United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued November 8, 2019 Decided July 31, 2020

No. 19-5048

AMERICAN HOSPITAL ASSOCIATION, ET AL.,
APPELLEES

v.

ALEX MICHAEL AZAR, II, IN HIS OFFICIAL CAPACITY AS THE SECRETARY OF HEALTH AND HUMAN SERVICES AND UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
APPELLANTS

Consolidated with 19-5198

Appeals from the United States District Court
for the District of Columbia
(No. 1:18-cv-02084)

Alisa B. Klein, Attorney, U.S. Department of Justice, argued the cause for appellants. With her on the briefs were *Mark B. Stern* and *Laura E. Myron*, Attorneys, *Robert P. Charrow*, General Counsel, U.S. Department of Health & Human Services, *Janice L. Hoffman*, Associate General Counsel, *Susan Maxson Lyons*, Deputy Associate General Counsel for Litigation, and *Robert W. Balderston*, Attorney.

Thomas R. Barker and *Andrew M. London* were on the brief for *amicus curiae* Federation of American Hospitals in support of defendants-appellants.

William B. Schultz argued the cause for plaintiffs-appellees. With him on the brief was *Margaret M. Dotzel*.

Before: SRINIVASAN, *Chief Judge*, and MILLETT and PILLARD, *Circuit Judges*.

Opinion for the Court filed by *Chief Judge* SRINIVASAN.

Opinion dissenting in part filed by *Circuit Judge* PILLARD.

SRINIVASAN, *Chief Judge*: When hospitals provide outpatient care to patients insured by Medicare Part B, the federal government reimburses the hospitals for the care. Until recently, the government reimbursed all hospitals at a uniform rate for providing covered drugs. In 2018, though, the Department of Health and Human Services reduced the reimbursement rate for covered drugs by 28.5% for certain hospitals known as "340B hospitals" by virtue of their participation in the federal 340B Drug Pricing Program for underserved populations. HHS cut the reimbursement rate for 340B hospitals because they can obtain drugs far more cheaply than other hospitals. As HHS saw it, Medicare should not reimburse hospitals more than they paid to acquire the drugs.

Several hospitals and hospital associations challenge HHS's decision, claiming that it rests on an impermissible construction of the governing statute. The district court agreed with the plaintiffs that HHS had exceeded its statutory authority by reducing drug reimbursement rates for 340B hospitals. We disagree. We hold that HHS's decision to lower

drug reimbursement rates for 340B hospitals rests on a reasonable interpretation of the Medicare statute.

I.

A.

The Medicare program provides health insurance to the elderly and disabled. Medicare Part A provides coverage for inpatient care, i.e., care provided while a patient is admitted to a hospital or skilled nursing facility. Medicare Part B covers various other services including outpatient (or same-day) hospital care. Part B thus pays for certain drugs, such as immunosuppressants or chemotherapy drugs, administered in a hospital setting on an outpatient basis. Part B beneficiaries generally pay 20% of their bill out of pocket as coinsurance.

The Department of Health and Human Services (HHS) annually establishes Part B reimbursement rates through notice-and-comment rulemaking. In setting the rates, HHS uses the "Outpatient Prospective Payment System," or OPPS. *See* 42 U.S.C. § 1395*l*(t). *See generally Am. Hosp. Ass'n v. Azar*, No. 19-5352, slip op. at 3–6 (D.C. Cir. July 17, 2020). The OPPS requires HHS to fix the amounts it will pay providers for certain services before the year begins (rather than after the care has been provided). Congress moved to that prospective system to enhance HHS's ability to control Part B costs. *See* Medicare Program; Prospective Payment System for Hospital Outpatient Services, 65 Fed. Reg. 18,434, 18,436–37 (Apr. 7, 2000); *Paladin Cmty. Mental Health Ctr. v. Sebelius*, 684 F.3d 527, 528–29 (5th Cir. 2012).

For most types of covered care, the Medicare statute instructs HHS to set annual OPPS reimbursement rates through a complex formula that gives the agency significant discretion.

See 42 U.S.C. § 1395*l*(t)(2). For certain kinds of services, however, the OPPS limits that discretion and sets out a specific methodology for calculating payment rates. That is the case for certain drugs covered by Part B, known as "specified covered outpatient drugs" or SCODs.

The statute requires HHS to calculate the reimbursement rate for SCODs in one of two ways. First, under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I), which we will refer to as subclause (I), HHS may use "the average acquisition cost for the drug . . . as determined by the Secretary taking into account . . . hospital acquisition cost survey data." Second, under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II), which we call subclause (II), "if hospital acquisition cost data are not available," HHS must use "the average price for the drug" as established by a separate, cross-referenced statute. In the event HHS uses average price under subclause (II), that price metric may be "adjusted by [HHS] as necessary for purposes of this paragraph." *Id.*

Since 2006, when those two statutory pricing alternatives took effect, HHS has not had the "hospital acquisition cost survey data" contemplated by subclause (I). As a result, HHS has had to use the average price metric. *See* Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 77 Fed. Reg. 68,210, 68,385–86 (Nov. 15, 2012). The parties here agree that, by virtue of a statutory cross-reference, a drug's default "average price" equals 106% of its "average sales price," or ASP. *See* 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) (citing 42 U.S.C. § 1395w-3a(c)). HHS calculates ASP every quarter using sales data confidentially provided by drug manufacturers.

HHS's average price "methodology . . . has always yielded a finalized payment rate [for SCODs] in the range of

ASP+4 percent to ASP+6 percent," or 104% to 106% of ASP. 77 Fed. Reg. at 68,386. As a result, all hospitals have been paid the same rate—104% to 106% of ASP—for SCODs. Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 52,356, 52,494–95 (Nov. 13, 2017). From 2013 to 2017, that rate was 106% of ASP, unadjusted from the statutory default average price.

B.

That changed in late 2017, when HHS announced SCOD payment rates for the upcoming 2018 OPPS year. Invoking its subclause (II) authority to "adjust" the average price metric, HHS for the first time established two separate rates: one rate for hospitals participating in a drug discount program known as the "340B program," and another rate for all other hospitals. The rate for non-340B hospitals remained at ASP+6%, or 106% of ASP. The rate for 340B hospitals was "adjusted" down to ASP minus 22.5%, or 77.5% of ASP.

To understand HHS's reasons for reducing SCOD reimbursement rates for 340B hospitals, it is helpful to review the background of the 340B program. The program takes its name from the section of the Public Health Service Act that authorizes it. *See* Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967–71 (1992). The program allows covered entities (including eligible hospitals) to purchase drugs from manufacturers at heavily discounted rates. *See* 42 U.S.C. § 256b(a)(4). The covered entities generally care for underserved populations, and the discounted rates enable the providers to "stretch scarce Federal resources as far as possible." H.R. Rep. No. 102-384 (II), at 12 (1992).

The program requires manufacturers, as a condition of having their drugs covered by Medicaid, to sell each covered drug to 340B entities at a "ceiling price" (set by statutory formula). 42 U.S.C. § 256b(a). The program covers at least 3,500 drugs, 82 Fed. Reg. at 52,494, and the government estimates that 340B sales make up approximately 2.8% of the total U.S. drug market. Health Resources and Services Administration, *Justification of Estimates for Appropriations Committees Fiscal Year 2018*, at 244, https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-2018.pdf.

Over the past several years, observers have raised concerns about the intersection of the 340B program with Medicare Part B. Government reports found that 340B hospitals typically pay between 20% and 50% below ASP for covered drugs. When hospitals provide 340B drugs that qualify as SCODs to patients, the hospitals then seek reimbursement from Medicare Part B. Until 2018, the reimbursement rate was 106% of ASP. There was thus a large gap between the amount a 340B hospital would spend to acquire a SCOD and the higher amount Medicare would reimburse that hospital. The gap ranged from 25% to 55% of the cost of the drug. *See, e.g.*, U.S. Government Accountability Off., GAO-15-442, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals (June 2015), https://www.gao.gov/assets/680/670676.pdf.

When it came time to set 2018 OPPS rates, HHS decided to address the 340B-Part B payment gap. HHS believed that the gap "allow[ed] [340B] providers to generate significant profits when they administer[ed] Part B drugs." 82 Fed. Reg. at 52,494. Seeking to shrink those revenues, HHS imposed a 28.5% cut, from 106% of ASP to 77.5% of ASP, to the rates at which it would reimburse 340B hospitals for SCODs. *See id.*

at 52,496. The new rate was based on a "conservative" estimate, presented by the Medicare Payment Advisory Committee, that 22.5% below ASP equaled the "average minimum discount that a 340B participating hospital receive[d]" when purchasing SCODs. *Id.* HHS estimated that its 28.5% cut to SCOD reimbursement rates for Part B hospitals would save Medicare $1.6 billion in 2018. *Id.* at 52,509. As called for by the OPPS statute, HHS did not pocket the savings, but instead redistributed them to all hospitals in a budget-neutral manner by raising other Part B reimbursement rates. *Id.* at 52,623; *see* 42 U.S.C. § 1395*l*(t)(14)(H).

By addressing the 340B-Part B payment gap, HHS hoped to mitigate "unnecessary utilization and potential overutilization of [Part B] drugs." Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 33,558, 33,633 (July 20, 2017). HHS cited a GAO study which found that 340B hospitals prescribed more drugs than other hospitals, a disparity unexplained by salient distinctions between the hospitals or their patient populations. *Id.* at 52,494. HHS also sought to reduce the disproportionate coinsurance payments borne by Medicare Part B beneficiaries (mostly elderly patients) for 340B SCODs: because the amount of a patient's coinsurance payment is a fixed percentage of the medical bill as measured by the OPPS payment level, and because the latter amount for SCODs exceeded 340B hospitals' actual costs to obtain the drugs, patients' out-of-pocket coinsurance payments for SCODs became inflated, sometimes even exceeding a hospital's costs to acquire the drugs. *See id.*

Ultimately, HHS found it "inappropriate for Medicare to subsidize other activities" by 340B hospitals—as laudable as those activities may be—"through Medicare payments for [Part

B] drugs." *Id.* at 52,495. In order to "better and more appropriately reflect the resources and acquisition costs that [340B] hospitals incur," HHS acted to close the Part B-340B gap. *Id.* (formatting modified). HHS relied on its authority to "adjust" the average price metric under subclause (II) of the statute:

> We believe our authority under section [1395*l*](t)(14)(A)(iii)(II) of the Act to "calculate and adjust" drug payments "as necessary for purposes of this paragraph" gives the Secretary broad discretion to adjust payments for drugs, which we believe includes an ability to adjust Medicare payment rates according to whether or not certain drugs are acquired at a significant discount.

Id. at 52,499.

C.

The plaintiffs here are three hospitals and three hospital associations, to whom we will refer collectively as the Hospitals. On November 13, 2017, the day HHS published the rule reducing 340B reimbursement rates for SCODs, the Hospitals brought a challenge to HHS's action. *See Am. Hosp. Ass'n v. Hargan*, 289 F. Supp. 3d 45, 50 (D.D.C. 2017). The district court dismissed the suit on the ground that the Hospitals had yet to present a concrete claim for payment to HHS, as required by statute. *See id.* at 47. We affirmed. *Am. Hosp. Ass'n v. Azar*, 895 F.3d 822, 828 (D.C. Cir. 2018).

The Hospitals quickly submitted payment claims as required. HHS rejected them, claiming that the Medicare statute precludes administrative review of adjustments to OPPS

payment rates, including SCOD reimbursement rates. The Hospitals then filed this action. Before the district court ruled, HHS promulgated OPPS rates for fiscal year 2019, which retained the 28.5% SCOD reimbursement cut for 340B hospitals that the Hospitals had initially challenged. 53 Fed. Reg. 83,818 (Nov. 21, 2018). After submitting additional payment claims, the Hospitals filed a supplemental complaint challenging the 2019 Rule as well. *See* Suppl. Compl. ¶¶ 73–75 (Dkt. 39).

This time, the district court reached the merits. After concluding that the Medicare statute did not preclude its review of the reductions in SCOD reimbursement, the court held that the rate cut exceeded HHS's statutory authority to "adjust" SCOD rates. *Am. Hosp. Ass'n v. Azar*, 348 F. Supp. 3d 62, 79 (D.D.C. 2018). The court remanded to the agency to come up with a remedy in the first instance. The court then entered final judgment, paving the way for this appeal.

II.

We must first address a threshold challenge to our jurisdiction. The government asserts that paragraph 1395*l*(t)(12) of the OPPS statute, 42 U.S.C. § 1395*l*(t)(12), precludes judicial review of HHS's adjustments to SCOD rates. The district court disagreed, and so do we. Unable to find "clear and convincing evidence that Congress intended" that result, as would be required to overcome the "strong presumption that Congress intends judicial review of administrative action," we conclude that the challenged rate adjustment is subject to judicial review. *Amgen, Inc. v. Smith*, 357 F.3d 103, 111 (D.C. Cir. 2004) (quoting *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 670 (1986)).

Paragraph 1395*l*(t)(12) states that "[t]here shall be no administrative or judicial review" of certain enumerated actions undertaken by HHS in administering the OPPS. The question is whether changes to SCOD reimbursement rates are among the listed, nonreviewable actions. The government says yes, contending that changes to SCOD reimbursement rates fall within two provisions of paragraph (12): subparagraphs (12)(A) and (12)(C).

The first provision, subparagraph (12)(A), bars review of the "development of the classification system under paragraph (2), including the establishment of groups and relative payment weights for covered OPD [outpatient department] services, of wage adjustment factors, other adjustments, and methods described in paragraph (2)(F)." 42 U.S.C. § 1395*l*(t)(12)(A); *see also Am. Hosp. Ass'n*, No. 19-5352, slip op. at 11. The second provision, subparagraph (12)(C), bars review of "periodic adjustments made under paragraph ([9])." *Id.* § 1395*l*(t)(12)(C). (While the provision in fact refers to "paragraph (6)," all agree that the reference contains a scrivener's error and that Congress in fact intended to refer to paragraph (9).) The reach of subparagraphs (12)(A) and (12)(C) turns on the scope of the provisions they cross-reference: paragraphs (2) and (9), respectively.

Begin with paragraph (2), which sets out the general methodology HHS must use to set standard OPPS payments. Under paragraph (2), HHS "develop[s] a classification system." *Id.* § 1395*l*(t)(2)(A). In doing so, HHS groups certain medical services together that are "comparable clinically and with respect to the use of resources." *Id.* § 1395*l*(t)(2)(B). The resulting groups are known as ambulatory payment classifications, or APCs. Next, HHS establishes "relative payment weights" for the grouped services in an APC based on hospital costs. *Id.* § 1395*l*(t)(2)(C). HHS then sets default

payment amounts for the services in each APC corresponding to the weights.

Paragraph (9), meanwhile, requires HHS to annually review and adjust the standard OPPS payment rates initially set under paragraph (2). Specifically, HHS must reassess its grouping and weighting decisions, as well as the other separate payment adjustments it makes under paragraph (2) (such as labor-cost adjustments), to "take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors." *Id.* § 1395*l*(t)(9)(A).

HHS determines most annual OPPS payment levels through the exercise of paragraph (2) and (9) authority. Recall, however, that the Medicare statute does not allow HHS to use that discretion-laden authority to establish payment rates for *all* Part B services. Reimbursement rates for specified covered outpatient drugs—the rates at issue here—instead must be keyed to one of two statutory formulas set out in paragraph 1395*l*(t)(14): average acquisition cost (if hospital cost data are available) under subclause (I), or average price under subclause (II). SCOD payments "shall be equal" to one of those two options. *Id.* § 1395*l*(t)(14)(A)(iii).

Returning to our original question of whether HHS's adjustment to SCOD reimbursement rates fall within the bars on judicial review set out in subparagraphs (12)(A) or (12)(C), the answer is no as a textual matter. Neither (12)(A) nor (12)(C) addresses—and thus neither purports to preclude—any action taken by HHS under paragraph (14) of the statute. And none of the actions described in subparagraphs (12)(A) or (12)(C) plausibly, let alone clearly, comprises SCOD reimbursement adjustments.

In particular, subparagraph (12)(A) precludes review of "the development of the [APC] classification system," "the establishment of groups and relative payment weights," "wage adjustment factors," and "other adjustments." *Id.* § 1395(t)(12)(A). As just discussed, SCOD rates are not set using the paragraph (2) grouping and weighting process, so a change to SCOD rates does not come under the first two of those descriptions. Such a change is also not a "wage adjustment[]." Nor is it covered by the term "other adjustments," which we have read to reach only the "adjustments . . . necessary to ensure equitable payments" under subparagraph (2)(E) (i.e., "equitable adjustments"), *see Amgen*, 357 F.3d at 113.

Subparagraph (12)(C), similarly, does not by its plain terms appear to cover SCOD payment reductions. It covers "periodic adjustments made under paragraph [9]." 42 U.S.C. § 1395*l*(t)(12)(C). By the terms of paragraph (9), that annual adjustment power extends only to actions initially taken under paragraph (2). And as just discussed, none of those actions textually corresponds to a decision to reduce SCOD rates.

Our analysis of the text draws support from Congress's history of amendments to the OPPS statute. When adding new provisions to subsection 1395*l*(t), Congress has tended to say expressly when it wishes to preclude judicial review of decisions made under an added provision. In 1999, Congress added paragraphs (5), (6), and (7) to subsection (t). In the same legislation, Congress also added clause (E) to paragraph (12), which provided that certain "determination[s]" made under paragraphs (5) and (6), but not any decisions under paragraph (7), would not be judicially reviewable. *See* Pub. L. No. 106-113, § 201(d), 113 Stat. 1501 (1999). In 2015, Congress included a preclusion-of-judicial-review provision directly within the newly added paragraph (21), rather than amending

paragraph (12). *See* Pub. L. No. 114-74, § 603, 129 Stat. 584, 598 (2015). By contrast, when Congress added paragraph (14) in 2003, it did so without any indication of an intention to preclude judicial review of SCOD rate-setting decisions.

According to the government, though, Congress had no need to expressly preclude judicial review of actions taken under paragraph (14) because those actions are *inherently* ones under paragraphs (2) and (9) (and thus necessarily fall within the judicial-review bars in subparagraphs (12)(A) and (12)(C)). The nub of the government's argument is that paragraph (14) does not in fact set up a "standalone payment regime" outside the general paragraph (2) system. Appellant's Reply Br. 15. Rather, the government contends, paragraph (14) merely "provides instructions to HHS about how to exercise its paragraph 2 and 9 authority when setting and revising payments" for SCODs. *Id.* On that view, even though HHS must follow paragraph (14)'s specific commands when setting the SCOD reimbursement rate, when HHS does so, it exercises authority located not in (14) but in paragraphs (2) and (9).

Ultimately, it is the government's burden to support that theory by "clear and convincing evidence," *Amgen*, 357 F.3d at 111, especially given the absence of statutory text unambiguously precluding judicial review. Applying that standard, we are insufficiently persuaded of the proposition that HHS's authority to annually set SCOD rates is located in paragraphs (2) and (9) rather than paragraph (14).

First, Congress on several occasions has specifically noted, directly in the statutory text, that certain OPPS-related decisions fall under paragraph (2). When Congress authorized HHS to make "outlier adjustments" and "pass-through payments," it fleshed out how those actions would work in paragraphs (5) and (6) respectively, but lodged the authority to

make the adjustments in the newly added subparagraph (2)(E). *See* 42 U.S.C. § 1395*l*(t)(2)(E). When Congress added paragraphs (13) and (18), which address adjustments for rural and cancer hospitals, respectively, it similarly provided that those adjustments would fall under subparagraph (2)(E). 42 U.S.C. § 1395*l*(t)(13)(B) ("the Secretary shall provide for an appropriate adjustment under paragraph (2)(E)"); *id.* § 1395*l*(t)(18)(B) ("the Secretary shall . . . provide for an appropriate adjustment under paragraph (2)(E)"). But when Congress added the SCOD reimbursement provisions of paragraph (14) in 2003, it included no such language referencing paragraph (2).

Second, both the statute's text and HHS's longstanding practice strongly suggest that paragraph (2) and (9)'s "adjustment" authorities do not encompass paragraph (14). If setting SCOD rates were an exercise of paragraph (2) authority, HHS would be authorized to use its subparagraph (2)(E) equitable-adjustment authority to change the rates. But it does not appear HHS may make such adjustments to SCOD rates.

As a matter of statutory text, paragraph (14) provides its own authorizations for HHS to adjust SCOD rates. Subclause (I) of paragraph (14), which sets out the average-acquisition-cost formula, says that the Secretary "may vary [the calculated reimbursement rate] by hospital group." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I). Subclause (II), which requires SCOD reimbursement to reflect a drug's average price, allows the Secretary to "calculate[] and adjust[] [the average price metric] as necessary for purposes of this paragraph." *Id.* § 1395*l*(t)(14)(A)(iii)(II). And both the average-acquisition-cost and average-price formulas are "subject to subparagraph (E)," which authorizes the Secretary to "adjust" SCOD payments to account for "overhead and related expenses, such as pharmacy services and handling costs." *Id.*

§ 1395*l*(t)(14)(E). It would be odd for Congress in paragraph (14) to provide HHS with those specific authorities to "adjust" SCOD rates if HHS nonetheless has the general authority to adjust those rates as it sees fit under paragraph (2) or (9).

HHS's longstanding practice, and the 2018 and 2019 Rules at issue here, corroborate that understanding. HHS has never purported to use its paragraph (2) or (9) authorities either to set SCOD rates or to deviate from the default "average price" rate set out in subclause (II). And it did not do so here. Instead, in the 2018 Rule, HHS grounded its action in in the "calculate and adjust" provision of paragraph (14), subclause (II). 82 Fed. Reg. at 52,499–500. The government claims that HHS invoked its paragraph (9) authority in the 2018 Rule's preamble. But the preamble stated only that the Rule would "describe [that] and various other statutory authorities in the relevant sections of this final rule." *Id*. at 52,362. And in the section of the Rule explaining HHS's statutory authority to make the 340B-related reduction to SCOD rates, there is no reference to paragraph (9). *See id*. at 52,496, 52,499–502.

Of particular note, HHS made no claim that the rate cut at issue here was an exercise of its subparagraph (2)(E) equitable-adjustment authority, even though the change might be seen to serve equitable goals. HHS relied solely on its paragraph (14), subclause (II) adjustment authority, even as it invoked its subparagraph (2)(E) equitable-adjustment power in connection with at least two other rate changes in the 2018 OPPS Rule. *See id*. at 52,364–65 (explaining that HHS makes an additional payment for radioisotopes used in diagnostic imaging "based on the authority set forth at section [1395*l*](t)(2)(E)"); *id*. at 52,421 ("we are using our equitable adjustment authority" to change reimbursement for retinal procedure).

Third, paragraph (14) operates as a standalone payment regime for all practical purposes. The statute contemplates that HHS will set SCOD payment rates in a vacuum, without taking into account other OPPS rate-setting decisions. SCOD rates are not set through relative weighting with rates for other reimbursable care. And if HHS changes the payment weights for other APCs, SCOD prices need not change because SCOD rates are unaffected by the statute's budget-neutrality requirement. Recall that SCOD rates must equal either average acquisition cost or average price. Although subparagraph (14)(H) requires that "[a]dditional expenditures resulting from this paragraph" be "taken into account" for overall budget neutrality for the OPPS, that language recognizes that the expenditures "resulting" from the application of paragraph (14) will be calculated first, irrespective of other adjustments made to other OPPS payments. 42 U.S.C. § 1395*l*(t)(14)(H). Only then are those set-in-stone numbers put into the budget-neutrality calculator.

On this score, HHS again has consistently read the statute the way we do. *See, e.g.*, 77 Fed. Reg. at 68,262 ("Payments for [SCODs] are included in the budget neutrality adjustments . . . but the budget neutral weight scaler is not applied to their payments because they are developed through a separate methodology, outside the relative payment weight based process."). That understanding of the statute's structure sits uncomfortably, to say the least, with HHS's position in this case that paragraph (14) does no more than instruct HHS how to exercise its paragraph (2) and (9) authorities.

The government lastly relies on subparagraph (14)(H), reading that provision to indicate that setting of SCOD rates is an exercise of paragraph (9)'s annual-adjustment authority. Subparagraph (14)(H), enacted along with the rest of paragraph (14) in 2003, requires that SCOD payments be counted for

budget-neutrality purposes in years after 2005, but specifies that the payments "shall *not* be taken into account" for budget-neutrality purposes in 2004 and 2005. 42 U.S.C. § 1395*l*(t)(14)(H) (emphasis added); *see also id.* § 1395*l*(t)(9)(B). According to the government, the specification that SCOD payments would not be subject to budget neutrality in 2004 and 2005 suggests that budget neutrality otherwise applies, which would be the case if SCOD rate-setting were an exercise of paragraph (9) authority (given that all paragraph (9) adjustments must be budget neutral, *see id.* § 1395l(t)(9)(B)).

We disagree with the premise that SCOD rates can factor into OPPS budget neutrality only if the setting of SCOD rates is an exercise of paragraph (9) authority. It is at least possible, if not probable, that Congress conceived of the SCOD rate-setting program as entirely distinct from the general paragraph (2) and (9) program, yet still wanted the output of the SCOD program to matter for overall budget neutrality. Recall that Congress required HHS to move to the prospective OPPS system, constrained by a budget-neutrality requirement, in order to control Medicare Part B spending and promote more predictable annual growth. In view of those goals, Congress, when creating a standalone payment regime for SCODs, might still have wanted to achieve budget neutrality for Part B payments as a whole. Thus, Congress's choice to make that desire explicit for years after 2005 (and to carve out the two prior years) does not necessarily imply that HHS exercises paragraph (9) authority whenever it adjusts SCOD rates.

To sum up: subparagraphs (12)(A) and (12)(C) do not, by their terms, clearly cover HHS's decision to cut SCOD reimbursement to 340B hospitals. While the government argues that SCOD rate-setting is merely a species of general OPPS rate-setting under paragraphs (2) and (9), and that

Congress thus intended SCOD payment decisions to be similarly insulated from review, that account, at a minimum, is not *clearly* correct. As a result, the government has failed to "overcom[e] the strong presumption that Congress did not mean to prohibit" our review. *Bowen*, 476 U.S. at 672.

III.

Proceeding to the merits, the sole question before us is whether HHS had statutory authority to impose its 28.5% cut to SCOD reimbursement rates for 340B hospitals. HHS located its authority in subclause (II) of paragraph (14) of the OPPS statute. Under that provision, when HHS sets SCOD payment amounts tethered to average drug prices, HHS has express authority to "adjust[]" the amounts "as necessary for purposes of this paragraph." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II). In our view, HHS reasonably interpreted subclause (II)'s adjustment authority to enable reducing SCOD payments to 340B hospitals, so as to avoid reimbursing those hospitals at much higher levels than their actual costs to acquire the drugs.

On that issue of statutory interpretation, HHS is entitled to *Chevron* deference, which it has invoked here (although it did not do so expressly until a post-argument letter submitted to the Court). *See Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842 (1984). When an agency "interpret[s] a statute it is charged with administering in a manner (and through a process) evincing an exercise of its lawmaking authority," that interpretation is entitled to *Chevron* treatment, and the agency cannot forfeit *Chevron*'s applicability. *SoundExchange, Inc. v. Copyright Royalty Board*, 904 F.3d 41, 54–55 (D.C. Cir. 2018). HHS established SCOD reimbursement rates for 340B hospitals through notice-and-comment rulemaking and explained why it "believe[d] that [its]

proposal [was] within [its] statutory authority to promulgate." 82 Fed. Reg. at 52,499. HHS's understanding of its statutory authority thus is entitled to *Chevron* deference. *See Am. Hosp. Ass'n*, No. 19-5352, slip op. at 14; *Tenet HealthSystems HealthCorp. v. Thompson*, 254 F.3d 238, 248 (D.C. Cir. 2001); *see also Barnhart v. Walton*, 535 U.S. 212, 222 (2002).

Under *Chevron*, we first ask whether "Congress has directly spoken to the precise question at issue." *Chevron*, 467 U.S. at 842. Here, the "precise question at issue" is whether HHS's adjustment authority in subclause (II) encompasses a reduction to SCOD reimbursement rates aimed at bringing reimbursements to 340B hospitals into line with their actual costs to acquire the drugs. If the statute does not directly foreclose HHS's understanding, we defer to the agency's reasonable interpretation. *See id.* at 844. We conclude that HHS's interpretation of subclause (II) is not directly foreclosed and is reasonable.

By way of brief review, paragraph (14), as its title confirms, addresses "[d]rug . . . payment rates"—specifically, the rates at which hospitals are reimbursed for SCODs furnished to beneficiaries in supplying covered care. 42 U.S.C. § 1395*l*(t)(14). Under subclause (I) of the paragraph, the "amount of payment," as a default matter, "shall be equal" to hospitals' "average acquisition cost for the drug." *Id.* § 1395*l*(t)(14)(A)(iii)(I). But if pertinent "hospital acquisition cost data are not available," then payment levels are determined under subclause (II). Under that provision, the amount of payment equals "the average price for the drug"—which, by statutory cross-reference, is the drug's average sales price (ASP) charged by manufacturers—but subject to "adjust[ment] . . . as necessary for purposes of this paragraph." *Id.* § 1395*l*(t)(14)(A)(iii)(II).

Much is undisputed about HHS's application of subclause (II)'s adjustment authority to reduce SCOD payment rates to 340B hospitals. First, HHS properly found that the "hospital acquisition cost data" contemplated by subclause (I) was unavailable, such that HHS needed to determine payment rates in accordance with subclause (II)'s fallback reliance on average drug prices. Second, 340B hospitals obtain SCODs at substantially lower cost than other providers, such that reimbursing those hospitals at the same rate as other providers would give sizable revenues to the hospitals. Third, HHS's 28.5% SCOD rate reduction for 340B hospitals is a fair, or even conservative, measure of the reduction needed to bring payments to those hospitals into parity with their costs to obtain the drugs. *See* 82 Fed. Reg. at 52,500. Fourth, absent the reduction, at least some Medicare beneficiaries served by 340B hospitals (generally underserved populations) would pay out-of-pocket copayments for the drugs that substantially exceed the normal copay share of providers' cost to obtain the drugs—with beneficiaries' copayments sometimes exceeding 340B hospitals' *full* cost to purchase the drugs. And fifth, the roughly $1.6 billion in savings from reducing SCOD reimbursement payments to 340B hospitals is not kept by the agency but is redistributed to all providers as additional reimbursement payments for other services. *See generally* pp. 6–8, *supra*.

That is the backdrop against which we consider whether HHS permissibly understood its subclause (II) adjustment authority to encompass its reduction to reimbursement payments to 340B hospitals for SCODs. Was HHS obligated to continue reimbursing 340B hospitals for SCODs in amounts substantially exceeding their costs to obtain the drugs, with the resulting effects that concerned the agency on out-of-pocket copayments owed by Medicare beneficiaries? We think the agency was not compelled to continue doing so.

The central question is whether HHS permissibly conceived of the "purposes of this paragraph," i.e., paragraph (14), in exercising its subclause (II) authority to "adjust[]" payment rates "as necessary for the purposes of this paragraph," 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II). According to the agency, a "manifest purpose of paragraph 14 is to compensate providers for the average acquisition cost" of SCODs. Appellant's Br. 30. In accordance with that understanding, HHS explained in the 2018 Rule that "a payment amount of ASP minus 22.5 percent for drugs acquired under the 340B Program is better aligned to hospitals' acquisition costs and thus this adjustment . . . is necessary for Medicare OPPS payment policy." 82 Fed. Reg. at 52,501.

Paragraph (14)'s structure supports HHS's understanding that the provision's core purposes include reimbursing hospitals for their costs to acquire SCODs. Paragraph (14)'s primary (and default) instruction for determining SCOD payment amounts, set out in subclause (I), is to equate them to "average acquisition cost." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I). That alone indicates that Congress's primary goal is to reimburse providers for their acquisition costs. And if direct acquisition-cost data of a kind contemplated by subclause (I) is unavailable, HHS must then, as a fallback matter under subclause (II), equate payment amounts to "average price," subject to adjustment. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II). By prescribing the use of ASP as a backup when the requisite acquisition-cost data is unavailable, Congress signaled that average price functions as a stand-in for costs.

HHS has long understood average price under subclause (II) to serve as a "proxy for average acquisition cost." 77 Fed. Reg. at 68,386. HHS has used ASP since 2006, stating then and all along that its "intent" in using ASP was "to pay for drugs and biologicals based on their hospital acquisition costs."

Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates, 70 Fed. Reg. 68,516, 68,642 (Nov. 10, 2005). For non-340B hospitals, ASP is an accurate approximation of acquisition costs: HHS's Inspector General has found that, for non-340B hospitals, ASP comes within roughly 1% of acquisition costs. HHS Office of Inspector General, Memorandum Report: Payment for Drugs Under the Hospital Outpatient Prospective Payment System 1, 9 (Oct. 22, 2010). But for 340B hospitals, ASP substantially exceeded SCOD acquisition costs by the time of the 2018 Rule—hence the need for an adjustment under subclause (II) to bring payments to 340B hospitals into line with their costs.

The OPPS statute exhibits in other ways Congress's evident purpose of aligning SCOD reimbursement with hospital costs. Paragraph (14) itself expressly authorizes a separate adjustment to SCOD payment rates to account for "overhead costs" and "related expenses" ("such as pharmacy services and handling costs"). *Id.* § 1395*l*(t)(14)(E). And more broadly, many other OPPS provisions reflect the goal of aligning payments to hospitals with their costs. *See id.* § 1395*l*(t)(2)(C) (grouping and weighting under paragraph (2) must be "based on median . . . hospital costs"); *id.* § 1395*l*(t)(2)(D) ("wage adjustment factor" must account for "relative differences in labor and labor-related costs"); *id.* § 1395*l*(t)(5)(B) ("outlier adjustments" must "approximate the marginal cost of care"); *id.* § 1395*l*(t)(9)(A) ("periodic . . . adjustments" must be based on "new cost data"); *id.* § 1395*l*(t)(13)(A) (authorizing adjustments if "costs incurred by hospitals located in rural areas . . . exceed those costs incurred by hospitals located in urban areas"); *id.* § 1395*l*(t)(18)(B) (same for cancer hospitals).

All of that supports HHS's understanding that the "purposes" of paragraph 14 for which the agency can "adjust[]" SCOD payments under subclause (II) include aligning payments to hospitals with their drug acquisition costs. *Id.* § 1395*l*(t)(14)(A)(iii)(II). That is precisely what HHS did when it imposed its 28.5% reduction in payments to 340B hospitals for SCODs.

