 2010 guidance permitting covered entities to utilize an unlimited number of contract pharmacies to dispense 340B drugs, Lilly publicly announced that it was "discontinu[ing] its practice of voluntarily honoring

requests for 340B 'contract pharmacies' for orders on all Lilly products." Am. Comp. Exh. F (August 19, 2020 Letter from Lilly to HRSA); *see also* Exh. G (notifying covered entities that they "will not be eligible to purchase [Lilly] products at the 340B ceiling price for shipment to a contract pharmacy"). However, Lilly promised to continue to honor orders by covered entities to ship 340B drugs to contract pharmacies in two instances: (1) where the covered entity lacks an in-house pharmacy and thus needs to partner with an outside pharmacy to dispense outpatient drugs; and (2) where the covered entity wholly owns the outside pharmacy and thus can assure the pharmacy's compliance with the 340B Program.[4] In cases where a covered entity lacks an in-house pharmacy and otherwise participates in contract pharmacy arrangements, we understand Lilly to require the covered entity to submit additional paperwork designating a single contract pharmacy for delivery and to engage in a process through which Lilly determines the eligibility of that contract pharmacy.

HRSA's August 2020 Violation Letter

In response to Lilly's newly announced policy, on August 26, 2020, HRSA notified Lilly in writing that the agency was "considering whether your new proposed policy constitutes a violation of section 340B and whether sanctions apply," including, "but [] not limited to, civil monetary penalties pursuant to 42 U.S.C. § 256b(d)(1)(B)(vi). Violation Letter Administrative Record ("VLTR") at 7627. In this letter, HRSA disputed

[4] Lilly is not restricting insulin to a single contract pharmacy, but only if insurance is not billed for the insulin, no markup or dispensing fee is charged to the patient, and the covered entity provides Lilly detailed information demonstrating compliance with these conditions.

Lilly's claim that its "plan did not give rise to an enforceable violation of the 340B statute," and warned Lilly that its newly imposed restrictions "would undermine the entire 340B Program and the Congressional intent behind enactment of the 340B statute," while "restrict[ing] access" for "underserved and vulnerable populations" in the midst of the COVID-19 global pandemic. *Id.* HRSA notified Lilly that the agency was "continu[ing] to examine whether Lilly's actions amount to attempts to circumvent th[e] statutory requirement by inappropriately restricting access to 340B drugs." *Id.*

Despite these warnings and concerns from HRSA, beginning in September 2020 and continuing through the present, Lilly has restricted access to 340B discounts through contract-pharmacy arrangements in the manner outlined in its August 19, 2020 notice to HHS. We are informed that several other global pharmaceutical manufacturers, including Sanofi-Aventis, AstraZeneca, and Novartis, followed suit, imposing, with certain modifications, similar restrictions on covered entities' use of contract pharmacies. In response to these actions, several covered entities have filed lawsuits against HHS,[5] seeking to compel HHS, *inter alia*, to reverse the drug manufacturers' unilateral changes in policies regarding contract pharmacies.

HHS's General Counsel's December 2020 Advisory Opinion

On December 30, 2020, following the filings of lawsuits against Defendants in various federal district courts around the country by covered entities and contract pharmacies challenging the drug manufacturers' unilateral restrictions on their

[5] *See, e.g.*, *Ryan White Clinics for 340B Access v. Azar*, No. 20-cv-2906 (D.D.C. Oct. 9, 2020); *Am. Hosp. Ass'n v. HHS*, No. 20-cv-8806 (N.D. Cal. Dec. 11, 2020).

participation in the 340B Program, HHS's General Counsel issued an Advisory Opinion stating in part "that to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." HHS Gen. Counsel, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program ("2020 Advisory Opinion") at 1, *available at* https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf (last visited March 9, 2021). The 2020 Advisory Opinion further opined that "the core requirement of the 340B statute … is that manufacturers must 'offer' covered outpatient drugs at or below the ceiling price for 'purchase by' covered entities" and that "[t]his fundamental requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs." *Id.* at 2.

The 2020 Advisory Opinion by HHS's General Counsel highlights the fact that covered entities had relied on contract pharmacies for decades for the distribution of these drugs and that the system is compatible with Congressional intent because "the Program is aimed at benefiting providers that are small, remote, resource-limited, receiving federal assistance, or serving disadvantaged populations," which are "the poster children of providers that one would expect to lack an in-house pharmacy." *Id.* at 4. The 2020 Advisory Opinion anchors HHS's interpretation in the statute itself, according to the General Counsel, and therefore no rulemaking was required, and no expansion of the 340B Program had been effectuated because Congress, in formulating the 340B

procedures, did not permit drug manufacturers to specifically condition access to discounted drugs on covered entities' operation of an in-house pharmacy to take physical delivery of drug purchases. *Id.* at 2–4.

Initiation of the Instant Litigation and Similar Lawsuits

Approximately two weeks following the issuance of the 2020 Advisory Opinion, on January 12, 2021, Lilly filed the instant lawsuit challenging its interpretation(s). That same day, two other pharmaceutical manufacturers, Sanofi-Aventis and AstraZeneca, filed similar federal lawsuits. *See Sanofi-Aventis*, No. 3:21-cv-634 (D.N.J. Jan 12, 2021); *AstraZeneca*, No. 1:21-cv-27 (D. Del. Jan. 12, 2021). Within a matter of a few days, two more pharmaceutical companies, Novo Nordisk and PhRMA, filed similar suits. *See Novo Nordisk v. Azar*, No. 21-cv-00806-FLW (D.N.J. Jan. 15, 2021); *PhRMA v. Cochran*, No. 8:21-cv-198-GLR (D. Md. Jan. 22, 2021).

HRSA's May 2021 Enforcement Letter

Following the issuance of the 2020 Advisory Opinion, Defendants took no other immediate enforcement action against either Lilly, or, to our knowledge, any of the other drug manufacturers, based on the pharmaceutical companies' unilateral changes in their contract pharmacy distribution policies. However, based at least in part on pressure on Congress generated by the covered entities and contract pharmacies objecting to Defendants' lack of enforcement, Congress pressed Defendants to act. On May 12, 2021, HHS Secretary Becerra, in testimony regarding the 340B Program before the U.S. House of Representatives, assured Congress that action would be taken, saying, "We are on this one. … Everyone has to follow the law."

Five days later, on May 17, 2021, HRSA issued a 340B-violation letter (the "May 17 Letter") notifying Lilly that, after a comprehensive and months' long review of Lilly's contract pharmacy policy, "HRSA has determined that Lilly's actions have resulted in overcharges and are in direct violation of the 340B statute." May 17, 2021 Letter. The May 17 Letter instructed Lilly to "immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements" and to "credit or refund all covered entities for overcharges that have resulted from Lilly's policy." *Id.*

The May 17 Letter reminded Lilly that it had "signed a Pharmaceutical Pricing Agreement (PPA) and PPA addendum" and was "bound by the terms of the PPA." *Id.* Citing the statute, the May 17 Letter reiterated the requirement that Lilly must offer covered entities 340B drugs at or below the applicable ceiling price if such drug is made available to any other purchaser at any price, an obligation that "is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs" to its patients, and asserted that "[n]othing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities." *Id.*

The May 17 Letter contained a final warning to Lilly that its "[c]ontinued failure to provide the 340B price to covered entities utilizing contract pharmacies" would "result in CMPs [civil monetary penalties]" in addition to repayment unless HHS is satisfied with "Lilly's willingness to comply with" HRSA's view of its "obligations under section 340B." *Id.* Lilly was directed to provide, within days, "an update on its plan to restart

selling, without restriction, covered inpatient drugs at the 340B price to covered entities that dispense medications through contract pharmacy arrangements," on the basis of which information HHS would "determine whether CMPs are warranted based on Lilly's willingness to comply with its obligations under 340B(a)(1)."[6] *Id.*

Lilly sent a written response to HHS explaining that it believes its policy fully complies with the text, structure, and purpose of the 340B statute. *See* Dkt. 115, 115-1. Lilly has therefore continued to apply its contract pharmacy policy per its August 2020 announcement. Plaintiffs recently informed the Court that, in a letter dated September 22, 2021, HRSA wrote to inform them that, "[g]iven Lilly's continued refusal to comply, HRSA has referred this issue to the HHS Office of the Inspector General (OIG) in accordance with the 340B Program Ceiling Price and Civil Monetary Penalties Final Rule." Dkt. 143-1.

Investigation That Led to May 17, 2021 Letter

As referenced above, following Lilly's August 2020 announcement regarding its contract pharmacy policy, Defendants informed Lilly that it planned to undertake a review of that policy to determine whether it violated the 340B statute. Defendants described their conclusions from that review and evaluative process in the May 17 Letter,

[6] Plaintiffs sought a temporary restraining order enjoining enforcement of the May 17 Letter, which, following a hearing, the Court orally denied on May 27, 2021. That denial was based primarily on Plaintiffs' failure to establish that they were likely to suffer irreparable harm if the request were denied. The Court did, however, extend the deadline within which Lilly was required to respond to the May 17 Letter by supplying the requested information.

noting that their review actually commenced months prior to the issuance of the 2020 Advisory Opinion.

The administrative record filed in this case spans more than 8,000 pages and consists of some 6,000-plus pages of complaints from covered entities regarding alleged overcharges. Defendants' May 17 Letter does not identify any specific covered-entity complaints which formed the basis of HRSA's determination, but certain complaints from covered entities and other stakeholders were cited as a part of Defendants' investigation, including the following:

- Beverly Hospital reported that "manufacturer(s) [are] deliberately refusing [the] 340B Price," explaining that restrictions had forced it to pay "WAC [wholesale acquisition cost] for [340B] contract pharmacy orders," which is the highest commercial rate.[7] VLTR_1460–61. The complaint included a spreadsheet showing specific transactions in which the hospital claims the 340B ceiling price was denied and subjected it to WAC costs on Lilly's medications of up to $3,683 per unit, which resulted in $126,508 in lost 340B savings, in October 2020. VLTR_1463. In December 2020, Beverly Hospital again alerted HRSA in writing that Lilly was "deliberately withholding 340B pricing," as illustrated on an accompanying spreadsheet showing numerous Lilly medications where the hospital was charged in amounts exceeding $3,000 per unit, far above the ceiling price, resulting in a loss of more than $70,000 in 340B savings for that month. VLTR_1464–68.