In arguing that HHS lacked authority under subclause (II) to undertake that measure, the Hospitals focus on subclause (I)'s requirement that, if payment amounts are keyed to "average acquisition cost" under that provision—as opposed to average price under subclause (II)—then the agency must take "into account the hospital acquisition cost survey data under subparagraph (D)." *Id.* § 1395*l*(t)(14)(A)(iii)(I). And subparagraph (D) imposes stringent data-quality requirements, mandating that the cost surveys "shall have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each [SCOD]." *Id.* § 1395*l*(t)(14)(D)(iii).

Because Congress required HHS to "tak[e] into account" robust study data when setting SCOD rates at average acquisition cost under subclause (I), the Hospitals argue, HHS cannot use its subclause (II) authority to adjust ASP in order to approximate acquisition cost. As the Hospitals see it, if HHS wants to set SCOD rates based on the cost to hospitals to acquire the drugs, the agency must get the data contemplated by subclause (I). If it were otherwise, the Hospitals contend, subclause (I)'s requirement to take into account the data collected under subparagraph (D) would be meaningless: HHS could simply forgo the study required by subclause (I) and instead use subclause (II) to approximate drug acquisition costs. Our dissenting colleague, too, stresses the same point. Dissenting Op. 5.

That argument, on which the district court relied, *see Azar*, 348 F. Supp. 3d at 82–83, is not without force. We, though, are ultimately unpersuaded. For the Hospitals' argument to carry the day under *Chevron*, we would need to conclude that Congress unambiguously barred HHS from seeking to align reimbursements with acquisition costs under subclause (II), or that HHS's belief that it could do was unreasonable. And HHS would be barred from doing so even if, as here, it is undisputed both that payment amounts otherwise would substantially exceed hospitals' costs and that the proposed adjustment accurately and reliably approximates procurement costs.

Given that the survey data contemplated by subclause (I) aims to assure the reliability of cost-acquisition data, we do not read the statute to foreclose an adjustment to ASP under subclause (II) that is based on reliable cost measures of the kind undisputedly at issue here. That is particularly so because, whereas the Hospitals question whether HHS's interpretation could enable sidestepping subclause (I)'s data-reliability requirements altogether, the Hospitals' own reading raises a similar interpretive dilemma. Subclause (II), as explained, expressly empowers HHS to "adjust" payments based on ASP "as necessary for purposes of" paragraph (14). And under the Hospitals' reading, those "purposes" cannot include the goal of approximating hospital acquisition costs. But the Hospitals point to no other "purpose" that could permissibly support an adjustment. The Hospitals' argument thus renders subclause (II)'s adjustment authority superfluous.

The Hospitals submit that "[t]he purpose of paragraph (14) is to establish the rate for separately payable drugs." Appellees' Br. 42–43. That may be true at a high level of generality—indeed, the title of paragraph (14) is "Drug APC payment rates"—but it is unhelpful to the Hospitals for our

purposes. After all, HHS's rate reduction for payments to 340B hospitals does "establish the rate for separately payable drugs."

The Hospitals also suggest that subclause (II)'s adjustment authority enables adjustments to account for overhead costs. Appellees' Br. 49. But that reading would leave subclause (II)'s adjustment authority duplicative of authority already conferred by subparagraph (14)(E). That subparagraph, as noted, authorizes HHS to make adjustments to account for "overhead and related expenses, such as pharmacy services and handling costs." 42 U.S.C. § 1395*l*(t)(14)(E)(i). If subclause (II)'s adjustment authority were merely meant to reinforce subparagraph (14)(E)'s authority to account for overhead costs, then why would subclause (II) not simply say so, in comparable language? Instead, subclause (II) frames its grant of authority in notably broader terms addressed to the overall purposes of paragraph (14), not just the specific, "overhead and related expenses" focus of subparagraph (14)(E).

The Hospitals' reading of subclause (II)'s adjustment authority as addressed to overhead costs, it bears noting, would necessarily mean that the purpose of granting that authority is to enable bringing ASP closer to drug acquisition costs—precisely what the Hospitals otherwise say the agency cannot aim to do when exercising its subclause (II) authority. But under the Hospitals' evident understanding, the agency can try to get ASP closer to actual costs only to the extent of taking into account overhead costs, without going further to bring ASP all the way into alignment with acquisition costs. That half-measure understanding of subclause (II)'s adjustment authority is incompatible with its broad terms, which speak generally to the "purposes" of paragraph (14), including, in particular, approximating drug acquisition costs.

Our dissenting colleague nonetheless endorses the Hospitals' suggestion that subclause (II)'s adjustment authority, while framed generally, should be read as focused on overhead costs. Dissenting Op. 5–8. Our colleague briefly suggests that there may be no redundancy between subclause (II) and subparagraph (14)(E) under that reading because, she posits, the two provisions both allow for adjustments to account for overhead costs, but at different times, with (14)(E) in the nature of a time-limited, naturally-expiring allowance and subparagraph (II) an ensuing, ongoing one. *Id.* at 5–6. Again, though, if the provisions were designed to cover the same terrain (even if at different times), one would expect them to use similar language in defining the territory, which they conspicuously do not. And at any rate, the statutory text confirms that the provisions are designed to work side-by-side contemporaneously, not at different times: Congress rendered subclause (II)'s provisions expressly "subject to paragraph (E)," such that the agency, when acting under subclause (II), could make adjustments to ASP *both* under that provision's own, broadly-framed adjustment authority *and* under subparagraph (14)(E)'s more specific authority addressed to overhead costs. 42 U.S.C. § 1395*l*(t)(14)(A).

Our dissenting colleague ultimately allows that the Hospitals' overhead-costs interpretation of subclause (II)'s adjustment authority means that the provision may reiterate—i.e., make "double sure"—subparagraph (14)(E)'s express authority to account for overhead costs. Dissenting Op. 6. But our colleague still believes that the Hospitals' reading of the statute is unambiguously compelled at *Chevron* step one. *Id.* at 1. In her evident view, any superfluity occasioned by that reading is less substantial than the superfluity occasioned by the agency's reading. *Id.* at 8–9. But even assuming there is a reliable metric for comparing degrees of superfluity across readings in that fashion, that kind of comparison is not the stuff

of a *Chevron* step one resolution. Rather, when competing readings of a statute would each occasion their own notable superfluity, that manifests the kind of statutory ambiguity that *Chevron* permits the agency to weigh and resolve. *See National Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 666 (2007); *Peter Pan Bus Lines, Inc. v. Fed. Motor Carrier Safety Admin.*, 471 F.3d 1350, 1354 (D.C. Cir. 2006) ("[S]ection 13902 contains surplusage under either reading and, as a result, we cannot say that either proffered construction reflects the Congress's unambiguously expressed intent.").

The Hospitals separately suggested in oral argument that subclause (II)'s adjustment authority could pertain to improving the accuracy of the sales-price metric specifically for hospitals (as opposed to other providers). ASP reflects sales prices to all manner of medical providers, including pharmacies, clinics, independent physician practices, and the like. *See* 42 U.S.C. § 1395w-3a(c). As the Hospitals see it, HHS can adjust ASP to arrive at a metric that better reflects the prices paid by hospitals alone. But nothing in subclause (II)'s general adjustment authority suggests that it is so narrowly focused. And in any event, to the extent HHS might adjust ASP to more accurately reflect prices paid by hospitals, it is unclear whether there would then remain any appreciable difference between such a hospital-specific ASP and hospital acquisition costs. Yet the Hospitals' whole point is that HHS cannot rely on its subclause (II) adjustment authority to approximate acquisition costs.

Especially in view of the Hospitals' inability to present an interpretation of HHS's subclause (II) adjustment authority that would give it meaningful independent content, we cannot conclude that the statute forecloses HHS from reducing SCOD reimbursement rates for 340B hospitals with the object of bringing payments into alignment with acquisition costs.

Rather, in the specific circumstances of this case, HHS permissibly read the statute to allow it to implement the 340B payment reduction. Although subclause (I) calls for the "average acquisition cost" payment metric to "tak[e] into account" subparagraph (D)'s survey data, here, HHS relied on data of undisputed reliability. Moreover, the agency acted on that data in a cautious way, adopting a "conservative, lower-bound estimate" of the 340B discount's size. 82 Fed. Reg. at 52,504 (quotation marks omitted). In those circumstances, HHS reasonably concluded that it need not continue subsidizing 340B providers with Part B (i.e. taxpayer) funds and Medicare beneficiaries' copayments. We of course do not consider the wisdom of that decision as a policy matter in the first instance, but only whether the agency had statutory authority to reach it. *See Chevron*, 467 U.S. at 845. We conclude that the agency's decision rests on a permissible understanding of its statutory authority.

Shifting tack, the Hospitals contend that even if HHS can seek to approximate acquisition costs in exercising its subclause (II) adjustment authority, HHS's 28.5% rate cut is simply too large and sweeping to qualify as an "adjustment." That argument falls short under a straightforward application of *Chevron*. The statutory term "adjust" is ambiguous as to size. The Hospitals offer various definitions of "adjust" that include qualifiers such as "slightly," *e.g.*, *Adjust*, Oxford Dictionaries, https://www.lexico.com/definition/adjust ("alter or move (something) slightly in order to achieve the desired fit, appearance, or result"), but HHS responds with many definitions that lack such qualifiers, *e.g.*, *Adjust*, Merriam-Webster, https://www.merriam-webster.com/dictionary/adjust ("to bring to a more satisfactory state").

The Hospitals point to our decision in *Amgen*, which considered an "adjustment" under HHS's subparagraph (2)(E)

authority to make equitable adjustments. In the course of upholding the challenged adjustment, we observed that "similar limits inhere in the term 'adjustments' to those the Supreme Court found in the word 'modify'" in *MCI Telecomms. Corp v. Am. Tel. & Tel. Co.*, 512 U.S. 218, 225 (1994). *Amgen*, 357 F.3d at 117. And the *MCI* Court stated that "modify" means "to change moderately or in minor fashion." *MCI*, 512 U.S. at 225. But we do not read *Amgen* to prescribe that "adjust" in the OPPS statute refers only to minor changes. To the contrary, *Amgen* explained that it "ha[d] no occasion to engage in line drawing to determine when 'adjustments' cease being 'adjustments.'" 357 F.3d at 117. Even if there are limits to what HHS could permissibly consider an "adjustment," that line has not been crossed here, where the agency acted on a conservative estimate drawn from data of undisputed reliability.

The Hospitals' last argument is that HHS's subclause (II) adjustment authority does not allow adjusting reimbursement rates for 340B hospitals alone. According to the Hospitals, the reimbursement rate set under subclause (II) must be uniform across all hospitals. The Hospitals rely on subclause (I)'s statement that payment rates set under that provision must equal "the average acquisition cost for the drug for that year (which, at the option of the Secretary, *may vary by hospital group* (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics))." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I) (emphasis added). The Hospitals stress that subclause (II), by comparison, says nothing about authority to vary the average price metric by hospital group. That silence, to the Hospitals, means that when HHS sets SCOD reimbursement rates under subclause (II), it must apply the same rate to every recipient hospital.

Congress, however, was not silent about HHS's adjustment power in subclause (II). Whereas subclause (I) does not grant HHS any general authority to adjust reimbursement rates, subclause (II) affirmatively grants HHS general adjustment authority for deployment "as necessary for purposes of" paragraph (14). And as explained, HHS reasonably believes that a central purpose of paragraph (14) is to accurately reimburse hospitals for their acquisition costs. There is no reason to think that HHS's general adjustment authority when acting under subclause (II) excludes the more focused license to vary rates by hospital group when acting under subclause (I). In particular, the Hospitals provide no reason why, if HHS knows that a certain group of hospitals has far lower (or far higher) costs than others, Congress would want to preclude HHS from acting on that information in a suitably tailored fashion when exercising its adjustment authority under subclause (II). At a minimum, the statute does not clearly preclude HHS from adjusting the SCOD rate in a focused manner to address problems with reimbursement rates applicable only to certain types of hospitals. That is enough to reject the Hospitals' argument under *Chevron*.

* * * * *

For the foregoing reasons, we reverse the judgment of the district court.

So ordered.

PILLARD, *Circuit Judge*, dissenting in part: I agree with my colleagues that the Medicare Outpatient Prospective Payment System (OPPS) statute does not preclude judicial review of HHS's 28.5% reduction in reimbursement rates to 340B hospitals that administer Specified Covered Outpatient Drugs (SCODs). On the merits, however, I disagree that subclause (II) authorized HHS to implement for 340B hospitals alone the challenged rate reductions in its 2018 and 2019 OPPS rules.

The statute sets forth two alternative bases for HHS's calculation of the relevant reimbursement rates: It may set those rates under subclause (I) based on average acquisition cost (reflecting the average cost that hospitals actually incurred in purchasing the drug), or under subclause (II) based on average sales price (reflecting the average price, updated quarterly, at which manufacturers sold the drug to most purchasers, not limited to hospitals). *See* 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I)-(II). When the two subclauses at issue here are read together, the conclusion is unavoidable that HHS may institute its large reductions, tailored for a distinct hospital group, only under subclause (I), which requires the agency to take into account specific data undisputedly absent here.

The majority concludes that HHS may act on other data (not meeting Congress' specifications) to make those reductions pursuant to subclause (II). That reading impermissibly nullifies subclause (I) and the data requirements spelled out at length in subparagraph (D). *See id.* § 1395*l*(t)(14)(D). I would therefore hold that the agency's interpretation of subclause (II) is foreclosed at *Chevron* step one. Because HHS's actions cannot be squared with the text of the OPPS statute, I respectfully dissent from part III of the majority opinion.

* * *

Reproduced in full, subclauses (I) and (II) provide that, for every year after 2005, the reimbursement rate "shall be equal, subject to subparagraph (E)"—

> (I) to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on the volume of covered [outpatient department] services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D); or
>
> (II) if hospital acquisition cost data are not available, the average price for the drug in the year established under section 1395u(o) of this title, section 1395w-3a of this title, or section 1395w-3b of this title, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of this paragraph.

42 U.S.C. § 1395*l*(t)(14)(A)(iii). Subparagraph (E) in turn authorizes the Secretary to make "adjustment[s] in payment rates for overhead costs," for instance to account for "pharmacy services and handling costs," based on the findings of a 2005 Medicare Payment Advisory Commission (MedPAC) report. *Id*. § 1395*l*(t)(14)(E).

The two subclauses together provide that, if HHS sets reimbursements rates based on hospitals' actual average acquisition costs, HHS must consider congressionally specified acquisition-cost data. *See id*. § 1395*l*(t)(14)(D). And—crucial for the challenged differential reimbursement rate for 340B hospitals—HHS may only segment reimbursement rates by hospital group if it has collected the specified data and set the rates keyed to hospital acquisition costs in view of that data.

The two subclauses operate as alternatives: Subclause (I) lays out what the agency may do when it has collected and taken into account the "hospital acquisition cost survey data under subparagraph (D)," whereas subclause (II) lays out what the agency may do "if the hospital acquisition cost data are not available." *Id.* § 1395*l*(t)(14)(A)(iii). If the agency has that data, it may set reimbursement rates based on the "average acquisition cost for the drug for that year," and "vary by hospital group" any reimbursement rates. *Id.* § 1395*l*(t)(14)(A)(iii)(I). But "if hospital acquisition cost data are not available," *id.* § 1395*l*(t)(14)(A)(iii)(II), the agency must set reimbursement amounts under subclause (II) by resort to what it has previously called the "statutory default" rate for a given drug in a given year, *see, e.g.*, 2013 OPPS Rule, 77 Fed. Reg. 68,210, 68,386 (Nov. 15, 2012). That statutory default rate is the drug's average sales price charged to hospitals, clinics, pharmacies, and other providers, drawn from data that drug manufacturers submit to HHS every quarter. *See id.* §§ 1395w-3a(c), 1396r-8(b)(3)(A)(iii). Subclause (II) provides for the average sales price to be "adjusted . . . as necessary for purposes of this paragraph" but, unlike subclause (I), grants no authority to vary the reimbursement rates by hospital group. *Id.* § 1395*l*(t)(14)(A)(iii)(II).

As everyone agrees, HHS has never collected the "hospital acquisition cost data" that the statute contemplates, so must proceed under its subclause (II) authority to set reimbursement rates for the 2018 and 2019 OPPS rules. *See, e.g.*, HHS Br. 9; 2018 Proposed OPPS Rule, 82 Fed. Reg. 33,558, 33,634 (proposed July 20, 2017). The question before us is whether the agency may set and vary by hospital group SCOD reimbursement rates in the manner that subclause (I) authorizes, without collecting and considering the data that subclause (I) specifies, by invoking its authority under subclause (II) to adjust the average-sales-price-based

reimbursement rate and, in effect, simply deem that to be a rate reflecting hospitals' average acquisition cost. The majority concludes that the agency's circumvention of subclause (I) in this manner is a permissible construction of the statute for several reasons, none of which I find persuasive.

First, the majority argues, based primarily on the text of subclause (I) and other provisions in the OPPS statute, that Congress' "primary goal is to reimburse providers for their acquisition costs." Maj. Op. at 21. But the statute's overarching goal is not its only goal, to be achieved however the agency sees fit. When it comes to Medicare Part B payments for SCODs, paragraph (14) specifically tells us when and how Congress intended HHS to pursue acquisition-cost-based reimbursement. Only subclause (I), not subclause (II), authorizes HHS to set different reimbursement rates for distinct hospital groups—rather than a uniform, drug-by-drug "average price for the drug in the year," 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II)—and to do so only by taking into account the different acquisition costs identified in the robust, hospital-specific data that Congress required the agency to collect.

The majority finds it inconceivable that Congress would require the same sales-price-based reimbursement rate for all types of hospitals when hospitals' acquisition costs vary widely. *See, e.g.*, Maj. Op. at 24. But in authorizing the average-sales-price methodology, which takes account of most discounts and rebates that purchasers receive, Congress was attuned to the many factors rendering non-uniform the amounts different hospitals actually pay for the same drugs. Given Congress' awareness that various hospitals—not only 340B hospitals—pay more or less than others, I see nothing inconceivable about Congress requiring disparities in reimbursement rates to certain types of hospitals to be

identified and acted upon based only on the most complete and accurate data.

If Congress wanted HHS, in the absence of subclause (I)'s hospital-specific data regarding average acquisition costs, just to do its best to approximate those costs and then vary them by hospital groups according to its unchecked policy judgment, it easily could have written the statute to say so. Instead, subclause (II) mandates that the base reimbursement rate "shall be equal" to the specified drug's statutory default rate premised on average sales price, subject to adjustments, and entirely omits the authority granted in subclause (I) to "vary by hospital group" the pricing data or resultant rate. 42 U.S.C. § 1395*l*(t)(14)(A)(iii). I cannot discern in the statute any congressional intention that the adjustment authority be used to set markedly different prices for different hospital groups. I would instead affirm the district court's conclusion that HHS "cannot fundamentally rework the statutory scheme—by applying a different methodology than the provision requires—to achieve under sub[clause] (II) what [it] could not do under sub[clause] (I) for lack of adequate data." *Am. Hosp. Ass'n v. Azar*, 348 F. Supp. 3d 62, 82 (D.D.C. 2018).

Second, the majority reasons that this data-sensitive reading of the two subclauses cannot be correct because it "renders subclause (II)'s adjustment authority superfluous." Maj. Op. at 24. But the Hospitals' reading of the subclause (II) adjustment authority as primarily cross-referencing incremental modifications like the overhead-cost adjustment described in subparagraph (E) does not make the former altogether redundant. As the Hospitals explain, subparagraph (E) authorized adjustments for overhead with reference to a one-time, 2005 MedPAC report, whereas subclause (II)'s authority to make "adjust[ments] . . . as necessary for purposes of this paragraph," 42 U.S.C.

§ 1395*l*(t)(14)(A)(iii)(II), encompasses "adjustments" for overhead in the same manner on an ongoing basis. *See* Hospitals Br. 5-6, 49.

In any event, reading section 1395*l*(t)(14) to contain overlapping references to a limited adjustment authority—making "double sure" the point is made—does not create the kind of superfluity that renders a statute ambiguous. *Mercy Hosp., Inc. v. Azar*, 891 F.3d 1062, 1068 (D.C. Cir. 2018) (quoting *Fla. Health Scis. Ctr., Inc. v. HHS*, 830 F.3d 515, 520 (D.C. Cir. 2016)). As we have recognized with respect to the Medicare statute, a "little overlap, either by accident or design, is to be expected in any complex statutory scheme with interdependent provisions" and does not alone create ambiguity. *Id*. The fact that average price data lumps together pharmaceutical sales to hospitals from sales to non-hospital providers seems to explain Congress' clear decision to omit from subclause (II) the authority in subclause (I) to vary reimbursement by hospital group. Without subclause (I)'s hospital-specific cost data, billion-dollar decisions differentiating among particular hospital groups could rest on significantly less exact information.

Moreover, to the extent that past agency practice bears on the question of statutory construction before us, it only confirms the Hospitals' reading that the agency's subclause (II) adjustment authority references overhead adjustments like those contemplated by subparagraph (E). As the agency described at length in 2012, during the preceding six years HHS had made no adjustments to its estimate of average sales prices other than occasional small tweaks to account for overhead costs (and, in any case, purported to rely only on its subclause (I) authority). *See* 2013 OPPS Rule, 77 Fed. Reg. at 68,383-86 (explaining the agency's methodology year by year over this period); *see also* 2016 OPPS Rule, 80

Fed. Reg. 70,298, 70,439 (Nov. 13, 2015) (providing a similar summary of the agency's past methodology); Hospitals Br. 49 ("[W]hen HHS previously made adjustments to the ASP-plus-6% rate, it explained at the time that it was doing so to account for estimates of overhead."). Indeed, the focus of the agency in those years was on collecting more accurate overhead-cost data to better tailor its adjustments. *See, e.g.*, 2013 OPPS Rule, 77 Fed. Reg. at 68,385. And, in the five years before the two challenged rules at issue, the agency simply adopted the statutory default rate of 106% of the average sales price under subclause (II) without making any adjustments at all. *See* 2018 OPPS Rule, 82 Fed. Reg. 52,362, 52,490 (Nov. 13, 2017).

In sum, at no point in any of the materials that the majority cites—and at no point of which I am aware—has HHS ever previously used its subclause (II) adjustment authority to make adjustments that are not modest changes to account for overhead. HHS itself has not claimed otherwise in its briefing before us. And HHS certainly has never used that adjustment authority to implement variations by hospital group. *See, e.g.*, HHS Br. 13 ("The final rule for 2018 established a *new sub-classification* for drugs purchased by 340B providers . . . ." (emphasis added)).

The Hospitals' limited reading of the adjustment authority that subclause (II) confers is supported by our previous caution that the term "adjustment" in this statute—like the term "modify" at issue in *MCI Telecommunications Corp. v. AT&T Co.*, 512 U.S. 218, 225 (1994), which the Court held "means to change moderately or in minor fashion"—cannot permit "basic and fundamental changes in the scheme." *Amgen, Inc. v. Smith*, 357 F.3d 103, 117 (D.C. Cir. 2004) (quoting *MCI*, 512 U.S. at 225). The majority distinguishes *Amgen* by quoting our observation there that we had "no occasion to engage in line drawing to determine when 'adjustments' cease

being 'adjustments.'" *Id*. But that observation made eminent sense in a dispute "involving only the payment amount for a single drug," and we went on to warn that a "more substantial departure from the default amounts would, at some point, violate the Secretary's obligation to make such payments and cease to be an 'adjustment.'" *Id*. (alteration omitted). Given the scale and segmentation of the rate cut at issue—reducing SCOD reimbursements by nearly a third, thereby eliminating $1.6 billion annually in reimbursements to many of the most financially vulnerable hospitals in the Medicare program—I disagree that, "[e]ven if there are limits to what HHS could permissibly consider an 'adjustment,' that line has not been crossed here." Maj. Op. at 29.

Not only is the majority wrong to reject the Hospitals' reading as creating unexplained surplusage, *see* Maj. Op. at 24-27, but the superfluity concerns cut decisively the other way. As discussed above, the majority essentially reads subclause (I) out of the statute by permitting the agency to do under subclause (II) without the requisite data what subclause (I) authorizes only with that data. The majority also renders superfluous the entirety of subparagraph (D). *See* 42 U.S.C. § 1395*l*(t)(14)(D). That subparagraph, occupying nearly a full column in the U.S. Code, specifies in detail how the "[a]cquisition cost survey for hospital outpatient drugs" is to be conducted, first by the Government Accountability Office (GAO) and later by HHS, after that agency has "tak[en] into account" the Comptroller General's "recommendations" as to the "frequency and methodology of subsequent surveys." *Id*. § 1395*l*(t)(14)(D)(i)-(ii). Subparagraph (D) further includes a provision dealing with "survey requirements," mandating that the GAO and HHS surveys "shall have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug." *Id*. § 1395*l*(t)(14)(D)(iii).

And a later clause details how acquisition-cost variations by hospital group are to be identified in GAO's initial surveys if they are to justify reimbursement-rate variations, noting that the Comptroller General "shall determine and report to Congress if there is (and the extent of any) variation in hospital acquisition costs for drugs among hospitals based on the volume of covered [outpatient department] services performed by such hospitals or other relevant characteristics of such hospitals (as defined by the Comptroller General)." *Id.* § 1395*l*(t)(14)(D)(iv).

The majority's reading drains each of these provisions of meaning. It allows the agency simply to purport to approximate hospital acquisition costs, and to claim authority to vary reimbursement rates by hospital group, based on adjusted average price data that HHS recasts as acquisition cost data, but that lacks the characteristics and process of collection that Congress specified in subclause (I). The Hospitals' reading does give distinct meaning to subclause (II)'s allowance for adjustment; it is the majority's reading that occasions significant superfluity without regard to Congress' structural decision to make subclauses (I) and (II) distinct alternatives.

Finally, the majority repeatedly justifies its reading by reference to the policy benefits of the agency's rate reductions and the reasonableness of the agency's alternative data and resulting estimates. *See, e.g.*, Maj. Op. at 18, 20, 22, 24, 27-28. The majority views it as relevant "backdrop," for example, that one result of the agency's proposed cuts will be to lower copayments for Medicare beneficiaries served by 340B hospitals, and to avoid the prospect of any beneficiary possibly paying more in a copayment than the hospital paid to buy the prescribed drugs. *Id.* at 20; *but see* HHS Off. of Inspector Gen., OEI-12-14-00030, Part B Payments for 340B-Purchased

Drugs 9 n.26 (Nov. 2015) (OIG Report) (noting that 340B hospitals "may waive all or part of the beneficiary's coinsurance"). And the majority notes HHS's worries that 340B hospitals might overprescribe drugs that bring reimbursement revenue. *See* Maj. Op. at 7; *but see* U.S. Gov't Accountability Off., GAO-15-442, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals 31 (June 2015) (noting HHS's view that "higher spending for Part B drugs at 340B hospitals" might "lead to better clinical outcomes" for patients served by those safety-net hospitals, who often are in "meaningful[ly]" poorer health than other patients). The majority also expresses confidence that the agency examined "data of undisputed reliability," Maj. Op. at 28, "acted on that data in a cautious way," *id*., and implemented a "fair, or even conservative, measure of the reduction needed to bring payments to those hospitals in parity with their costs to obtain the drugs," *id*. at 20. "In those circumstances," the majority declares, "HHS reasonably concluded that it need not continue subsidizing 340B providers with Part B (i.e. taxpayer) funds and Medicare beneficiaries' copayments." *Id*. at 28.

Those circumstances would perhaps be relevant were this a challenge to the agency's rules as arbitrary and capricious. But concerns about the program's effects, and confidence in the agency's care in using data other than those the statute requires, cannot somehow authorize the agency to do what the statute does not. As the Supreme Court has held, an "agency has no power to 'tailor' legislation to bureaucratic policy goals by rewriting unambiguous statutory terms." *Util. Air Regulatory Grp v. EPA*, 573 U.S. 302, 325 (2014). And, unmoored from the statute's express data-quality requirements, the asserted reliability of the quite different data HHS gathered here provides no assurance for its next rulemaking. Whether HHS's actions might have perceptible policy advantages does

not affect whether the statute authorizes what the agency has done.

It bears noting that, even were they relevant, the claimed policy benefits of the agency's new rate reductions are far from clear. The Section 340B drug discount program, enacted in 1992 as part of the Public Health Service Act, *see* 42 U.S.C. § 256b, permits 340B hospitals to "generate revenue" through "insurance reimbursement[] that may exceed the 340B price paid for the drugs." U.S. Gov't Accountability Off., GAO-11-836, Manufacturer Discounts in the 340B Program Offer Benefits, But Federal Oversight Needs Improvement 2 (2011) (GAO Report). As HHS itself has recognized, Congress anticipated that such above-cost reimbursement revenue would help to fund the public and nonprofit safety-net hospitals that qualify for 340B pricing: "Under the design of the 340B Program and Part B payment rules, the difference between what Medicare pays and what it costs to acquire the drugs is fully retained by the participating covered entities, allowing them to stretch scarce Federal dollars in service to their communities." OIG Report i (Executive Summary); *see also* HHS Off. of Inspector Gen. Memorandum Report: Payment for Drugs Under the Hospital Outpatient Prospective Payment System 8 (Oct. 22, 2010) (describing above-cost SCOD reimbursements to 340B hospitals as "an expected result given the purpose of the 340B Program").

The challenged rules took a major bite out of 340B hospitals' funding. Often operating at substantial losses, 340B hospitals rely on the revenue that Medicare Part B provides in the form of standard drug-reimbursement payments that exceed those hospitals' acquisition costs. 340B hospitals "have used the additional resources to provide critical healthcare services to communities with underserved populations that could not otherwise afford these services." Hospitals Br. 9 (citing GAO

Report at 17-18); *see also Cares Cmty. Health v. HHS*, 944 F.3d 950, 955 (D.C. Cir. 2019). Although stakeholders have debated "whether statutory changes should be made to enable Medicare and/or Medicaid to share in these savings," OIG Report 2, Congress has not made any such change. And, as written, subparagraph (E) does not empower the Secretary to "adjust" away from 340B hospitals substantial annual revenue they garner under the separate, unchallenged 340B statute to provide care to underserved communities.

The net effect of HHS's 2018 and 2019 OPPS rules is to redistribute funds from financially strapped, public and nonprofit safety-net hospitals serving vulnerable populations—including patients without any insurance at all—to facilities and individuals who are relatively better off. If that is a result that Congress intended to authorize, it remains free to say so. But because the statute as it is written does not permit the challenged rate reductions, I respectfully dissent.

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United States Court of Appeals, District of Columbia Circuit.

MACK TRUCKS, INC. and Volvo Group North America, LLC, Petitioners v. ENVIRONMENTAL PROTECTION AGENCY, Respondent. Navistar, Inc., Intervenor.

Nos. 12-1077, 12-1078, 12-1099.
Argued May 14, 2012.
Decided June 12, 2012. **[**195]**
On Petitions for Review of a Final Rule of the United States Environmental Protection Agency. **[**196]**

Before: SENTELLE, Chief Judge, BROWN and GRIFFITH, Circuit Judges.

[*89]
Christopher T. Handman argued the cause for petitioners. With him on the briefs were R. Latane Montague, Sean Marotta, Timothy K. Webster, Samuel I. Gutter, Karen K. Mongoven, Alec C. Zacaroli, and Julie R. Domike.

Michele L. Walter, Attorney, U.S. Department of Justice, argued the cause and filed the brief for respondent.

Cary R. Perlman and Laurence H. Levine were on the brief intervenor Navistar, Inc. in support of respondents.

BROWN, Circuit Judge:

Opinion for the Court filed by Circuit Judge BROWN.

In January 2012, EPA promulgated an interim final rule (IFR) to permit manufacturers of heavy-duty diesel engines to pay nonconformance penalties (NCPs) in exchange for the right to sell noncompliant engines. EPA took this action without providing formal notice or an opportunity for comment, invoking the "good cause" exception provided in the Administrative Procedure Act (APA). Because we find that none of the statutory criteria for "good cause" are satisfied, we vacate the IFR.

I

In 2001, pursuant to Section 202 of the Clean Air Act ("the Act"), EPA enacted a rule requiring a 95 percent reduction in the emissions of nitrogen oxide from heavy-duty diesel engines. 66 Fed.Reg. 5,002 (Jan. 18, 2001). By delaying the effective date until 2010, EPA gave industry nine years to innovate the necessary new technologies. *Id. at 5*,010. (EPA and manufacturers refer to the rule as the "2010 NO_x standard." 77 Fed.Reg. 4,678, 4,681 (Jan. 31, 2012).)

During those nine years, most manufacturers of heavy-duty diesel engines, including Petitioners, invested hundreds of millions of dollars to develop a technology called "selective catalytic reduction." This technology converts nitrogen oxide into nitrogen and water by using a special after treatment system and a diesel-based chemical agent. With selective catalytic reduction, manufacturers have managed to meet the 2010 NO_x standard.

One manufacturer, Navistar, took a different approach. For its domestic sales, Navistar opted for a form of "exhaust

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gas recirculation," but this technology proved less successful; Navistar's engines do not meet the 2010 NO_x standard. All else being equal, Navistar would therefore be unable to sell these engines in the United States — unless, of course, it adopted a different, compliant technology. But for the last few years, Navistar has been able to lawfully forestall that result and continue selling its noncompliant engines by using banked emission credits.[fn1] Simply put, it bet on finding a way to make exhaust gas recirculation a feasible and compliant technology before its finite supply of credits ran out.

Navistar's day of reckoning is fast approaching: its supply of credits is dwindling and its **[***2]** engines remain noncompliant. In October 2011, Navistar informed EPA that it would run out of credits sometime in 2012. EPA, estimating that Navistar "might have as little as three to four months" of available credits before it "would be forced to stop introducing its engines into commerce," leapt into action.**[**197]** [fn2] **[*90]** Resp't Br', at 2-3. Without formal notice and comment, EPA hurriedly promulgated the IFR on January 31, 2012, pursuant to its authority under 42 U.S.C. § 7525(g), to make NCPs available to Navistar.[fn3]

To issue NCPs under its regulations, EPA must first find that a new emissions standard is "more stringent" or "more difficult to achieve" than a prior standard, that "substantial work will be required to meet the standard for which the NCP is offered," and that "there is likely to be a technological laggard." 40 C.F.R. § 86.1103-87. EPA found these criteria were met. The 2010 NO_x standard permits a significantly smaller amount of emissions than the prior standard, so the first criterion is easily satisfied. As for the second, EPA simply said that, because compliant engines (like Petitioners') use new technologies to be compliant, "[i]t is therefore logical to conclude . . . that substantial work was required to meet the emission standard." 77 Fed.Reg. at 4,681. Finally, EPA determined that there was likely to be a technological laggard because "an engine manufacturer [Navistar] . . . has not yet met the requirements for technological reasons" and because "it is a reasonable possibility that this manufacturer may not be able to comply for technological reasons." *Id.*

Having determined that NCPs are appropriate, EPA proceeded to set the amount of the penalty and establish the "upper limit" of emissions permitted even by a penalty-paying manufacturer. The IFR provides that manufacturers may sell heavy-duty diesel engines in model years 2012 and 2013 as long as they pay a penalty of $1,919 per engine and as long as the engines emit fewer than 0.50 grams of nitrogen oxide per horsepower-hour. *Id. at 4*,682-83. This "upper limit" thus permits emissions of up to two-and-a-half times the 0.20 grams permitted under the 2010 NO_x standard with which Navistar is meant to comply and with which Petitioners do comply. *See id.*, at 4,681.

EPA explained its decision to forego notice and comment procedures by invoking the "good cause" exception of the APA, *id. at 4*,680, which provides that an agency may dispense with formal notice and comment procedures if the agency "for good cause finds . . . that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest," 5 U.S.C. § 553(b)(3)(B). EPA cited four factors to show the existence of good cause: (1) notice and comment would mean "the possibility of an engine manufacturer [Navistar] . . . being unable to certify a complete product line of engines for model year 2012 and/or 2013," (2) EPA was only "amending limited provisions in existing NCP regulations," (3) the IFR's "duration is limited," and (4) "there is no risk to the public interest in allowing manufacturers to certify using NCPs before the point at which EPA could make them available through a full notice-and-comment rule-making." 77 Fed.Reg. at 4,680.

Petitioners each requested administrative **[***3]** stays of the IFR, protesting that EPA lacked good cause within the meaning of the APA. Petitioners also objected to the substance of the NCP, arguing that EPA **[**198]** **[*91]** misapplied its own regulatory criteria for determining when such a penalty is warranted, and that EPA arbitrarily and capriciously set the amount of the penalty and the "upper limit" level of permissible emissions. EPA denied those requests. Petitioners promptly filed an emergency motion with this Court to expedite review, which we granted.

II

Navistar, which has intervened on behalf of EPA, claims Petitioners lack standing to challenge the IFR. EPA does not

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make such a claim but, of course, we have the independent "obligation to satisfy [ourselves]" of our own jurisdiction before proceeding to the merits. *Dominguez v. UAL Corp.*, 666 F.3d 1359, 1362 (D.C.Cir.2012).

Navistar's sole argument is that Petitioners' lack procedural standing. We have no need to reach this question, however, since Petitioners clearly have standing as direct competitors of Navistar: they allege the IFR "authorizes allegedly illegal transactions that have the clear and immediate potential to compete with [their] own sales." *Sherley v. Sebelius*, 610 F.3d 69, 72-73 (D.C.Cir.2010). Navistar admits it is using NCPs to sell competitive engines, *see* Navistar Motion, at 3, so this injury is anything but conjectural. Petitioners' injury is also "clear[ly]" traceable to the IFR which authorizes that allegedly illegal competition, and is redressable by a vacatur of the IFR. *Sherley*, 610 F.3d at 72. Finally, because "NCP provisions mandate that penalties . . . remove any competitive disadvantage to manufacturers whose engines or vehicles achieve the required degree of emission reduction," Petitioners' "interest in avoiding anticompetitive injury plainly falls within the zone of interests Congress sought to protect." *Nat'l Petrochem. & Refiners Ass'n*, 287 F.3d at 1148. Even Navistar does not suggest otherwise in its brief.

We therefore proceed to the merits.

III

Petitioners argue first that Section 206 of the Act requires notice and comment; alternatively, they claim EPA lacked good cause in any event. The APA provides that, "[e]xcept when notice or hearing is required by statute," an agency is relieved of its obligation to provide notice and an opportunity to comment "when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(3)(B).[fn4] **[*92]**

[199]** A

Is notice or hearing expressly required by statute? Section 206(g)(1) of the Act, 42 U.S.C. § 7525(g)(1), says that NCPs shall be provided "under regulations promulgated by the Administrator after notice and opportunity for public hearing." According to Petitioners, this is an express requirement of notice and comment that bars EPA from even invoking the good cause exception in this case. Read alone, this language seems to support their argument. But we cannot read one subsection in isolation. *Davis v. Mich. Dep't of Treasury*, 489 U.S. 803, 809, 109 S.Ct. 1500, 103 L.Ed.2d 891 (1989). The rest of Section 206(g) clearly reveals, as EPA points out, that this requirement applies *only* to the **[***4]** very first NCP rule — which set out the regulatory criteria governing future NCPs — not for each and every NCP subsequently promulgated. Because EPA's position is clearly correct, we have no need to invoke any rule of deference. *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837, 843-44, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984).

Subsection (g)(2), the very next paragraph, says that "no [NCP] may be issued under paragraph (1) . . . if the degree by which the manufacturer fails to meet any standard . . . exceeds the percentage determined under regulations promulgated by the Administrator to be practicable. *Such regulations* . . . shall be promulgated not later than one year after August 7, 1977." 42 U.S.C. § 7525 (g)(2) (emphasis added). The regulations to which subsection (g)(2) refers are clearly the regulations promulgated under subsection (g)(1). Subsection (g)(2) explains they are of a guiding nature and, importantly, that they must be issued by certain a date in 1977. This language cannot possibly be read to describe each and every NCP. Petitioners' interpretation of subsection (g)(1), suggesting that it does refer to every NCP, would render subsection (g)(2) not just superfluous, but impossible — a result we must avoid. *Motor & Equip. Mfrs. Ass'n, Inc. v. EPA*, 627 F.2d 1095, 1108 (D.C.Cir.1979). Subsection (g)(3) makes the flaw in Petitioners' interpretation even clearer: "The regulations promulgated under paragraph (1) shall, not later than one year after August 7, 1977, provide for nonconformance penalties in amounts determined under a formula established by the Administrator." 42 U.S.C. § 7525(g)(3). Once again, this provision and its deadline reveal that subsection (g)(1) refers to a one-time promulgation of a formula that governs future penalty applications. Reading Section 206(g) as a whole, it is clear nothing in that provision requires EPA to provide notice and comment every time it applies the original formula to the establishment of specific penalties.

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Contrary to Petitioners' fears, the Act's lack of a notice and comment requirement does not mean that *no* procedures are statutorily required when NCPs are issued. The APA's general rule requiring notice and comment — absent identified exceptions — still obviously applies. Indeed, EPA has always argued that the IFR is justified under the good cause exception, not that it is justified because notice and comment is never required. *See* 77 Fed. Reg. at 4,680.

B

Because the Act does not contain any notice-and-comment requirement applicable **[**200] [*93]** to the IFR, EPA may invoke the APA's good cause exception. We must therefore determine whether notice and comment were "impracticable, unnecessary, or contrary to the public interest."[fn5] U.S.C. § 553(b)(3)(B). On that question, it would appear we owe EPA's findings no particular deference. *See Jifry v. FAA*, 370 F.3d 1174, 1178-79 (D.C.Cir.2004) (finding good cause without resorting to deference); *Util. Solid Waste Activities Grp. v. EPA* 236 F.3d 749, 754 (D.C.Cir.2001) (finding no good cause without invoking deference). But we need not decide the standard of review since, even if we were to review EPA's assertion of "good cause" simply to determine if it is arbitrary or capricious, 5 U.S.C. § 706(2)(A), we would still find it lacking.

We have repeatedly made clear that the good cause exception "is to be narrowly construed and only reluctantly **[***5]** countenanced." *Util. Solid Waste Activities Grp.*, 236 F.3d at 754; *Tenn. Gas Pipeline Co. v. FERC*, 969 F.2d 1141, 1144 (D.C.Cir.1992); *New Jersey v. EPA* 626 F.2d 1038, 1045 (D.C.Cir.1980); *see also Jifry*, 370 F.3d at 1179 ("The exception excuses notice and comment in emergency situations, or where delay could result in serious harm."); *Am. Fed. of Gov't Emps. v. Block*, 655 F.2d 1153, 1156 (D.C.Cir.1981) ("As the legislative history of the APA makes clear, moreover, the exceptions at issue here are not `escape clauses' that may be arbitrarily utilized at the agency's whim. Rather, use of these exceptions by administrative agencies should be limited to emergency situations. . . .").

First, an agency may invoke the impracticability of notice and comment. 5 U.S.C. § 553(b)(3)(B). Our inquiry into impracticability "is inevitably fact- or context-dependent," *Mid-Tex Electric Coop. v. FERC*, 822 F.2d 1123, 1132 (D.C.Cir.1987). For the sake of comparison, we have suggested agency action could be sustained on this basis if, for example, air travel security agencies would be unable to address threats posing "a possible imminent hazard to aircraft, persons, and property within the United States," *Jifry*, 370 F.3d at 1179, or if "a safety investigation shows that a new safety rule must be put in place immediately," *Util. Solid Waste Activities Grp.*, 236 F.3d at 755 (ultimately finding that not to be the case and rejecting the agency's argument), or if a rule was of "life-saving importance" to mine workers in the event of a mine explosion, *Council of the S. Mountains, Inc. v. Donovan*, 653 F.2d 573, 581 (D.C.Cir.1981) (describing that circumstance as "a special, possibly unique, case").

By contrast, the context of this case reveals that the only purpose of the IFR is, as Petitioners put it, "to rescue a lone manufacturer from the folly of its own choices." Pet. Br. at 29; *see* 77 Fed.Reg. at 4,680 (expressing EPA's concern that providing notice and comment would mean "the possibility of an engine manufacturer [Navistar] . . . being unable to certify a complete product line of engines for model year 2012 and/or 2013"). The IFR does not stave off any imminent threat to the environment or safety or national security. It does not remedy any real emergency at all, save the "emergency" facing Navistar's bottom line. Indeed, all EPA points to is "the serious harm to Navistar and its employees" and "the ripple effect on its customers and suppliers," Resp't Br. at 28, but the same could be said for any manufacturer facing a standard with which its product does not comply.

EPA claims the harm to Navistar and the resulting up- and down-stream impacts should still be enough under our precedents. The only case on which it relies, however, is one in which an entire industry and its customers were imperiled. *See**[**201]** [*94]* *Am. Fed. of Gov't Emps.*, 655 F.2d at 1157. Navistar's plight is not even remotely close to such a weighty, systemic interest, especially since it is a consequence brought about by Navistar's own choice to continue to pursue a technology which, so far, is noncompliant. At bottom, EPA's approach would give agencies "good cause" under the APA every time a manufacturer in a regulated field felt a new regulation imposed some degree of economic hardship, even if the company could have avoided that hardship had it made different business choices. This is both nonsensical and in direct tension **[***6]** with our longstanding position that the exception should be "narrowly construed and only reluctantly countenanced." *Util. Solid Waste Activities Grp.*, 236 F.3d at 754.

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Second, an agency may claim notice and comment were "unnecessary." 5 U.S.C. § 553(b)(3)(B). This prong of the good cause inquiry is "confined to those situations in which the administrative rule is a routine determination, insignificant in nature and impact, and inconsequential to the industry and to the public." *Util. Solid Waste Activities Grp.*, 236 F.3d at 755. This case does not present such a situation. Just as in *Utility Solid Waste*, the IFR is a rule "about which these members of the public [the petitioners] were greatly interested," so notice and comment were not "unnecessary." *Id.* EPA argues that since the IFR is just an interim rule, good cause is satisfied because "the interim status of the challenged rule is a significant factor" in determining whether notice and comment are unnecessary. Resp't Br. at 35; 77 Fed.Reg. at 4,680 (finding good cause because the IFR's "duration is limited"). But we held, in the very case on which EPA relies, that "the limited nature of the rule cannot in itself justify a failure to follow notice and comment procedures." *Mid-Tex Electric Coop.*, 822 F.2d at 1132. And for good reason: if a rule's interim nature were enough to satisfy the element of good cause, then "agencies could issue interim rules of limited effect for any plausible reason, irrespective of the degree of urgency" and "the good cause exception would soon swallow the notice and comment rule." *Tenn. Gas Pipeline*, 969 F.2d at 1145.

EPA's remaining argument that notice and comment were "unnecessary" is that the IFR was essentially ministerial: EPA simply input numbers into an NCP-setting formula without substantially amending the NCP regime. Resp't Br. at 36; 77 Fed.Reg. at 4,680. But even if it were true that EPA arrived at the level of the penalty and the upper limit in this way (and Petitioners strenuously argue that EPA actually *amended* the NCP regime in order to arrive at the upper limit level in the IFR5), that argument does not account for how EPA determined NCPs were warranted in this case in the first place — another finding to which Petitioners object. EPA's decision to implement an NCP, perhaps even more than the level of the penalty itself, is far from inconsequential or routine, and EPA does not even attempt to defend it as such.

Finally, an agency may invoke the good cause exception if providing notice and comment would be contrary to the public interest. 5 U.S.C. § 553(b)(3)(B). In the IFR, EPA says it has good cause since "there is no risk to the public interest in allowing manufacturers to [use] NCPs before the point at which EPA could make them available through a full notice-and-comment **[**202] [*95]** rulemaking," 77 Fed.Reg. at 4,680, but this misstates the statutory criterion. The question is not whether *dispensing* with notice and comment would be contrary to the public interest, but whether *providing* notice and comment would be contrary to the public interest. By improperly framing the question in this way, the IFR inverts the — presumption, apparently suggesting that notice and comment is usually unnecessary. We cannot permit this subtle malformation **[***7]** of the APA. The public interest prong of the good cause exception is met only in the rare circumstance when ordinary procedures — generally presumed to serve the public interest — would in fact harm that interest. It is appropriately invoked when the timing and disclosure requirements of the usual procedures would defeat the purpose of the proposal — if, for example, "announcement of a proposed rule would enable the sort of financial manipulation the rule sought to prevent." *Util. Solid Waste Activities Grp.*, 236 F.3d at 755. In such a circumstance, notice and comment could be dispensed with "in order to prevent the amended rule from being evaded." *Id.* In its brief, EPA belatedly frames the inquiry correctly, but goes on to offer nothing more than a recapitulation of the harm to Navistar and the associated "ripple effects." Resp't Br. at 38. To the extent this is an argument not preserved by EPA in the IFR, we cannot consider it, *see SEC v. Chenery Corp.*, 332 U.S. 194, 196, 67 S.Ct. 1575, 91 L.Ed. 1995 (1947), but regardless, it is nothing more than a reincar-nation of the impracticability argument we have already rejected.

IV

Because EPA lacked good cause to dispense with required notice and comment procedures, we conclude the IFR must be vacated without reaching Petitioners' alternative arguments. We are aware EPA is currently in the process of promulgating a final rule — with the benefit of notice and comment — on this precise issue. However, we strongly reject EPA's claim that the challenged errors are harmless simply because of the pendency of a properly-noticed final rule. Were that true, agencies would have no use for the APA when promulgating any interim rules. So long as the agency eventually opened a final rule for comment, every error in every interim rule — no matter how egregious — could be excused as a harmless error.

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We do recognize the pending final rule means our vacatur of the IFR on these procedural grounds will be of limited practical impact. Before the ink is dry on that final rule, we offer two observations about the parameters of this rulemaking. First, NCPs are meant to be a temporary bridge to compliance for manufacturers that have "made every effort to comply." *United States v. Caterpillar, Inc.*, 227 F.Supp.2d 73, 88 (D.D.C.2002). As EPA itself has explained, NCPs are not designed to bail out manufacturers that voluntarily choose, for whatever reason, not to adopt an existing, compliant technology. *See* 77 Fed.Reg. 4,736, 4,739 (Jan. 31, 2012) ("NCPs have always been intended for manufacturers that cannot meet an emission standard for technological reasons rather than manufacturers choosing not to comply."); 50 Fed.Reg. 35,402, 35,403 (Aug. 30, 1985) (stating that NCPs are inappropriate "if many manufacturers' vehicles/engines were already meeting the revised standard or could do so with relatively minor calibration changes or modifications"). Based solely on what EPA has offered in the IFR, it at least appears to us that NCPs are likely inappropriate in this case.

Second, we emphasize that "no legislation pursues its purposes at all costs," **[**203] [*96]** *Rodriguez v. United States*, 480 U.S. 522, 525-26, 107 S.Ct. 1391, 94 L.Ed.2d 533 (1987), especially when Congress explicitly says as much in the legislation. Though the Clean **[***8]** Air Act requires EPA to issue NCPs when it determines the necessary criteria are satisfied, it also expressly demands that EPA "remove any competitive disadvantage to manufacturers whose engines or vehicles achieve the required degree of emission reduction." 42 U.S.C. § 7525(g)(3)(E). As it is presented in the IFR, we are highly skeptical that the penalty and upper limit provided for in this NCP satisfy this congressional demand to protect compliant manufacturers.

That being said, EPA is certainly free to make whatever findings it deems appropriate in the pending final rulemaking — subject, of course, to this Court's review. For now, therefore, we simply hold that EPA lacked good cause for not providing formal notice-and-comment rulemaking, and accordingly vacate the IFR and remand for further proceedings.

So ordered.

[fn1] We have discussed EPA's emissions credits system more fully in *National Petrochemical & Refiners Association v. EPA*, 287 F.3d 1130, 1148(D.C.Cir.2002).

[fn2] At oral argument, EPA and counsel for Navistar indicated that now, seven months after it notified EPA of its credit shortage, Navistar still has and successfully uses credits to sell some noncompliant engines. Oral Arg. Recording at 32:35-33:15. Navistar also avails itself of the NCPs authorized by the IFR in other markets. Navistar, Inc.'s Motion for Leave to Intervene at 3 (Feb. 28, 2012) ["Navistar Motion"].

[fn3] The NCP is theoretically available to any heavy-duty diesel engine manufacturer, but by discussing only Navistar's predicament in its brief and in the IFR, EPA all but concedes that it issued the IFR for solely Navistar's benefit. *See* Resp't Br. at 11-13; 77 Fed.Reg. at 4,681. Navistar similarly averred in its motion to intervene that "there is no doubt that the engine manufacturer described in EPA's Interim Final Rule is Navistar." Navistar Motion, at 3.

[fn4] The APA provides a second exception to the notice-and-comment requirement: the requirement is lifted when "persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law." 5 U.S.C. § 553(b). Navistar, and only Navistar, argues that Petitioners had such actual notice of the IFR, but Petitioners knew only that EPA was gathering information for a possible NCP and merely orally supplied some information they thought might be relevant to setting the levels of the penalty and upper limit. EPA did not provide a draft of the IFR, did not advise Petitioners of the levels, did not explain or discuss its methodology, and did not ask Petitioners to discuss whether NCPs were justified in the first place. Jorgensen Aff. ¶ 15; Kayes Aff. ¶ 12-17; Greszler Aff. ¶ 11-13. In fact, according to Petitioners' affidavits, EPA suggested the information was being gathered to develop a proposal which would in turn be subject to ordinary notice and comment — not that this was the end of the road. *E.g.*, Greszler Aff. ¶ 13. EPA has not argued to the contrary before this Court, and Navistar offers no support for its position that such scant and misleading notice is sufficient. It certainly pales in comparison to what the APA requires of formal notice. *See* 5 U.S.C. § 553(b)(3) (notice shall include "the terms or substance of the proposed rule or a description of the subjects and issues involved"); *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d

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506, 549 (D.C.Cir.1983) ("Agency notice must describe the range of alternatives being considered with reasonable specificity. Otherwise, interested parties will not know what to comment on, and notice will not lead to better-informed agency decisionmaking."). It would be wholly illogical to require any less from actual notice.

[fn5] EPA admits in its brief that "Petitioners are correct that in past rules, EPA based the penalty rates [on certain factors]" and that "that was not the case for the Interim Rule." Resp't. Br. at 52.

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Mack Trucks, Inc. v. EPA, 682 F.3d 87, 401 U.S. App. D.C. 194, 74 ERC 1929 (D.C. Cir. 2012), Court Opinion

Table Of Authorities (17 cases)

Authorities Summary	
Positive	16
Distinguished	1
Caution	0
Superseded	0
Negative	0
Total	17

1 Cited , Quoted — Dominguez v. UAL Corp., 666 F.3d 1359 (D.C. Cir. 2012)

Navistar, which has intervened on behalf of EPA, claims Petitioners lack standing to challenge the IFR. EPA does not make such a claim but, of course, we have the independent "obligation to satisfy [ourselves]" of our own jurisdiction before proceeding to the merits. *Dominguez v. UAL Corp.* , **666 F.3d 1359** , **1362** (D.C.Cir.2012).

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2 Cited , Quoted — Sherley v. Sebelius, 610 F.3d 69, 391 U.S. App. D.C. 258 (D.C. Cir. 2010)

Navistar's sole argument is that Petitioners' lack procedural standing. We have no need to reach this question, however, since Petitioners clearly have standing as direct competitors of Navistar: they allege the IFR "authorizes allegedly illegal transactions that have the clear and immediate potential to compete with [their] own sales." *Sherley v. Sebelius* , **610 F.3d 69** , **72-73** (D.C.Cir.2010). Navistar admits it is using NCPs to sell competitive engines, *see* Navistar Motion, at 3, so this injury is anything but conjectural. Petitioners' injury is also "clear[ly]" traceable to the IFR which authorizes that allegedly illegal competition, and is redressable by a vacatur of the IFR. *Sherley* , **610 F.3d at 72** . Finally, because "NCP provisions mandate that penalties . . . remove any competitive disadvantage to manufacturers whose engines or vehicles achieve the required degree of emission reduction," Petitioners' "interest in avoiding anticompetitive injury plainly falls within the zone of interests Congress sought to protect." *Nat'l Petrochem. & Refiners Ass'n* , **287 F.3d at 1148** . Even Navistar does not suggest otherwise in its brief.

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3 Discussed , Quoted — Jifry v. FAA, 370 F.3d 1174, 361 U.S. App. D.C. 450 (D.C. Cir. 2004)

Because the Act does not contain any notice-and-comment requirement applicable <*Page 93> to the IFR, EPA may invoke the APA's good cause exception. We must therefore determine whether notice and comment were "impracticable, unnecessary, or contrary to the public interest." [fn5] U.S.C. § 553(b)(3)(B). On that question, it would appear we owe EPA's findings no particular deference. *See* *Jifry v. FAA* , **370 F.3d 1174** , **1178-79**

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(D.C.Cir.2004) (finding good cause without resorting to deference); *Util. Solid Waste Activities Grp. v. EPA* **236 F.3d 749** , **754** (D.C.Cir.2001) (finding no good cause without invoking deference). But we need not decide the standard of review since, even if we were to review EPA's assertion of "good cause" simply to determine if it is arbitrary or capricious, **5 U.S.C. § 706** (2)(A), we would still find it lacking.

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We have repeatedly made clear that the good cause exception "is to be narrowly construed and only reluctantly countenanced." *Util. Solid Waste Activities Grp.* , **236 F.3d at 754** ; *Tenn. Gas Pipeline Co. v. FERC* , **969 F.2d 1141** , **1144** (D.C.Cir.1992); *New Jersey v. EPA* **626 F.2d 1038** , **1045** (D.C.Cir.1980); *see also Jifry* , **370 F.3d at 1179** ("The exception excuses notice and comment in emergency situations, or where delay could result in serious harm."); *Am. Fed. of Gov't Emps. v. Block* , **655 F.2d 1153** , **1156** (D.C.Cir.1981) ("As the legislative history of the APA makes clear, moreover, the exceptions at issue here are not `escape clauses' that may be arbitrarily utilized at the agency's whim. Rather, use of these exceptions by administrative agencies should be limited to emergency situations. . . .").

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First, an agency may invoke the impracticability of notice and comment. **5 U.S.C. § 553** (b)(3)(B). Our inquiry into impracticability "is inevitably fact- or context-dependent," *Mid-Tex Electric Coop. v. FERC* , **822 F.2d 1123** , **1132** (D.C.Cir.1987). For the sake of comparison, we have suggested agency action could be sustained on this basis if, for example, air travel security agencies would be unable to address threats posing "a possible imminent hazard to aircraft, persons, and property within the United States," *Jifry* , **370 F.3d at 1179** , or if "a safety investigation shows that a new safety rule must be put in place immediately," *Util. Solid Waste Activities Grp.* , **236 F.3d at 755** (ultimately finding that not to be the case and rejecting the agency's argument), or if a rule was of "life-saving importance" to mine workers in the event of a mine explosion, *Council of the S. Mountains, Inc. v. Donovan* , **653 F.2d 573** , **581** (D.C.Cir.1981) (describing that circumstance as "a special, possibly unique, case").

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4 Cited , Quoted United States v. Caterpillar, Inc., 227 F. Supp. 2d 73, 55 ERC 1769 (D.D.C. 2002)

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We do recognize the pending final rule means our vacatur of the IFR on these procedural grounds will be of limited practical impact. Before the ink is dry on that final rule, we offer two observations about the parameters of this rulemaking. First, NCPs are meant to be a temporary bridge to compliance for manufacturers that have "made every effort to comply." *United States v. Caterpillar, Inc.* , **227 F.Supp.2d 73** , **88** (D.D.C.2002). As EPA itself has explained, NCPs are not designed to bail out manufacturers that voluntarily choose, for whatever reason, not to adopt an existing, compliant technology. *See* **77 Fed.Reg. 4,736** , 4,739 (Jan. 31, 2012) ("NCPs have always been intended for manufacturers that cannot meet an emission standard for technological reasons rather than manufacturers choosing not to comply."); **50 Fed.Reg. 35,402** , 35,403 (Aug. 30, 1985) (stating that NCPs are inappropriate "if many manufacturers' vehicles/engines were already meeting the revised standard or could do so with relatively minor calibration changes or modifications"). Based solely on what EPA has offered in the IFR, it at least appears to us that NCPs are likely inappropriate in this case.

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5 Cited , Quoted Nat'l Petrochemical & Refiners Ass'n v. EPA, 287 F.3d 1130, 351 U.S. App. D.C. 127, 54 ERC 1257 (D.C. Cir. 2002)

Navistar's sole argument is that Petitioners' lack procedural standing. We have no need to reach this question, however, since Petitioners clearly have standing as direct competitors of Navistar: they allege the IFR "authorizes allegedly illegal transactions that have the clear and immediate potential to compete with [their] own sales." *Sherley v. Sebelius* , **610 F.3d 69** , **72-73** (D.C.Cir.2010). Navistar admits it is using NCPs to sell competitive engines, *see* Navistar Motion, at 3, so this injury is anything but conjectural. Petitioners' injury is also "clear[ly]" traceable to the IFR which authorizes that allegedly illegal competition, and is redressable by a vacatur of the IFR. *Sherley* , **610 F.3d at 72** . Finally, because "NCP provisions mandate that penalties . . . remove any competitive disadvantage to manufacturers whose engines or vehicles achieve the required degree of emission reduction," Petitioners' "interest in avoiding anticompetitive injury plainly falls within the zone of interests Congress sought to protect." *Nat'l Petrochem. & Refiners Ass'n* , **287 F.3d at 1148** . Even Navistar does not suggest otherwise in its brief.

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One manufacturer, Navistar, took a different approach. For its domestic sales, Navistar opted for a form of "exhaust gas recirculation," but this technology proved less successful; Navistar's engines do not meet the 2010 NO standard. All else being equal, Navistar would therefore be unable to sell these engines in the United States — unless, of course, it adopted a different, compliant technology. But for the last few years, Navistar has been able to lawfully forestall that result and continue selling its noncompliant engines by using banked emission credits. [fn1] Simply put, it bet on finding a way to make exhaust gas recirculation a feasible and compliant technology before its finite supply of credits ran out.

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[fn1] We have discussed EPA's emissions credits system more fully in *National Petrochemical & Refiners Association v. EPA* , **287 F.3d 1130** , **1148** (D.C.Cir.2002).

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6 Distinguished , Quoted — Util. Solid Waste Activities Grp. v. EPA, 236 F.3d 749, 344 U.S. App. D.C. 382, 51 ERC 1961, 9 ILRD 457 (D.C. Cir. 2001)

Because the Act does not contain any notice-and-comment requirement applicable <*Page 93> to the IFR, EPA may invoke the APA's good cause exception. We must therefore determine whether notice and comment were "impracticable, unnecessary, or contrary to the public interest." [fn5] U.S.C. § 553(b)(3)(B). On that question, it would appear we owe EPA's findings no particular deference. *See* *Jifry v. FAA* , **370 F.3d 1174** , **1178-79** (D.C.Cir.2004) (finding good cause without resorting to deference); *Util. Solid Waste Activities Grp. v. EPA* **236 F.3d 749** , **754** (D.C.Cir.2001) (finding no good cause without invoking deference). But we need not decide the standard of review since, even if we were to review EPA's assertion of "good cause" simply to determine if it is arbitrary or capricious, **5 U.S.C. § 706** (2)(A), we would still find it lacking.

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We have repeatedly made clear that the good cause exception "is to be narrowly construed and only reluctantly countenanced." *Util. Solid Waste Activities Grp.* , **236 F.3d at 754** ; *Tenn. Gas Pipeline Co. v. FERC* , **969 F.2d 1141** , **1144** (D.C.Cir.1992); *New Jersey v. EPA* **626 F.2d 1038** , **1045** (D.C.Cir.1980); *see also Jifry* , **370 F.3d at 1179** ("The exception excuses notice and comment in emergency situations, or where delay could result in serious harm."); *Am. Fed. of Gov't Emps. v. Block* , **655 F.2d 1153**

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First, an agency may invoke the impracticability of notice and comment. **5 U.S.C. § 553** (b)(3)(B). Our inquiry into impracticability "is inevitably fact- or context-dependent," *Mid-Tex Electric Coop. v. FERC* , **822 F.2d 1123** , **1132** (D.C.Cir.1987). For the sake of comparison, we have suggested agency action could be sustained on this basis if, for example, air travel security agencies would be unable to address threats posing "a possible imminent hazard to aircraft, persons, and property within the United States," *Jifry* , **370 F.3d at 1179** , or if "a safety investigation shows that a new safety rule must be put in place immediately," *Util. Solid Waste Activities Grp.* , **236 F.3d at 755** (ultimately finding that not to be the case and rejecting the agency's argument), or if a rule was of "life-saving importance" to mine workers in the event of a mine explosion, *Council of the S. Mountains, Inc. v. Donovan* , **653 F.2d 573** , **581** (D.C.Cir.1981) (describing that circumstance as "a special, possibly unique, case").
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EPA claims the harm to Navistar and the resulting up- and down-stream impacts should still be enough under our precedents. The only case on which it relies, however, is one in which an entire industry and its customers were imperiled. *See* <*Page 94> *Am. Fed. of Gov't Emps.* , **655 F.2d at 1157** . Navistar's plight is not even remotely close to such a weighty, systemic interest, especially since it is a consequence brought about by Navistar's own choice to continue to pursue a technology which, so far, is noncompliant. At bottom, EPA's approach would give agencies "good cause" under the APA every time a manufacturer in a regulated field felt a new regulation imposed some degree of economic hardship, even if the company could have avoided that hardship had it made different business choices. This is both nonsensical and in direct tension with our longstanding position that the exception should be "narrowly construed and only reluctantly countenanced." *Util. Solid Waste Activities Grp.* , **236 F.3d at 754** .
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Second, an agency may claim notice and comment were "unnecessary." **5 U.S.C. § 553** (b)(3)(B). This prong of the good cause inquiry is "confined to those situations in which the administrative rule is a routine determination, insignificant in nature and impact, and inconsequential to the industry and to the public." *Util. Solid Waste Activities Grp.* , **236 F.3d at 755** . This case does not present such a situation. Just as in *Utility Solid Waste* , the IFR is a rule "about which these members of the public [the petitioners] were greatly interested," so notice and comment were not "unnecessary." ***Id*** . EPA argues that since the IFR is just an interim rule, good cause is satisfied because "the interim status of the challenged rule is a significant factor" in determining whether notice and comment are unnecessary. Resp't Br. at 35; **77 Fed.Reg. at 4,680** (finding good cause because the IFR's "duration is limited"). But we held, in the very case on which EPA relies, that "the limited nature of the rule cannot in itself justify a failure to follow notice and comment procedures." *Mid-Tex Electric Coop.* , **822 F.2d at 1132** . And for good reason: if a rule's interim nature were enough to satisfy the element of good cause, then "agencies could issue interim rules of limited effect for any plausible reason, irrespective of the degree of urgency" and "the good cause exception would soon swallow the notice and comment rule." *Tenn. Gas Pipeline* , **969 F.2d at 1145** .

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Finally, an agency may invoke the good cause exception if providing notice and comment would be contrary to the public interest. **5 U.S.C. § 553** (b)(3)(B). In the IFR, EPA says it has good cause since "there is no risk to the public interest in allowing manufacturers to [use] NCPs before the point at which EPA could make them available through a full notice-and-comment <*Page 95> rulemaking," **77 Fed.Reg. at 4,680** , but this misstates the statutory criterion. The question is not whether *dispensing* with notice and comment would be contrary to the public interest, but whether *providing* notice and comment would be contrary to the public interest. By improperly framing the question in this way, the IFR inverts the — presumption, apparently suggesting that notice and comment is usually unnecessary. We cannot permit this subtle malformation of the APA. The public interest prong of the good cause exception is met only in the rare circumstance when ordinary procedures — generally presumed to serve the public interest — would in fact harm that interest. It is appropriately invoked when the timing and disclosure requirements of the usual procedures would

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defeat the purpose of the proposal — if, for example, "announcement of a proposed rule would enable the sort of financial manipulation the rule sought to prevent." *Util. Solid Waste Activities Grp.* , **236 F.3d at 755** . In such a circumstance, notice and comment could be dispensed with "in order to prevent the amended rule from being evaded." ***Id*** . In its brief, EPA belatedly frames the inquiry correctly, but goes on to offer nothing more than a recapitulation of the harm to Navistar and the associated "ripple effects." Resp't Br. at 38. To the extent this is an argument not preserved by EPA in the IFR, we cannot consider it, *see SEC v. Chenery Corp.* , **332 U.S. 194** , **196** , **67 S.Ct. 1575** , **91 L.Ed. 1995** (1947), but regardless, it is nothing more than a reincar-nation of the impracticability argument we have already rejected.

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7 Cited , Quoted Tenn. Gas Pipeline Co. v. FERC, 969 F.2d 1141, 297 U.S. App. D.C. 141 (D.C. Cir. 1992)

We have repeatedly made clear that the good cause exception "is to be narrowly construed and only reluctantly countenanced." *Util. Solid Waste Activities Grp.* , **236 F.3d at 754** ; *Tenn. Gas Pipeline Co. v. FERC* , **969 F.2d 1141** , **1144** (D.C.Cir.1992); *New Jersey v. EPA* **626 F.2d 1038** , **1045** (D.C.Cir.1980); *see also Jifry* , **370 F.3d at 1179** ("The exception excuses notice and comment in emergency situations, or where delay could result in serious harm."); *Am. Fed. of Gov't Emps. v. Block* , **655 F.2d 1153** , **1156** (D.C.Cir.1981) ("As the legislative history of the APA makes clear, moreover, the exceptions at issue here are not `escape clauses' that may be arbitrarily utilized at the agency's whim. Rather, use of these exceptions by administrative agencies should be limited to emergency situations. . . .").