- The University of Utah Health reported that it "has been unable to purchase Eli Lilly products at the 340B ceiling price for delivery to its contract pharmacy," which, the University explained, "is contrary to the 340B statute … and the Pharmaceutical Price Agreement (PPA) Lilly has entered with HRSA." VLTR_5831. According to the University, "Lilly has removed the 340B pricing … [s]o when a [covered entity] replenishes a

[7] The 340B ceiling price is statutorily protected information: 42 U.S.C. § 256b(d)(1)(B)(iii); thus, it is redacted in the administrative record, as well as are other figures that would allow the ceiling price for any particular drug to be easily calculated. We understand the claim to be undisputed, however, that the ceiling prices for medications referenced herein are only a fraction of the WAC prices.

drug on the 340B account for a contract pharmacy, they are actually charged the WAC price. We were charged $3597.83 for a package when the 340B ceiling price is" much higher. VLTR_5834. Shortly thereafter, the University filed another complaint stating it "purchased 2 packages of NDC 00002840001 on 9/17/2020 [and was] charged $4597.83 per package when the ceiling price is" significantly lower. VLTR_5844. The University was charged similar prices again on September 25, 2020. VLTR_5852.

- St. Joseph Medical Center submitted a complaint with an actual invoice attached, showing that it was charged the "WAC pricing" for 340B-covered drugs after the "manufacturer ceased to provide 340B pricing suddenly." VLTR_1837, VLTR_1842. The invoice shows that the drugs were ordered and paid for by St. Joseph but shipped to Franciscan Pharmacy Tacoma and that Lilly charged $326 for one of the drugs and $274 for another, both of which are far above the statutory ceiling price. VLTR_1842.

- A covered entity hospital in South Dakota reported that, when it tried to purchase drugs through its existing wholesaler, "[s]ome accounts had the NDC [drug identifier] taken off the catalog," meaning that the drug was no longer available for purchase by the covered entity, while "some accounts had a WAC[] price listed." VLTR_1373. The covered entity stated that, "[t]he purchases that were made were done on the 340B account in what we feel was WAC[] pricing" and confirmed that it did in fact place orders and pay the WAC cost for those drugs. *Id.*

- Another covered entity included a screenshot from its ordering system showing that all formulations of Humalog, a Lilly insulin product, were marked as "Ineligible" for purchase on its 340B account." VLTR_1590. That community health center reported that it "is forced to pay WAC for these products if purchased for a contract pharmacy" to dispense and included a screenshot showing that it paid up to $763 per unit for Lilly insulin, (VLTR_1593, VLTR_1597), which should be provided to covered entities at "one-penny-per-milliliter prices." Compl. ¶ 82.

- A critical-access hospital in Nebraska documented numerous instances where it paid prices far above the 340B ceiling price for Lilly drugs, including instances where it paid $326, $339, $551, and $797 for Lilly insulin. VLTR_3110, VLTR_3116–17, VLTR_3119–20, VLTR_3122–23, VLTR_3125–26. The hospital stated that, "[a]s far as [it was] aware," those prices reflect "the WAC price," even though the orders were placed and paid for on its 340B account and the sales "counted as a 340B transaction as [they] met all criteria to be 340B." VLTR_3154.

- Blue Ridge Medical Center reported that "Eli Lilly is blocking 340B prices for their drugs ordered by [the medical center] that are shipped to my contract pharmacies. I am forced to pay WAC for those products for my contract pharmacies." VLTR_1607. Likewise, a family clinic included with its complaint an email from its wholesaler confirming that, under Lilly's policy, a "covered entity pays WAC if the pharmacy" where its purchases are shipped "is not the Eli Lilly approved pharmacy." RVLTR_3300. Lancaster Health Center notified the agency that Lilly is "refusing to fulfill orders (for any of their manufactured products) placed by [the] covered entity and shipped to my contract pharmacies at 340B prices. I am forced to pay WAC for these products" and that Lilly "refus[es] to ship my orders to my contract pharmacies." VLTR_3303, VLTR_3314–15. The Chief Executive of Windrose Health Network reported to HRSA in March 2021 that, "Eli Lilly is blocking 340B prices for their drugs ordered by [the] covered entity that are shipped to my contract pharmacies. I am forced to pay WAC for these products."[8] VLTR_6645–46.

- HRSA also gathered evidence from tribal leaders in multiple states detailing the harm 340B restrictions were inflicting on income-disadvantaged tribal members and underfunded rural health clinics, including one tribe that reported that its pharmacy bill has more than doubled, that it is "not financially feasible for the tribe to operate its own pharmacy," and that it had paid more than $3,400 for roughly 100 pills, which it described as "[un]sustainable costs." VLTR_7894, VLTR_7898.

- Representatives from Avita Pharmacy, a national chain that contracts almost exclusively with and dispenses for covered entities, reported that each of its 270 covered-entity clients, 98% of which do not operate their own pharmacies, were being denied 340B pricing and thus stand to lose millions of dollars in lost revenue. VLTR_7891–92. The representatives expressed concern that the changes "will lead to imminent harm to patients and possible site closures," and that some health centers were forced to charge $300 for insulin that had been dispensed for as little as $0. *Id.*

[8] The administrative record is replete with complaints from numerous covered entities repeating this message nearly verbatim—"I am forced to pay WAC [wholesale acquisition cost] for [the drugs] for my contract pharmacies"—which we have not individually referenced here.

Based on Defendants' investigation and their evaluation of this evidence[9] as well as a review of Lilly's explanations for its policy, HRSA concluded that Lilly's policy regarding contract pharmacies violates the 340B statute, prompting the issuance of the May 17 Letter. The specific complaints were never disclosed to Lilly nor was Lilly invited to respond prior to the issuance of the May 17 Letter.

Withdrawal of the December 2020 Advisory Opinion

Approximately one month following the issuance of the May 17 Letter, on June 16, 2021, the Honorable Leonard P. Stark, Chief Judge of the United States District Court for the District of Delaware, issued a memorandum opinion in a companion 340B case, *AstraZeneca Pharmaceuticals LP v. Becerra*, C.A. No. 21-27-LPS, 2021 WL 2458063 (D. Del. June 16, 2021), denying the defendants' motion to dismiss AstraZeneca's APA challenge to the December 2020 Advisory Opinion. Judge Stark ruled that the district court had jurisdiction to consider AstraZeneca's claim, and that, contrary to the agency's contention, the position outlined in the Advisory Opinion was neither compelled by the unambiguous text of the 340B statute nor the sole reasonable interpretation of the statute; thus, "[b]ecause the Opinion wrongly determines that purportedly unambiguous statutory language mandates its conclusion regarding covered entities' permissible use of an

[9] According to HRSA, in issuing its May 17 Letter, the agency also considered an abundance of other evidence that we have not specifically included in this factual recitation, such as evidence regarding the importance of contract pharmacy arrangements for covered entities, even for those that also operate an in-house pharmacy, the impact Lilly's restrictions have had on insulin patients in particular, and the significant financial impact Lilly's restrictions have had on covered entities, much of which is also addressed in the *amicus* briefs. Because we have not relied on this evidence specifically in determining whether the May 17 Letter violates the APA, we do not recount it here in detail.

unlimited number of contract pharmacies, the Opinion is legally flawed." *Id.* at *8. Judge Stark's judgment of June 30, 2021 set aside and vacated the Advisory Opinion on grounds that it was arbitrary and capricious in violation of the APA for the reasons set forth in the June 16 Order.

On June 18, 2021, two days following Judge Stark's order in *AstraZeneca*, HHS's Office of General Counsel issued a "Notice of Withdrawal" of the 2020 Advisory Opinion, stating that, effective that date, the Advisory Opinion was being "voluntarily withdrawn." The notice states that HHS's Office of General Counsel "disagree[s] with the decision of the District Court in *AstraZeneca Pharmaceuticals*," but, "in the interest of avoiding confusion and unnecessary litigation," it was withdrawing the opinion. The notice explicitly states that the withdrawal does not impact HRSA's enforcement efforts as set forth in the May 17 Letter because "HRSA's enforcement process operated independently from the issuance of the Opinion, and operates independently from the Opinion's withdrawal." Dkt. 119-1.

Currently Pending Motions

Against the backdrop of this prolix procedural history, we turn to address Defendants' Motion to Dismiss, or, in the alternative, for Summary Judgment, filed on April 19, 2021, and Plaintiffs' Cross Motion for Summary Judgment [Dkt. 89] and Motion for Preliminary Injunction [Dkt. 94], filed on May 10, 2021 and May 20, 2021, respectively, on which oral argument was conducted on July 30, 2021. We have carefully considered the administrative record, the parties' extensive briefing of these issues as well as the briefs submitted by several *amici curiae*.