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8 Cited — Davis v. Michigan Dept. of the Treasury, 489 U.S. 803, 109 S. Ct. 1500, 103 L. Ed. 2d 891, 10 EBC 2097 (1989)

Is notice or hearing expressly required by statute? **Section 206(g)(1)** of the Act, **42 U.S.C. § 7525** (g)(1), says that NCPs shall be provided "under regulations promulgated by the Administrator after notice and opportunity for public hearing." According to Petitioners, this is an express requirement of notice and comment that bars EPA from even invoking the good cause exception in this case. Read alone, this language seems to support their argument. But we cannot read one subsection in isolation. *Davis v. Mich. Dep't of Treasury* , **489 U.S. 803** , **809** , **109 S.Ct. 1500** , **103 L.Ed.2d 891** (1989). The rest of Section 206(g) clearly reveals, as EPA points out, that this requirement applies *only* to the very first NCP rule — which set out the regulatory criteria governing future NCPs — not for each and every NCP subsequently promulgated. Because EPA's position is clearly correct, we have no need to invoke any rule of deference. *Chevron, U.S.A., Inc. v. NRDC* , **467 U.S. 837** , **843-44** , **104 S.Ct. 2778** , **81 L.Ed.2d 694** (1984).

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9 Cited , Quoted — Mid-Tex Elec. Coop., Inc. v. FERC, 822 F.2d 1123, 262 U.S. App. D.C. 61 (D.C. Cir. 1987)

First, an agency may invoke the impracticability of notice and comment. **5 U.S.C. § 553** (b)(3)(B). Our inquiry into impracticability "is inevitably fact- or context-dependent," *Mid-Tex Electric Coop. v. FERC* , **822 F.2d 1123** , **1132** (D.C.Cir.1987). For the sake of comparison, we have suggested agency action could be sustained on this basis if, for example, air travel security agencies would be unable to address threats posing "a possible imminent hazard to aircraft, persons, and property within the United States," *Jifry* , **370 F.3d at 1179** , or if "a safety investigation shows that a new safety rule must be put in place immediately," *Util. Solid Waste Activities Grp.* , **236 F.3d at 755** (ultimately finding that not to be the case and rejecting the agency's argument), or if a rule was of "life-saving importance" to mine

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10 Cited , Quoted Rodriguez v. United States, 480 U.S. 522, 107 S. Ct. 1391, 94 L. Ed. 2d 533 (1987)

Second, we emphasize that "no legislation pursues its purposes at all costs," <*Page 96> *Rodriguez v. United States* , **480 U.S. 522** , **525-26** , **107 S.Ct. 1391** , **94 L.Ed.2d 533** (1987), especially when Congress explicitly says as much in the legislation. Though the Clean Air Act requires EPA to issue NCPs when it determines the necessary criteria are satisfied, it also expressly demands that EPA "remove any competitive disadvantage to manufacturers whose engines or vehicles achieve the required degree of emission reduction." **42 U.S.C. § 7525** (g)(3)(E). As it is presented in the IFR, we are highly skeptical that the penalty and upper limit provided for in this NCP satisfy this congressional demand to protect compliant manufacturers.

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11 Cited — Chevron U. S. A. Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 104 S. Ct. 2778, 81 L. Ed. 2d 694, 21 ERC 1049 (1984)

Is notice or hearing expressly required by statute? **Section 206(g)(1)** of the Act, **42 U.S.C. § 7525** (g)(1), says that NCPs shall be provided "under regulations promulgated by the Administrator after notice and opportunity for public hearing." According to Petitioners, this is an express requirement of notice and comment that bars EPA from even invoking the good cause exception in this case. Read alone, this language seems to support their argument. But we cannot read one subsection in isolation. *Davis v. Mich. Dep't of Treasury* , **489 U.S. 803** , **809** , **109 S.Ct. 1500** , **103 L.Ed.2d 891** (1989). The rest of Section 206(g) clearly reveals, as EPA points out, that this requirement applies *only* to the very first NCP rule — which set out the regulatory criteria governing future NCPs — not for each and every NCP subsequently promulgated. Because EPA's position is clearly correct, we have no need to invoke any rule of deference. *Chevron, U.S.A., Inc. v. NRDC* , **467 U.S. 837** , **843-44** , **104 S.Ct. 2778** , **81 L.Ed.2d 694** (1984).
...

12 Cited , (See) , Quoted — Small Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d 506, 227 U.S. App. D.C. 201, 18 ERC 1681, 18 ERC 2033 (D.C. Cir. 1983)

Petitioners argue first that **Section 206** of the Act requires notice and comment; alternatively, they claim EPA lacked good cause in any event. The APA provides that, "[e]xcept when notice or hearing is required by statute," an agency is relieved of its obligation to provide notice and an opportunity to comment "when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." **5 U.S.C. § 553** (b)(3)(B). [fn4] <*Page 92>
...

[fn4] The APA provides a second exception to the notice-and-comment requirement: the requirement is lifted when "persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law." **5 U.S.C. § 553** (b). Navistar, and only Navistar, argues that Petitioners had such actual notice of the IFR, but Petitioners knew only that EPA was gathering information for a possible NCP and merely orally supplied some information they thought might be relevant to setting the levels of the penalty and upper limit. EPA did not provide a draft of the IFR, did not advise Petitioners of the levels, did not explain or discuss its methodology, and did not ask Petitioners to discuss whether NCPs were

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justified in the first place. Jorgensen Aff. ¶ 15; Kayes Aff. ¶ 12-17; Greszler Aff. ¶ 11-13. In fact, according to Petitioners' affidavits, EPA suggested the information was being gathered to develop a proposal which would in turn be subject to ordinary notice and comment — not that this was the end of the road. *E.g.* , Greszler Aff. ¶ 13. EPA has not argued to the contrary before this Court, and Navistar offers no support for its position that such scant and misleading notice is sufficient. It certainly pales in comparison to what the APA requires of formal notice. *See* **5 U.S.C. § 553** (b)(3) (notice shall include "the terms or substance of the proposed rule or a description of the subjects and issues involved"); *Small Refiner Lead Phase-Down Task Force v. EPA* , **705 F.2d 506** , **549** (D.C.Cir.1983) ("Agency notice must describe the range of alternatives being considered with reasonable specificity. Otherwise, interested parties will not know what to comment on, and notice will not lead to better-informed agency decisionmaking."). It would be wholly illogical to require any less from actual notice.

...

13 Discussed , Quoted Council of the S. Mountains, Inc. v. Donovan, 653 F.2d 573, 209 U.S. App. D.C. 318 (D.C. Cir. 1981)

First, an agency may invoke the impracticability of notice and comment. **5 U.S.C. § 553** (b)(3)(B). Our inquiry into impracticability "is inevitably fact- or context-dependent," *Mid-Tex Electric Coop. v. FERC* , **822 F.2d 1123** , **1132** (D.C.Cir.1987). For the sake of comparison, we have suggested agency action could be sustained on this basis if, for example, air travel security agencies would be unable to address threats posing "a possible imminent hazard to aircraft, persons, and property within the United States," *Jifry* , **370 F.3d at 1179** , or if "a safety investigation shows that a new safety rule must be put in place immediately," *Util. Solid Waste Activities Grp.* , **236 F.3d at 755** (ultimately finding that not to be the case and rejecting the agency's argument), or if a rule was of "life-saving importance" to mine workers in the event of a mine explosion, *Council of the S. Mountains, Inc. v. Donovan* , **653 F.2d 573** , **581** (D.C.Cir.1981) (describing that circumstance as "a special, possibly unique, case").

...

14 Cited , (See also) , Quoted American Federation of Government Employees v. Block, 655 F.2d 1153, 210 U.S. App. D.C. 336 (D.C. Cir. 1981)

We have repeatedly made clear that the good cause exception "is to be narrowly construed and only reluctantly countenanced." *Util. Solid Waste Activities Grp.* , **236 F.3d at 754** ; *Tenn. Gas Pipeline Co. v. FERC* , **969 F.2d 1141** , **1144** (D.C.Cir.1992); *New Jersey v. EPA* **626 F.2d 1038** , **1045** (D.C.Cir.1980); *see also Jifry* , **370 F.3d at 1179** ("The exception

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excuses notice and comment in emergency situations, or where delay could result in serious harm."); *Am. Fed. of Gov't Emps. v. Block* , **655 F.2d 1153** , **1156** (D.C.Cir.1981) ("As the legislative history of the APA makes clear, moreover, the exceptions at issue here are not `escape clauses' that may be arbitrarily utilized at the agency's whim. Rather, use of these exceptions by administrative agencies should be limited to emergency situations. . . .").
...

..

EPA claims the harm to Navistar and the resulting up- and down-stream impacts should still be enough under our precedents. The only case on which it relies, however, is one in which an entire industry and its customers were imperiled. *See* <*Page 94> *Am. Fed. of Gov't Emps.* , **655 F.2d at 1157** . Navistar's plight is not even remotely close to such a weighty, systemic interest, especially since it is a consequence brought about by Navistar's own choice to continue to pursue a technology which, so far, is noncompliant. At bottom, EPA's approach would give agencies "good cause" under the APA every time a manufacturer in a regulated field felt a new regulation imposed some degree of economic hardship, even if the company could have avoided that hardship had it made different business choices. This is both nonsensical and in direct tension with our longstanding position that the exception should be "narrowly construed and only reluctantly countenanced." *Util. Solid Waste Activities Grp.* , **236 F.3d at 754** .
...

15 Cited — New Jersey, Dep't of Envtl. Prot. v. EPA, 626 F.2d 1038, 200 U.S. App. D.C. 174, 15 ERC 2238 (D.C. Cir. 1980)

We have repeatedly made clear that the good cause exception "is to be narrowly construed and only reluctantly countenanced." *Util. Solid Waste Activities Grp.* , **236 F.3d at 754** ; *Tenn. Gas Pipeline Co. v. FERC* , **969 F.2d 1141** , **1144** (D.C.Cir.1992); *New Jersey v. EPA* **626 F.2d 1038** , **1045** (D.C.Cir.1980); *see also Jifry* , **370 F.3d at 1179** ("The exception excuses notice and comment in emergency situations, or where delay could result in serious harm."); *Am. Fed. of Gov't Emps. v. Block* , **655 F.2d 1153** , **1156** (D.C.Cir.1981) ("As the legislative history of the APA makes clear, moreover, the exceptions at issue here are not `escape clauses' that may be arbitrarily utilized at the agency's whim. Rather, use of these exceptions by administrative agencies should be limited to emergency situations. . . .").
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16 Cited — Motor & Equip. Mfrs. Ass'n v. EPA, 627 F.2d 1095, 201 U.S. App. D.C. 109, 13 ERC 1737 (D.C. Cir. 1979)

Subsection (g)(2), the very next paragraph, says that "no [NCP] may be issued under paragraph (1) . . . if the degree by which the manufacturer fails to meet any standard . . . exceeds the percentage determined under regulations promulgated by the Administrator to be practicable. *Such regulations* . . . shall be promulgated not later than one year after August 7, 1977." **42 U.S.C. § 7525 (g)(2)** (emphasis added). The regulations to which subsection (g)(2) refers are clearly the regulations promulgated under subsection **(g)(1)** . Subsection **(g)(2)** explains they are of a guiding nature and, importantly, that they must be issued by certain a date in 1977. This language cannot possibly be read to describe each and every NCP. Petitioners' interpretation of subsection **(g)(1)** , suggesting that it does refer to every NCP, would render subsection **(g)(2)** not just superfluous, but impossible — a result we must avoid. *Motor & Equip. Mfrs. Ass'n, Inc. v. EPA* , **627 F.2d 1095** , **1108** (D.C.Cir.1979). Subsection **(g)(3)** makes the flaw in Petitioners' interpretation even clearer: "The regulations promulgated under paragraph (1) shall, not later than one year after August 7, 1977, provide for nonconformance penalties in amounts determined under a formula established by the Administrator." **42 U.S.C. § 7525** (g)(3). Once again, this provision and its deadline reveal that subsection **(g)(1)** refers to a one-time promulgation of a formula that governs future penalty applications. Reading **Section 206(g)** as a whole, it is clear nothing in that provision requires EPA to provide notice and comment every time it applies the original formula to the establishment of specific penalties.

...

17 Cited , (See) — SEC v. Chenery Corp., 332 U.S. 194, 67 S. Ct. 1575, 91 L. Ed. 1995 (1947)

Finally, an agency may invoke the good cause exception if providing notice and comment would be contrary to the public interest. **5 U.S.C. § 553** (b)(3)(B). In the IFR, EPA says it has good cause since "there is no risk to the public interest in allowing manufacturers to [use] NCPs before the point at which EPA could make them available through a full notice-and-comment <*Page 95> rulemaking," **77 Fed.Reg. at 4,680** , but this misstates the statutory criterion. The question is not whether *dispensing* with notice and comment would be contrary to the public interest, but whether *providing* notice and comment would be contrary to the public interest. By improperly framing the question in this way, the IFR inverts the — presumption, apparently suggesting that notice and comment is usually unnecessary. We cannot permit this subtle malformation of the APA. The public interest prong of the good cause exception is met only in the rare

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circumstance when ordinary procedures — generally presumed to serve the public interest — would in fact harm that interest. It is appropriately invoked when the timing and disclosure requirements of the usual procedures would defeat the purpose of the proposal — if, for example, "announcement of a proposed rule would enable the sort of financial manipulation the rule sought to prevent." *Util. Solid Waste Activities Grp.* , **236 F.3d at 755** . In such a circumstance, notice and comment could be dispensed with "in order to prevent the amended rule from being evaded." ***Id*** . In its brief, EPA belatedly frames the inquiry correctly, but goes on to offer nothing more than a recapitulation of the harm to Navistar and the associated "ripple effects." Resp't Br. at 38. To the extent this is an argument not preserved by EPA in the IFR, we cannot consider it, *see SEC v. Chenery Corp.* , **332 U.S. 194** , **196** , **67 S.Ct. 1575** , **91 L.Ed. 1995** (1947), but regardless, it is nothing more than a reincar-nation of the impracticability argument we have already rejected.

...

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United States Court of Appeals for the District of Columbia Circuit

Mobil Oil Corporation, et al., Petitioners
v.
U.S. Environmental Protection Agency, Respondent.
American Iron and Steel Institute, et al., Intervenors.
And Consolidated Cases.

Nos. 92-1211, 92-1229, 92-1230, 92-1233, 92-1234 and 92-1237.

Argued March 7, 1994.

Decided September 23, 1994.
Petitions for Review of an Order of the Environmental Protection Agency.
Michael W. Steinberg and Donald J. Patterson (for American Min. Congress), Washington, DC, argued the cause for consolidated petitioners and intervenors. With them on the briefs were Edward M. Green, Roderick T. Dwyer, and Nancy D. Tammi (for American Min. Congress), Karl S. Bourdeau and Barton C. Green (for American Iron and Steel Institute), Ralph J. Colleli, Jr., G. William **[**263]** Frick, and Hunter Prillaman (for American Petroleum Institute), David F. Zoll, Washington, DC, and Ronald A. Shipley, Germantown, MD (for Chemical Mfrs. Ass'n), Douglas H. Green and William R. Weissman (for Edison Elec. Institute), James K. Jackson (for Mobil Oil Corp.), Richard A. Flye (for The Fertilizer Institute), and Paul E. Gutermann and John N. Moore, Washington, DC (for Zinc Corp. of America and Horsehead Resource Development Co.).

Thomas S. Llewellyn (for Mobil Oil Corp.), Gordon D. Quin, Whippany, NJ (for The Fertilizer Institute), John N. Hanson (for American Min. Congress), and Norman L. Rave, Jr., Washington, DC (for Edison Electric Institute), Washington, DC, entered appearances.

Mary Elizabeth Ward and Scott A. Schachter, Attys., U.S. Dept. of Justice, Washington, DC, argued the cause for respondents. With them on the brief was Lois J. Schiffer, Acting Asst. Atty. Gen., Washington, DC. Barry M. Hartman and Caroline H. Wehling, Counsel, U.S. Environmental Protection Agency ("EPA"), and Raymond Ludwiszewski, Acting Gen. Counsel, EPA, Washington, DC, entered appearances for respondent.

Eli D. Eilbott and David R. Case, Washington, DC, were on the brief for intervenor Hazardous Waste Treatment Council.

Before EDWARDS, BUCKLEY, and RANDOLPH, Circuit Judges. Opinion for the court filed by Circuit Judge BUCKLEY.

[*580] BUCKLEY, Circuit Judge:

Petitioners raise numerous challenges to the "mixture" and "derived-from" rules promulgated by the Environmental Protection Agency under authority of Subtitle C of the Resource Conservation and Recovery Act of 1976 ("RCRA"), *42 U.S.C. §§ 6901-6992k* (1988 & Supp. IV 1992). We do not address these challenges, however, because we conclude that subsequent congressional action has rendered the dispute moot. Petitioners American Mining Congress and The Fertilizer Institute also challenge the so-called "Bevill mixture rule," promulgated under the same authority, which we vacate in part.

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I. Background

RCRA provides a comprehensive scheme for handling solid wastes. As part of this regime, Subchapter III, *42 U.S.C. §§ 6921-6939b* (1988 & Supp. IV 1992) ("Subtitle C"), subjects hazardous wastes to stringent cradle-to-grave regulation. The statute defines "hazardous waste" as

> a solid waste, or combination of solid wastes, which because of its quantity, concentration, or physical, chemical, or infectious characteristics may--
>
> (A) cause, or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness; or
>
> (B) pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed.

42 U.S.C. § 6903(5) (1988). Subtitle C also established a two-step process for the identification of hazardous wastes: The EPA would first promulgate criteria for identifying the "characteristics" of hazardous waste, "taking into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue, and other related factors such as flammability, corrosiveness, and other hazardous characteristics." *Id. § 6921(a)* (1988). Then, on the basis of those criteria, the EPA would "promulgate regulations identifying the characteristics of hazardous waste, and listing particular hazardous wastes (within the meaning of *section 6903(5)* of this title), which shall be subject to the provisions of [Subtitle C]." *Id. § 6921(b)(1)*.

Pursuant to this mandate, the EPA issued proposed rules in 1978. 43 Fed.Reg. 58,946 (1978). In that proposal, the EPA stated that it would identify hazardous wastes on the basis of the following characteristics: ignitability, corrosivity, reactivity and toxicity. *43 Fed.Reg. at 58*,950, 58,955-57. Wastes displaying any of these characteristics were to be listed, as were wastes that independently satisfied the statutory definition of **[**264] [*581]** "hazardous waste" contained in 42 U.S.C. § 6903(5). *43 Fed.Reg. at 58*,955, col. 2. A listed waste would remain subject to Subtitle C regulation until it was certified to the EPA that the waste was "non-hazardous according to the results of each characteristic or property tested." *43 Fed.Reg. at 58*,953, col. 3.

The EPA issued its final rule on May 19, 1980, in which it published a list of some 400 hazardous wastes. 45 Fed.Reg. 33,084, 33,122-27 (1980). The final rule also promulgated the "mixture" and "derived-from" rules. The mixture rule provided that a solid waste would be treated as hazardous if "[i]t is a mixture of solid waste and one or more [listed] hazardous wastes...." *Id. at 33*,119, col. 3. The derived-from rule provided that

> [a]ny solid waste generated from the treatment, storage, or disposal of a hazardous waste, including any sludge, spill residue, ash, emission control dust or leachate (but not including precipitation run-off) is a hazardous waste.

45 Fed.Reg. at 33,120, col. 1. Thus a substance that was mixed with a listed hazardous waste or derived from a hazardous waste was to be regulated as a hazardous waste regardless of whether the mixture or derivative actually "[p]ose[d] a substantial present or potential hazard to human health or the environment...." 42 U.S.C. § 6903(5). Any mixture or derived-from waste, however, could escape Subtitle C regulation through a "delisting" process. *See 45 Fed.Reg. at 33*,116, col. 3 (waste may be delisted if demonstrated that it is non-hazardous "based on the results of specific tests for each of the hazardous properties for which the waste was listed").

The initial promulgation of the mixture and derived-from rules was challenged on both substantive and procedural grounds. On December 6, 1991, we vacated both rules because the EPA had "entirely failed to comply with [the Administrative Procedure Act's] notice-and-comment requirements...." *Shell Oil Co. v. EPA*, 950 F.2d 741, 752

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(D.C.Cir.1991). As we disposed of the case on procedural grounds, we did not determine whether the EPA had exceeded its authority under RCRA in issuing the rules.

On March 3, 1992, the EPA issued an "interim final rule," reinstating the vacated mixture and derived-from rules under authority of the APA's "good cause" exception, 5 U.S.C. § 553(b)(3)(B), which permits the issuance of a rule without notice and prior opportunity for comment on a finding that such are "impractical, unnecessary, or contrary to the public interest." 57 Fed.Reg. 7,628, 7,628-29 (1992). In doing so, the EPA sought to obtain "the time to sort through more fully the implications of alternative regulatory approaches and understand the scope and effect of current Subtitle C rules." *57 Fed.Reg. at 7*,630, col. 3. The EPA promised to publish options for modifying or replacing the rules by April 28, 1992; and it included a provision terminating the interim final rules on April 28, 1993 ("sunset provision"). *Id.*

The promised revisions were issued on May 20, 1992. These included a "Hazardous Waste Identification Rule" ("HWIR") that would effect "modifications to the RCRA regulatory framework which will address over-regulatory situations created by the 'mixture' and 'derived-from' rules." 57 Fed.Reg. 21,450, 21,452, col. 1 (1992). In the HWIR, the EPA conceded that the mixture and derived-from rules were overinclusive, resulting in a regime where "millions of tons of mixtures and derived-from residuals that must be managed as hazardous waste [under Subtitle C] because of their history (*i.e.*, what they were mixed with or derived-from) may actually pose quite low hazards." *Id. at 21*,451, col. 3.

Five months later, on October 6, 1992, Congress adopted an amendment to an EPA appropriations bill that reads as follows:

> EPA shall promulgate revisions to paragraphs (a)(2)(iv) [the mixture rule] and (c)(2)(i) [the derived-from rule] of 40 CFR 261.3, as reissued on March 3, 1992, by October 1, 1994, but any revision to such paragraphs shall not be promulgated or become effective prior to October 1, 1993. Notwithstanding paragraph (e) of 40 CFR 261.3 [the "sunset provision"], as reissued on March 3, 1992, paragraphs (a)(2)(iv) and (c)(2)(i) of such regulations shall not be terminated or withdrawn until revisions are promulgated and become effective in **[**265] [*582]** accordance with the preceding sentence. The deadline of October 1, 1994 shall be enforceable under *section 7002* of the Solid Waste Disposal Act.

Pub.L. No. 102-389, 106 Stat. 1571, 1602 (Oct. 6, 1992) ("Chafee Amendment"). The EPA contends that this amendment codifies the mixture and derived-from rules, mooting petitioners' challenges thereto.

Three weeks later, the EPA issued notices announcing its withdrawal of the HWIR proposal and rescission of the sunset provision. 57 Fed.Reg. 49,280, 49,280, col. 1 (1992) (withdrawing HWIR proposal); 57 Fed.Reg. 49,278, 49,278, col. 1 (withdrawing the sunset provision). In both notices, the EPA announced its intent to promulgate revisions to the mixture and derived-from rules within 12 to 24 months. *57 Fed.Reg. at 49*,278, col. 2; *57 Fed.Reg. at 49*,280, col. 3.

We are also asked to review the EPA's treatment of wastes consisting of a mixture of a "Bevill waste" and one or more hazardous wastes. Bevill wastes are derived from the extraction, beneficiation, and processing of ores and minerals and are exempted from Subtitle C regulation by virtue of the Bevill Amendment to RCRA, 42 U.S.C. § 6921(b)(3)(A)(ii) (1988). *See generally Horsehead Resource Dev. Co. v. Browner*, 16 F.3d 1246 (D.C.Cir.1994). In 1989, the EPA promulgated regulations determining which mineral processing wastes qualified as Bevill wastes. At the same time, the agency issued what petitioners refer to as the "Bevill mixture rule." The "Bevill mixture rule" had two distinct provisions that are relevant here. One provision described how mixtures of Bevill wastes and characteristic wastes were to be treated, while the other declared that mixtures of Bevill wastes and listed wastes were governed by the Subtitle C mixture rule. 54 Fed.Reg. 36,592, 36,622-23, 36,641 (1989). The Bevill mixture rule was contested in *Solite Corp. v. EPA*, 952 F.2d 473 (D.C.Cir.1991), where we concluded that, because the EPA had assumed the validity of the Subtitle C mixture rule in "extending [it] to the Bevill context," our decision in *Shell Oil* vacating and remanding the Subtitle C mixture rule required us to vacate and remand the Bevill mixture rule as well. Id. at 493-94. In the interim final rule, the EPA repromulgated the characteristic waste provision of the Bevill mixture rule as well as the Subtitle C

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mixture and derived-from rules. 57 Fed.Reg. 7,628-32. Petitioners American Mining Congress and The Fertilizer Institute ("Bevill petitioners") challenge that action.

II. Discussion

The EPA's regulations are to be upheld so long as they are not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A) (1988). Therefore, if an agency has acted within its authority and presents a rational basis for its actions, we must affirm. *See KCST-TV, Inc. v. FCC*, 699 F.2d 1185, 1191 (D.C.Cir.1983). Before investigating whether the EPA has met those standards, we must consider its mootness argument.

A. Challenge to the Subtitle C Mixture and Derived-from Rules

A "court is not empowered to decide moot questions or abstract propositions, or to declare, for the government of future cases, principles or rules of law which cannot affect the result as to the thing in issue in the case before it." *California v. San Pablo & Tulare R.R. Co.*, 149 U.S. 308, 314, 13 S.Ct. 876, 878, 37 L.Ed. 747 (1893). In enacting the Chafee Amendment, Congress mandated that "paragraphs (a)(2)(iv) [the mixture rule] and (c)(2)(i) [the derived-from rule] shall not be terminated or withdrawn until revisions are promulgated and become effective." Pub.L. No. 102-389, 106 Stat. at 1603. Thus, we must examine whether Congress has rendered the case moot by precluding us from granting petitioners the relief they seek--an order vacating the interim rules.

Petitioners argue that we may disregard the Chafee Amendment because it speaks only to the agency, not to the courts. The relevant language of the statute reads:

> EPA shall promulgate revisions to [the Subtitle C mixture and derived-from rules] as reissued on March 3, 1992, by October 1, 1994, but any revisions to such paragraphs shall not be promulgated or become **[**266] [*583]** effective prior to October 1, 1993. Notwithstanding [the "sunset provision"], as reissued on March 3, 1992, [the mixture and derived-from rules] *shall not be terminated or withdrawn* until revisions are promulgated and become effective in accordance with the preceding sentence.

106 Stat. at 1602-03 (emphasis added). The key phrase is "terminated or withdrawn." Petitioners contend that courts do not "terminate" or "withdraw" regulations, they only "review" and "vacate" them. Under this interpretation, the "terminated or withdrawn" phrase speaks only to the agency; and its sole effect is to override the sunset provision and require the EPA to promulgate revisions to the Subtitle C mixture and derived-from rules by October 1, 1994.

We believe that the Chafee Amendment does more than that. We read its language as binding us as well as the agency. By precluding termination of the regulations, Congress expressed a firm intent that the two rules remain in effect until October 1, 1994, when they will be replaced by new rules that the EPA is to issue by that date. That purpose would be frustrated if courts remained free to vacate the interim final rule before the new rules came into effect, thereby creating the regulatory gap the Chafee Amendment was enacted to prevent. *Cf. Robertson v. Seattle Audubon Soc'y*, ___ U.S. ___, ___, 112 S.Ct. 1407, 1414, 118 L.Ed.2d 73 (1992) (rejecting argument that Congress in an appropriations act spoke only to the agency: "A statutory directive binds *both* the executive officials who administer the statute *and* the judges who apply it in particular cases") (emphasis in original).

Because we are precluded from offering petitioners the relief they seek, their challenge to these rules is moot. *Nevada v. Watkins*, 943 F.2d 1080, 1083-87 (9th Cir.1991) (state challenge of Secretary of Energy's decision to examine the possibility of situating a nuclear waste repository at Yucca Mountain mooted by congressional action requiring the Secretary to conduct further investigations only at Yucca Mountain and eliminating his authority to consider other potential sites).

We turn, then, to the Bevill petitioners' challenges.

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B. Challenges to EPA Treatment of Mixtures of Bevill and Hazardous Wastes

The EPA addressed the problems arising out of the Bevill Amendment in a final rule issued on September 1, 1989. *54 Fed.Reg. at 36*,592. It dealt with Bevill/characteristic waste mixtures by revising the definition of hazardous waste in *section 261.3* of its regulations. As revised and subsequently reissued, the definition distinguishes between two kinds of Bevill/characteristic waste mixtures. The first deals with a Bevill waste that is mixed with a waste that "exhibits any of the characteristics of hazardous waste." *Id. § 261.3(a)*(2)(i). The resulting mixture will be subject to Subtitle C regulation

> if it exhibits a characteristic that would not have been exhibited by the excluded [e.g., Bevill] waste alone if such mixture had not occurred or if it continues to exhibit any of the characteristics exhibited by the non-excluded wastes prior to mixture.

40 C.F.R. § 261.3(a)(2)(i). The second deals with a Bevill waste that is mixed with a listed waste that is listed "solely because it exhibits one or more of the characteristics of hazardous waste." This mixture will be subject to Subtitle C regulation unless "the resultant mixture no longer exhibits any characteristic of hazardous waste ... for which the hazardous waste ... was listed." *Id. § 261.3(a)*(2)(iii). With regard to mixtures of Bevill and listed wastes, the EPA concluded that it would stand by the position it had taken in its April 17, 1989, notice of proposed rulemaking; namely, that they would be governed by the Subtitle C mixture rules. *54 Fed.Reg. at 36*,623.

These provisions, which deal, respectively, with Bevil/characteristic waste and Bevill/listed waste mixtures, together constitute the "Bevill mixture rule" that we vacated in *Solite*, 952 F.2d at 493-94, and that the EPA reissued in the interim final rule. The Bevill petitioners object to its reissuance on both procedural and substantive grounds.

In *Solite*, we vacated the Bevill mixture rule on the ground that it assumed the validity of the Subtitle C mixture rule, which we **[**267] [*584]** had vacated in *Shell Oil*. In doing so, we stated that

> [i]f the EPA desires to and successfully does repromulgate the Subtitle C rule, it will similarly be able to repromulgate the Bevill rule, and attempt to justify the latter by reference to the former. Alternatively, the Agency may wish to justify the Bevill rule on independent grounds.

Solite, 952 F.2d at 493-94. In its interim final rule, the agency justified its reinstatement of the Bevill mixture rule as follows:

> The [*Solite*] court's opinion did not explicitly address the status of EPA's rule change regarding the application of the hazardous waste characteristics to mixtures of Bevill-exempt wastes. The court in *Shell Oil* vacated the "mixture rule" of 40 CFR § 261.3(a)(2)(iv), which addresses mixtures of listed wastes and other solid wastes. Thus, to the extent that the *Solite* court addressed mixtures involving listed and Bevill wastes, today's actions will reinstate the affected rules. *However, since the* Shell Oil *court did not address mixtures of characteristic and Bevill wastes, that part of the decision by the* Solite *court appears to be in error*.

57 Fed.Reg. at 7,631 (emphasis added).

The Bevill petitioners contest what they describe as the "summary repromulgation" of the Bevill mixture rule on two procedural grounds: First, they assert that the rule was issued without the prior notice and opportunity for comment and without the reasoned explanation required by the Administrative Procedure Act ("APA"), 5 U.S.C. § 553(b) & (c); and second, they maintain that the EPA did not demonstrate that it had good cause to dispense with prior notice and comment, as required by 5 U.S.C. § 553(b)(3)(B). We consider this argument as it applies to each provision of the Bevill mixture rule.

1. *The Bevill/Characteristic Waste Provision*

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The Bevill petitioners acknowledge that the EPA had provided notice and secured comment before the initial issuance of the Bevill/characteristic waste provision in 1989. They assert, nevertheless, that intervening events required a fresh opportunity for comment. The EPA responds, in its brief, that it was not required to reopen notice and comment proceedings because the comments received in response to its April 17, 1989, notice of proposed rulemaking remain fresh and relevant enough to satisfy the requirements of the APA. The agency maintains, further, that because it had fully explained its reasons for promulgating this provision at the time of its original issuance, there was no need for it to reiterate them in the interim final rule.

We agree with petitioners that the EPA's repromulgation of the Bevill/characteristic waste provision was procedurally flawed. In *Action on Smoking and Health v. CAB*, 699 F.2d 1209 (D.C.Cir.1983), we vacated a Civil Aeronautics Board regulation that rescinded three earlier rules because the agency had failed to provide an adequate statement of its action's "basis and purpose," as required by the APA. Id. at 1217-19. When the CAB repromulgated the regulation without satisfying APA rulemaking requirements, we again vacated the rule. *Action on Smoking and Health v. CAB*, 713 F.2d 795 (D.C.Cir.1983) (*"ASH"*). In doing so, we reminded the agency that "[t]o 'vacate,' ... means to 'annul; to cancel or rescind; to declare, to make, or to render, void; to defeat; ... to set aside,'" id. at 797, and that if it wished to rescind the three earlier rules, it would have to do so through a new rulemaking. Id. at 798. In *Solite*, we vacated the original Bevill mixture rule. Accordingly, to repromulgate the rule, the EPA must comply with the applicable provisions of the APA.

This does not necessarily require the EPA to "start from scratch" and initiate new notice and comment proceedings. Id. at 800. The APA's good cause exception may be invoked on a finding "that notice and public procedure thereon are ... unnecessary." 5 U.S.C. § 553(b)(3)(B) (1988). If the original record is still fresh, a new round of notice and comment might be unnecessary. Such a finding, however, must be made by the agency and supported in the record; it is not self-evident. "Although the Administrative Procedure Act does not establish a 'useful life' for a notice and comment record, clearly the life of such a record is not infinite." *ASH*, 713 F.2d at 800 **[**268]** . **[*585]** New information relevant to the agency's decisionmaking might well have come to light after the original notice and comment proceedings and before the repromulgation of the rule. Because the EPA neither initiated a new rulemaking nor invoked the APA's good cause exception in the record, we again vacate the Bevill/characteristic waste provision of the Bevill mixture rule and do not reach petitioners' substantive objections to the provision.