Legal Analysis

I. Applicable Legal Standards

A. The Administrative Procedures Act

Plaintiffs allege that the 2020 Advisory Opinion and the May 17 Letter constitute final agency actions and as such each is unconstitutional and violative of the APA. The APA "sets forth the full extent of judicial authority to review executive agency action for procedural correctness." *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 513 (2009) (citation omitted). The standard of review under the APA "is a narrow one," and the plaintiff bears the burden of proof. *See Sierra Club v. Marita*, 46 F.3d 606, 619 (7th Cir. 1995). Where, as here, a plaintiff seeks to set aside agency action, he or she must show that the action was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "contrary to constitutional right, power, privilege, or immunity," "in excess of statutory jurisdiction, authority, or limitations," or "without observance of procedure required by law." 5 U.S.C. § 706(2)(A), (B), (C), (D). The purpose of APA review is limited; the courts' role in screening for "arbitrary" or "capricious" actions is to "insist that an agency examine the relevant data and articulate a satisfactory explanation for its action." *F.C.C.*, 556 U.S. at 513 (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). A court does not "substitute its judgment for that of the agency," and should "uphold a decision of less than ideal clarity if the agency's path may be reasonably discerned." *Id.* at 513-14 (citation omitted).

B. Motion to Dismiss Standard

Defendants seek the dismissal of Plaintiffs' APA claims based on the Advisory Opinion, pursuant to Federal Rule of Civil Procedure 12(b)(6), alleging the APA claims fail to state claims upon which relief can be granted. In this procedural context, the Court accepts as true all well-pled factual allegations in the complaint and draws all ensuing inferences in favor of the non-movant. *Lake v. Neal*, 585 F.3d 1059, 1060 (7th Cir. 2009). Nevertheless, the complaint must "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests," and its "[f]actual allegations must . . . raise a right to relief above the speculative level." *Pisciotta v. Old Nat'l Bancorp*, 499 F.3d 629, 633 (7th Cir. 2007) (quotation marks and citations omitted). The complaint must therefore include "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *see* Fed. R. Civ. P. 8(a)(2). Stated otherwise, a facially plausible complaint is one which permits "the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

C. Summary Judgment Standard

Summary judgment is appropriate where there are no genuine disputes of material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). A court must grant a motion for summary judgment if it appears that no reasonable trier of fact could find in favor of the nonmovant on the basis of the designated admissible evidence. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1986). We neither weigh the evidence nor evaluate

the credibility of witnesses, id. at 255, but view the facts and the reasonable inferences flowing from them in the light most favorable to the nonmovant. *McConnell v. McKillip*, 573 F. Supp. 2d 1090, 1097 (S.D. Ind. 2008).

Cases arising under the APA are typically resolved by summary judgment on the basis of the administrative record compiled by the agency. *See Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 744-45 (1985). "The factfinding capacity of the district court is thus typically unnecessary to judicial review of agency decisionmaking …. [C]ourts are to decide, on the basis of the record the agency provides, whether the action passes muster under the appropriate APA standard of review." *Id.* at 744. Here, faced with cross motions for summary judgment, we therefore will address and resolve the claims raised by Plaintiffs without necessity of either an evidentiary hearing or trial on the merits. *See Cronin v. USDA*, 919 F.2d 439, 445 (7th Cir. 1990).

II. Discussion

It is undisputed that the 340B Program being administered today is vastly more expansive than that implemented when the program was first enacted by Congress in 1992. That growth is tied in no small way to the steady growth of the nation's healthcare safety net system such that today significantly more patients rely on this network of service providers than ever before.[10] The broadly-based need for such care and related

[10] Counsel for Plaintiffs has represented to the Court that the 340B Program is now the second largest federal drug distribution/financing program, involving 30 billion discounted purchases each year, which constitutes nearly ten percent of overall pharmaceutical sales in the U.S.

essential healthcare services, including prescription medications, is clear, expansive and a demand made even more critical by the current global pandemic.

As discussed previously, one method by which covered entities make 340B drugs more accessible to their patients is through arrangements with contract pharmacies. Reliance on such arrangements was a common practice at the time the 340B statute was enacted, though "[t]he statute [was] silent as to the role that contract pharmacies may play in connection with covered entities' purchases of 340B drugs." *AstraZeneca Pharms. LP*, 2021 WL 2458063, at *9. Recognizing that such arrangements were both commonplace, and, for a vast majority of covered entities, a necessary aspect of their process for effectively dispensing 340B drugs to their patients, HRSA advised covered entities in its 1996 Guidance that, if a covered entity did not operate its own in-house pharmacy, it was authorized to contract with a single outside pharmacy to effectively dispense 340B drugs.

A single outside pharmacy to serve as the exclusive pipeline for 340B drugs dispensed by a covered entity soon proved inadequate to the demand. As the number of covered entities grew, the number of outside pharmacies to distribute 340B drugs contracted by those covered entities also significantly increased. Indeed in 2010, HRSA issued Guidance authorizing covered entities to contract with not just a single outside pharmacy, but with an unlimited number of such entities, without restriction as to the size or nature of the geographic area served by the covered entity. Plaintiffs maintain that the greatly expanded program permitted contract pharmacies participating in the 340B Program to dramatically alter the nature of the program from that created when the

originating statute was enacted. At the outset of the program, Plaintiffs explain, the covered entity interfaced directly with a contract pharmacy to supply sufficient inventory to meet the demands of 340B patients. Today, the typical dispensing process requires covered entities and contract pharmacies to submit to a "replenishment model", whereby a contract pharmacy dispenses the drug to a patient, after which, assuming the patient has been identified as eligible for 340B savings based on a 340B-tailored software program, the covered entity receives notice that it is allowed to place a 340B order with the manufacturer to "replenish" the contract pharmacy's supply of the previously dispensed drug, which the manufacturer then ships to the contract pharmacy for retention in its neutral inventory.[11]

It requires almost no imagination to appreciate how, with the significant expansion of the 340B Program and the proliferation of contract pharmacy arrangements, more opportunities for abuse within the system have arisen. Plaintiffs criticize the government for its alleged failure to recognize and remedy the hardships and unfairnesses that have resulted from the expansion on drug manufacturers who participate in the 340B Program and have had to absorb the brunt of these costs and abuses. Without sufficient oversight

[11] The "replenishment model" consist of three main steps: First, the contract pharmacy dispenses a drug to a patient and 340B-tailored software programs operated under the oversight of the covered entity subsequently determine whether the patient is eligible for 340B savings. Second, once the software determines that a sufficient number of 340B-eligible dispenses have accumulated to reach a pre-set packages size, the software notifies the covered entity that it may place an order on its 340B account for that amount of 340B drugs to replenish the contract pharmacy's stock. Third, the covered entity is billed for the purchase and the replenishment drugs are shipped to the contract pharmacy, where they are placed in neutral inventory. Pedley Decl. ¶ 10.

by the government of the covered entities' contract pharmacy arrangements and/or enforcement of the statutory prohibitions against diversion and duplicate discounting, the manufacturers, they say, are at the mercy of a system run amok. HRSA's explanation for its lack of monitoring and/or enforcement of the 340B statute with regard to contract pharmacy arrangements, according to Plaintiffs, directly conflicts with HHS's General Counsel's Advisory Opinion and HRSA's rationale behind the May 17 Letter. Against this backdrop, Plaintiffs have brought their challenges to these agency actions under the APA.

Plaintiffs specifically allege that both the December 2020 Advisory Opinion by HHS's General Counsel and the agency's May 17 Letter are unconstitutional final agency actions which violate the APA, in the following respects: (1) notice and comment procedures were not followed; (2) the actions taken exceeded the agency's statutory authority; (3) the actions taken are arbitrary and capricious; and (4) the actions taken are contrary to the Fifth Amendment's Takings Clause and Article I of the United States Constitution. We address each of these challenges below.

A. December 2020 Advisory Opinion

1. Mootness

As referenced above, HHS's Office of General Counsel withdrew the December 2020 Advisory Opinion on June 18, 2021, which Defendants contend renders moot Plaintiffs' challenges to the Advisory Opinion. We are not persuaded by this argument. "A defendant's voluntary cessation of challenged conduct does not necessarily render a case moot." *Freedom From Religion Found., Inc. v. Concord Cmty. Schs.*, 885 F.3d

1038, 1051 (7th Cir. 2018) (citing *City of Mesquite v. Aladdin's Castle, Inc.*, 455 U.S. 283, 289 (1982)). A case becomes moot only "if events make it 'absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur.'" *Id.* (quoting *United States v. Concentrated Phosphate Export Ass'n*, 393 U.S. 199, 203 (1968)). "The party asserting mootness bears the 'heavy' burden of proof on this 'stringent' standard." *Id.* (quoting *Friends of the Earth, Inc. v. Laidlow Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 189 (2000)).

Defendants' claim of mootness falls well short of this definition. HHS's withdrawal does not include any indication that the agency has fully and for all time (in the context of this case at least) abandoned the position laid out in the December 2020 Advisory Opinion. Its withdrawal simply notes the agency's "disagreement" with the reasoning set forth in Judge Stark's recent opinion in *AstraZeneca Pharmaceuticals*, which held in favor of the drug manufacturer on the claims challenging the Advisory Opinion, noting that the Advisory Opinion was withdrawn by the government only to "avoid[] confusion and unnecessary litigation"; in fact, enforcement efforts directed toward drug manufacturers' policies regarding contract pharmacies will likely continue. Dkt. 119-1. Accordingly, it is not at all clear that the agency's "allegedly wrongful behavior could not reasonably be expected to recur," which makes Plaintiffs' claims challenging the Advisory Opinion far from moot. We shall thus address them in that light.

2. Defendants' Motion to Dismiss

Defendants seek the dismissal of Plaintiffs' APA claims challenging the Advisory Opinion on two grounds: first, that the Advisory Opinion does not constitute final agency action and is therefore not reviewable by the Court; and second, that Plaintiffs' legal challenge to the Advisory Opinion is untimely. For the following reasons, we again find neither argument persuasive.

For an agency's action to be deemed final and thus judicially reviewable, "the action must mark the consummation of the agency's decisionmaking process," meaning, it cannot be "of a merely tentative or interlocutory nature;" "the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (internal quotation marks and citations omitted).