2. *Bevill/Listed Wastes Provision*

The EPA maintains that the Bevill/listed wastes provision, which applies the Subtitle C mixture rule to mixtures of Bevill and listed wastes, is nothing more than an interpretation of that rule and is therefore exempt from the APA's requirements. We agree that in construing the mixture rule to encompass such wastes, the EPA did not "create law"; rather, it made a "statement[ ] as to what [it] thinks the ... regulation means." *Gibson Wine Co., Inc. v. Snyder*, 194 F.2d 329, 331 (D.C.Cir.1952); *Cabais v. Egger*, 690 F.2d 234, 238 (D.C.Cir.1982) (same). Such interpretations are not subject to the APA's notice and hearing requirements. 5 U.S.C. § 553(b)(3)(A). Because the interpretation preceded the adoption of the Chafee Amendment, it was effectively enacted into law as part of the Subtitle C mixture rule. *See Public Citizen, Inc. v. FAA*, 988 F.2d 186, 194 (D.C.Cir.1993) ("Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it reenacts a statute without change."). Therefore, the Bevill petitioners' challenge to this provision of the Bevill mixture rule is moot for the same reason as is their challenge to the Subtitle C mixture and derived-from rules.

III. Conclusion

We hold that petitioners' challenges to the Subtitle C mixture and derived-from rules, including the EPA's interpretation of the former to apply to mixtures of Bevill and listed wastes, are moot because the Chafee Amendment has enacted those rules as so interpreted into law. We vacate the provision of the Bevill mixture rule concerning Bevill/characteristic waste mixtures because the provision was reissued without compliance with the rulemaking

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requirements of the APA.

So ordered.

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California v. San Pablo & Tulare R.R. Co., 149 U.S. 308, 314, 13 S.Ct. 876, 878, 37 L.Ed. 747 (1893)
Robertson v. Seattle Audubon Soc'y, ___ U.S. ___, ___, 112 S.Ct. 1407, 1414, 118 L.Ed.2d 73 (1992)
Nevada v. Watkins, 943 F.2d 1080, 1083-87 (9th Cir.1991)
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Public Citizen, Inc. v. FAA, 988 F.2d 186, 194 (D.C.Cir.1993)

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Mobil Oil Corp. v. EPA, 35 F.3d 579, 308 U.S. App. D.C. 262, 39 ERC 1481 (D.C. Cir. 1994), Court Opinion

Table Of Authorities (12 cases)

Authorities Summary	
Positive	12
Distinguished	0
Caution	0
Superseded	0
Negative	0
Total	12

1 Cited , (See generally) — Horsehead Res. Dev. Co. v. Browner, 16 F.3d 1246, 305 U.S. App. D.C. 35, 38 ERC 1073 (D.C. Cir. 1994)

We are also asked to review the EPA's treatment of wastes consisting of a mixture of a "Bevill waste" and one or more hazardous wastes. Bevill wastes are derived from the extraction, beneficiation, and processing of ores and minerals and are exempted from Subtitle C regulation by virtue of the Bevill Amendment to RCRA, 42 U.S.C. § 6921(b)(3)(A)(ii) (1988). *See generally* *Horsehead Resource Dev. Co. v. Browner* , **16 F.3d 1246** (D.C.Cir.1994). In 1989, the EPA promulgated regulations determining which mineral processing wastes qualified as Bevill wastes. At the same time, the agency issued what petitioners refer to as the "Bevill mixture rule." The "Bevill mixture rule" had two distinct provisions that are relevant here. One provision described how mixtures of Bevill wastes and characteristic wastes were to be treated, while the other declared that mixtures of Bevill wastes and listed wastes were governed by the Subtitle C mixture rule. **54 Fed.Reg. 36** ,592, 36,622-23, 36,641 (1989). The Bevill mixture rule was contested in *Solite Corp. v. EPA* , **952 F.2d 473** (D.C.Cir.1991), where we concluded that, because the EPA had assumed the validity of the Subtitle C mixture rule in "extending [it] to the Bevill context," our decision in *Shell Oil* vacating and remanding the Subtitle C mixture rule required us to vacate and remand the Bevill mixture rule as well. **Id. at 493-94** . In the interim final rule, the EPA repromulgated the characteristic waste provision of the Bevill mixture rule as well as the Subtitle C mixture and derived-from rules. **57 Fed.Reg. 7** ,628-32. Petitioners American Mining Congress and The Fertilizer Institute ("Bevill petitioners") challenge that action.

...

2 Cited , (See) , Quoted — Pub. Citizen, Inc. v. FAA, 988 F.2d 186, 300 U.S. App. D.C. 238 (D.C. Cir. 1993)

The EPA maintains that the Bevill/listed wastes provision, which applies the Subtitle C mixture rule to mixtures of Bevill and listed wastes, is nothing more than an interpretation of that rule and is therefore exempt from the APA's requirements. We agree that in construing the mixture rule to encompass such wastes, the EPA did not "create law"; rather, it made a "statement[ ] as to what [it] thinks the ... regulation means." *Gibson Wine Co., Inc. v. Snyder* , **194 F.2d 329, 331** (D.C.Cir.1952); *Cabais v. Egger* , **690 F.2d**

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234, 238 (D.C.Cir.1982) (same). Such interpretations are not subject to the APA's notice and hearing requirements. 5 U.S.C. § 553(b)(3)(A) . Because the interpretation preceded the adoption of the Chafee Amendment, it was effectively enacted into law as part of the Subtitle C mixture rule. *See Public Citizen, Inc. v. FAA* , **988 F.2d 186, 194** (D.C.Cir.1993) ("Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it reenacts a statute without change."). Therefore, the Bevill petitioners' challenge to this provision of the Bevill mixture rule is moot for the same reason as is their challenge to the Subtitle C mixture and derived-from rules.

...

3 Cited , (Cf.) Robertson v. Seattle Audubon Society, 503 U.S. 429, 112 S. Ct. 1407, 118 L. Ed. 2d 73, 34 ERC 1313 (1992)

We believe that the Chafee Amendment does more than that. We read its language as binding us as well as the agency. By precluding termination of the regulations, Congress expressed a firm intent that the two rules remain in effect until October 1, 1994, when they will be replaced by new rules that the EPA is to issue by that date. That purpose would be frustrated if courts remained free to vacate the interim final rule before the new rules came into effect, thereby creating the regulatory gap the Chafee Amendment was enacted to prevent. *Cf. Robertson v. Seattle Audubon Soc'y* , **___ U.S. ___, ___** , **112 S.Ct. 1407, 1414** , **118 L.Ed.2d 73** (1992) (rejecting argument that Congress in an appropriations act spoke only to the agency: "A statutory directive binds *both* the executive officials who administer the statute *and* the judges who apply it in particular cases") (emphasis in original).

...

4 Discussed , Quoted Solite Corp. v. EPA, 952 F.2d 473, 293 U.S. App. D.C. 117, 34 ERC 1537 (D.C. Cir. 1991)

We are also asked to review the EPA's treatment of wastes consisting of a mixture of a "Bevill waste" and one or more hazardous wastes. Bevill wastes are derived from the extraction, beneficiation, and processing of ores and minerals and are exempted from Subtitle C regulation by virtue of the Bevill Amendment to RCRA, 42 U.S.C. § 6921(b)(3)(A)(ii) (1988). *See generally Horsehead Resource Dev. Co. v. Browner* , **16 F.3d 1246** (D.C.Cir.1994). In 1989, the EPA promulgated regulations determining which mineral processing wastes qualified as Bevill wastes. At the same time, the agency issued what petitioners refer to as the "Bevill mixture rule." The "Bevill mixture rule" had two distinct provisions that are relevant here. One provision described how mixtures of Bevill wastes and characteristic wastes

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were to be treated, while the other declared that mixtures of Bevill wastes and listed wastes were governed by the Subtitle C mixture rule. **54 Fed.Reg. 36** ,592, 36,622-23, 36,641 (1989). The Bevill mixture rule was contested in *Solite Corp. v. EPA* , **952 F.2d 473** (D.C.Cir.1991), where we concluded that, because the EPA had assumed the validity of the Subtitle C mixture rule in "extending [it] to the Bevill context," our decision in *Shell Oil* vacating and remanding the Subtitle C mixture rule required us to vacate and remand the Bevill mixture rule as well. **Id. at 493-94** . In the interim final rule, the EPA repromulgated the characteristic waste provision of the Bevill mixture rule as well as the Subtitle C mixture and derived-from rules. **57 Fed.Reg. 7** ,628-32. Petitioners American Mining Congress and The Fertilizer Institute ("Bevill petitioners") challenge that action.

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These provisions, which deal, respectively, with Bevil/characteristic waste and Bevill/listed waste mixtures, together constitute the "Bevill mixture rule" that we vacated in *Solite* , **952 F.2d at 493-94** , and that the EPA reissued in the interim final rule. The Bevill petitioners object to its reissuance on both procedural and substantive grounds.

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Solite , **952 F.2d at 493-94** . In its interim final rule, the agency justified its reinstatement of the Bevill mixture rule as follows:

...

5 Cited , Quoted — Shell Oil Co. v. EPA, 950 F.2d 741, 292 U.S. App. D.C. 332, 34 ERC 1049 (D.C. Cir. 1991)

The initial promulgation of the mixture and derived-from rules was challenged on both substantive and procedural grounds. On December 6, 1991, we vacated both rules because the EPA had "entirely failed to comply with [the Administrative Procedure Act's] notice-and-comment requirements...." *Shell Oil Co. v. EPA* , **950 F.2d 741, 752** (D.C.Cir.1991). As we disposed of the case on procedural grounds, we did not determine whether the EPA had exceeded its authority under RCRA in issuing the rules.

...

6 Discussed — Nevada v. Watkins, 943 F.2d 1080, 33 ERC 1947 (9th Cir. 1991)

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Because we are precluded from offering petitioners the relief they seek, their challenge to these rules is moot. *Nevada v. Watkins* , **943 F.2d 1080, 1083-87** (9th Cir.1991) (state challenge of Secretary of Energy's decision to examine the possibility of situating a nuclear waste repository at Yucca Mountain mooted by congressional action requiring the Secretary to conduct further investigations only at Yucca Mountain and eliminating his authority to consider other potential sites).

...

7 Cited , Quoted Action on Smoking & Health v. Civil Aeronautics Bd., 713 F.2d 795, 230 U.S. App. D.C. 1 (D.C. Cir. 1983)

We agree with petitioners that the EPA's repromulgation of the Bevill/ characteristic waste provision was procedurally flawed. In *Action on Smoking and Health v. CAB* , **699 F.2d 1209** (D.C.Cir.1983), we vacated a Civil Aeronautics Board regulation that rescinded three earlier rules because the agency had failed to provide an adequate statement of its action's "basis and purpose," as required by the APA. **Id. at 1217-19** . When the CAB repromulgated the regulation without satisfying APA rulemaking requirements, we again vacated the rule. *Action on Smoking and Health v. CAB* , **713 F.2d 795** (D.C.Cir.1983) (*"ASH"*). In doing so, we reminded the agency that "[t]o 'vacate,' ... means to 'annul; to cancel or rescind; to declare, to make, or to render, void; to defeat; ... to set aside,'" **id. at 797** , and that if it wished to rescind the three earlier rules, it would have to do so through a new rulemaking. **Id. at 798** . In *Solite* , we vacated the original Bevill mixture rule. Accordingly, to repromulgate the rule, the EPA must comply with the applicable provisions of the APA.

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This does not necessarily require the EPA to "start from scratch" and initiate new notice and comment proceedings. **Id. at 800** . The APA's good cause exception may be invoked on a finding "that notice and public procedure thereon are ... unnecessary." 5 U.S.C. § 553(b)(3)(B) (1988). If the original record is still fresh, a new round of notice and comment might be unnecessary. Such a finding, however, must be made by the agency and supported in the record; it is not self-evident. "Although the Administrative Procedure Act does not establish a 'useful life' for a notice and comment record, clearly the life of such a record is not infinite." *ASH* , **713 F.2d at 800** . (*585) New information relevant to the agency's decisionmaking might well have come to light after the original notice and comment proceedings and

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before the repromulgation of the rule. Because the EPA neither initiated a new rulemaking nor invoked the APA's good cause exception in the record, we again vacate the Bevill/characteristic waste provision of the Bevill mixture rule and do not reach petitioners' substantive objections to the provision.

...

8 Discussed — Action on Smoking & Health v. Civil Aeronautics Bd., 699 F.2d 1209, 226 U.S. App. D.C. 57 (D.C. Cir. 1983)

We agree with petitioners that the EPA's repromulgation of the Bevill/ characteristic waste provision was procedurally flawed. In *Action on Smoking and Health v. CAB* , **699 F.2d 1209** (D.C.Cir.1983), we vacated a Civil Aeronautics Board regulation that rescinded three earlier rules because the agency had failed to provide an adequate statement of its action's "basis and purpose," as required by the APA. **Id. at 1217-19** . When the CAB repromulgated the regulation without satisfying APA rulemaking requirements, we again vacated the rule. *Action on Smoking and Health v. CAB* , **713 F.2d 795** (D.C.Cir.1983) (*"ASH"*). In doing so, we reminded the agency that "[t]o 'vacate,' ... means to 'annul; to cancel or rescind; to declare, to make, or to render, void; to defeat; ... to set aside,'" **id. at 797** , and that if it wished to rescind the three earlier rules, it would have to do so through a new rulemaking. **Id. at 798** . In *Solite* , we vacated the original Bevill mixture rule. Accordingly, to repromulgate the rule, the EPA must comply with the applicable provisions of the APA.

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9 Cited , (See) — KCST-TV, Inc. v. FCC, 699 F.2d 1185, 226 U.S. App. D.C. 33, 53 R.R.2d 139 (D.C. Cir. 1983)

The EPA's regulations are to be upheld so long as they are not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A) (1988). Therefore, if an agency has acted within its authority and presents a rational basis for its actions, we must affirm. *See KCST-TV, Inc. v. FCC* , **699 F.2d 1185, 1191** (D.C.Cir.1983). Before investigating whether the EPA has met those standards, we must consider its mootness argument.

...

10 Discussed — Cabais v. Egger, 690 F.2d 234, 223 U.S. App. D.C. 121 (D.C. Cir. 1982)

The EPA maintains that the Bevill/listed wastes provision, which applies the Subtitle C mixture rule to mixtures of Bevill and listed wastes, is nothing more than an interpretation of that rule and is therefore exempt from the APA's

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requirements. We agree that in construing the mixture rule to encompass such wastes, the EPA did not "create law"; rather, it made a "statement[ ] as to what [it] thinks the ... regulation means." *Gibson Wine Co., Inc. v. Snyder* , **194 F.2d 329, 331** (D.C.Cir.1952); *Cabais v. Egger* , **690 F.2d 234, 238** (D.C.Cir.1982) (same). Such interpretations are not subject to the APA's notice and hearing requirements. 5 U.S.C. § 553(b)(3)(A) . Because the interpretation preceded the adoption of the Chafee Amendment, it was effectively enacted into law as part of the Subtitle C mixture rule. *See Public Citizen, Inc. v. FAA* , **988 F.2d 186, 194** (D.C.Cir.1993) ("Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it reenacts a statute without change."). Therefore, the Bevill petitioners' challenge to this provision of the Bevill mixture rule is moot for the same reason as is their challenge to the Subtitle C mixture and derived-from rules.

...

11 Cited , Quoted Gibson Wine Co. v. Snyder, 194 F.2d 329, 90 U.S. App. D.C. 135 (D.C. Cir. 1952)

The EPA maintains that the Bevill/listed wastes provision, which applies the Subtitle C mixture rule to mixtures of Bevill and listed wastes, is nothing more than an interpretation of that rule and is therefore exempt from the APA's requirements. We agree that in construing the mixture rule to encompass such wastes, the EPA did not "create law"; rather, it made a "statement[ ] as to what [it] thinks the ... regulation means." *Gibson Wine Co., Inc. v. Snyder* , **194 F.2d 329, 331** (D.C.Cir.1952); *Cabais v. Egger* , **690 F.2d 234, 238** (D.C.Cir.1982) (same). Such interpretations are not subject to the APA's notice and hearing requirements. 5 U.S.C. § 553(b)(3)(A) . Because the interpretation preceded the adoption of the Chafee Amendment, it was effectively enacted into law as part of the Subtitle C mixture rule. *See Public Citizen, Inc. v. FAA* , **988 F.2d 186, 194** (D.C.Cir.1993) ("Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it reenacts a statute without change."). Therefore, the Bevill petitioners' challenge to this provision of the Bevill mixture rule is moot for the same reason as is their challenge to the Subtitle C mixture and derived-from rules.

...

12 Cited , Quoted California v. San Pablo & Tulare R.R., 149 U.S. 308, 13 S. Ct. 876, 37 L. Ed. 747 (1893)

A "court is not empowered to decide moot questions or abstract propositions, or to declare, for the government of future cases, principles or rules of law which cannot affect the result as to the thing in issue in the case before it." *California v. San Pablo & Tulare R.R. Co.* , **149 U.S. 308, 314** , **13**

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S.Ct. 876, 878 , **37 L.Ed. 747** (1893). In enacting the Chafee Amendment, Congress mandated that "paragraphs (a)(2)(iv) [the mixture rule] and (c)(2)(i) [the derived-from rule] shall not be terminated or withdrawn until revisions are promulgated and become effective." Pub.L. No. 102-389, 106 Stat. at 1603. Thus, we must examine whether Congress has rendered the case moot by precluding us from granting petitioners the relief they seek--an order vacating the interim rules.

...

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Supreme Court of the United States

Motor Vehicle Manufacturers Association of the United States, Inc., et al.

v.

State Farm Mutual Automobile Insurance Co. et al.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 82-354.

Argued April 26, 1983

Decided June 24, 1983 **[***449] [**2859]**

*

The National Traffic and Motor Vehicle Safety Act of 1966 (Act) directs the Secretary of Transportation to issue motor vehicle safety standards that "shall be practicable, shall meet the need for motor vehicle safety, and shall be stated in objective terms." In issuing these standards, the Secretary is directed to consider "relevant available motor vehicle safety data," whether the proposed standard is "reasonable, practicable and appropriate" for the particular type of motor vehicle for which it is prescribed, and "the extent to which such standards will contribute to carrying out the purposes" of the Act. The Act authorizes judicial review, under the Administrative Procedure Act, of "all orders establishing, amending, or revoking" a motor **[**2860]** vehicle safety standard. The National Highway Traffic Safety Administration (NHTSA), to which the Secretary has delegated his authority to promulgate safety standards, rescinded the requirement of Modified Standard 208 that new motor vehicles produced after September 1982 be equipped with passive restraints (automatic seatbelts or airbags) to protect the safety of the occupants of the vehicle in the event of a collision. In explaining the rescission, NHTSA maintained that it was no longer able to find, as it had in 1977 when Modified Standard 208 was issued, that the automatic restraint requirement would produce significant safety benefits. In 1977, NHTSA had assumed that airbags would be installed in 60% of all new cars and automatic seatbelts in 40%. But by 1981 it became apparent that automobile manufacturers planned to install automatic seatbelts in approximately 99% of the new cars and that the overwhelming majority of such seatbelts could be easily detached and left that way permanently, thus precluding the realization of the lifesaving potential of airbags and requiring the same type of affirmative action that was the stumbling block **[*30]** to achieving high usage of manual belts. For this reason, NHTSA concluded that there was no longer a basis for reliably predicting that Modified Standard 208 would lead to any significant increased usage of restraints. Hence, in NHTSA's view, the automatic restraint requirement was no longer reasonable or practicable. Moreover, given the high expense of implementing such a requirement and the limited benefits arising therefrom, NHTSA feared that many consumers would regard Modified Standard 208 as an instance of ineffective regulation. On petitions for review of NHTSA's rescission of the passive restraint requirement, the Court of Appeals held that the rescission was arbitrary and capricious **[***450]** on the grounds that NHTSA's conclusion that it could not reliably predict an increase in belt usage under the Standard was an insufficient basis for the rescission, that NHTSA inadequately considered the possibility of requiring manufacturers to install nondetachable rather than detachable passive belts, and that the agency failed to give any consideration to requiring compliance with the Standard by the installation of airbags. The court found that congressional reaction to various versions of the Standard

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"raised doubts" that NHTSA's rescission "necessarily demonstrates an effort to fulfill its statutory mandate" and that therefore the agency was obligated to provide "increasingly clear and convincing reasons" for its action.

Held: NHTSA's rescission of the passive restraint requirement in Modified Standard 208 was arbitrary and capricious; the agency failed to present an adequate basis and explanation for rescinding the requirement and must either consider the matter further or adhere to or amend the Standard along lines which its analysis supports. Pp. 40-57.

(a) The rescission of an occupant crash protection standard is subject to the same standard of judicial review--the "arbitrary and capricious" standard--as is the promulgation of such a standard, and should not be judged by, as petitioner Motor Vehicle Manufacturers Association contends, the standard used to judge an agency's refusal to promulgate a rule in the first place. The Act expressly equates orders "revoking" and "establishing" safety standards. The Association's view would render meaningless Congress' authorization for judicial review of orders revoking safety standards. An agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance. While the scope of review under the "arbitrary and capricious" standard is narrow and a court is not to substitute its judgment for that of the agency, the agency nevertheless must examine the relevant data and articulate a satisfactory explanation for its action. In reviewing that explanation, a court must consider whether the decision was based on a **[*31]** consideration of the relevant factors and **[**2861]** whether there was a clear error of judgment. Pp. 40-44.

(b) The Court of Appeals correctly found that the "arbitrary and capricious" standard of judicial review applied to rescission of agency regulations, but erred in intensifying the scope of its review based upon its reading of legislative events. While an agency's interpretation of a statute may be confirmed or ratified by subsequent congressional failure to change that interpretation, here, even an unequivocal ratification of the passive restraint requirement would not connote approval or disapproval of NHTSA's later decision to rescind the requirement. That decision remains subject to the "arbitrary and capricious" standard. Pp. 44-46.

(c) The first reason for finding NHTSA's rescission of Modified Standard 208 was arbitrary and capricious is that it apparently gave no consideration to modifying the Standard to require that airbag technology be utilized. Even if NHTSA's conclusion that detachable automatic seatbelts will not attain anticipated safety benefits because so many individuals will detach the mechanism were acceptable in its entirety, standing alone it would not justify any more than an amendment of the Standard to disallow compliance by means of one technology which will not provide effective passenger protection. It does not cast doubt on the need for a passive restraint requirement or upon the efficacy of airbag technology. The airbag is more than a policy alternative to the passive restraint requirement; it is a technology alternative within the ambit of the existing standard. Pp. 46-51.

(d) NHTSA was too quick to dismiss the safety benefits of automatic seatbelts. Its explanation for rescission of the passive restraint requirement is not sufficient to enable this Court to conclude that the rescission was the product of **[***451]** reasoned decisionmaking. The agency took no account of the critical difference between detachable automatic seatbelts and current manual seatbelts, failed to articulate a basis for not requiring nondetachable belts, and thus failed to offer the rational connection between facts and judgment required to pass muster under the "arbitrary and capricious" standard. Pp. 51-57.

220 U. S. App. D. C. 170 , 680 F. 2d 206 , vacated and remanded.

WHITE, J., delivered the opinion of the Court, in which BRENNAN, MARSHALL, BLACKMUN, and STEVENS, JJ., joined, and in all but Parts V-B and VI of which BURGER, C. J., and POWELL, REHNQUIST, and O'CONNOR, JJ., joined. REHNQUIST, J., filed an opinion concurring in part and dissenting in part, in which BURGER, C. J., and POWELL and O'CONNOR, JJ., joined, post, p. 57.

[*32] Solicitor General Lee argued the cause for petitioners in No. 82-398. With him on the briefs were Assistant Attorney General McGrath, Deputy Solicitor General Geller, Edwin S. Kneedler, Robert E. Kopp, Michael F. Hertz, Frank Berndt, David W. Allen, Enid Rubenstein, and Eileen T. Leahy. Lloyd N. Cutler argued the cause for petitioners in No. 82-354. With him on the briefs were John H. Pickering, William R. Perlik, Andrew B. Weissman, William R. Richardson, Jr., Milton D. Andrews, Lance E. Tunick, William H. Crabtree, Edward P. Good, Henry R. Nolte, Jr., Otis

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M. Smith, Charles R. Sharp, and William L. Weber, Jr. Raymond M. Momboisse, Sam Kazman, and Ronald A. Zumbrun filed briefs for petitioners in No. 82-355.

James F. Fitzpatrick argued the cause for respondents in all cases. With him on the brief for respondents State Farm Mutual Automobile Insurance Co. et al. were Michael N. Sohn, John M. Quinn, and Merrick B. Garland. Robert Abrams, Attorney General of New York, Robert S. Hammer, Assistant Attorney General, Peter H. Schiff, Martin Minkowitz, and Milton L. Freedman filed a brief for respondent Superintendent of Insurance of the State of New York. Raymond J. Rasenberger, Lawrence C. Merthan, Jerry W. Cox, and Lowell R. Beck filed a brief for respondents National Association of Independent Insurers et al.†

JUSTICE WHITE delivered the opinion of the Court.

The development of the automobile gave Americans unprecedented freedom to travel, but exacted a high price for **[*33]** enhanced mobility. Since 1929, motor vehicles have been the leading cause of accidental deaths and injuries in the United States. In 1982, 46,300 Americans died in motor vehicle accidents and hundreds of thousands more were maimed and injured.1 While a consensus exists that the current loss of life on our highways is unacceptably high, improving safety does not admit to easy solution. In 1966, Congress decided that at least part of the answer lies in improving the design and safety features of the vehicle itself.2 But much of the technology for building safer cars was undeveloped or untested. Before changes in automobile design could be mandated, the effectiveness of these changes had to be studied, their costs examined, and public acceptance **[**2862]** considered. This task called for considerable expertise and Congress responded by enacting the National Traffic and Motor Vehicle Safety Act of 1966 (Act), 80 Stat. 718 , as amended, 15 U. S. C. § 1381 *et seq.* (1976 ed. and Supp. V). The Act, created for the purpose of "reduc[ing] traffic accidents and deaths and injuries to persons resulting from traffic accidents," 15 U. S. C. § 1381 , directs the Secretary of Transportation or his delegate to issue motor vehicle safety standards that "shall be practicable, shall meet the need for motor vehicle safety, and shall be stated in objective terms." 15 U. S. C. § 1392(a) (1976 ed., Supp. V). In issuing these standards, the Secretary is **[***452]** directed to consider "relevant available motor vehicle safety data," whether the proposed standard "is reasonable, practicable and appropriate" for the particular type of motor vehicle, and the "extent to which **[*34]** such standards will contribute to carrying out the purposes" of the Act. 15 U. S. C. §§ 1392(f)(1), (3), (4).3

The Act also authorizes judicial review under the provisions of the Administrative Procedure Act (APA), 5 U. S. C. § 706 , of all "orders establishing, amending, or revoking a Federal motor vehicle safety standard," 15 U. S. C. § 1392(b) . Under this authority, we review today whether NHTSA acted arbitrarily and capriciously in revoking the requirement in Motor Vehicle Safety Standard 208 that new motor vehicles produced after September 1982 be equipped with passive restraints to protect the safety of the occupants of the vehicle in the event of a collision. Briefly summarized, we hold that the agency failed to present an adequate basis and explanation for rescinding the passive restraint requirement and that the agency must either consider the matter further or adhere to or amend Standard 208 along lines which its analysis supports.

I

The regulation whose rescission is at issue bears a complex and convoluted history. Over the course of approximately 60 rulemaking notices, the requirement has been imposed, amended, rescinded, reimposed, and now rescinded again.

As originally issued by the Department of Transportation in 1967, Standard 208 simply required the installation of seatbelts in all automobiles. 32 Fed. Reg. 2415 . It soon became apparent that the level of seatbelt use was too low to reduce traffic injuries to an acceptable level. The Department therefore began consideration of "passive occupant restraint systems"--devices that do not depend for their effectiveness **[*35]** upon any action taken by the occupant except that necessary to operate the vehicle. Two types of automatic crash protection emerged: automatic seatbelts and airbags. The automatic seatbelt is a traditional safety belt, which when fastened to the interior of the door remains attached without impeding entry or exit from the vehicle, and deploys automatically without any action on the part of the passenger. The airbag is an inflatable device concealed in the dashboard and steering column. It automatically

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inflates when a sensor indicates that deceleration forces from an accident have exceeded a preset minimum, then rapidly deflates to dissipate those forces. The lifesaving potential of these devices was immediately recognized, and in 1977, after substantial on-the-road experience with both devices, it was estimated by NHTSA that passive restraints could prevent approximately 12,000 deaths and over 100,000 serious injuries annually. 42 Fed. Reg. 34298 **[***453]** .

In 1969, the Department formally proposed a standard requiring the installation of passive restraints, 34 Fed. Reg. 11148 , thereby commencing a lengthy series of proceedings. In 1970, the agency revised **[**2863]** Standard 208 to include passive protection requirements, 35 Fed. Reg. 16927, and in 1972, the agency amended the Standard to require full passive protection for all front seat occupants of vehicles manufactured after August 15, 1975. 37 Fed. Reg. 3911 . In the interim, vehicles built between August 1973 and August 1975 were to carry either passive restraints or lap and shoulder belts coupled with an "ignition interlock" that would prevent starting the vehicle if the belts were not connected.4 On review, the **[*36]** agency's decision to require passive restraints was found to be supported by "substantial evidence" and upheld. *Chrysler Corp. v. Department of Transportation*, 472 F. 2d 659 (CA6 1972).5

In preparing for the upcoming model year, most car makers chose the "ignition interlock" option, a decision which was highly unpopular, and led Congress to amend the Act to prohibit a motor vehicle safety standard from requiring or permitting compliance by means of an ignition interlock or a continuous buzzer designed to indicate that safety belts were not in use. Motor Vehicle and Schoolbus Safety Amendments of 1974, *Pub. L. 93-492, § 109* , 88 Stat. 1482 , 15 U. S. C. § 1410b(b) . The 1974 Amendments also provided that any safety standard that could be satisfied by a system other than seatbelts would have to be submitted to Congress where it could be vetoed by concurrent resolution of both Houses. 15 U. S. C. § 1410b(b)(2) .6

The effective date for mandatory passive restraint systems was extended for a year until August 31, 1976. 40 Fed. Reg. 16217 (1975); *id.*, at 33977. But in June 1976, Secretary of Transportation William T. Coleman, Jr., initiated a new rulemaking on the issue, 41 Fed. Reg. 24070 . After hearing testimony and reviewing written comments, Coleman extended the optional alternatives indefinitely and suspended the passive restraint requirement. Although he found passive **[*37]** restraints technologically and economically feasible, the Secretary based his decision on the expectation that there **[***454]** would be widespread public resistance to the new systems. He instead proposed a demonstration project involving up to 500,000 cars installed with passive restraints, in order to smooth the way for public acceptance of mandatory passive restraints at a later date. Department of Transportation, The Secretary's Decision Concerning Motor Vehicle Occupant Crash Protection (Dec. 6, 1976), App. 2068.

Coleman's successor as Secretary of Transportation disagreed. Within months of assuming office, Secretary Brock Adams decided that the demonstration project was unnecessary. He issued a new mandatory passive restraint regulation, known as Modified Standard 208. 42 Fed. Reg. 34289 (1977); 49 CFR § 571.208 (1978) . The Modified Standard mandated the phasing in of passive restraints beginning with large cars in model year 1982 and extending to all cars by model year 1984. The two principal systems that would satisfy the Standard were airbags and passive belts; the choice of which system to install was left to the manufacturers. In *Pacific Legal Foundation v. Department of Transportation*, 193 U. S. App. D. C. 184 , 593 F. 2d 1338 , cert. denied, 444 U. S. 830 (1979), **[**2864]** the Court of Appeals upheld Modified Standard 208 as a rational, nonarbitrary regulation consistent with the agency's mandate under the Act. The Standard also survived scrutiny by Congress, which did not exercise its authority under the legislative veto provision of the 1974 Amendments.7

Over the next several years, the automobile industry geared up to comply with Modified Standard 208. As late as July 1980, NHTSA reported: **[*38]**

> "On the road experience in thousands of vehicles equipped with air bags and automatic safety belts has confirmed agency estimates of the life-saving and injury-preventing benefits of such systems. When all cars are equipped with automatic crash protection systems, each year an estimated 9,000 more lives will be saved, and tens of thousands of serious injuries will be prevented." NHTSA, Automobile Occupant Crash Protection, Progress Report No. 3, p. 4; App. in No. 81-2220 (CADC), p. 1627 (hereinafter App.).

In February 1981, however, Secretary of Transportation Andrew Lewis reopened the rulemaking due to changed economic circumstances and, in particular, the difficulties of the automobile industry. 46 Fed. Reg. 12033 . Two months later, the agency ordered a one-year delay in the application of the Standard to large cars, extending the deadline to September 1982, *id.*, at 21172, and at the same time, proposed the possible rescission of the entire

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Standard. *Id.*, at 21205. After receiving written comments and holding public hearings, NHTSA issued a final rule (Notice 25) that rescinded the passive restraint requirement contained in Modified Standard 208. **[***455]**

II

In a statement explaining the rescission, NHTSA maintained that it was no longer able to find, as it had in 1977, that the automatic restraint requirement would produce significant safety benefits. Notice 25, *id.*, at 53419. This judgment reflected not a change of opinion on the effectiveness of the technology, but a change in plans by the automobile industry. In 1977, the agency had assumed that airbags would be installed in 60% of all new cars and automatic seatbelts in 40%. By 1981 it became apparent that automobile manufacturers planned to install the automatic seatbelts in approximately 99% of the new cars. For this reason, the lifesaving potential of airbags would not be realized. Moreover, it now appeared that the overwhelming majority of passive belts **[*39]** planned to be installed by manufacturers could be detached easily and left that way permanently. Passive belts, once detached, then required "the same type of affirmative action that is the stumbling block to obtaining high usage levels of manual belts." *Id.*, at 53421. For this reason, the agency concluded that there was no longer a basis for reliably predicting that the Standard would lead to any significant increased usage of restraints at all.

In view of the possibly minimal safety benefits, the automatic restraint requirement no longer was reasonable or practicable in the agency's view. The requirement would require approximately $1 billion to implement and the agency did not believe it would be reasonable to impose such substantial costs on manufacturers and consumers without more adequate assurance that sufficient safety benefits would accrue. In addition, NHTSA concluded that automatic restraints might have an adverse effect on the public's attitude toward safety. Given the high expense and limited benefits of detachable belts, NHTSA feared that many consumers would regard the Standard as an instance of ineffective regulation, adversely affecting the public's view of safety regulation and, in particular, "poisoning . . . popular sentiment toward **[**2865]** efforts to improve occupant restraint systems in the future." *Id.*, at 53424.