Plaintiffs contend that the Advisory Opinion does, in fact, mark the culmination of the agency's decisionmaking process regarding manufacturers' delivery obligations in relation to covered entities that utilize contract pharmacy arrangements. The Advisory Opinion states that, "to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is *obligated* to deliver its covered drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." VLTR_8048 (emphasis added). In addition, the Opinion provides that "manufacturers *may not* refuse to offer the ceiling price to covered entities, even where the latter use distribution systems involving contract pharmacies." VLTR_8055 (emphasis added). The Advisory Opinion asserts that the "*plain meaning*"

of the statute "*requires* manufacturers to sell covered drugs to covered entities at or below the ceiling price, independent of whether the entity opts to use contract pharmacies to dispense the drugs." VLTR_8049 (emphasis added). These provisions clearly represent "a definitive pronouncement of [agency] policy," *Home Builders Ass'n of Greater Chi. v. United States Army Corps of Engineers*, 335 F.3d 607, 615 (7th Cir. 2003), and advance an interpretation the agency "believes is the only permissible interpretation of the statute." *California Cmties. Against Toxics v. EPA*, 934 F.3d 627, 636 (D.C. Cir. 2019) (emphasis removed). Accordingly, the first element of "final agency action" is satisfied.

As for the second requirement, the mandatory language utilized in the Advisory Opinion purports to "determine" manufacturers' "obligations" under the 340B statute with regard to their dealings with covered entities utilizing contract pharmacies to dispense 340B drugs. As Plaintiffs note, the directives set out in the Advisory Opinion have legal consequences, particularly under the recently issued ADR procedures, which warn that drug manufacturers' "fail[ure] to heed the determination" carries "the risk of significant criminal and civil penalties." *Id.* at 637.

Defendants' defense of the Advisory Opinion focuses on what they maintain is nothing more than a restatement of the position espoused by the agency since at least the time of the issuance of the 2010 Guidance, allowing covered entities to enter into "complex arrangements" that include contracts with "multiple pharmacies" and expressly providing that "[u]nder section 340B, if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating

manufacturer, the statute directs the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price." 75 Fed. Reg. at 10,277. Thus, according to Defendants, the Advisory Opinion neither asserted any legal obligations nor imposed any penalties or consequences apart from those in the statute itself.

Defendants' arguments would carry more weight if, prior to the issuance of the Advisory Opinion, the agency had not indicated on several occasions that its enforcement powers were limited and that it lacked authority to "compel[]" manufacturers "to provide 340B discounts on drugs dispensed by contract pharmacies." Tom Mirga, *HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable*, 340B Report (July 9, 2020); *accord Am. Hosp. Ass'n v. Dep't of Health & Human Servs.*, No. 4:20-cv-08806-YGR, 2021 WL 616323, at *3 (N.D. Cal. Feb. 17, 2021) (quoting HRSA email). The Advisory Opinion thus directly conflicts with this interpretation of the agency's limited authority. Defendants' argument that the Opinion "did little but restate what [Lilly] already knew," is belied by this history. Dkt. 88 at 15. Moreover, as recognized by Judge Stark in *AstraZeneca Pharmaceuticals*, to the extent the Advisory Opinion relies on the "shall … offer" provision of the 340B statute, it necessarily "treads new ground" since that language was not added to the statute until after the agency issued the 2010 Guidance. 2021 WL 2458063, at *5 (internal quotation marks and citation omitted). The Advisory Opinion therefore satisfies the second requirement for "final agency action," making it reviewable by the Court. The motion to dismiss on this ground is unavailing.

Defendants' parallel contention that Plaintiffs' challenge to the Advisory Opinion is nothing more than "an untimely collateral attack on the agency's consistent, twenty-

five-year statutory interpretation," (Dkt. 88 at 19), and therefore must be dismissed on statute of limitations grounds, fares no better. This argument is premised on the same mischaracterization of the Advisory Opinion we have addressed and rejected above, to wit, that it plows no new ground and simply restates the agency's view previously expressed in the 2010 Guidance. We find that description disingenuous, adopting our prior reasoning and rejecting the accuracy of this conclusion. Accordingly, Defendants' motion to dismiss Plaintiffs' APA claims related to the Advisory Opinion is denied.

3. Cross-Motions for Summary Judgment

In reviewing Plaintiffs' APA challenges to the Advisory Opinion, HHS's General Counsel wrote that, "to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." VLTR_8076–77. The General Counsel also wrote that "the situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant." VLTR_8050. According to the Opinion, "manufacturers may not refuse to offer the ceiling price to covered entities, even where the latter use distribution systems involving contract pharmacies," VLTR_8055, and the "plain meaning" of the statute "requires manufacturers to sell covered drugs to covered entities at or below the ceiling price, independent of whether the entity opts to use contract pharmacies to dispense the drugs." VLTR_8049.

In reading the Advisory Opinion as a whole, it is clear that drug manufacturers' obligations under the government's interpretation of the 340B statute include their

honoring the ceiling price when selling to covered entities, regardless of the drug distribution model they utilize, and in line with Judge Starks' framing in *AstraZeneca Pharmaceuticals*, unambiguously requiring drug manufacturers *to deliver* 340B drugs to an unlimited number of contract pharmacies, if acting as "agents" of the covered entity. This is true despite the statute's silence both as to covered entities' entitlement to utilize unlimited contract pharmacy arrangements and as to any delivery obligations imposed on drug manufacturers. As Judge Stark, in rejecting this interpretation of the 340B statutory language, it "simply cannot bear the weight that the government places on it." 2021 WL 2458063, at *9.

We share these reservations as to the government's claims as set forth in *AstraZeneca Pharmaceuticals*, namely that the Advisory Opinion is "legally flawed" in its "'unjustified assumption' that Congress imposed [Counsel's] interpretation as a statutory requirement." *Id.* at *11. In such cases, agency action "must be declared invalid, even though the agency might be able to adopt the [interpretation] in the exercise of its discretion, if it 'was not based on the agency's own judgment but rather on the unjustified assumption that it was Congress' judgment" that such an interpretation was required. *Prill v. N.L.R.B.*, 755 F.2d 941, 948 (D.C. Cir. 1985) (quoting *FCC v. RCA Commc'ns*, 346 U.S. 86, 96 (1953)).

We therefore conclude that the Advisory Opinion must be vacated on the grounds that it reflects an arbitrary and capricious agency action. However, no order of remand is necessary, given HHS's voluntary withdrawal of it. Plaintiffs' motion for summary judgment on Count III of the Second Amended Complaint is therefore granted and

Defendants' cross motion is denied. The parties' cross motions for summary judgment on all other APA claims related to the Advisory Opinion (Counts I, II, and IV) are denied without prejudice.

B. May 17 Letter

We turn next to address the May 17 Letter. Plaintiffs maintain that, having found the Advisory Opinion violative of the APA, we must reach the same conclusion as to the May 17 Letter. We do not share that view. Unlike the Advisory Opinion, HRSA's determination in the May 17 Letter does not rely on a general, overarching requirement on behalf of manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies. Rather, the Letter is limited to the finding that Lilly's unilaterally adopted policy, whereby it will offer 340B pricing to all covered entities only so long as the 340B drugs ordered by the covered entity are shipped to an in-house or wholly-owned pharmacy or to a single designated contract pharmacy approved by Lilly, violates both the requirements set forth in the 340B statute and Lilly's PPA. Lilly is obligated to honor the 340B price for drugs purchased by covered entities and offer 340B pricing to covered entities on any drug that it sells to any other purchaser. Whether this specific agency finding in the May 17 Letter is lawful under the APA is the issue before us here.

Plaintiffs contend, and both sides agree, that the May 17 Letter constitutes a final agency action. Plaintiffs assert that it is both procedurally and substantively lacking under the APA for the reasons that it was issued without following proper notice and comment procedure, it exceeds the agency's statutory authority, it violates the United States Constitution, and it is arbitrary and capricious and an abuse of discretion and

otherwise not in accordance with law. We address these summary judgment claims in turn below.

1. Notice and Comment

We first address Plaintiffs' contention that the May 17 Letter is procedurally defective under the APA because required notice and comment procedures were not followed. It is well-established, however, that "[t]he APA does not require administrative agencies to follow notice and comment procedures in all situations." *Metro. Sch. Dist. of Wayne Twp., Marion Cnty., Ind. v. Davila*, 969 F.2d 485, 488 (7th Cir. 1992). Rather, "Section 553(b)(3)(A) specifically excludes 'interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice,' from notice and comment procedures." *Id.* at 488–89. While the Seventh Circuit has recognized the distinction between interpretive rules, which are exempt from notice and comment procedures, and legislative rules, which require such procedures, the Court has conceded that the distinction "is admittedly far from crystal-clear." *Id.* at 489 (quotation marks and citation omitted). Upon careful review, we conclude that the May 17 Letter is interpretive, not legislative, and therefore not subject to notice and comment requirements under the APA.

The "starting point" in our analysis of whether a rule is interpretive "is the agency's characterization of the rule," which, while not determinative "is a relevant factor." *Id.* (citations omitted). "An interpretive rule simply states what the administrative agency thinks the [underlying] statute means, and only reminds affected parties of existing duties." *Id.* (citations omitted); *see also Dismas Charities, Inc. v. U.S.*

Dep't of Justice, 401 F.3d 666 (6th Cir. 2005) ("[A] pure legal determination of what the applicable law already is does not require notice and comment under APA § 553(b)."). Moreover, where a rule is "based on specific statutory provisions … and its validity stands or falls on the correctness of the agency's interpretation of the statute" it is "clear the rule is an interpretive one." *Id.* at 492.

Here, the May 17 Letter clearly reflects an interpretation of the 340B statute. *See* Dkt. 94-1 ("HRSA has determined that Lilly's actions have resulted in overcharges and are in direct violation of the 340B statute."). The agency then supports this conclusion that Lilly's contract-pharmacy restrictions have resulted in unlawful overcharges by citing to the language of specific statutory provisions, and the validity of the agency's conclusion stands or falls on the correctness of its interpretation of the statute. Although the May 17 Letter clearly addresses the scope of Plaintiffs' duties and obligations under the 340B statute, an action "affecting rights and obligations is not *ipso facto* legislative." *Davila*, 969 F.2d at 493. For these reasons, we hold that the May 17 Letter is an interpretive rule that is exempt from notice and comment and thus not violative of the APA on these procedural grounds.

2. Exceeds Statutory Authority/Contrary to Law

Plaintiffs next claim that the May 17 Letter violates the APA because its assertions are contrary to law and exceed the agency's statutory authority by requiring Lilly, on pain of penalty, to do the following: (1) to offer drugs to contract pharmacies at 340B prices, thereby creating an exception to the statutory prohibition on diversion and effectively

expanding the statutory definition of "covered entities" to include contract pharmacies, and (2) to require Lilly to offer 340B discounts for transactions in which covered entities do not actually "purchase" covered outpatient drugs.

In response, Defendants maintain that the May 17 Letter neither exceeds the agency's statutory authority nor is contrary to law because the agency, duly tasked with administering the 340B program, correctly determined that Lilly's unilaterally adopted policy, pursuant to which it will ship 340B drugs only to covered entities at in-house and wholly-owned pharmacies, or, if the covered entity does not operate an in-house pharmacy, to a single contract pharmacy designated by the covered entity, has resulted in overcharges to covered entities in violation of its obligations under the 340B statute and its PPA.

In evaluating agency actions under the APA, courts must "hold unlawful and set aside" any that are "not in accordance with the law" or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(d). "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*." *City of Arlington, Tex. v. F.C.C.*, 569 U.S. 290, 297 (2013) (emphasis in original). In the case before us, there is no dispute between the parties that HRSA operates within its statutory authority in auditing drug manufacturers in an effort to ensure compliance with 340B pricing requirements. In determining whether the May 17 Letter is valid, Lilly's policy must be contrary to the 340B statute.

Thus, the question here is whether HRSA correctly concluded that Lilly's contract pharmacy restrictions violated the statutory prohibition on overcharging covered entities. Resolution of this issue turns on the interpretation of the 340B statute.

In engaging in statutory interpretation, the first issue "always, is the question whether Congress had 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). "[I]t is elementary that no deference is due to agency interpretations at odds with the plain language of the statute itself." *Smith v. City of Jackson*, 544 U.S. 228, 266 (2005) (O'Connor, J., concurring) (internal quotation marks and citation omitted).

If the statute is deemed ambiguous with respect to the specific issue, however, the level of deference afforded to the agency's interpretation varies. *United States v. Mead Corp.*, 533 U.S. 218, 227–31 (2001). Here, Defendants concede that, if the Court determines the 340B statute to be ambiguous, the agency's statutory interpretation is entitled to, at most, the level of deference outlined in *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). *Skidmore* deference directs that, the agency's interpretation is "'entitled to respect'—but only to the extent that [it has the] 'power to persuade.'" *Arobelidze v. Holder*, 653 F.3d 513, 520 (7th Cir. 2011) (quoting *Bailey v. Pregis Innovative Packaging, Inc.*, 600 F.3d 748, 751 (7th Cir. 2010)). In applying *Skidmore* deference to an agency's interpretation, courts consider "the thoroughness evident in [the agency's]

consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." *Id.* (quoting *Skidmore*, 323 U.S. at 140).

Applying these principles, we begin with an examination of the plain language of the statute at issue, that is, "the text of the statute." *United States v. All Funds on Deposit with R.J. O'Brien & Assocs.*, 783 F.3d 607, 622 (7th Cir. 2015). Courts "must presume that a legislature says in a statute what it means and means in a statute what it says there." *United States v. Rosenbohm*, 564 F.3d 820, 823 (7th Cir. 2009) (quotation marks and citation omitted). If the language of a statute is "clear and unambiguous," it "must ordinarily be regarded as conclusive," absent any "clearly expressed legislative intent to the contrary." *Id.* (quotation marks and citation omitted). "The plainness or ambiguity of statutory language is determined by reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole." *Robinson v. Shell Oil, Co.*, 519 U.S. 337, 341 (1997) (citations omitted).

The May 17 Letter relies on the text of section 340B(a)(1) as support for its determination that Lilly's policy has resulted in drug overcharges in violation of the law. By statute, the HHS Secretary is required to "enter into an agreement with each manufacturer of outpatient drugs under which the amount required to be paid … to the manufacturer for covered outpatient drugs … does not exceed" the applicable ceiling price and "shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made

available to any other purchaser at any price."[12] The May 17 Letter also references the fact that manufacturers that have signed a PPA and PPA addendum, as Lilly has, are required by the terms of the PPA to comply with these statutory requirements.

The 340B statute is silent as to contract pharmacy arrangements and drug manufacturers' *delivery* obligations. Plaintiffs argue that, because the plain statutory language does not impose any delivery obligation on the manufacturer and does not dictate any other aspect of the manufacturer's offer beyond the price or require Lilly to offer anything to or through contract pharmacies, Lilly is under no obligation to deliver 340B drugs to whatever destination a covered entity may command. Lilly maintains that its policy of both directly and through wholesalers, "offer[ing] each covered entity" the right to "purchase" "at or below the applicable ceiling price" all "covered outpatient drugs" that Lilly produces comports with its statutory obligations. By merely refusing to *deliver* the drugs to more than one location, it is not acting beyond the unambiguous dictates of the statute. Thus, according to Lilly, the May 17 Letter is contrary to law because HRSA's determination that Lilly's policy violates the 340B statute, necessarily

[12] Plaintiffs claim that the government's defense of the May 17 Letter cannot rest on the "purchased by" provision of the 340B statute because HRSA does not rely on that provision in the letter, and it is a "foundational principle" of administrative law that "a court may uphold agency action only on the grounds that the agency invoked when it took the action." *Michigan v. EPA*, 576 U.S. 743, 758 (2015). It is true that the May 17 letter nowhere quotes the "purchased by" provision, but it does provide that HRSA determined that Lilly's policy violates Section 340B(a)(1) and its PPA, both of which contain the "purchased by" requirement in addition to the "shall … offer" provision. In any event, we think we are on solid ground in interpreting the "shall … offer" provision in context with the "purchased by" provision, given that case law makes clear that the meaning of statutory language is determined not only by reference to the text itself, but also "the specific context in which that language is used, and the broader context of the statute as a whole." *Robinson*, 519 U.S. at 341.

reads into that provision a delivery requirement that does not appear in the text of the statute.

Plaintiffs argue that their construction of the statute best aligns with the ordinary meaning of the word "offer," which does not include any obligation to "deliver" a product to someone other than the purchaser. *See Black's Law Dictionary* (11th ed. 2019) (defining "offer" as: "1. The act or an instance of presenting something for acceptance," "2. A promise to do … some specified thing in the future, conditioned on an act … or return promise being given in exchange," and "3. A price at which one is ready to buy or sell; an amount of money that one is willing to pay or accept for something."). Relying on these definitions, Plaintiffs contend that the mere fact that a seller must "offer" goods to a particular buyer at a particular price imposes no obligations on where or how the seller must ship the good. Any construction of the term "offer" which incorporates a delivery requirement does not align with or reflect the plain meaning of that term.

We accept that, "[a] fundamental canon of statutory construction instructs that in the absence of statutory definition, we [are to] give terms their ordinary meaning." *Bass v. Stolper, Koritzinsky, Brewster & Neider, S.C.*, 111 F.3d 1322, 1325 (7th Cir. 1997). However, we must "interpret the relevant words, not in vacuum, but with reference to the statutory context, structure, history, and purpose," *Abramski v. United States*, 573 U.S. 169, 179 (2014) (citation omitted), because "it is a fundamental principle of statutory construction (and, indeed, of language itself) that the meaning of a word cannot be determined in isolation, but must be drawn from the context in which it is used." *Textron*

Lycoming Reciprocating Engine Div., Avco Corp. v. United Auto., Aerospace & Agric. Implement Workers of Am., Int'l Union and Its Local 787, 523 U.S. 653, 657 (1998) (quotation marks and citation omitted).

Defendants fault Plaintiffs' construction of the term "offer" as violative of this statutory canon based on their isolating a single word in the statute and interpreting it out of context, since the statute clearly requires drug manufacturers not simply to *offer*, but also to *sell* discounted drugs to covered entities. According to Defendants, when read as a whole, the unambiguous statutory requirements reflect Congress's clear intent, in enacting the 340B statute, to create a comprehensive drug distribution scheme to enable safety net providers to purchase the identified 340B drugs in a manner that ensures access to the discounted medications. Congress in no way intended to allow regulated entities to unilaterally erect barriers—such as Lilly's delivery restrictions—the effect of which frustrate the overarching purpose of the program based on a rationale that such restrictions are not explicitly prohibited by the plain language of the statute. Defendants stress that nothing in the statutory text supports the view that manufacturers' obligations are qualified, restricted, or dependent on the manner in which the covered entity chooses to distribute the covered outpatient drugs nor is a manufacturer otherwise permitted to condition its performance under the statute on such an interpretation.