State Farm Mutual Automobile Insurance Co. and the National Association of Independent Insurers filed petitions for review of NHTSA's rescission of the passive restraint Standard. The United States Court of Appeals for the District of Columbia Circuit held that the agency's rescission of the passive restraint requirement was arbitrary and capricious. 220 U. S. App. D. C. 170 , 680 F. 2d 206 (1982). While observing that rescission is not unrelated to an agency's refusal to take action in the first instance, the court concluded that, in this case, NHTSA's discretion to rescind the passive restraint requirement had been restricted by various forms of congressional "reaction" to the passive restraint issue. It then **[*40]** proceeded to find that the rescission of Standard 208 was arbitrary and capricious for three reasons. First, the court found insufficient as a basis for rescission NHTSA's conclusion that it could not reliably predict an increase in belt usage under the Standard. The court held that there was insufficient evidence in the record to sustain NHTSA's position on this issue, and **[***456]** that, "only a well justified refusal to seek more evidence could render rescission non-arbitrary." *Id.*, at 196 , 680 F. 2d, at 232 . Second, a majority of the panel8 concluded that NHTSA inadequately considered the possibility of requiring manufacturers to install nondetachable rather than detachable passive belts. Third, the majority found that the agency acted arbitrarily and capriciously by failing to give any consideration whatever to requiring compliance with Modified Standard 208 by the installation of airbags.

The court allowed NHTSA 30 days in which to submit a schedule for "resolving the questions raised in th[e] opinion." *Id.*, at 206 , 680 F. 2d, at 242 . Subsequently, the agency filed a Notice of Proposed Supplemental Rulemaking setting forth a schedule for complying with the court's mandate. On August 4, 1982, the Court of Appeals issued an order staying the compliance date for the passive restraint requirement until September 1, 1983, and requested NHTSA to inform the court whether that compliance date was achievable. NHTSA informed the court on October 1, 1982, that based on representations by manufacturers, it did not appear that practicable compliance could be achieved before September 1985. On November 8, 1982, we granted certiorari, 459 U. S. 987 , and on November 18, the Court of Appeals entered an order recalling its mandate.

III

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Unlike the Court of Appeals, we do not find the appropriate scope of judicial review to be the "most troublesome **[*41]** question" in these cases. Both the Act and the 1974 Amendments concerning occupant crash protection standards indicate that motor vehicle safety standards are to be promulgated under the informal rulemaking procedures of the Administrative Procedure Act. 5 U. S. C. § 553 . The agency's action in promulgating such standards therefore may be set aside if found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U. S. C. § 706(2)(A) ; *Citizens to Preserve Overton Park v. Volpe*, 401 U. S. 402, 414 (1971); *Bowman Transportation, Inc. v. Arkansas-Best Freight System, Inc.*, 419 U. S. 281 (1974). We believe that the rescission or modification of an occupant-protection standard is subject to the same test. Section 103(b) of the Act, 15 U. S. C. § 1392(b) , states that the procedural and judicial review provisions of the Administrative Procedure Act "shall apply to all orders establishing, amending, or revoking a Federal motor vehicle safety standard," and suggests no difference in the scope of judicial review depending upon the nature of the agency's action. **[**2866]**

Petitioner Motor Vehicle Manufacturers Association (MVMA) disagrees, contending that the rescission of an agency rule should be judged by the same standard a court would use to judge an agency's refusal to promulgate a rule in the first place--a standard petitioner believes **[***457]** considerably narrower than the traditional arbitrary-and-capricious test. We reject this view. The Act expressly equates orders "revoking" and "establishing" safety standards; neither that Act nor the APA suggests that revocations are to be treated as refusals to promulgate standards. Petitioner's view would render meaningless Congress' authorization for judicial review of orders revoking safety rules. Moreover, the revocation of an extant regulation is substantially different than a failure to act. Revocation constitutes a reversal of the agency's former views as to the proper course. A "settled course of behavior embodies the agency's informed judgment that, by pursuing that course, it will carry out the policies **[*42]** committed to it by Congress. There is, then, at least a presumption that those policies will be carried out best if the settled rule is adhered to." *Atchison, T. & S. F. R. Co. v. Wichita Bd. of Trade*, 412 U. S. 800, 807-808 (1973). Accordingly, an agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance.

In so holding, we fully recognize that "[r]egulatory agencies do not establish rules of conduct to last forever," *American Trucking Assns., Inc. v. Atchison, T. & S. F. R. Co.*, 387 U. S. 397, 416 (1967), and that an agency must be given ample latitude to "adapt their rules and policies to the demands of changing circumstances." *Permian Basin Area Rate Cases*, 390 U. S. 747, 784 (1968). But the forces of change do not always or necessarily point in the direction of deregulation. In the abstract, there is no more reason to presume that changing circumstances require the rescission of prior action, instead of a revision in or even the extension of current regulation. If Congress established a presumption from which judicial review should start, that presumption--contrary to petitioners' views--is not *against* safety regulation, but *against* changes in current policy that are not justified by the rulemaking record. While the removal of a regulation may not entail the monetary expenditures and other costs of enacting a new standard, and, accordingly, it may be easier for an agency to justify a deregulatory action, the direction in which an agency chooses to move does not alter the standard of judicial review established by law.

The Department of Transportation accepts the applicability of the "arbitrary and capricious" standard. It argues that under this standard, a reviewing court may not set aside an agency rule that is rational, based on consideration of the relevant factors, and within the scope of the authority delegated to the agency by the statute. We do not disagree with **[*43]** this formulation.9 The scope of review **[***458]** under the "arbitrary and capricious" standard is narrow and a court is not to substitute its judgment for that of the agency. Nevertheless, the agency must examine the relevant data and articulate a satisfactory explanation for its action including a "rational connection between the facts found and the choice made." *Burlington Truck Lines, Inc. v. United States*, 371 U. S. 156, 168 (1962). In reviewing that explanation, we must "consider whether the decision was based on a consideration of the relevant **[**2867]** factors and whether there has been a clear error of judgment." *Bowman Transportation, Inc. v. Arkansas-Best Freight System, Inc.*, *supra*, at 285 ; *Citizens to Preserve Overton Park v. Volpe*, *supra*, at 416 . Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise. The reviewing court should not attempt itself to make up for such deficiencies; we may not supply a reasoned basis for the agency's action that the agency itself has not given. *SEC v. Chenery Corp.*, 332 U. S. 194, 196 (1947). We will, however, "uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." *Bowman Transportation, Inc. v. Arkansas-Best Freight System, Inc.*, *supra*, at 286 . See also *Camp v.*

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Pitts, 411 U. S. 138, 142-143 (1973) (*per curiam*). For purposes of these cases, it is also relevant that Congress required a record of the rulemaking proceedings to be compiled **[*44]** and submitted to a reviewing court, 15 U. S. C. § 1394 , and intended that agency findings under the Act would be supported by "substantial evidence on the record considered as a whole." S. Rep. No. 1301, 89th Cong., 2d Sess., 8 (1966); H. R. Rep. No. 1776, 89th Cong., 2d Sess., 21 (1966).

IV

The Court of Appeals correctly found that the arbitrary-and-capricious test applied to rescissions of prior agency regulations, but then erred in intensifying the scope of its review based upon its reading of legislative events. It held that congressional reaction to various versions of Standard 208 "raise[d] doubts" that NHTSA's rescission "necessarily demonstrates an effort to fulfill its statutory mandate," and therefore the agency was obligated to provide "increasingly clear and convincing reasons" for its action. 220 U. S. App. D. C., at 186, 193 , 680 F. 2d, at 222, 229 . Specifically, the Court of Appeals found significance in three legislative occurrences:

> "In 1974, Congress banned the ignition interlock but did not foreclose NHTSA's pursuit of a passive restraint standard. In 1977, Congress allowed the standard to take effect when neither of the concurrent resolutions needed for disapproval was passed. In 1980, a majority of each house indicated support for the concept of mandatory passive restraints and a majority of each house supported the unprecedented attempt to require **[***459]** some installation of airbags." *Id.*, at 192 , 680 F. 2d, at 228 .

From these legislative acts and nonacts the Court of Appeals derived a "congressional commitment to the concept of automatic crash protection devices for vehicle occupants." *Ibid.*

This path of analysis was misguided and the inferences it produced are questionable. It is noteworthy that in this Court respondent State Farm expressly agrees that the post-enactment legislative history of the Act does not heighten the **[*45]** standard of review of NHTSA's actions. Brief for Respondent State Farm Mutual Automobile Insurance Co. 13. State Farm's concession is well taken for this Court has never suggested that the *standard* of review is enlarged or diminished by subsequent congressional action. While an agency's interpretation of a statute may be confirmed or ratified by subsequent congressional failure to change that interpretation, Bob Jones University v. United States , 461 U. S. 574, 599-602 (1983); *Haig v. Agee*, 453 U. S. 280, 291-300 (1981), in the cases before us, even an unequivocal ratification--short of statutory **[**2868]** incorporation--of the passive restraint standard would not connote approval or disapproval of an agency's later decision to rescind the regulation. That decision remains subject to the arbitrary-and-capricious standard.

That we should not be so quick to infer a congressional mandate for passive restraints is confirmed by examining the postenactment legislative events cited by the Court of Appeals. Even were we inclined to rely on inchoate legislative action, the inferences to be drawn fail to suggest that NHTSA acted improperly in rescinding Standard 208. First, in 1974 a mandatory passive restraint standard was technically not in effect, see n. 6, *supra*; Congress had no reason to foreclose that course. Moreover, one can hardly infer support for a mandatory standard from Congress' decision to provide that such a regulation would be subject to disapproval by resolutions of disapproval in both Houses. Similarly, no mandate can be divined from the tabling of resolutions of disapproval which were introduced in 1977. The failure of Congress to exercise its veto might reflect legislative deference to the agency's expertise and does not indicate that Congress would disapprove of the agency's action in 1981. And even if Congress favored the Standard in 1977, it--like NHTSA--may well reach a different judgment, given changed circumstances four years later. Finally, the Court of Appeals read too much into floor action on the 1980 authorization bill, a bill which was not enacted into law. Other **[*46]** contemporaneous events could be read as showing equal congressional hostility to passive restraints.10

V

The ultimate question before us is whether NHTSA's rescission of **[***460]** the passive restraint requirement of Standard 208 was arbitrary and capricious. We conclude, as did the Court of Appeals, that it was. We also conclude,

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but for somewhat different reasons, that further consideration of the issue by the agency is therefore required. We deal separately with the rescission as it applies to airbags and as it applies to seatbelts.

A

The first and most obvious reason for finding the rescission arbitrary and capricious is that NHTSA apparently gave no consideration whatever to modifying the Standard to require that airbag technology be utilized. Standard 208 sought to achieve automatic crash protection by requiring automobile manufacturers to install either of two passive restraint devices: airbags or automatic seatbelts. There was no suggestion in the long rulemaking process that led to Standard 208 that if only one of these options were feasible, no passive restraint standard should be promulgated. Indeed, the agency's original proposed Standard contemplated the installation of inflatable restraints in all cars.11 Automatic belts **[*47]** were added as a means of complying with the Standard because they were believed to be as effective as airbags in achieving the goal of occupant crash protection. 36 Fed. Reg. 12859 (1971). At that time, the passive belt approved by the agency could not be detached.12 Only later, **[**2869]** at a manufacturer's behest, did the agency approve of the detachability feature--and only after assurances that the feature would not compromise the safety benefits of the restraint.13 Although it was then foreseen that 60% of the new cars would contain airbags and 40% would have automatic seatbelts, the ratio between the two was not significant as long as the passive belt would also assure greater passenger safety.

The agency has now determined that the detachable automatic belts will not attain anticipated safety benefits because so many individuals will detach the mechanism. Even if this conclusion were acceptable in its entirety, see *infra*, at 51-54, standing alone it would not justify any more than an amendment of Standard 208 to disallow compliance by means of the one technology which will not **[***461]** provide effective passenger protection. It does not cast doubt on the need for a passive restraint standard or upon the efficacy of airbag technology. In its most recent rulemaking, the agency again acknowledged the lifesaving potential of the airbag: **[*48]**

> "The agency has no basis at this time for changing its earlier conclusions in 1976 and 1977 that basic air bag technology is sound and has been sufficiently demonstrated to be effective in those vehicles in current use . . . ." NHTSA Final Regulatory Impact Analysis (RIA) XI-4 (Oct. 1981), App. 264.

Given the effectiveness ascribed to airbag technology by the agency, the mandate of the Act to achieve traffic safety would suggest that the logical response to the faults of detachable seatbelts would be to require the installation of airbags. At the very least this alternative way of achieving the objectives of the Act should have been addressed and adequate reasons given for its abandonment. But the agency not only did not require compliance through airbags, it also did not even consider the possibility in its 1981 rulemaking. Not one sentence of its rulemaking statement discusses the airbags-only option. Because, as the Court of Appeals stated, "NHTSA's . . . analysis of airbags was nonexistent," 220 U. S. App. D. C., at 200 , 680 F. 2d, at 236 , what we said in Burlington Truck Lines, Inc. v. United States , 371 U. S., at 167 , is apropos here:

> "There are no findings and no analysis here to justify the choice made, no indication of the basis on which the [agency] exercised its expert discretion.
>
> We are not prepared to and the Administrative Procedure Act will not permit us to accept such . . . practice. . . . Expert discretion is the lifeblood of the administrative process, but 'unless we make the requirements for administrative action strict and demanding, *expertise*, the strength of modern government, can become a monster which rules with no practical limits on its discretion.' New York v. United States , 342 U. S. 882, 884 (dissenting opinion)" (footnote omitted).

We have frequently reiterated that an agency must cogently explain why it has exercised its discretion in a given manner, **[*49]** *Atchison, T. & S. F. R. Co. v. Wichita Bd. of Trade*, 412 U. S., at 806 ; *FTC v. Sperry & Hutchinson Co.*, 405 U. S. 233, 249 (1972); *NLRB v. Metropolitan Life Ins. Co.*, 380 U. S. 438, 443 (1965); and we reaffirm this principle again today.

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The automobile industry has opted for the passive belt over the airbag, but surely it is not enough that the regulated industry has eschewed a given safety device. For nearly a decade, the automobile industry waged the regulatory equivalent **[**2870]** of war against the airbag14 and lost--the inflatable restraint was proved sufficiently effective. Now the automobile **[***462]** industry has decided to employ a seatbelt system which will not meet the safety objectives of Standard 208. This hardly constitutes cause to revoke the Standard itself. Indeed, the Act was necessary because the industry was not sufficiently responsive to safety concerns. The Act intended that safety standards not depend on current technology and could be "technology-forcing" in the sense of inducing the development of superior safety design. See *Chrysler Corp. v. Department of Transportation*, 472 F. 2d, at 672-673 . If, under the statute, the agency should not defer to the industry's failure to develop safer cars, which it surely should not do, a fortiori it may not revoke a safety standard which can be satisfied by current technology simply because the industry has opted for an ineffective seatbelt design.

Although the agency did not address the mandatory airbag option and the Court of Appeals noted that "airbags seem to have none of the problems that NHTSA identified in passive seatbelts," 220 U. S. App. D. C., at 201 , 680 F. 2d, at 237 , petitioners recite a number of difficulties that they **[*50]** believe would be posed by a mandatory airbag standard. These range from questions concerning the installation of airbags in small cars to that of adverse public reaction. But these are not the agency's reasons for rejecting a mandatory airbag standard. Not having discussed the possibility, the agency submitted no reasons at all. The short--and sufficient--answer to petitioners' submission is that the courts may not accept appellate counsel's *post hoc* rationalizations for agency action. *Burlington Truck Lines, Inc. v. United States*, 371 U. S., at 168 . It is well established that an agency's action must be upheld, if at all, on the basis articulated by the agency itself. *Ibid.* ; *SEC v. Chenery Corp.*, 332 U. S., at 196 ; *American Textile Mfrs. Institute, Inc. v. Donovan*, 452 U. S. 490, 539 (1981).15

Petitioners also invoke our decision in *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc.*, 435 U. S. 519 (1978), as though it were a talisman under which any agency decision is by definition unimpeachable. Specifically, it is submitted that to require an agency to consider an airbags-only alternative is, in essence, to dictate to the agency the procedures it is to follow. Petitioners both misread Vermont Yankee and misconstrue the nature of the remand that is in order. In Vermont Yankee , we held that a court may not impose additional procedural requirements upon an agency. We do not require today any specific procedures **[*51]** which NHTSA must follow. Nor do we broadly require an agency to consider **[***463]** all policy alternatives in reaching decision. It is true that rulemaking "cannot be found wanting simply because the agency failed to include every alternative device and **[**2871]** thought conceivable by the mind of man . . . regardless of how uncommon or unknown that alternative may have been . . . ." *Id.*, at 551 . But the airbag is more than a policy alternative to the passive restraint Standard; it is a technological alternative within the ambit of the existing Standard. We hold only that given the judgment made in 1977 that airbags are an effective and cost-beneficial lifesaving technology, the mandatory passive restraint rule may not be abandoned without any consideration whatsoever of an airbags-only requirement.

B

Although the issue is closer, we also find that the agency was too quick to dismiss the safety benefits of automatic seatbelts. NHTSA's critical finding was that, in light of the industry's plans to install readily detachable passive belts, it could not reliably predict "even a 5 percentage point increase as the minimum level of expected usage increase." 46 Fed. Reg. 53423 (1981). The Court of Appeals rejected this finding because there is "not one iota" of evidence that Modified Standard 208 will fail to increase nationwide seatbelt use by at least 13 percentage points, the level of increased usage necessary for the Standard to justify its cost. Given the lack of probative evidence, the court held that "only a well justified refusal to seek more evidence could render rescission non-arbitrary." 220 U. S. App. D. C., at 196 , 680 F. 2d, at 232 .

Petitioners object to this conclusion. In their view, "substantial uncertainty" that a regulation will accomplish its intended purpose is sufficient reason, without more, to rescind a regulation. We agree with petitioners that just as an agency reasonably may decline to issue a safety standard if it is uncertain about its efficacy, an agency may also revoke a **[*52]** standard on the basis of serious uncertainties if supported by the record and reasonably explained. Rescission of the passive restraint requirement would not be arbitrary and capricious simply because there was no evidence in direct support of the agency's conclusion. It is not infrequent that the available data do not settle a

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regulatory issue, and the agency must then exercise its judgment in moving from the facts and probabilities on the record to a policy conclusion. Recognizing that policymaking in a complex society must account for uncertainty, however, does not imply that it is sufficient for an agency to merely recite the terms "substantial uncertainty" as a justification for its actions. As previously noted, the agency must explain the evidence which is available, and must offer a "rational connection between the facts found and the choice made." *Burlington Truck Lines, Inc. v. United States*, *supra*, at 168 . Generally, one aspect of that explanation would be a justification for rescinding the regulation before engaging in a search for further evidence.

In these cases, the agency's explanation for rescission of the passive restraint requirement is *not* sufficient to enable us to conclude that the rescission was the product of reasoned decisionmaking. To reach **[***464]** this conclusion, we do not upset the agency's view of the facts, but we do appreciate the limitations of this record in supporting the agency's decision. We start with the accepted ground that if used, seatbelts unquestionably would save many thousands of lives and would prevent tens of thousands of crippling injuries. Unlike recent regulatory decisions we have reviewed, *Industrial Union Dept. v. American Petroleum Institute*, 448 U. S. 607 (1980); *American Textile Mfrs. Institute, Inc. v. Donovan*, 452 U. S. 490 (1981), the safety benefits of wearing seatbelts are not in doubt, and it is not challenged that were those benefits to accrue, the monetary costs of implementing the Standard would be easily justified. We move next to the fact that there is no direct evidence in support of the agency's finding that detachable automatic belts cannot be predicted **[*53]** to yield a substantial increase in **[**2872]** usage. The empirical evidence on the record, consisting of surveys of drivers of automobiles equipped with passive belts, reveals more than a doubling of the usage rate experienced with manual belts.16 Much of the agency's rulemaking statement--and much of the controversy in these cases--centers on the conclusions that should be drawn from these studies. The agency maintained that the doubling of seatbelt usage in these studies could not be extrapolated to an across-the-board mandatory standard because the passive seatbelts were guarded by ignition interlocks and purchasers of the tested cars are somewhat atypical.17 Respondents insist these studies demonstrate that Modified Standard 208 will substantially increase seatbelt usage. We believe that it is within the agency's discretion to pass upon the generalizability of these field studies. This is precisely the type of issue which rests within the expertise of NHTSA, and upon which a reviewing court must be most hesitant to intrude.

But accepting the agency's view of the field tests on passive restraints indicates only that there is no reliable real-world experience that usage rates will substantially increase. To be sure, NHTSA opines that "it cannot reliably predict even a 5 percentage point increase as the minimum level of **[*54]** expected increased usage." Notice 25, 46 Fed. Reg. 53423 (1981). But this and other statements that passive belts will not yield substantial increases in seatbelt usage apparently take no account of the critical difference between detachable automatic belts and current manual belts. A detached passive belt does require an affirmative act to reconnect it, but--unlike **[***465]** a manual seatbelt--the passive belt, once reattached, will continue to function automatically unless again disconnected. Thus, inertia--a factor which the agency's own studies have found significant in explaining the current low usage rates for seatbelts18--works in *favor* of, not *against*, use of the protective device. Since 20% to 50% of motorists currently wear seatbelts on some occasions,19 there would seem to be grounds to believe that seatbelt use by occasional users will be substantially increased by the detachable passive belts. Whether this is in fact the case is a matter for the agency to decide, but it must bring its expertise to bear on the question.

The agency is correct to look at the costs as well as the benefits of Standard 208. The agency's conclusion that the incremental costs of the requirements were no longer reasonable was predicated on its prediction that the safety benefits of the regulation **[**2873]** might be minimal. Specifically, the **[*55]** agency's fears that the public may resent paying more for the automatic belt systems is expressly dependent on the assumption that detachable automatic belts will not produce more than "negligible safety benefits." *Id.*, at 53424. When the agency reexamines its findings as to the likely increase in seatbelt usage, it must also reconsider its judgment of the reasonableness of the monetary and other costs associated with the Standard. In reaching its judgment, NHTSA should bear in mind that Congress intended safety to be the pre-eminent factor under the Act:

> "The Committee intends that safety shall be the overriding consideration in the issuance of standards under this bill. The Committee recognizes . . . that the Secretary will necessarily consider reasonableness of cost, feasibility and adequate leadtime." S. Rep. No. 1301, 89th Cong., 2d Sess., 6 (1966).
>
> "In establishing standards the Secretary must conform to the requirement that the standard be practicable. This would require consideration of all relevant factors, including technological ability to achieve the goal

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> of a particular standard as well as consideration of economic factors.
>
> "Motor vehicle safety is the paramount purpose of this bill and each standard must be related thereto." H. R. Rep. No. 1776, 89th Cong., 2d Sess., 16 (1966).

The agency also failed to articulate a basis for not requiring nondetachable belts under Standard 208. It is argued that the concern of the agency with the easy detachability **[***466]** of the currently favored design would be readily solved by a continuous passive belt, which allows the occupant to "spool out" the belt and create the necessary slack for easy extrication from the vehicle. The agency did not separately consider the continuous belt option, but treated it together with the ignition interlock device in a category it titled "Option of Adopting Use-Compelling Features." 46 Fed. Reg. 53424 (1981). **[*56]** The agency was concerned that use-compelling devices would "complicate the extrication of [an] occupant from his or her car." *Ibid.* "[T]o require that passive belts contain use-compelling features," the agency observed, "could be counterproductive [, given] . . . widespread, latent and irrational fear in many members of the public that they could be trapped by the seat belt after a crash." *Ibid.* In addition, based on the experience with the ignition interlock, the agency feared that use-compelling features might trigger adverse public reaction.

By failing to analyze the continuous seatbelts option in its own right, the agency has failed to offer the rational connection between facts and judgment required to pass muster under the arbitrary-and-capricious standard. We agree with the Court of Appeals that NHTSA did not suggest that the emergency release mechanisms used in nondetachable belts are any less effective for emergency egress than the buckle release system used in detachable belts. In 1978, when General Motors obtained the agency's approval to install a continuous passive belt, it assured the agency that nondetachable belts with spool releases were as safe as detachable belts with buckle releases. 43 Fed. Reg. 21912, 21913-21914 (1978). NHTSA was satisfied that this belt design assured easy extricability: "[t]he agency does not believe that the use of [such] release mechanisms will cause serious occupant egress problems . . . ." *Id.*, at 52493, 52494 . While the agency is entitled to change its view on the acceptability of continuous passive belts, it is obligated to explain its reasons for doing so.

The agency also failed to offer any explanation why a continuous passive belt would engender the same adverse public reaction as the ignition interlock, and, as the Court of Appeals concluded, "every indication in the record points the other way." 220 U. S. App. D. C., at 198 , 680 F. 2d, at 234 .20 **[*57]** We **[**2874]** see no basis for equating the two devices: the continous belt, unlike the ignition interlock, does not interfere with the operation of the vehicle. More importantly, it is the agency's responsibility, not this Court's, to explain its decision.

VI

"An agency's view of what is in the public interest may change, either with or without a change in circumstances. But an agency changing its course must supply a reasoned analysis . . . ." *Greater Boston Television Corp. v. FCC*, 143 U. S. App. D. C. 383, 394 , 444 F. 2d 841, 852 (1970) (footnote omitted), cert. denied, 403 U. S. 923 (1971). We do not accept all of the reasoning of **[***467]** the Court of Appeals but we do conclude that the agency has failed to supply the requisite "reasoned analysis" in this case. Accordingly, we vacate the judgment of the Court of Appeals and remand the cases to that court with directions to remand the matter to the NHTSA for further consideration consistent with this opinion.21

So ordered.

JUSTICE REHNQUIST, with whom THE CHIEF JUSTICE, JUSTICE POWELL, and JUSTICE O'CONNOR join, concurring in part and dissenting in part.

I join Parts I, II, III, IV, and V-A of the Court's opinion. In particular, I agree that, since the airbag and continuous **[*58]** spool automatic seatbelt were explicitly approved in the Standard the agency was rescinding, the agency should explain why it declined to leave those requirements intact. In this case, the agency gave no explanation at all. Of course, if the agency can provide a rational explanation, it may adhere to its decision to rescind the entire Standard.

I do not believe, however, that NHTSA's view of detachable automatic seatbelts was arbitrary and capricious. The agency adequately explained its decision to rescind the Standard insofar as it was satisfied by detachable belts.

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The statute that requires the Secretary of Transportation to issue motor vehicle safety standards also requires that "[e]ach such . . . standard shall be practicable [and] shall meet the need for motor vehicle safety." 15 U. S. C. § 1392(a) (1976 ed., Supp. V). The Court rejects the agency's explanation for its conclusion that there is substantial uncertainty whether requiring installation of detachable automatic belts would substantially increase seatbelt usage. The agency chose not to rely on a study showing a substantial increase in seatbelt usage in cars equipped with automatic seatbelts *and* an ignition interlock to prevent the car from being operated when the belts were not in place *and* which were voluntarily purchased with this equipment by consumers. See *ante*, at 53, n. 16. It is reasonable for the agency to decide that this study does not support any conclusion concerning the effect of automatic seatbelts that are installed in all cars whether the consumer wants them or not and are not linked to an ignition interlock system.

The Court rejects this explanation because "there would seem to be grounds to believe that seatbelt use by occasional users will be substantially increased by the detachable passive belts," *ante*, at 54, **[***468]** and the agency did not adequately explain its rejection of these grounds. It seems to me that the agency's explanation, while by **[**2875]** no means a model, is adequate. The agency acknowledged that there would probably be some increase in belt usage, but concluded that the increase would be small and not worth the cost of mandatory **[*59]** detachable automatic belts. 46 Fed. Reg. 53421-53423 (1981). The agency's obligation is to articulate a "'rational connection between the facts found and the choice made.'" *Ante*, at 42, 52, quoting *Burlington Truck Lines, Inc. v. United States*, 371 U. S. 156, 168 (1962). I believe it has met this standard.

The agency explicitly stated that it will increase its educational efforts in an attempt to promote public understanding, acceptance, and use of passenger restraint systems. 46 Fed. Reg. 53425 (1981). It also stated that it will "initiate efforts with automobile manufacturers to ensure that the public will have [automatic crash protection] technology available. If this does not succeed, the agency will consider regulatory action to assure that the last decade's enormous advances in crash protection technology will not be lost." *Id.*, at 53426 .

The agency's changed view of the standard seems to be related to the election of a new President of a different political party. It is readily apparent that the responsible members of one administration may consider public resistance and uncertainties to be more important than do their counterparts in a previous administration. A change in administration brought about by the people casting their votes is a perfectly reasonable basis for an executive agency's reappraisal of the costs and benefits of its programs and regulations. As long as the agency remains within the bounds established by Congress,* it is entitled to assess administrative records and evaluate priorities in light of the philosophy of the administration.

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fn * Together with No. 82-355, Consumer Alert et al. v. State Farm Mutual Automobile Insurance Co. et al.; and No. 82-398, United States Department of Transportation et al. v. State Farm Mutual Automobile Insurance Co. et al., also on certiorari to the same court.

fn † Briefs of amici curiae urging affirmance were filed by *Dennis J. Barbour* for the American College of Preventive Medicine et al.; by *Nathan Lewin* for the American Insurance Association; by *Philip R. Collins* and *Thomas C. McGrath, Jr.*, for the Automotive Occupant Protection Association; by *Alexandra K. Finucane* for the Epilepsy Foundation of America et al.; by *Katherine I. Hall* for the Center for Auto Safety et al.; by *Simon Lazarus III* for Mothers Against Drunk Drivers; and by *John H. Quinn, Jr.*, and *John Hardin Young* for the National Association of Insurance Commissioners.

fn 1 National Safety Council, 1982 Motor Vehicle Deaths By States (May 16, 1983).

fn 2 The Senate Committee on Commerce reported:

> "The promotion of motor vehicle safety through voluntary standards has largely failed. The unconditional imposition of mandatory standards at the earliest practicable date is the only course commensurate with the highway death and injury toll." S. Rep. No. 1301, 89th Cong., 2d Sess., 4 (1966).

fn 3 The Secretary's general authority to promulgate safety standards under the Act has been delegated to the

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Administrator of the National Highway Traffic Safety Administration (NHTSA). 49 CFR § 1.50(a) (1982) . This opinion will use the terms NHTSA and agency interchangeably when referring to the National Highway Traffic Safety Administration, the Department of Transportation, and the Secretary of Transportation.

fn 4 Early in the process, it was assumed that passive occupant protection meant the installation of inflatable airbag restraint systems. See 34 Fed. Reg. 11148 (1969). In 1971, however, the agency observed that "[s]ome belt-based concepts have been advanced that appear to be capable of meeting the complete passive protection options," leading it to add a new section to the proposed standard "[t]o deal expressly with passive belts." 36 Fed. Reg. 12859 .

fn 5 The court did hold that the testing procedures required of passive belts did not satisfy the Act's requirement that standards be "objective." 472 F. 2d, at 675 .

fn 6 Because such a passive restraint standard was not technically in effect at this time due to the Sixth Circuit's invalidation of the testing requirements, see n. 5, *supra*, the issue was not submitted to Congress until a passive restraint requirement was reimposed by Secretary Adams in 1977. To comply with the Amendments, NHTSA proposed new warning systems to replace the prohibited continuous buzzers. 39 Fed. Reg. 42692 (1974). More significantly, NHTSA was forced to rethink an earlier decision which contemplated use of the interlocks in tandem with detachable belts. See n. 13, *infra*.

fn 7 No action was taken by the full House of Representatives. The Senate Committee with jurisdiction over NHTSA affirmatively endorsed the Standard, *S. Rep. No. 95-481* (1977), and a resolution of disapproval was tabled by the Senate. 123 Cong. Rec. 33332 (1977).

fn 8 Judge Edwards did not join the majority's reasoning on these points.

fn 9 The Department of Transportation suggests that the arbitrary-and-capricious standard requires no more than the minimum rationality a statute must bear in order to withstand analysis under the Due Process Clause. We do not view as equivalent the presumption of constitutionality afforded legislation drafted by Congress and the presumption of regularity afforded an agency in fulfilling its statutory mandate.

fn 10 For example, an overwhelming majority of the Members of the House of Representatives voted in favor of a proposal to bar NHTSA from spending funds to administer an occupant restraint standard unless the standard permitted the purchaser of the vehicle to select manual rather than passive restraints. 125 Cong. Rec. 36926 (1979).

fn 11 While NHTSA's 1970 passive restraint requirement permitted compliance by means other than the airbag, 35 Fed. Reg. 16927 , "[t]his rule was a de facto air bag mandate since no other technologies were available to comply with the standard." Graham & Gorham, NHTSA and Passive Restraints: A Case of Arbitrary and Capricious Deregulation, 35 Ad. L. Rev. 193, 197 (1983). See n. 4, *supra*.

fn 12 Although the agency suggested that passive restraint systems contain an emergency release mechanism to allow easy extrication of passengers in the event of an accident, the agency cautioned that "[i]n the case of passive safety belts, it would be required that the release not cause belt separation, and that the system be self-restoring after operation of the release." 36 Fed. Reg. 12866 (1971).

fn *13 In April* 1974, NHTSA adopted the suggestion of an automobile manufacturer that emergency release of passive belts be accomplished by a conventional latch--provided the restraint system was guarded by an ignition interlock and warning buzzer to encourage reattachment of the passive belt. 39 Fed. Reg. 14593 . When the 1974 Amendments prohibited these devices, the agency simply eliminated the interlock and buzzer requirements, but continued to allow compliance by a detachable passive belt.

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fn 14 See, *e. g.*, Comments of Chrysler Corp., Docket No. 69-07, Notice 11 (Aug. 5, 1971) (App. 2491); Chrysler Corp. Memorandum on Proposed Alternative Changes to FMVSS 208, Docket No. 44, Notice 76-8 (1976) (App. 2241); General Motors Corp. Response to the Dept. of Transportation Proposal on Occupant Crash Protection, Docket No. 74-14, Notice 08 (May 27, 1977) (App. 1745). See also *Chrysler Corp. v. Department of Transportation*, 472 F. 2d 659 (CA6 1972).

fn 15 The Department of Transportation expresses concern that adoption of an airbags-only requirement would have required a new notice of proposed rulemaking. Even if this were so, and we need not decide the question, it would not constitute sufficient cause to rescind the passive restraint requirement. The Department also asserts that it was reasonable to withdraw the requirement as written to avoid forcing manufacturers to spend resources to comply with an ineffective safety initiative. We think that it would have been permissible for the agency to temporarily suspend the passive restraint requirement or to delay its implementation date while an airbag mandate was studied. But, as we explain in text, that option had to be considered before the passive restraint requirement could be revoked.

fn 16 Between 1975 and 1980, Volkswagen sold approximately 350,000 Rabbits equipped with detachable passive seatbelts that were guarded by an ignition interlock. General Motors sold 8,000 1978 and 1979 Chevettes with a similar system, but eliminated the ignition interlock on the 13,000 Chevettes sold in 1980. NHTSA found that belt usage in the Rabbits averaged 34% for manual belts and 84% for passive belts. RIA, at IV-52, App. 108. For the 1978-1979 Chevettes, NHTSA calculated 34% usage for manual belts and 72% for passive belts. On 1980 Chevettes, the agency found these figures to be 31% for manual belts and 70% for passive belts. *Ibid.*

fn 17 "NHTSA believes that the usage of automatic belts in Rabbits and Chevettes would have been substantially lower if the automatic belts in those cars were not equipped with a use-inducing device inhibiting detachment." Notice 25, 46 Fed. Reg. 53422 (1981).

fn 18 NHTSA commissioned a number of surveys of public attitudes in an effort to better understand why people were not using manual belts and to determine how they would react to passive restraints. The surveys reveal that while 20% to 40% of the public is opposed to wearing manual belts, the larger proportion of the population does not wear belts because they forgot or found manual belts inconvenient or bothersome. RIA, at IV-25, App. 81. In another survey, 38% of the surveyed group responded that they would welcome automatic belts, and 25% would "tolerate" them. See RIA, at IV-37, App. 93. NHTSA did not comment upon these attitude surveys in its explanation accompanying the rescission of the passive restraint requirement.

fn 19 Four surveys of manual belt usage were conducted for NHTSA between 1978 and 1980, leading the agency to report that 40% to 50% of the people use their belts at least some of the time. RIA, at IV-25, App. 81.

fn 20 The Court of Appeals noted previous agency statements distinguishing interlocks from passive restraints. 42 Fed. Reg. 34290 (1977); 36 Fed. Reg. 8296 (1971); RIA, at II-4, App. 30.

fn 21 Petitioners construe the Court of Appeals' order of August 4, 1982, as setting an implementation date for Standard 208, in violation of *Vermont Yankee* 's injunction against imposing such time constraints. *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc.*, 435 U. S. 519, 544-545 (1978). Respondents maintain that the Court of Appeals simply stayed the effective date of Standard 208, which, not having been validly rescinded, would have required mandatory passive restraints for new cars after September 1, 1982. We need not choose between these views because the agency had sufficient justification to suspend, although not to rescind, Standard 208, pending the further consideration required by the Court of Appeals, and now, by us.

fn * Of course, a new administration may not refuse to enforce laws of which it does not approve, or to ignore

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statutory standards in carrying out its regulatory functions. But in this case, as the Court correctly concludes, *ante*, at 44-46, Congress has not required the agency to require passive restraints.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS
7501 Wisconsin Ave Suite 1100W
Bethesda, MD 20814,

Plaintiff,

v.

ALEX M. AZAR II, Secretary of the United States Department of Health and Human Services, in his official capacity only
200 Independence Avenue, S.W.
Washington, DC 20201,

and

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue, S.W.
Washington, DC 20201,

Defendants.

Case No: 20-cv-3032

COMPLAINT FOR DECLARATORY, INJUNCTIVE, AND MANDAMUS RELIEF

Plaintiff, National Association of Community Health Centers ("NACHC"), as an association and authorized representative of its Federally Qualified Health Center ("FQHC") members, brings this action against Defendants Alex M. Azar II and the United States Department of Health and Human Services ("HHS"), and for its Complaint alleges:

NATURE OF ACTION

1. This is a civil action under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(1), to compel the promulgation of administrative dispute resolution ("ADR") regulations—to implement the only process available to Plaintiff and its members to adjudicate and remedy violations of Section 340B of the Public Health Service ("PHS") Act—as required by § 7102 of the Patient Protection and Affordable Care Act ("PPACA"), Pub. L. No. 111-148, 124 Stat. 821-827 (March 23, 2010).

2. Defendants are, and have since September 2010 been, in violation of the clear and nondiscretionary statutory command in PPACA § 7102(a) to promulgate regulations by a date certain. As a direct result, FQHCs across the country that participate in the 340B Drug Pricing Program ("340B Program" or "340B") as "covered entities" are suffering the very harm the statutorily mandated ADR process is designed to remedy—drug manufacturer overcharging.

3. The 340B Program requires drug manufacturers to provide discounts on covered outpatient drugs purchased by covered entities for those manufacturers to have their products covered by Medicare and Medicaid. Since 1996, consistent with HHS guidance, drug manufacturers, either directly or through wholesale distributors, have shipped FQHC-purchased covered outpatient drugs to FQHCs' "contract pharmacies"—pharmacies that dispense drugs to the FQHC's patients under a contractual relationship with the FQHC. These contract pharmacy arrangements are consistent with longstanding HHS guidance, as well as with the authorizing statute for the FQHC program, Section

330 of the PHS Act, *codified at* 42 U.S.C. § 254b *et seq*.

4. A handful of the nation's largest pharmaceutical companies recently announced that, with few exceptions, they would no longer allow covered entities (including FQHCs) to purchase their covered outpatient drugs at 340B Program discount prices when those drugs would be shipped to a covered entity's contract pharmacy.

5. The manufacturers' abrupt about-face, after decades of shipping FQHCs' purchases of 340B-priced drugs to their contract pharmacies—during a global pandemic and a recession—is not only callous, but also a clear violation of 340B statutory requirements and the binding pharmaceutical pricing agreements ("PPAs") manufacturers have with HHS. Both the 340B statute, codified at 42 U.S.C. § 256b, and the PPAs (which simply incorporate 340B statutory requirements) require that manufacturers "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).

6. Indeed, the documented refusal by these manufacturers to make their covered outpatient drugs available to covered entities at or below 340B ceiling prices when shipped to a contract pharmacy is an emulation of the examples of "knowing and intentional" overcharging given by HHS, by way of illustration, in its civil monetary penalty ("CMP") regulations, 42 CFR § 10.11(b).

7. Although HHS publicly and rightly criticized at least one drug manufacturer's unilateral pricing actions, it has to Plaintiff's knowledge stopped short of

any enforcement or corrective action.

8. HHS's lack of action occurs in a world in which, by failing to promulgate regulations as required by statute, it has tied the covered entities' hands and deprived them of their exclusive means to protect themselves—the mandated ADR process. Per *Astra USA v. Santa Clara County*, 563 U.S. 110, 121–22 (2011), the 340B statute provides an exclusive remedy, and Congress, through the PPACA, opted to strengthen and formalize HRSA's enforcement authority, to make the new adjudicative framework the proper remedy for covered entities complaints, and to render the agency's resolution of those complaints binding, subject to review under the APA.

9. Outside of 340B's exclusive remedial scheme, covered entities have no other—much less an adequate—remedy available to them to challenge the drug manufacturers' violation of the 340B statute or to remedy the significant harm these violations have caused and will continue to cause.

10. As a direct result of Defendants' unlawful inaction, FQHCs and their patients, who are typically among the most vulnerable and medically underserved, are being irreparably harmed. Those harms, which include threats to FQHCs' patients' health and safety, will continue absent either an immediate enforcement action by HHS, or an injunction compelling the immediate implementation of the FQHCs' remedy for manufacturer overcharging.

PARTIES

11. NACHC is a national, nonprofit corporation whose primary objective is to

further—through extensive education, training, and advocacy—the mission and purpose of FQHCs. FQHCs are community-based, patient-directed nonprofit organizations that play a vital role in our nation's health care safety net by providing primary and other health care and related services—including pharmaceutical services—to medically underserved populations throughout the nation and its territories, regardless of any individual patient's insurance status or ability to pay for such services.

12. To facilitate that role, FQHCs are afforded special status, reimbursement rights, and other privileges in various federal health care programs, including a recognition as 340B Program covered entities since the program's 1992 inception. Each FQHC is obligated by the PHS Act and its implementing regulations to reinvest any program income—*e.g.* revenue generated through 340B, Medicare, Medicaid, or private insurance reimbursement for services—in furtherance of its health care safety net mission.

13. The 340B Program is designed to reduce drug costs for certain classes of safety net providers enumerated in the 340B statute, including FQHCs, that care for medically underserved and vulnerable populations. Any savings, or "nongrant income," the 340B Program generates for FQHCs is derived directly from the statutorily-mandated and defined discount pricing scheme that, by placing a non-discretionary duty on manufacturers to offer discount drugs to covered entities, costs taxpayers nothing.

14. The failure or refusal of HHS to implement the ADR process, despite a statutory mandate to do so, is an issue of substantial significance and considerable

importance to FQHCs across the nation and its territories and to their over 30 million patients. The ADR process provides an exclusive remedy for covered entities overcharged by drug manufacturers for covered outpatient drugs in violation of the 340B statute. *Astra USA*, 563 U.S. at 121–22. Until that process is implemented, FQHCs are left with no remedy, and are entirely dependent on HHS's unilateral enforcement authority.

15. As an association, NACHC has standing to bring this action on behalf of its FQHC members because: they would otherwise have standing to sue in their own right; the ability of FQHCs to effectively participate in the 340B Program and to remedy instances of manufacturer overcharging is directly linked to NACHC's own existence, as a trade association of and for FQHCs; and, the individual participation of FQHCs as parties is unnecessary, as the relief sought—namely, declaratory and injunctive relief (not damages)—applies equally to all covered entity FQHCs.

16. NACHC's board of directors voted unanimously to authorize this action.

17. Defendant Alex M. Azar II is Secretary of HHS and is sued in his official capacity.

18. Defendant HHS, a federal agency within the meaning of the APA, is responsible for administering a variety of federal health care programs, including the 340B Program, 42 U.S.C. § 256b, and the Section 330 Health Center Program, 42 U.S.C. § 254b. The Secretary of HHS has delegated responsibility for the 340B Program to HHS's Health Resources and Services Administration ("HRSA") division, which

oversees both the 340B Program and the Section 330 Health Center Program.

JURISDICTION AND VENUE

19. This Court has jurisdiction over this matter under 28 U.S.C. §§ 1331 and 1361. Venue is proper in this district under 28 U.S.C. § 1391(e) because Defendants are agencies, officers, or employees of the United States and a substantial part of the events or omissions giving rise to the claim occurred in this District.

ALLEGATIONS

Federally Qualified Health Centers

20. "FQHCs occupy a unique place in the health services ecology," *Community Health Care Association of New York v. Shah et al*., 770 F.3d 129, 157 (2d Cir. 2014). Indeed, the FQHC designation reflects and is a product of a carefully reticulated legislative scheme, as between the PHS, Medicaid, Medicare, and 340B statutes.

21. By and large, and for purposes of this action, an FQHC is a community-based non-profit "health center" that receives (or is eligible to receive) federal grant funds under Section 330 of the PHS Act to provide care to medically underserved populations in communities that otherwise would not have those services available. 42 U.S.C. § 254b(a), (e), (k).

22. A health center is required by Section 330 to, among other things: (1) serve an area or population designated by the Secretary to be medically underserved; (2) have a community-based board of directors (*i.e*. a majority of its directors must be patients of the center "who, as a group, represent the individuals being served by the center . . ."); (3)

provide primary health care services, including "pharmaceutical services as may be appropriate for particular centers," and related services; (4) provide enabling services such as outreach and transportation, education, and patient case management; (5) participate in Medicaid; and (6) serve all residents of its community and make all of its "required" and "additional" services equally available to all of its patients, regardless of any individual's ability to pay for them. *See* 42 U.S.C. § 254b(a), (b), (j), (k).

23. Section 330 expressly authorizes each health center to provide its services, including pharmaceutical services, through its own staff or through "contracts or cooperative arrangements" with other entities, or a combination thereof. 42 U.S.C. § 254b(a)(1).

24. As HHS has long recognized, that statutory authority affords FQHCs the flexibility to provide pharmacy services to their patients through contractual arrangements with private pharmacies, instead of—or in addition to—doing so through an in-house pharmacy (one owned, controlled, and operated by the health center). *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549-01 (Aug. 23, 1996); Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272-01 (Mar. 5, 2010).

25. Section 330 grant funds are appropriated to cover or subsidize the cost of services to *un*insured or *under*insured individuals who are unable to pay for them. 42 U.S.C. § 254b(e)(5)(A). Section 330 grant funds are not to be used as a subsidy for

private or public health insurance programs, such as Medicaid. To prevent such a subsidy, health centers are statutorily (a) required to "make every reasonable effort to collect appropriate reimbursement for its costs in providing health services to persons who are entitled to insurance benefits," including Medicaid. *id*. at § 254b(k)(3)(F). For the same reason, FQHCs are prohibited from giving discounts on their services absent a patient's inability to pay. *Id.* at § 254b(k)(3)(F), (G).

26. The purpose of the FQHC designation (first established in 1989) and the associated payment right in Medicaid—is to "ensure that health centers receiving funds under [Section 330] would not have to divert Public Health Services Act funds to cover the cost of serving Medicaid patients." *Three Lower Counties Community Health Services v. Maryland*, 498 F.3d 294, 297–98 (4th Cir. 2007) (citing H.R. Rep. No. 101-247, at 392–93, *reprinted in* 1989 U.S.C.C.A.N. 2118–19). This is accomplished through a requirement that states reimburse 100 percent of each FQHC's reasonable costs in furnishing covered ambulatory services to Medicaid beneficiaries. Consolidated Appropriations Act, 2001, Pub. L. 106-554, (Dec. 21, 2000), *codified at* 42 U.S.C. § 1396a(bb) (requiring states to pay each FQHC a prospective per-visit payment rate based on its historical costs in base years and with annual adjustments for inflation and changes in scope of services).

27. Given the purpose and history of the FQHC designation in Medicaid and Medicare, it should come as no surprise that FQHCs appear first on the statutory list of provider types that qualify as "covered entities" eligible to purchase discounted drugs

under the 340B Program. 42 U.S.C. § 256b(a)(4)(A). Those discounts complement and reinforce each FQHC's statutory duty to make all its services equally available to all its patients, regardless of any individual patient's ability to pay for them.

The 340B Program

28. The 340B Program, 42 U.S.C. § 256b, requires drug manufacturers (as a condition of having their drugs covered by Medicare and Medicaid) to enter into an agreement with HHS (known as a pharmaceutical pricing agreement, or PPA) to make "covered outpatient drugs" available to "covered entities" at prices that do not exceed a "ceiling price," as determined by a statutory formula. 42 U.S.C. § 256b(a)(1).

29. By reducing drug costs to FQHCs and other 340B covered entities—which are predominantly providers of safety net services to poor, underserved, and either *un*insured or *under*insured populations—the 340B Program furthers its legislative objective 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(II), 12 (1992).

30. Plaintiff's FQHC members use the savings they generated through the 340B Program to provide additional services in their federally designated service (or "catchment") area. For example, FQHCs use their 340B savings to cover the cost of medication for *un*insured or *under*insured patients who could not otherwise afford it. FQHCs also use the savings to expand access to necessary medical and crucial enabling services, including but not limited to medication therapy management, behavioral health

care, dental services, vaccinations, case management and care coordination services, translation/interpretation services for patients with limited English language ability, and transportation assistance that enables patients to reach their health care appointments.

31. FQHCs have some flexibility in determining how best to meet the needs of their patient population and community, but their use of any 340B savings must further their health center project. 42 U.S.C. § 254b(e)(5)(D).

32. Each 340B covered entity is statutorily prohibited from: (a) reselling or transferring a drug purchased at a 340B discount to a person who is *not* a patient of the covered entity ("diversion"), and (b) causing a manufacturer to provide a 340B discount and a fee-for-service Medicaid rebate for the same drug ("duplicate discount"). 42 U.S.C. § 256b(5)(A), (B).

33. Each covered entity is subject to audits by both HHS and manufacturers to ensure compliance with the diversion and duplicate discount prohibitions. 42 U.S.C. § 256b(a)(5)(C). Many, if not most, FQHC covered entities also perform their own internal auditing functions to ensure compliance. Each covered entity is ultimately solely responsible for its own compliance with 340B Program requirements.

34. Prior to 2010, HHS had implemented an informal dispute resolution process, akin to nonbinding mediation, to provide for adjudication and resolution of (a) claims by covered entities that drug manufacturers were charging above the ceiling price for their drugs ("overcharging"); and (b) claims by manufacturers that covered entities were causing or failing to adequately prevent diversion or duplicate discounts.

35. That process, however, was "underutilized (because it was a voluntary process)." 340B Drug Pricing Program Administrative Dispute Resolution Process, 75 Fed. Reg. 57233-01 (Sept. 20, 2010). It was underutilized by covered entities, in particular, because the entities could not independently verify the 340B ceiling prices they were being charged and thus could not identify or quantify any overcharge (as noted *infra*, such access was not provided until 2019).

36. In its 1996 informal dispute resolution guidance, 61 Fed. Reg. 65406-01, HHS stated that a manufacturer must extend the ceiling price to covered entities even if it believes it has ample evidence to indicate prohibited entity activity (diversion or duplicate discounts). In that case, the guidance states that "the manufacturer may bring the claim to the Department through the informal dispute process." Manufacturer Audit Guidelines and Dispute Resolution Process 0905-ZA-19, 61 Fed. Reg. 65406-01 (Dec. 12, 1996). But HHS stresses that only if "the entity is found *guilty* [by HHS] of prohibited activity and a decision is made to *remove the entity from the covered entity list*, will the manufacturers no longer be required to extend the discount." *Id.* (emphasis added).

37. Over the years, the HHS Office of Inspector General ("OIG") has concluded that a lack of drug price transparency and statutory "oversight mechanisms" hampered HHS's ability to administer the 340B Program. *See, e.g.,* HHS OIG, D. Levinson, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, p. ii (OEI-05-02-00072, Oct. 2005) ("HRSA lacks the oversight mechanisms and authority to

ensure that [covered] entities pay at or below the 340B ceiling price."); HHS OIG, D. Levinson, *Review of 340B Prices*, p. 11 (OEI–05–02–00073, July 2006) (estimating that covered entities overpaid $3.9 million in June 2005 alone); *accord Astra USA*, 563 U.S. at 121 (recognizing and citing same).

The PPACA's 2010 Improvements to 340B Program Integrity

38. In 2010, the PPACA made significant changes and improvements to the 340B Program. First, it expanded the program by adding new categories of covered entities. Second, and especially important here, it directed the HHS Secretary to promulgate regulations to implement an ADR process to adjudicate and remedy disputes between the program's participants. PPACA, §§ 7101, 7102; *see also Astra USA*, 563 U.S. at 121–22.

39. In particular, § 7102(a)(3), under the title "Improvements to 340B Program Integrity," provides in pertinent part:

> *Not later than* 180 days after the date of enactment of the [PPACA], the Secretary *shall promulgate regulations* to establish and implement an administrative process *for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section*, and claims by manufacturers, after the conduct of audits as authorized by subsection (a)(5)(D), of violations of subsections (a)(5)(A) or (a)(5)(B),[1] including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraphs (1)(B) and (2)(B).

42 U.S.C. § 256b(d)(3) (emphasis added).

40. The clear purpose and plain meaning of § 256b(d)(3) is to impose a

[1] Subsections (a)(5)(A) and (B) of § 256b prohibit duplicate discounts and diversion, respectively.

nondiscretionary duty on the HHS Secretary to implement, within 180 days of PPACA's enactment, a dispute resolution process capable of fairly and expeditiously resolving program participant claims of noncompliance—such as those at issue here—through binding and enforceable decisions of a designated HHS official or body (the "HHS adjudicator").

41. The Secretary's statutory deadline to implement the ADR process expired on September 19, 2010, 180 days after the PPACA became law on March 23, 2010. *Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 138 F. Supp. 3d 31, 46 (D.D.C. October 14, 2015) (noting, in 2015, that HHS was "five years overdue in complying with Congress's mandate that it set up an administrative dispute resolution process within 180 days of the ACA's passage").

42. Instead of promulgating the mandated regulations by the statutory deadline, HHS waited until the eve of its expiration to issue two *advance* notices of proposed rulemaking: one for the ADR process, and one covering both CMPs to be levied against manufacturers that knowingly and intentionally overcharge a covered entity and ceiling price calculation requirements. It is unclear why HHS split the rulemaking in this manner, but § 256b(d)(3) explicitly commands the implementation of the entire set of program integrity rules within the same 180-day deadline.

43. In the advance notice of proposed rulemaking ("ANPRM") for the ADR process, HHS solicited information and public comments "to help" develop and draft a proposed rule, even though HHS had fourteen years of experience under its informal

dispute resolution process by then. *See* 75 Fed. Reg. 57233 (publishing informal dispute resolution guidance four years after the program's enactment). The ANPRM specifically sought comments on the following issues: "(1) Administrative procedures, (2) existing models, (3) threshold requirements, (4) hearings, (5) decision-making officials or bodies, (6) appropriate appeals procedures, (7) deadlines, (8) discovery procedures, (9) manufacturer audits, (10) consolidation of manufacturer claims, (11) covered entity consolidation of claims; (12) claims by organizations representing covered entities, and (13) integration of dispute resolution with other 340B requirements added by the Affordable Care Act." *Id*. at 57234.

44. Both ANPRMs afforded a 30-day comment period (until November 19, 2010) for interested parties, but otherwise said nothing about a timeline for either anticipated rulemaking. And thereafter HHS proceeded with no hint of urgency, despite the statutory deadline and the rules' important purpose.

45. To the contrary, it was not until five years later that HHS issued its first notice of proposed rulemaking ("NPRM") for its Ceiling Price and CMP rules. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 80 Fed. Reg. 34583-01 (June 17, 2015). The NPRM indicated that "[t]he administrative dispute resolution process remains under development" and "HHS intends to address dispute resolution in future rulemaking." *Id*. at 34584.

46. More than a year later—and nearly six years beyond the statutory deadline—HHS issued a NPRM for the ADR rules, indicating that, in developing the

proposal, it had considered the comments it received in response to the 2010 ANPRM. *See* 340B Drug Pricing Program; Administrative Dispute Resolution, 81 Fed. Reg. 53381-01 (Aug. 12, 2016). The 2016 NPRM afforded a two-month comment period (until October 11, 2016) and indicated that the ADR rules, when finalized, would "replace" the informal, nonbinding dispute resolution process HRSA had published twenty years earlier in December 1996. *Id*. at 53382.

47. On January 5, 2017, after an earlier reopening of the applicable comment period, HHS issued its final Ceiling Price and CMP rules, with a delayed effective date of March 6, 2017. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210-01 (Jan. 5, 2017). In the preamble, HHS noted that "CMPs provide a critical enforcement mechanism for HHS *if manufacturers do not comply with statutory pricing obligations under the 340B Program*." *Id*. (emphasis added). At the same time, HHS noted that "issues related to overcharges," since the program's inception, "have been resolved between a manufacturer and a covered entity and any issues have generally been due to technical errors in the calculation." *Id.* at 1227. HHS anticipated that the imposition of a CMP "would occur very rarely if at all" because such penalties are reserved for manufacturer overcharging that is "knowing and intentional." *Id*. at 1227–28.

48. Even though HHS, in publishing its January 5, 2017 rules, "envision[ed] using these penalties in rare situations," it did provide illustrations of the sort of "rare" situation it would consider as "knowing and intentional" overcharging by a manufacturer.

Id. at 1221–27.

49. HHS's examples of knowing and intentional manufacturer overcharges included situations in which a covered entity places an order for non-340B priced drugs where the covered entity was doing so *because the manufacturer had refused to sell or make the drug available at the 340B ceiling price. Id*. at 1224–26. HHS explained, in other words:

> Covered entity orders of non-340B priced drugs will not subsequently be considered an instance of overcharging unless the manufacturer's documented refusal to sell or make drugs available at the 340B price resulted in the covered entity purchasing at the non-340B price. When a manufacturer's documented refusal to sell or make drugs available at the 340B ceiling price results in the covered entity purchasing at the non-340B price, a manufacturer's sale at the non-340B price could be considered an instance of overcharging. An example of 'documented refusal' would include *any type of manufacturers' written communication related to reasons a manufacturer is not providing 340B ceiling prices* to either a single covered entity or group of covered entities. *HHS does not agree that a manufacturer could consider not selling a 340B drug at the 340B ceiling price to a covered entity based on possible non-compliance with program requirements*.

Id. at 1226 (emphasis added).

50. Per the Federal Register notice, multiple commenters suggested that a manufacturer should be able, as an exception to an otherwise knowing and intentional overcharge, to deny a covered entity a 340B price (and charge retail prices) if, in doing so, the manufacturer is acting on "credible evidence that a covered entity is engaged in diversion of 340B drugs." *Id.* at 1223. The commenters asserted that "if a manufacturer has evidence a covered entity is improperly diverting a drug, it should be able to charge the covered entity a price above the 340B ceiling price." *Id.* The commenters suggested

that manufacturers would be in a better position than HHS to provide this "check on 340B drug diversion, since manufacturers have better and timelier access to sales data than does HHS." *Id.*

51. HHS squarely rejected the notion that a manufacturer can exercise such self-help or act as judge and jury of disputes between covered entities and manufacturers. In particular, HHS stated:

> HHS does not believe that unilaterally overcharging a covered entity based upon suspicion of diversion is warranted under the statutory language. Manufacturers cannot condition the sale of a 340B drug at the 340B ceiling price because they have concerns or specific evidence of possible non-compliance by a covered entity. Manufacturers that suspect diversion are encouraged to work in good faith with the covered entity, conduct an audit per the current audit guidelines, or contact HHS directly.

Id.

52. On the issue of knowledge and intent, HHS also explained that the manufacturer need not have acted knowingly or intentionally at the time of the covered entity's drug purchase. That is, the requisite knowledge and intent for a civil monetary penalty could arise thereafter, if the manufacturer subsequently learned of the overcharge and refused to refund or issue a credit to the covered entity. *Id*. at 1225–26. Such a willful disregard for the fact that a covered entity had been overcharged would constitute a reverse liability, so to speak.

53. Finally, in the January 5, 2017 Ceiling and CMP final rule notice, HHS indicated that it "anticipates finalizing the administrative dispute resolution regulation after the comments [to its 2016 NPRM, 81 Fed. Reg. 53381-01] have been reviewed and

considered." 82 Fed. Reg. at 1212.

54. But no ADR regulation was ever made final. Instead, HHS withdrew its proposed ADR rules on August 1, 2017, with no indication as to when future action on those already long-overdue rules would be forthcoming.

55. HHS also delayed the effective date of its Ceiling Price and CMP rules several times, until it was sued, on September 11, 2018, for arbitrarily and unlawfully withholding or delaying a mandatory agency action, in violation of the APA. *See, American Hosp. Ass'n v. U.S. Dept. of Health and Human Serv.*, No. 18-cv-02112 (D.D.C. voluntarily dismissed Apr. 25, 2019).

56. While the lawsuit remained pending, Defendants, for the first time, provided two things: a final effective date of January 1, 2019 for its Ceiling Price and CMP regulation, and covered entity access—as of April 1, 2019 and through an HHS website—to "the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary," as required by 42 U.S.C. § 256b(d)(B)(iii). 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 83 Fed. Reg. 61,563-01 (Nov. 30, 2018). Within the first 24 hours the pricing system was accessible to covered entities, it was accessed by over 275 authorized users. Decl. of Krista Pedley, ECF No. 35-1, *The American Hosp. Ass'n*, 18-cv-02112.

57. Thereafter, on April 25, 2019, the parties stipulated to the dismissal of the lawsuit as moot, under Federal Rule of Civil Procedure 41(a)(1)(A)(ii). Joint Status Report and Stipulation of Dismissal, ECF No. 36, *American Hosp. Ass'n*, 18-cv-02112.

Recent Drug Manufacturer Actions
Contrary to 340B Program Requirements

58. On or about July 1, 2020, pharmaceutical company Eli Lilly and Company ("Eli Lilly") posted a notice on HHS's designated 340B Program webpage informing 340B covered entities that, effective immediately, it would no longer distribute multiple formulations of the drug Cialis purchased at 340B pricing to the covered entities' contract pharmacies.

59. On or about September 2, 2020, Eli Lilly disseminated another notice (which HHS declined to post on its webpage) informing 340B covered entities that, effective the day prior, it would no longer distribute *any* of its 340B-priced products to any contract pharmacies of a covered entity, providing an infeasible exception for certain insulin products and allowing for possible mercy for covered entities that had no other pharmacy outlet.

60. The Cialis notice in early July preceded (or triggered) a series of other actions. Merck Sharpe & Dohme Corp., Sanofi, and Novartis, through a vendor called Second Sight Solutions, threatened "less collaborative" and "substantially more burdensome" steps (Merck) or to withhold shipping 340B drugs to contract pharmacies altogether beginning October 1 (Sanofi and Novartis) unless covered entities handed their patient contract pharmacy claims data over to the vendor for the vendor's perpetual use. Neither the manufacturers nor Second Sight Solutions had any right to access or exploit the valuable data, so they threatened to hold 340B drugs hostage instead. Novartis and Merck have not yet followed through with their threats (though they have not withdrawn

them), but Sanofi did on October 1, 2020.

61. In August 2020, drug manufacturer AstraZeneca informed covered entities that it would no longer ship 340B drugs purchased by covered entities to their contract pharmacies effective October 1, 2020. AstraZeneca followed through on its threat, with limited exceptions for covered entities that lack any other pharmacy outlet.

62. By imposing such conditions, these other drug manufacturers are (like Eli Lilly) effectively refusing to make their covered outpatient drugs available to covered entities at 340B pricing, as required by the 340B statute and their respective PPAs. The result is that FQHCs and other covered entities must purchase the manufacturers' drugs at retail prices to make those drugs available to their patients through a contract pharmacy.

Defendants' Preliminary Response to Eli Lilly's Unilateral Pricing Action

63. In a September 21, 2020 letter, HHS General Counsel Robert P. Charrow responded to a September 8, 2020 request from Eli Lilly for an advisory opinion as to whether Eli Lilly's "new unilateral policy" on 340B contract pharmacies "would subject Lilly to sanctions." HHS posted a copy of General Counsel Charrow's letter on HHS's 340B webpage. *See* Charrow Letter, attached hereto as Exhibit A, at 1.

64. Although General Counsel Charrow indicated that HHS "has significant initial concerns" with Eli Lilly's new policy, it "has yet to make a final determination as to any potential action." Exh. A at 1.

65. In any event, HHS has not taken any action to ensure that Eli Lilly, and the other drugs manufacturers described *supra*, are making their covered outpatient drugs

available at 340B discount prices to covered entities for dispensing at their contract pharmacies.

Mandated ADR Process and Remedies

66. The mandated ADR regulations are the only recourse available to covered entities—those whom the 340B program is designed to benefit—when drug manufacturers overcharge them for 340B drugs. *Astra USA*, 563 U.S. at 121–22.

67. Once implemented, the mandated ADR regulations would afford FQHC covered entities a substantial remedy against the manufacturer's unilateral pricing and overcharging actions.

68. In particular, the ADR regulations will implement a process and procedures by which the HHS adjudicator reviews and resolves covered entity claims of manufacturer overcharging, such as those at issue here, "fairly, efficiently, and expeditiously," through a final and binding decision, subject only to APA review. 42 U.S.C. § 256b(d).

69. The procedures will permit covered entities to "discover and obtain such information and documents from manufacturers and third parties as may be relevant to demonstrate the merits of a claim that charges for a manufacturer's product have exceeded the applicable ceiling price," and present such "documents and information" for the designated official's or body's consideration in adjudicating the claim. 42 U.S.C. § 256b(d)(3)(B)(iii).

70. The ADR procedures will also "permit multiple covered entities to jointly

assert claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding, and permit such claims to be asserted on behalf of covered entities by associations or organizations representing the interests of such covered entities and of which the covered entities are members." 42 U.S.C. § 256b(d)(3)(B)(vi).

71. The HHS adjudicator's resolution of a claim or claims under the ADR process "shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction." 42 U.S.C. § 256b(d)(3)(C).

72. For example, if the HHS adjudicator were to substantiate an overcharge claim, the adjudicator would require the manufacturer to "issue refunds . . . with an explanation of why and how the overcharge occurred, how the refunds will be calculated, and to whom the refunds will be issued." 42 U.S.C. § 256b(d)(1)(B)(ii). Thereafter, the HHS adjudicator would exercise continuing "[o]versight" authority "to ensure that the refunds are issued accurately and within a reasonable period of time, both in routine instances of retroactive adjustment to relevant pricing data and exceptional circumstances such as erroneous or intentional overcharging for covered outpatient drugs." *Id*.

73. Moreover, if a manufacturer's overcharging is alleged or found to be knowing and intentional, the matter would be referred to the Office of Inspector General for the potential imposition of "sanctions in the form of civil monetary penalties," up to "$5,000 for each instance of overcharging." 42 U.S.C. § 256b(d)(1)(B)(vi). Such penalties will be assessed "according to standards established in regulations to be

promulgated by the Secretary not later than 180 days after March 23, 2010." *Id*.

74. As explained above, the CMP regulations were not timely promulgated, but they are now final, with an effective date of January 1, 2019.

Irreparable Harms

75. Had the Secretary implemented the mandatory ADR process, as and when required, Plaintiff would have been able to submit a claim—as an association on behalf of FQHCs—as to each manufacturer listed above, and had those claims adjudicated and resolved expeditiously.

76. Indeed, had there been a final, binding ADR regulation providing covered entities a way to challenge prohibited overcharges, drug manufacturers may well have been reticent to take the unauthorized, unilateral actions at the heart of this suit.

77. There are no disputed facts. The manufacturers unilaterally stopped making their covered drugs available at or below ceiling prices to FQHC covered entities when those drugs are being shipped to contract pharmacies.

78. Moreover, it is highly likely that Plaintiff's claims, presented in such a process, would be successful, as HHS, in the preamble to its CMP rules (three years ago), described similar refusals to allow covered entities to purchase drugs at 340B discount pricing as examples of "knowing and intentional" overcharging.

79. By not implementing the mandatory ADR process, and by not exercising their enforcement authority independent of the ADR process, Defendants are depriving FQHCs of the only remedy they have to protect against manufacturer overcharging, and

Defendants are abdicating their statutory enforcement duties.

80. Plaintiff, as an association of and for FQHCs, is also aware of irreparable harm to FQHC patients that has occurred, is occurring, and will occur due to the drug manufacturers' overcharging activity and the lack of an administrative remedy to expeditiously hold them to account.