Defendants maintain that HRSA correctly determined, "[a]fter review of [Lilly's] policy and an analysis of the complaints HRSA [] received from covered entities," Dkt. 94-1, that Lilly's policy of limiting the delivery of 340B drugs to only a covered entity's

in-house pharmacy and/or to one contract pharmacy identified by the covered entity violates the the 340B statute and the requirements of its PPA. To buttress their conclusion, Defendants highlight the administrative record, which, they say, is replete with complaints received from covered entities that Lilly's policy has caused 340B prices to be removed from covered entities' contract pharmacy accounts, whether orders were placed/received directly from Lilly or its wholesalers. As a result, those prices are no longer available to covered entities unless the covered entity ships to an in-house pharmacy or submits paperwork to Lilly designating a single contract pharmacy for shipment, and many covered entities have had to pay amounts above the ceiling price for 340B drugs.

This is the finding set out in the May 17 Letter, to wit, that Lilly's policy has resulted in overcharges in violation of its obligations under the 340B statute its PPA to "ensure that the 340B ceiling price is available to all covered entities," because Lilly places extra-statutory conditions on its "offer" that have prevented covered entities from accessing 340B pricing and have instead required them to pay much higher wholesale acquisition costs to purchase 340B drugs. This policy, according to Defendants, runs afoul of Lilly's obligation under the "shall … offer" provision "to provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs," as reflected in the May 17 Letter, because Lilly's policy prevents covered entities from accessing discounted drugs through the same wholesale channels where drugs are made available for full-price purchase and also because it imposes

shipment and delivery conditions on 340B purchases that it does not impose on non-340B purchases.

In drafting the 340B statute, Congress clearly utilized broad, generalized language that "is silent as to the role contract pharmacies may play in connection with covered entities' purchases of 340B drugs." *AstraZeneca Pharms.*, 2021 WL 2458063, at *9. The breadth of the statutory language does not prevent a court from determining whether actions by an agency or a regulated entity contravene Congressional intent. Having previously ruled that the statute was not accurately reflected in HHS's General Counsel's Advisory Opinion's conclusion that drug manufacturers are required to deliver 340B drugs to an unlimited number of contract pharmacies, we determined that Plaintiffs' construction of the "shall … offer" provision swung too far in the opposite direction. By relying solely on the statute's silence, drug manufacturers would be authorized to unilaterally impose a wide variety of restrictions on their offers, the effect of which would assuredly render 340B drugs inaccessible to many covered entities.[13]

The Supreme Court recently held that there is no "such thing as a 'canon of donut holes,' in which Congress's failure to speak directly to a specific case that falls within a

[13] As Defendants argue, Lilly's refusal to deliver 340B drugs to more than one contract pharmacy often renders hollow its "offer" to sell. Because these are prescription drugs, some of which cover controlled substances, they can be shipped only to locations that provide the proper legal infrastructure, including state licensing, DEA registration, staff pharmacists, etc., to accept delivery of, and dispense, pharmaceuticals. Many covered entities do not have the capacity or authority to handle their own dispensing or to take delivery of Lilly's medications, even for those that do, covered entities often serve vulnerable populations scattered over large geographic areas, making it impossible for all patients to fill their prescriptions each month on-site or in a single contract pharmacy location. *E.g.*, VLTR_7260–61.

more general statutory rule creates a tacit exception. Instead, when Congress chooses not to include any exceptions to a broad rule, courts apply the broad rule." *Bostock v. Clayton Cnty.*, 140 S.Ct. 1731, 1747 (2020). Defendants therefore challenge Plaintiff's construction of the statute on this basis as reading into the statutory text an exception to the "shall … offer" and "purchased by" provisions for covered entities utilizing multiple contract pharmacies. That interpretation does not align with the Supreme Court's pronouncement in *Bostock*, say Defendants.

We share Defendants view here: in analyzing and interpreting the 340B statute, we must construe the terms in context, with an eye to "the specific context in which that language is used," including other provisions of the statute. *Robinson*, 519 U.S. at 341. What is clear is that, since its enactment, the 340B statute has required drug manufacturers to honor their PPAs as to the amount covered entities can be required to pay for 340B drugs, which cannot exceed the ceiling prices. Plaintiffs' construction of the "shall … offer" provision to authorize its refusal to honor the 340B price for covered entities' purchases based solely on delivery location or dispensing mechanism, thereby requiring covered entities to pay WAC prices for covered outpatient drugs if they do not operate an in-house pharmacy or fail to designate a single contract pharmacy Lilly approves for shipment, directly conflicts with the statutory requirement otherwise.

Congress's use of broad language in enacting this statute and specifically omitting any mention of where 340B drugs are to be delivered does not leave room for drug manufacturers to unilaterally condition or control the availability of their 340B pricing to

a particular delivery location of their choosing such that covered entities are prevented from accessing 340B pricing and required to purchase covered outpatient drugs at WAC prices. The fairest and most reasonable interpretation of the 340B statute would not authorize drug manufacturers to impose unilateral restrictions on the distribution of the drugs that "would frustrate Congress' manifest purpose" in enacting the statute. *United States v. Hayes*, 555 U.S. 415, 426–27 (2009).

Plaintiffs focus their characterization of the sales of 340B drugs to covered entities utilizing contract pharmacy arrangements as not actually being "purchases by" covered entities. Instead, they constitute diversion, which the statute elsewhere prohibits. It makes no sense, argue Plaintiffs, to interpret the "shall … offer" provision in a manner that mandates the same kind of diversion that the statute otherwise prohibits. Even Plaintiffs assert, however, that only contract pharmacies "engage in diversion at outsize rates," not that every contract pharmacy arrangement results in diversion. Dkt. 129 at 21. And there is no evidence establishing that every covered entity working with multiple contract pharmacies uses the "replenishment model" to order 340B drugs, which is the sole method of purchase that Plaintiffs have claimed constitutes diversion.[14] We are not persuaded, therefore, by Plaintiffs' contention that construing the 340B statute in the

[14] We note also that it is beyond the Court's purview to determine whether purchases made using the replenishment model constitute diversion as Congress explicitly required manufacturers to address diversion and duplicate-discounting concerns in the ADR process and to audit covered entities before availing themselves of the ADR process. 42 U.S.C. § 256b(d)(3)(B)(iv). While the lawfulness of the ADR process promulgated by Defendants is a separate issue in this litigation that, as discussed above, will be addressed at a later date, there can be no dispute that Congress mandated that any concerns regarding diversion be addressed first through ADR procedures, not in federal litigation.

manner Defendants posit "mandate[s] the same kind of diversion the statute elsewhere prohibits." *Id.* at 20.

Plaintiffs further contend that Defendants' construction of the statute, which Plaintiffs describe as imposing an unlimited delivery obligation on drug manufacturers that appears nowhere in the plain language of the statute, would violate the "no-elephants-in-mouseholes canon," which recognizes the rule that "Congress 'does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions.'" *Bostock*, 140 S.Ct. at 1753 (quoting *Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 468 (2001)). We repeat: we do not agree with Plaintiffs' premise that to uphold the agency's determination set forth in the May 17 Letter, we must interpret the 340B statute to require drug manufacturers to deliver to an unlimited number of contract pharmacies. Nevertheless, we acknowledge, as Plaintiffs emphasize, that the demand for 340B drugs and the prevalence of contract pharmacies has exploded in a way that Congress likely did not imagine either when the statute was first enacted in 1992 or when the "shall … offer" language was added to the statute in 2010. That said, the evidence before us establishes that reliance on outside pharmacies by covered entities was, even at the time of the statute's enactment, known to Congress as a common business practice; thus, by choosing to use broad language to define obligations and entitlements under the statute, Congress "virtually guaranteed that unexpected applications would emerge over time." *Id.* Accordingly, the "elephant" that is the greatly enhanced role of contract pharmacies in

the 340B program "has never hidden in a mousehole; it has been standing before us all along." *Id.*

Given the expansion of the 340B program and the vast proliferation of contract pharmacy arrangements since Congress's most recent amendments to the 340B statute, Congress may at some point choose to amend the statute to directly address these issues. But that is for Congress to determine; drug manufacturers may not usurp the role through unilateral extra-statutory restrictions. *See Patriotic Veterans, Inc. v. Indiana*, 736 F.3d 1041, 1047 (7th Cir. 2013) ("If Congress determines later that the plain language of the statute does not accurately reflect the true intent of Congress, it is for Congress to amend the statute).

Construing the 340B statute not to permit drug manufacturers to impose extra-statutory conditions on covered entities' access to discounted medications is not only a permissible construction, but, in our view, the construction that best aligns with congressional intent.[15] Accordingly, we hold that the May 17 Letter, which determined that Lilly's policy under which it delivers drugs to only one location per covered entity

[15] Having used the tools of statutory interpretation to arrive at what we believe is the appropriate and correct interpretation of the 340B statute, we need not discuss whether the agency's interpretation is entitled to *Skidmore* deference, apply the rule of lenity, or consider the statute's legislative history. We do note, however, that the 340B statute's legislative history is consistent with our holding. In 1992, Congress considered but removed from the statute a provision that would have restricted 340B-discounted sales to drugs "purchased and dispensed by, or under a contract entered into for on-site pharmaceutical services with" a covered entity. *See* S. Rep. No. 102-259, at 1–2. The fact that Congress once considered but rejected restricting covered entities' choice of dispensing mechanism in a manner consistent with Plaintiffs' position supports our statutory interpretation. *See Lomax v. Ortiz-Marquez*, 140 S. Ct. 1721, 1725 (2020) ("[T]his Court may not narrow a provision's reach by inserting words Congress chose to omit.").

and otherwise charges covered entities prices high above the ceiling price for covered outpatient drugs resulted in violations of the 340B statute's prohibition against overcharging, neither exceeds the agency's statutory authority nor is contrary to law.

3. Takings Clause/Unconditional Condition

Plaintiffs claim that interpreting the 340B statute in the manner championed by Defendants renders the May 17 Letter unconstitutional and violative of the APA because it effects a *per se* taking in violation of the Fifth Amendment to the United States Constitution. Under the Takings Clause of the Fifth Amendment, "private property" shall not "be taken for public use, without just compensation." U.S.CONST. amend. V. Specifically, Plaintiffs argue that the May 17 Letter effects a purely private taking of their property by forcing Lilly to transfer its drugs to contract pharmacies solely to serve those entities' private interests, and that, by requiring Lilly to succumb to a private taking of property to obtain coverage of its drugs under federal health-insurance programs, the May 17 Letter imposes an unconstitutional condition on a valuable government benefit. Compl. ¶¶ 289–96.

We are not persuaded by Plaintiffs' argument, however, primarily due to the fact that they have voluntarily chosen to participate in the 340B program and are thus free to terminate their participation if and when they may choose to do so. Such "voluntariness forecloses the possibility that the statute could result in an imposed taking of private property which would give rise to the constitutional right of just compensation …." *Southeast Arkansas Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016) (quoting

Minnesota Ass'n of Health Care Facilities, Inc. v. Minnesota Dep't of Pub. Welfare, 742 F.2d 442, 446 (8th Cir. 1984); *accord St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875–76 (7th Cir. 1983) (per curiam); *see also Ruckelshaus v. Monsato Co.*, 467 U.S. 986, 1007 (1984) (rejecting an unconstitutional-conditions challenge to a condition on a valuable government benefit (i.e., voluntary exchange of proprietary information in exchange for a license to sell a product) on grounds that if the plaintiff "is aware of the conditions" under which the property is relinquished and "the conditions are rationally related to a Government interest," the "voluntary" relinquishment of the property "in exchange for the economic advantages" of the benefit, "can hardly be called a taking."). We concede that in withdrawing from the 340B program Lilly would no longer receive coverage or reimbursement for its products under Medicaid and Medicare Part B, which would result in a significant financial impact for Lilly, but "economic hardship is not equivalent to legal compulsion for purposes of takings analysis." *Garelick v. Sullivan*, 987 F.2d 913, 917 (2d Cir. 1993); *see also Minnesota Ass'n of Health Care Facilities, Inc.*, 742 F.2d at 446 (holding that a "strong financial inducement to participate" in a regulated program does not render such participation involuntary).

For these reasons, we are not persuaded by Plaintiffs' claim that the government's position set forth in the May 17 Letter cannot be reconciled with the Takings Clause.[16] Plaintiffs have made clear their frustration with the government's lack of oversight over

[16] We note that Plaintiffs' takings-related arguments are potentially more persuasive when applied to the Advisory Opinion's interpretation of the 340B statute. However, as discussed above, the interpretation relied upon in the May 17 Letter is distinct from and less expansive than that espoused in the Advisory Opinion.

covered entities' dealings with contract pharmacies, which has forced Lilly and other drug manufacturers to absorb the financial impact of any such abuses of the 340B system, but we "conclude that the Takings Clause of the Fifth Amendment is not the proper vehicle for altering this harsh reality." *Baker Cnty. Med. Servs., Inc. v. United States Atty. Gen.*, 763 F.3d 1274, 1280 (11th Cir. 2014). "As is so often the case, [Lilly's] most effective remedy may lie with Congress rather than the courts." *Id.*

4. Arbitrary and Capricious

Finally, Plaintiffs maintain that, even if not contrary to law, the May 17 Letter is invalid under the APA because the position it espouses is arbitrary and capricious. A careful review of the May 17 Letter reveals its failure to acknowledge, never mind explain HRSA's change in position regarding its authority to enforce potential violations of the 340B statute connected to contract pharmacy arrangements. The May 17 Letter thus must be vacated and set aside as arbitrary and capricious and the issues outlined therein remanded to the agency.

The legal underpinnings of this ruling are clear. Under the APA, when an agency changes its existing position on a particular issue, it "must at least 'display awareness that it is changing position' and 'show that there are good reasons for the new policy.'" *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016) (quoting *Fox Television Stations, Inc.*, 556 U.S. at 515). In addition, "[i]n explaining its changed position, an agency must also be cognizant that longstanding policies may have 'engendered serious reliance interests that must be taken into account.'" *Id.* (quoting *Fox Television Stations*,

Inc., 556 U.S. at 515). "In such cases it is not that further justification is demanded by the mere fact of policy change; but that a reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy." *Id.* (quoting *Fox Television Stations, Inc.*, 556 U.S. at 515–16). Thus, "an [u]nexplained inconsistency' in agency policy is 'a reason for holding an interpretation to be an arbitrary and capricious change from agency practice.'" *Id.* (quoting *Nat'l Cable & Telecommunications Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005)).

HRSA contends that the May 17 Letter reflects its view that Lilly's policy violates the 340B statute, which is the position that the agency "has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to honor [covered entities'] purchases regardless of the dispensing mechanism." Dkt. 94-1. We accept that the agency has consistently espoused the view in non-binding guidance that drug manufacturers must comply with their obligations under the 340B statute regardless of the manner in which the covered entity chooses to dispense the drugs and must accommodate all contract pharmacy arrangements that the government permits. However, its exponential expansion of "what covered entities ***may*** do" with regard to contract pharmacy arrangements over the years, "has consequently changed what drug manufacturers ***must*** do." *AstraZeneca Pharms.*, 2021 WL 2458063, at *7 (emphasis in original).

Prior to December 2020, the agency consistently represented that its interpretation set forth in the 1996 and 2010 Guidance regarding contract pharmacy use was non-

binding and further, that the agency had limited authority to issue enforceable regulations regarding contract pharmacy arrangements. Specifically, in June 2020, in response to Lilly's announcement of its contract pharmacy policy, HRSA informed Lilly in writing that its prior "contract pharmacy advice" was not "binding" on manufacturers. VLTR_7590. Approximately one month later, in July 2020, HRSA publicly shared this view, explaining to a 340B-focused publication that "[t]he 2010 guidance … is not legally enforceable," and that the agency could enforce only direct violations of the statute, but could not "compel[]" manufacturers "to provide 340B discounts on drugs dispensed by contract pharmacies." Tom Mirga, *HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable*, 340B Report (July 9, 2020).

Throughout 2020, the agency continued to inform covered entities that, although "HRSA continues to strongly encourage manufacturers to sell 340B priced drugs to covered entities directly and through contract pharmacy arrangements," it lacked "comprehensive regulatory authority" to "issue enforceable regulations to ensure clarity in program requirements …." *E.g.*, VLTR_3272, VLTR_3285, VLTR_4194; *see also Am. Hosp. Ass'n*, 2021 WL 616323, at *3 (quoting July 8, 2020 email from HRSA Communications Director Martin Kramer recognizing that, while the agency strongly encouraged manufacturers to sell 340B drugs to covered entities through contract pharmacy arrangements, "HRSA's current authority to enforce certain 340B policies … is limited"). As a result, in communications with HRSA, covered entities and contract pharmacies recognized that it was HRSA's view that it "cannot require manufacturers to

offer drugs at the 340B ceiling price to be shipped to contract pharmacies because the 2010 contract pharmacy guidance … is not legally enforceable." VTLR_3283.

HRSA not only espoused the view that it lacked enforcement authority regarding contract pharmacy use, but also applied that view in practice in addressing covered entity compliance. Plaintiffs cite a December 2020 GAO report which states that HRSA declined in certain instances in 2019 to address the problem of covered entity statutory compliance via their contract pharmacy partners in part because, in HRSA's view, "the 340B statute does not address contract pharmacy use and, therefore, there may not have been a clear statutory violation" by the covered entity. GAO, GAO-21-107 ("GAO Report"), at 15–16, gao.gov/assets/gao-21-107.pdf; *see also id.* ("HRSA … did not issue eligibility findings for a failure to oversee 340B Program compliance at contract pharmacies through internal audits and other measures as set forth in guidance because the 340B statute does not address contract pharmacy use.").

The agency's view regarding the non-binding nature of its position that drug manufacturers should sell 340B drugs through contract pharmacy arrangements dramatically changed in December 2020, however, with the issuance of HHS General Counsel's[17] Advisory Opinion, which for the first time provided that participating manufacturers are obligated by statute to provide 340B discounts to covered entities

[17] HHS regulations provide that the HHS general counsel's office "[s]upervises all legal activities of the Department and its operating agencies," and "[f]urnishes all legal services and advice to … all offices, branches, or units of the Department in connection with the operation and administration of the Department and its programs, except with respect to functions expressly delegated by statute to the Inspector General." 86 Fed. Reg. 6,349, 6,351 (Jan. 21, 2021).

through contract pharmacy arrangements "to the extent" that a contract pharmacy is acting as an agent of the covered entity. VLTR_8048. Even after the issuance of the Advisory Opinion, Defendants' counsel represented to the Court at a February 26, 2021 hearing on Lilly's motion for a preliminary injunction to enjoin the ADR Rule that, "while the agency has determined that covered entities have a right generally to use contract pharmacy arrangements, the agency has not passed on the specifics of Lilly's new policy, because that belongs in the ADR" and "if the panel determines that Lilly's policy does not comply with the statute, it can refer its decision to HRSA for enforcement action," at which point HRSA considers "whether to impose penalties, sanctions, to refer the decision to the OIG for civil monetary penalties." Dkt. 72 at 76–77.

Less than three months thereafter, in the May 17 Letter, HRSA issued its final determination on the precise issue that counsel for Defendants had represented to the Court belonged in the ADR, to wit, whether Lilly's policy complied with the 340B statute. The May 17 Letter does not reference or explain HRSA's about-face regarding the agency's authority to compel drug manufacturers to offer 340B pricing to covered entities dispensing drugs through contract pharmacies and to enforce Lilly's failure to do so. The Advisory Opinion issued by HHS's General Counsel approximately five months prior relies on the theory that "covered entity and contract pharmacy are not distinct, but function as principal-agent" and thus "to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the

covered entity no more than the 340B ceiling price for those drugs." However, the May 17 Letter nowhere references the reasoning behind this opinion or explains HRSA's subsequent decision to abandon that view, despite the fact that the Advisory Opinion had at that point not yet been withdrawn by HHS.

Defendants argue that the May 17 Letter is not inconsistent with HRSA's previously expressed position regarding the enforceability of contract pharmacy arrangements for the reason that the May 17 Letter lays out its determination that Lilly was acting in direct violation of statutory requirements, which the agency has always maintained is within its scope of authority to enforce. This conclusion by the agency—that Lilly's policy, under which it does not sell 340B discounted drugs to covered entities dispensing drugs through more than one contract pharmacy, making it a clear violation of the statute—clearly conflicts with HRSA's representations to the GAO just a year before that declined to pursue potential compliance issues involving covered entities' dealings with contract pharmacies because "the 340B statute does not address contract pharmacy use and, therefore, there may not have been a clear statutory violation" by the covered entity. GAO Report at 15–16.

Given the well-established principle that when an agency adopts a position that is "radically different" from the agency's previous views, the APA requires the agency to "show that there are good reasons for the new policy" (*Cook Cnty. v. Wolf*, 962 F.3d 208, 230 (7th Cir. 2020) (quotation marks and citation omitted)) and because HRSA has failed even to acknowledge any change in its position regarding its ability to take enforcement

action related to drug manufacturers' dealings with covered entities through contract pharmacy arrangements, much less provide "good reasons" for such change, the determinations in the May 17 Letter are arbitrary and capricious and must be set aside and vacated and the issues remanded to the agency as actions violative of the APA.

III. Conclusion

While we have most assuredly crafted the most careful judgments of which we are capable with respect to the challenging issues raised by the parties in this litigation, we do not presume to have a full, integrated understanding of the way(s) in which the 340B program should properly and fairly be administered going forward in a way that attempts to reflect the dramatically altered healthcare landscape in which the regulated parties now operate. We do not know, for example, why the agency said for so long that it was not able to enforce its view of drug manufacturers' obligations under the statute in the context of contract pharmacy arrangements and then suddenly changed tack and said it was able to enforce these requirements. We cannot divine whether Congress intended for drug manufacturers to have unlimited delivery obligations under the statute, untethered to the particular covered entity's actual distribution needs. We have no insight into why there is apparently so much reluctance to promulgate a holistic legislative proposal to bring clarity to the scope of the regulated parties' obligations and entitlements under the statute with regard to contract pharmacy arrangements rather than engage in piecemeal interpretations and after the fact patchwork characterizing the history of the agency's attempts to manage this program. What we have come to see, however, is that the 340B

program can no longer be held together and implemented fairly for all concerned with non-binding interpretive guidelines and mixed, sometimes inconsistent messaging by the agency regarding the source and extent of its authority to enforce statutory compliance in the area of contract pharmacies.

In performing our analysis and reaching the conclusions recorded here, we have decided only the issues presented to us in this case. In doing so, we sought to understand and explain and apply the appropriate legal principles within the boundaries of justiciability. We are not authorized or qualified to go beyond this role by presuming to speak for Congress, the agency, the regulated entities, or other federal district courts assessing similar but distinct policies of other drug manufacturers. For the reasons detailed above, we have determined that, though the 340B statute does not unambiguously require drug manufacturers to deliver drugs to an unlimited number of contract pharmacies as the Advisory Opinion would require, the statute, correctly construed, does not permit drug manufacturers, such as Lilly, to impose unilateral extra-statutory restrictions on its offer to sell 340B drugs to covered entities utilizing multiple contract pharmacy arrangements. Thus, the May 17 Letter advancing the conclusion that Lilly's policy resulted in overcharges in violation of the 340B statute is not contrary to law or in excess of the agency's statutory authority nor is it unconstitutional or issued in violation of the APA's notice and comment procedures.

However, despite the agency's assertion that it has consistently advanced the view that drug manufacturers must comply with the 340B statutory requirements regardless of

the drug dispensing system used by covered entities, at the same time it has espoused the conflicting view that the agency does not have authority to issue binding regulations regarding contract pharmacies and operated with only limited enforcement authority with regard to its contract pharmacy guidance and that determining whether Lilly's policy complied with the statute was an issue that must be decided in the ADR process. Because the May 17 Letter fails to acknowledge or explain the agency's changed position(s) with regard to its authority to enforce statutory compliance when the alleged violation is entangled with a regulated entity's failure to comply with the agency's non-binding contract pharmacy guidance, we hold that it is arbitrary and capricious and thus violative of the APA.

In line with these findings and conclusions:

- Defendants' Motion to Dismiss as to Plaintiffs' APA claims challenging the Advisory Opinion issued by General Counsel of HHS on December 30, 2020 is DENIED.
- Plaintiffs' Motion for Summary Judgment on their claim that the Advisory Opinion is arbitrary and capricious and thus violates the APA (Count III) is GRANTED and Defendants' Cross-Motion for Summary Judgment on that claim is correspondingly DENIED.
- The parties' cross-motions on Plaintiffs' remaining APA claims challenging the Advisory Opinion on grounds that it was issued without following notice and comment procedures (Count I), exceeds the agency's statutory authority (Count II),

and violative of the Fifth Amendment's Takings Clause and Article I of the United States Constitution (Count IV), are DENIED WITHOUT PREJUDICE.

- Plaintiffs' Motion for Summary Judgment on their APA claims challenging the May 17 Letter on grounds that it is contrary to law or in excess of statutory authority (Count X), violative of the Fifth Amendment's Takings Clause and Article I of the United States Constitution (Count XI), and issued without following notice and comment procedures (Count XIII) is DENIED and Defendants' Cross Motion for Summary Judgment is correspondingly GRANTED as to these claims.
- Plaintiffs' Motion for Summary Judgment as to their claim that the May 17 Letter is arbitrary and capricious in violation of the APA (Count XII) is GRANTED and Defendants' Cross Motion for Summary Judgment is DENIED.

Having found that the 2020 Advisory Opinion and the May 17 Letter are both arbitrary and capricious actions that violate the APA, we hereby SET ASIDE and VACATE these agency actions and REMAND the May 17 Letter to the agency for further consideration/action consistent with the opinions explicated here. Although agency actions invalidated as arbitrary and capricious are typically remanded to the agency for further consideration, *Florida Power & Light Co. v. Lorion*, 470 U.S. 729 (1985), because the agency has already withdrawn the Advisory Opinion, no remand of that agency action is necessary.

The Court is making the requisite finding pursuant to Federal Rule of Civil Procedure 54(b) that there is no just reason for delay; thus, partial final judgment shall issue on Counts III and X–XIII to allow the parties to decide whether to seek expedited appellate review of these issues. The Court will address the parties' cross-motions for summary judgment as to Plaintiffs' APA claims challenging the ADR Rule (Counts V, VI, VII, VIII, and IX) in due course.

IT IS SO ORDERED.

Date: 10/29/2021

SARAH EVANS BARKER, JUDGE
United States District Court
Southern District of Indiana

Distribution:

AMERICA'S ESSENTIAL HOSPITALS

Nicholas Blake Alford
FAEGRE DRINKER BIDDLE & REATH LLP (Indianapolis)
Nicholas.Alford@faegredrinker.com

Joseph Neal Bowling
LEWIS WAGNER, LLP
nbowling@lewiswagner.com

Andrea Butler
KIRKLAND & ELLIS LLP
andrea.butler@kirkland.com

Ronald S. Connelly
POWERS PYLES SUTTER & VERVILLE, P.C.
ron.connelly@powerslaw.com

Kathryn Elias Cordell
KATZ KORIN CUNNINGHAM, P.C.
kcordell@kkclegal.com

Dina M. Cox
LEWIS WAGNER, LLP
dcox@lewiswagner.com

Margaret M. Dotzel
ZUCKERMAN SPAEDER LLP
mdotzel@zuckerman.com

Matthew Sidney Freedus
FELDESMAN TUCKER LEIFER FIDELL LLP
mfreedus@ftlf.com

Rosie Dawn Griffin
FELDESMAN TUCKER LEIFER FIDELL LLP
rgriffin@ftlf.com

Casey Trombley-Shapir Jonas
ZUCKERMAN SPAEDER LLP
cjonas@zuckerman.com

Andrew A. Kassof
KIRKLAND & ELLIS LLP - Chicago
akassof@kirkland.com

Jody D. Lowenstein
United States Department of Justice
jody.d.lowenstein@usdoj.gov

Alice McKenzie Morical
HOOVER HULL TURNER LLP
amorical@hooverhullturner.com

John C. O'Quinn
KIRKLAND & ELLIS LLP
john.oquinn@kirkland.com

Matthew S. Owen
KIRKLAND & ELLIS LLP
matt.owen@kirkland.com

Brian J. Paul
FAEGRE DRINKER BIDDLE & REATH LLP (Indianapolis)
brian.paul@faegredrinker.com

Andrea Roberts Pierson
FAEGRE DRINKER BIDDLE & REATH LLP (Indianapolis)
andrea.pierson@faegredrinker.com

Matthew D. Rowen
KIRKLAND & ELLIS LLP
matthew.rowen@kirkland.com

William B. Schultz
ZUCKERMAN SPAEDER LLP
wschultz@zuckerman.com

Kate Talmor
U.S. DEPARTMENT OF JUSTICE (Washington DC)
kate.talmor@usdoj.gov

Brendan Michael Tyler
FELDESMAN TUCKER LEIFER FIDELL LLP
btyler@ftlf.com

Christopher D. Wagner
HOOVER HULL TURNER LLP
cwagner@hooverhullturner.com

Diana M. Watral
KIRKLAND & ELLIS LLP - Chicago
diana.watral@kirkland.com