81. FQHC covered entities serve a patient population that is largely low-income and/or poor, and many FQHC patients are *under*insured (with, for example, high-deductible plans) or entirely uninsured, making them especially vulnerable to shifts in pharmaceutical pricing.

82. Many covered entity patients experience significant barriers to accessing healthcare—some caused by geography and infrastructure, some by the quotidian realities of life for low-income, working poor, migrant farmworker, or homeless individuals—and others caused by health or disability status, including comorbid chronic conditions such as diabetes and heart disease, mental and behavioral health diagnoses, and substance use disorder. For example, many of these patients have little to no disposable income to allocate to healthcare expenses, lack access to reliable transportation, live far from service providers in areas with extreme weather and/or poor infrastructure, communicate in a language other than English, or are mobility impaired.

83. The significant, irreparable harm these patients have suffered and will suffer is both direct and indirect.

84. Direct harm to covered entity patients has included, and will include,

drastic increases in the price of life-sustaining medications for chronic conditions like diabetes, respiratory diseases, cardiovascular disease, HIV/AIDS, and substance use disorder (*e.g.* opioid addiction). For example, uninsured health center patients accustomed to paying less than $16 for Eli Lilly insulin—purchased at 340B pricing and dispensed through their health center's contract pharmacy—now have to shoulder a cost of nearly $550 in some areas (and upwards of $700 in others) for the same amount of medication, or coordinate with and wait for their providers to approve the substitution of a more affordable alternative medication, if such substitution is possible.

85. Patients' geographic, transportation, and time-availability barriers also hinder access to discount medications, even where a health center's existing in-house pharmacy or pharmacies could theoretically make such medications available. For example, without contract pharmacy access or services, certain FQHCs serve patients would have to travel several hours to reach an in-house pharmacy at which they could fill a prescription purchased at 340B pricing.

86. A delay in obtaining certain health maintenance and life-sustaining medications can cause significant adverse health effects. In some cases, such a delay can be fatal. Likewise, a shift to a similar, but not identical, clinical alternative medication—assuming one exists—may not be well-tolerated or of the same efficacy, may result in serious side effects, or may cause medication compliance issues due to patient confusion or difficulty in adapting to a new regimen.

87. Covered entity patients also stand to be indirectly harmed by cuts to non-

reimbursable services that FQHCs currently support with 340B savings. These services—which may be drastically reduced or eliminated entirely due to significant decreases in 340B savings—include, for example, medication therapy management, behavioral health care, dental services, vaccinations, case management and care coordination services, translation/interpretation services for patients with limited English language ability, and transportation assistance that enables patients to reach their health care appointments.

COUNT ONE

87. The allegations contained in paragraphs 1–86 above are re-alleged and incorporated by reference.

88. The APA provides a remedy to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1).

89. Defendants have failed to comply with 42 U.S.C. § 256b(d)(3)'s clear and unequivocal mandate to establish and implement by regulation an ADR process to fairly, efficiently, and expeditiously adjudicate and remedy claims by covered entities that they have been overcharged for covered outpatient drugs by manufacturers participating in the 340B Program.

90. The PPACA became law on March 23, 2010. The statutory deadline for the mandated regulations expired on September 19, 2010. They are now more than ten years overdue.

91. Thus, Defendants have unlawfully withheld and unreasonably delayed the promulgation of final rules within the meaning of 5 U.S.C. § 706(1).

92. In the absence of the required rules and process, FQHCs are being deprived of an exclusive statutory remedy for manufacturer overcharging.

93. Neither Plaintiff nor FQHCs have any other adequate remedy to pursue or exhaust under the 340B Program or otherwise. An action under 5 U.S.C. § 706(1) is the only available means for Plaintiff or FQHCs to compel Defendants' compliance with 42 U.S.C. § 256b(d)(3).

94. Defendants' failure to fulfill 42 U.S.C. § 256b(d)(3)'s clear mandate, within the specified period, and despite the significant interests it seeks to protect, warrants declaratory and injunctive relief under 5 U.S.C. § 706(1).

COUNT TWO

95. The allegations contained in paragraphs 1–94 above are re-alleged and incorporated by reference.

96. A federal court may issue a writ in the nature of mandamus under 28 U.S.C. § 1361 to compel a federal official or agency to perform a mandatory duty.

97. Defendants have failed to perform a clear, nondiscretionary duty required by 42 U.S.C. § 256b(d)(3)—and owed to FQHC and other covered entities—to promulgate regulations by a certain (long past) deadline to implement an administrative process for the resolution of claims by covered entities that participating manufacturers have overcharged them for drugs purchased under the 340B Program.

98. Defendants' statutory deadline to do so expired more than ten years ago.

99. By failing to promulgate the mandated ADR regulations, Defendants are

depriving FQHCs and other covered entities of their exclusive statutory remedy for drug manufacturer overcharging.

100. FQHCs and other covered entities are currently experiencing that very harm—manufacturer overcharging—without a remedy.

101. Defendants' failure to fulfill 42 U.S.C. § 256b(d)(3)'s mandate, within the specified period, warrants a writ of mandamus under 28 U.S.C. § 1361.

PRAYER FOR RELIEF

WHEREFORE Plaintiff respectfully requests the Court:

A. Declare that Defendants violated 42 U.S.C. § 256b(d)(3) by failing to promulgate ADR regulations to implement a process to adjudicate and remedy 340B Program violations;

B. Declare that Defendants violated 5 U.S.C. § 706(1) by unlawfully withholding or unreasonably delaying ADR regulations mandated by 42 U.S.C. § 256b(d)(3);

C. Order Defendants to promulgate final ADR regulations, as required by 42 U.S.C. § 256b(d)(3), no later than 60 days from the Court's order;

D. Retain jurisdiction over this matter pending Defendants' promulgation of the final ADR regulations;

E. Award Plaintiff's reasonable litigation expenses, including attorneys' fees; and

F. Order such other relief as this Court deems just and proper.

Dated October 21, 2020

Respectfully submitted,

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UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

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FOR 340B ACCESS
1501 M Street, N.W., Suite 700
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and

MATTHEW 25 AIDS SERVICES, INC.
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Henderson, KY 42420,

and

CHATTANOOGA C.A.R.E.S., DBA CEMPA COMMUNITY CARE
1000 E. 3rd Street, Suite 300
Chattanooga, TN 37403,

Plaintiffs,

vs.

ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201,

and

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue, S.W.
Washington, DC 20201,

and

THOMAS J. ENGELS, in his official capacity as Administrator for the Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857,

Case No. 20-cv-2906

and

HEALTH RESOURCES AND SERVICES ADMINISTRATION
5600 Fishers Lane
Rockville, MD 20857

Defendants.

COMPLAINT FOR DECLARATORY, MANDAMUS, AND INJUNCTIVE RELIEF

INTRODUCTION

1. Plaintiffs ask this Court to compel the Secretary of Health and Human Services ("Secretary") and other federal Defendants to permit and enable Plaintiffs to use contract pharmacy arrangements under the federal 340B drug pricing program ("340B program") as mandated by statute and regulation. 42 U.S.C. § 256b (2018); 42 C.F.R. § 10.11 (2019). The 340B program, established at 42 U.S.C. § 256b ("340B program"), requires pharmaceutical manufacturers to sell discounted drugs to certain statutorily defined health care providers, known as "covered entities," as a condition of the manufacturers participating in the Medicaid and Medicare Part B insurance programs. Plaintiffs include a covered entity trade association and several covered entities (collectively, the "Plaintiff Covered Entities") that participate in the 340B program primarily, or exclusively, through agency relationships with third-party pharmacies, referred to as "contract pharmacies." Under these arrangements, the Plaintiff Covered Entities place orders for 340B discounted drugs that are shipped to the contract pharmacy and billed to the covered entity. Since 1996, the Secretary has expressly recognized that the 340B statute requires pharmaceutical manufacturers to provide 340B discounts when ordered by covered entities via contract pharmacies. In 2017, the Secretary enshrined this requirement in regulation. 42 C.F.R. § 10.11(b)(1).

2. Recently, however, four pharmaceutical manufacturers have flouted the 340B statute and regulation by openly refusing to sell 340B discounted drugs to covered entities when ordered via contract pharmacy arrangements. These manufacturers are Eli Lilly and Company ("Lilly"), Sanofi-Aventis U.S. LLC ("Sanofi"), AstraZeneca PLC ("AstraZeneca"), and Novartis Pharmaceuticals Corporation ("Novartis") (collectively, the "Drug Companies"). The Drug Companies have denied 340B discounts to the Plaintiff Covered Entities by refusing to sell their drugs through the 340B wholesaler accounts associated with contract pharmacies.

3. Only the Secretary can remedy these violations by the Drug Companies, and he has taken no action to bring them into compliance. Congress required the Secretary to implement administrative dispute resolution ("ADR") procedures that would have enabled the Plaintiff Covered Entities to challenge the Drug Companies' actions before a tribunal within the Department of Health and Human Services ("HHS"), but the Secretary has now missed the statutory deadline for issuing ADR regulations by a decade. Moreover, the Supreme Court held in 2011 that 340B covered entities may not sue pharmaceutical manufacturers for failing to comply with 340B requirements. *Astra USA, Inc. v. Santa Clara Cty., Cal.*, 563 U.S. 110, 113-14 (2011) ("*Astra*"). The Court's holding was premised, in part, on the Secretary's promise to implement ADR regulations. *Id*. at 116, 121. The Plaintiff Covered Entities are thus wholly reliant on the Secretary to enforce 340B program requirements, which he has failed to do by permitting the Drug Companies to overcharge the Plaintiff Covered Entities for drugs subject to 340B discounts.

4. The Secretary has violated the Due Process Clause of the Fifth Amendment to the U.S. Constitution by failing in his duties and obligations under federal law to protect the rights of the Plaintiff Covered Entities to pursue ADR actions subject to judicial review. The Secretary's

constitutional violation has harmed the Plaintiff Covered Entities and their patients, and during a national public health emergency brought about by the novel coronavirus ("COVID-19") pandemic, the Secretary has also deprived the nation's most vulnerable individuals of crucial health care services in a manner that causes irreparable harm contrary to the public interest.

5. The Plaintiff Covered Entities are suffering immediate and irreparable harms from the Secretary's failure to enforce the Plaintiff Covered Entities' rights to purchase covered outpatient drugs at 340B discounts via contract pharmacy arrangements. The savings from 340B discounts enable the Plaintiff Covered Entities to provide health care services that will be scaled back or eliminated altogether unless the Secretary acts now. Patient health is compromised, which is a serious and irreparable harm in the best of times and more so during a pandemic. The Secretary must promulgate ADR regulations. However, those regulations will take months to finalize, and the ADR process will be lengthy. Thus, the due process harms to the Plaintiff Covered Entities can only be cured in the short term by an order from this Court directing the Secretary to act now against the Drug Companies.

6. The Secretary has also violated the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(1), by unlawfully withholding the ADR regulations and enforcement of 340B program requirements. Likewise, the Plaintiff Covered Entities request a writ of mandamus requiring the Secretary to implement ADR regulations and to enforce the Plaintiff Covered Entities' rights to purchase covered outpatient drugs at 340B discounts via contract pharmacy arrangements.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. § 1331, which grants federal district courts original jurisdiction of all civil actions arising under the Constitution.

8. This Court also has subject matter jurisdiction under 28 U.S.C. § 1361, which grants each district court jurisdiction over "any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff."

9. The APA requires courts to hold unlawful and set aside agency action, findings, and conclusions determined to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C) (2018). The APA also directs courts to "compel agency action unlawfully withheld." *Id.* § 706(1). The APA authorizes judicial review of "final agency action for which there is no other adequate remedy in a court." *Id.* § 704.

10. This Court has jurisdiction over the person of the Defendants.

11. Venue for this action lies in this judicial district under 28 U.S.C. § 1391(e)(1).

PARTIES

12. Ryan White Clinics for 340B Access ("RWC-340B") is a national association of human immunodeficiency virus ("HIV")/acquired immunodeficiency syndrome ("AIDS") health care clinics and service providers that receive funding under the Ryan White Comprehensive AIDS Resources Emergency Act ("Ryan White CARE Act"), either through a primary grant or subgrant and participate as covered entities in the 340B program by virtue of receiving this federal funding. Entities that receive grants or subgrants under the Ryan White CARE Act are commonly referred to as "Ryan White clinics." Ryan White clinics are dedicated to caring for low-income and vulnerable patients living with HIV/AIDS and, as Defendant Secretary Azar has acknowledged, "are serving on the frontlines of this pandemic, supporting clients and communities at higher risk from COVID-19." HHS, *HHS Awards $90 Million to Ryan White*

HIV/AIDS Program Recipients for COVID-19 Response (Apr. 15, 2020), https://www.hhs.gov/about/news/2020/04/15/hhs-awards-90-million-ryan-white-hiv-aids-program-recipients-for-covid-19-response.html. RWC-340B's members rely on the savings generated from the 340B program to help finance their mission of serving low-income patients, including savings generated by contract pharmacy arrangements.

13. Matthew 25 AIDS Services, Inc. ("Matthew 25") is a not-for-profit health care provider with facilities in Henderson, Owensboro, and Bowling Green, Kentucky and a facility in Evansville, Indiana. Matthew 25 is a member of RWC-340B. Matthew 25 receives grant and subgrant funding through the Ryan White CARE Act. Matthew 25 participates in the 340B program as a covered entity by virtue of receiving this funding. Matthew 25 has been registered as a covered entity in the 340B program since 2002 and is still registered as a covered entity today. Matthew 25 does not operate an in-house pharmacy. Matthew 25 obtains 340B discounted drugs for its patients exclusively through contract pharmacies.

14. Chattanooga C.A.R.E.S., dba Cempa Community Care ("Cempa") is a not-for-profit health care provider located in Chattanooga, Tennessee. Cempa is a member of RWC-340B. Cempa is certified by HHS as an FQHC "look-alike" ("FQHC-LA") and receives grant funding under the Ryan White CARE Act. Cempa also receives funding from the federal Centers for Disease Control and Prevention ("CDC") as a sexually transmitted disease ("STD") clinic. Cempa is eligible to participate as a covered entity in the 340B program by virtue of being designated as an FQHC-LA, receiving Ryan White CARES Act funds, and receiving CDC STD clinic funds. Cempa has been registered in the 340B program since February 2020 and is still registered as a covered entity today. Cempa does not operate an in-house pharmacy. Cempa obtains 340B discounted drugs through multiple contract pharmacy arrangements.

15. Defendant Alex M. Azar II is the Secretary of Health and Human Services and is responsible for the conduct and policies of HHS, including conduct and policies of HRSA. He maintains an office at 200 Independence Avenue, S.W., Washington, D.C. 20201. He is sued in his official capacity.

16. Defendant HHS is a cabinet-level department of the United States government. HHS is headquartered at 200 Independence Avenue, S.W., Washington, D.C. 20201.

17. Defendant Health Resources and Services Administration ("HRSA") is the agency within HHS that is charged with administering the 340B program. HRSA is headquartered at 5600 Fishers Lane, Rockville, MD 20857.

18. Defendant Thomas J. Engels is the Administrator for HRSA and is the federal official responsible for administering the 340B program. He maintains an office at 5600 Fishers Lane, Rockville, MD 20857. He is sued in his official capacity.

BACKGROUND

I. The 340B Program

19. Congress established the 340B program in 1992 by enacting Section 602 of the Veterans Health Care Act of 1992. Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71. That legislation amended the Public Health Service Act with a new Section 340B, codified at 42 U.S.C. § 256b. Section 340B (in conjunction with certain related provisions of the Medicaid statute) requires the Secretary to execute Pharmaceutical Pricing Agreements ("PPAs") with manufacturers of certain outpatient drugs covered by the Medicaid program as a condition of the manufactures' participation in the Medicaid and Medicare Part B insurance programs. 42 U.S.C. §§ 256b(a)(1), 1396r–8(a)(1) (2018). The PPAs "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." *Id.* § 256b(a)(1). The "ceiling price" is "equal to the average manufacturer price for the drug under title XIX of the Social Security Act [Medicaid] in the preceding calendar quarter," reduced by a rebate percentage calculated under Medicaid. *Id.* § 256b(a)(1)-(2).

20. Congress intended the 340B program to allow 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(II), at 12 (1992). 340B covered entities collectively serve as the nation's healthcare "safety net," providing care and treatment to the neediest individuals, regardless of ability to pay. The 340B program is a vital and indispensable tool for 340B covered entities that qualify for the program based on receiving federal grants. The 340B program helps them offset the costs of uncompensated or under-compensated care, enabling covered entities to maximize their resources to meet the health care and pharmaceutical needs of the fragile communities they serve. Without the 340B program, many covered entities would be forced to restrict access significantly or, in some cases, cease operations. For these reasons, ensuring the accuracy of 340B discounts and protecting against manufacturer overcharges that deplete covered entities' limited resources are of critical importance to covered entities and the individuals they serve.

21. The 340B statute enumerates several types of health care providers that may qualify as covered entities eligible to participate in and purchase discounted drugs under the 340B program. 42 U.S.C. § 256b(a)(4).

22. The 340B statute defines as a covered entity "[a]n entity receiving a grant under subpart II of part C of subchapter XXIV (relating to categorical grants for outpatient early

intervention services for HIV disease)." *Id.* § 256b(a)(4)(D). Subchapter XXIV of the Public Health Service Act is commonly referred to as the Ryan White CARE Act. *See* Ryan White Comprehensive AIDS Resources Emergency Act of 1990, Pub. L. No. 101-381, 104 Stat. 576 (codified at 42 U.S.C. §§ 300ff–300ff-140 (2018)). Part C of the Ryan White CARE Act provides grants to entities that provide "core medical services" to individuals with HIV/AIDS. 42 U.S.C. § 300ff–51. With the exception of certain funds reserved pursuant to 42 U.S.C. § 300ff-51(c)(1), at least 75% of Part C grant funds must be used for core medical services, which include AIDS pharmaceutical assistance. *Id.* § 300ff–51(c)(1), (c)(3)(C). Part C grantees are small "local community-based organizations." *See* HRSA, *Part C: Early Intervention Services and Capacity Development Program Grants*, https://hab.hrsa.gov/about-ryan-white-hivaids-program/part-c-early-intervention-services-and-capacity-development-program-grants (last reviewed Oct. 2020). Many Part C grantees lack the financial resources to operate an in-house pharmacy.

23. The Ryan White HIV/AIDS Program provides primary health care, pharmaceutical treatments, and support services for low-income people with HIV/AIDS and treats over 500,000 HIV-positive individuals in all 50 states, the District of Columbia, Puerto Rico, and the Pacific Island jurisdictions. HRSA, *About the Ryan White HIV/AIDS Program*, https://hab.hrsa.gov/about-ryan-white-hivaids-program/about-ryan-white-hivaids-program (last reviewed Feb. 2019); HRSA, *HIV/AIDS Bureau Fact Sheets*, https://hab.hrsa.gov/publications/hivaids-bureau-fact-sheets (last reviewed Aug. 2020). The Secretary reports that the Ryan White HIV/AIDS Program is "critical" and "serves as an important source of ongoing access to HIV medication that can enable people living with HIV to live close to normal lifespans." HRSA, *About the Ryan White HIV/AIDS Program*,

https://hab.hrsa.gov/about-ryan-white-hivaids-program/about-ryan-white-hivaids-program (last reviewed Feb. 2019). "In 2017, 85.9 percent of Ryan White HIV/AIDS Program clients were virally suppressed, exceeding the national average of 59.8 percent." *Id.*

24. The 340B statute also defines as a covered entity "[a] Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act)," 42 U.S.C. 1396d(l)(2)(B) (2018). 42 U.S.C. § 256b(a)(4)(A). An FQHC is a community-based health care provider that receives federal grant funding and "provide[s] primary care services in underserved areas." HRSA, *Federally Qualified Health Centers*, https://www.hrsa.gov/opa/eligibility-and-registration/health-centers/fqhc/index.html (last reviewed May 2018). FQHCs must provide "care on a sliding fee scale based on ability to pay." *Id.* A FQHC-LA is category of FQHC that meets the requirements to be designated as an FQHC but does not receive federal grant funding. 42 U.S.C. § 1396d(l)(2)(B)(iii).

25. The Secretary has delegated authority to administer the 340B program to HRSA, a unit of HHS. The 340B statute provides HRSA with regulatory authority over the 340B program in three areas: (1) the establishment of an ADR process for resolving manufacturer and covered entity price disputes, (2) "the 'regulatory issuance' of precisely defined standards of methodology for calculation of ceiling prices, and (3) the imposition of monetary civil sanctions" against manufacturers for overcharging for 340B drugs. *Pharm. Research & Manufacturers of Am. v. United States Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28, 41 (D.D.C. 2014). In other areas of the 340B program, HRSA has issued interpretive guidance, often published as a final notice in the Federal Register after providing notice and soliciting comment from the public.

II. 340B Manufacturer Program Integrity Requirements

26. On March 23, 2010, the Patient Protection and Affordable Care Act ("Affordable Care Act" or "ACA") was signed into law. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 823 (2010). The ACA amended the 340B statute to include "improvements in program integrity," including "manufacturer compliance." *Id.* § 7102 (codified at 42 U.S.C. § 256b(d)(1)).

27. Among the required improvements was the imposition of civil monetary penalties ("CMPs") upon pharmaceutical manufacturers that "knowingly and intentionally" overcharge 340B covered entities. *Id.* Congress directed that "each instance of overcharging" would be subject to a penalty not to exceed $5,000. *Id.*

28. The Secretary issued a CMP regulation on January 5, 2017. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210 (Jan. 5, 2017) ("CMP Final Rule") (codified at 42 C.F.R. § 10.11). The regulation subjects manufacturers to CMPs not to exceed $5,000 for each instance of overcharging. 42 C.F.R. § 10.11(a). An "instance of overcharging" is defined as "any order for a covered outpatient drug, by NDC [national drug code], which results in a covered entity paying more than the ceiling price, as defined in § 10.10, for that covered outpatient drug." *Id.* § 10.11(b). Each order for an NDC is a single instance, regardless of the number of units ordered. *Id.* § 10.11(b)(1). An order "includes any order placed directly with a manufacturer or through a wholesaler, authorized distributor, or agent." *Id.*

29. When finalizing the CMP rule, the Secretary stated, "Failure to ensure the covered entities are receiving the 340B ceiling prices through a third party may be grounds for the assessment of CMPs under this final rule." CMP Final Rule, 82 Fed. Reg. at 1,224. The

Secretary also stated, "All requirements as set forth in this final rule for offering the 340B ceiling price to covered entities apply regardless of the distribution system." *Id.* at 1,225.

30. The ACA also amended the 340B statute to require the Secretary to establish "procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers." 42 U.S.C. § 256b(d)(1)(B)(ii).

III. 340B Administrative Dispute Resolution

31. The ACA, signed into law on March 23, 2010, mandated 340B ADR regulations within 180 days:

> Not later than 180 days after the date of enactment of the Patient Protection and Affordable Care Act, the Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section, and claims by manufacturers, after the conduct of audits as authorized by subsection (a)(5)(D), of violations of subsections (a)(5)(A) or (a)(5)(B), including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions.

ACA § 7102(a) (codified at 42 U.S.C. § 256b(d)(3)).

32. The Secretary's 180-day deadline to promulgate regulations for an ADR process fell on September 19, 2010.

33. On September 20, 2010, the Secretary published an "advance notice of proposed rulemaking and request for comments" in the Federal Register "to obtain information and public comment on how to efficiently and effectively implement the requirements to create an administrative dispute resolution process for the 340B Program authorized by Section 7102 of the Affordable Care Act." 340B Drug Pricing Program Administrative Dispute Resolution Process, 75 Fed. Reg. 57,233, 57,234 (Sept. 20, 2010). The September 20, 2010, Federal Register notice did not propose ADR regulations.

34. Nearly six years later, the Secretary published proposed ADR regulations. 340B Drug Pricing Program; Administrative Dispute Resolution, 81 Fed. Reg. 53,381 (Aug. 12, 2016). Those regulations, if finalized, would have established a panel ("ADR Panel") within HHS to adjudicate disputes between 340B covered entities and pharmaceutical manufacturers. *Id.* at 53,382. Under the proposed regulations, covered entities would have been entitled to bring disputes with drug manufacturers to the ADR Panel, including disputes related to 340B program overcharges. *Id.* at 53,383. The ADR Panel would have been empowered to issue a final, binding decision "to HRSA, as necessary, for appropriate enforcement action." *Id.* at 53,388.

35. On August 1, 2017, the Secretary withdrew the proposed ADR regulations without explanation. Office of Mgmt. & Budget, *RIN: 0906-AA90: 340B Drug Pricing Program; Administrative Dispute Resolution Process*, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201704&RIN=0906-AA90 (last visited Oct. 9, 2020).

IV. 340B Contract Pharmacies

36. Many 340B covered entities do not operate in-house pharmacies. Because the requirements to obtain a pharmacy license are complex and operating a pharmacy can be expensive, many covered entities choose not "to expend precious resources to develop their own in-house pharmacies." Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996) ("Contract Pharmacy Notice").

37. Thus, from the beginning of the 340B program, HHS recognized that the program could only function if certain covered entities purchased 340B discounted drugs under contract from third-party pharmacies:

> During the early period of program implementation, it became apparent that only a very small number of the 11,500 covered entities used in-house pharmacies (approximately 500), although additional entities participated by buying drugs for their physician dispensing activities. In addition, many of the larger groups of covered entities, including community and migrant health centers, hemophilia clinics and most of the Ryan White HIV service programs (e.g., State AIDS Drug Assistance Programs) depend upon outside pharmacy services. Yet, because the delivery of pharmacy services is central to the mission of (and a legal mandate in some instances for) these providers, they rely on outside pharmacies to fill the need. It would defeat the purpose of the 340B program if these covered entities could not use their affiliated pharmacies in order to participate in the 340B program. Otherwise, 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. Neither option is within the interest of the covered entities, the patients they serve, or is consistent with the intent of the law.

Id.

38. In 1995, HRSA published in the Federal Register proposed guidelines for contract pharmacy services under the 340B program. Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Contracted Pharmacy Services, 60 Fed. Reg. 55,586 (proposed Nov. 1, 1995).

39. In 1996, after considering comments submitted in response to its November 1, 1995 notice, HRSA published "final guidelines" in the Federal Register regarding contract pharmacy services under the 340B statute. Contract Pharmacy Notice, 61 Fed. Reg. 43,549 (Aug. 23, 1996).

40. "Contract pharmacy services," as HRSA's August 23, 1996 described it, means 340B covered entities' ability to contract with pharmacies as the covered entities' agents to dispense 340B drugs to the covered entities' patients. *Id.* at 43,550. Under such arrangements, the covered entities purchase 340B drugs from manufacturers and direct the manufacturers to ship the 340B drugs to an address other than the address listed in HRSA's database for the covered entities.

41. In its August 23, 1996, guidance, HRSA noted that "many covered entities … do not operate their own licensed pharmacies." *Id.* at 43,549. HRSA explained why the 340B program is essential for these covered entities:

> Because these 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. Covered entities could then use savings realized from participation in the program to help subsidize prescriptions for their lower income patients, increase the number of patients whom they can subsidize and expand services and formularies.

Id. The agency's guidance "encouraged" covered entities that did not operate their own licensed pharmacies to use contract pharmacy services. *Id.* at 43,555.

42. HRSA's August 23, 1996, guidance was clear that the 340B statute requires pharmaceutical manufacturers to sell 340B discounted drugs to covered entities through contract pharmacy arrangements:

> Comment: The use of contract pharmacy services is inconsistent with section 340B of the PHS [Public Health Service] Act and results in an unauthorized expansion of the program.
>
> Response: Section 340B, which established the Drug Pricing Program, requires manufacturers to sell to covered entities at or below a ceiling price determined by a statutory formula. The statute is silent as to permissible drug distribution systems. There is no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself. It 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.
>
> It 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. If the entity directs the drug shipment to its contract pharmacy, we see no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance. However, the entity must comply, under any distribution mechanism, with the statutory prohibition on drug diversion.

Id. at 43,549-50.

43. Responding to a separate comment regarding the requirements of notice and comment rulemaking under the APA, the agency stated:

> The guidelines explain how the Department intends to administer the 340B [program], further explain the statutory language by clarifying the meaning given by the Department to particular words or phrases, and do not exceed the purpose of 340B or conflict with any of its provisions. We believe that these guidelines create no new law and create no new rights or duties.

Id. at 43,550.

44. HRSA was also clear that covered entity arrangements with contract pharmacies are agency relationships:

> Comment: As a matter of State law, entities possess the right to hire retail pharmacies to act as their agents in providing pharmaceutical care to their patients. As a general rule, a person or entity privileged to perform an act may appoint an agent to perform the act unless contrary to public policy or an agreement requiring personal performance. Restatement of Agency 2d § 17 (1995). Hence, even in the absence of Federal guidelines, covered entities have the right to contract with retail pharmacies for the purpose of dispensing 340B drugs. By issuing guidelines in this area, ODP [Office of Drug Pricing] is not seeking to create a new right but rather is simply recognizing an existing right that covered entities enjoy under State law.
>
> Response: We agree. However, entities, under any distribution system, must comply with the statutory prohibition against diversion of 340B drugs to individuals who are not patients of the covered entities. Further, the dispensing of drugs, purchased with a 340B discount, must not result in the generation of a Medicaid rebate.

Id.

45. Although HRSA indicated that its August 23, 1996, contract pharmacy guidance was "designed to facilitate program participation for those eligible covered entities that do not have access to an appropriate 'in-house' pharmacy services," it clarified that "this is not a bar to the use of the mechanism by any covered entity," and "[t]he statute does not limit the covered entities' access to [various] avenues of drug purchasing." *Id.* at 43,551.

46. In 2007, HRSA again published proposed guidelines for contract pharmacies in the Federal Register. Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 72 Fed. Reg. 1,540 (proposed Jan. 12, 2007). Subsequently, HRSA published a final notice regarding contract pharmacies on March 5, 2010. Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010).

47. HRSA's March 5, 2010, guidance expanded the availability of contract pharmacy arrangements to accommodate covered entities contracting with multiple contract pharmacies. HRSA responded to a comment regarding its action as follows:

> Comment: The proposed revisions represent a substantive rulemaking under the APA because they constitute new obligations and burdens on manufacturers. They also create new rights for covered entities under the law.
>
> Response: HRSA disagrees. This guidance neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law. HRSA has used interpretive guidance and statements of policy to provide guidance since the inception of the program and to create a working framework for its administration. Contract pharmacy service guidelines have been considered by HRSA to be "interpretative rules and statements of policy" exempt from notice and comment rulemaking under the APA.

Id. at 10,273.

V. The Supreme Court's *Astra* Decision

48. In 2011, the Supreme Court held that 340B covered entities do not have the right to sue manufacturers for 340B overcharges and that only the Secretary may enforce the manufacturer's obligation to charge at or below the 340B ceiling price. *Astra*, 563 U.S. at 113-14.

49. In *Astra*, covered entities sued drug manufacturers for overcharges under the 340B program. AstraZeneca was among the defendant pharmaceutical manufacturers. The defendant manufacturers argued, with the support of the Secretary, that 340B covered entities do not have a private right of action against pharmaceutical manufacturers to enforce 340B program

requirements. At oral argument, the government's attorney stated the following regarding the ADR regulations:

> [T]here were OIG [Office of Inspector General] reports raising concerns with oversight and enforcement at a general level, and the way Congress reacted to that was to put in place this administrative remedy which will allow covered entities to bring these claims.

Transcript of Oral Argument at 28, *Astra USA, Inc. v. Santa Clara Cty., Cal.*, 563 U.S. 110 (2011) (No. 09-1273), https://www.supremecourt.gov/oral_arguments/argument_transcripts/2010/09-1273.pdf. Justice Ginsburg asked, "Are there plans to implement it?" *Id.* The government's attorney responded:

> Yes. The agency is moving ahead with that. The agency has already issued an advanced notice of proposed rulemaking back in the fall. And it has solicited comments about how the—the administrative scheme should look. That comment period has closed, and so now the agency is in the process of—of moving forward.

Id. at 28-29.

50. The Court's holding that covered entities do not have a private right of action against manufacturers was premised, in part, on the government's representations that ADR regulations would be forthcoming:

> The [2010 ADR provision] provides for more rigorous enforcement [and] directs the Secretary to develop formal procedures for resolving overcharge claims. Under those procedures, which are not yet in place, HRSA will reach an 'administrative resolution' that is subject to judicial review under the Administrative Procedure Act (APA).

Astra, 563 U.S. at 116 (citations omitted).

51. Notwithstanding Congress's mandate to implement ADR within 180 days of enactment of the law, as well its assurances to the Supreme Court, the Secretary has never implemented a 340B ADR program. More recently, HRSA has publicly stated that it has no intention of implementing the regulations. Tom Mirga, *HRSA: 340B Dispute Resolution Will*

Stay on Hold Until We Get Broader Regulatory Authority, 340B Report (Mar. 12, 2020), https://340breport.substack.com/p/your-340b-report-for-thursday-march-eae. Over a decade after its congressional mandate, HRSA defies Congressional intent and its own assurances to the U.S. Supreme Court regarding the mechanism mandated by law for covered entities to pursue complaints against manufacturers for overcharges under the 340B program.

VI. Manufacturer Actions to Reject Contract Pharmacy Arrangements

52. Despite honoring contract pharmacy arrangements for over 24 years, in the summer of 2020, several drug manufacturers announced their intentions either to refuse to honor contract pharmacy arrangements or to impose conditions on covered entities before honoring contract pharmacy arrangements.

A. Eli Lilly and Co.

53. On or around July 1, 2020, HRSA published a "limited distribution plan" on its official manufacturer notices Web page for several formulations of Lilly's drug Cialis. HRSA, *Manufacturer Notices to Covered Entities* (July 2020), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/limited-distribution-plan-notice-cialis.pdf. The limited distribution plan states that, effective July 1, 2020, Lilly will not offer 340B pricing for these drugs if a covered entity sought to purchase the drugs through a contract pharmacy arrangement. *Id*.

54. On information and belief, Lilly no longer offers Cialis in the specified formulations at or below the 340B ceiling price if a covered entity attempts to purchase the drug through a contract pharmacy.

55. On or around September 1, 2020, Lilly prepared and implemented a plan to cease offering 340B prices on drugs purchased by covered entities through contract pharmacy

arrangements for all of its retail drug products, with a qualified exception for its insulin products. Lilly prepared a limited distribution plan that was effective on September 1, 2020, but not published on HRSA's website:

> Effective September 1, 2020, Lilly is limiting distribution of all 340B ceiling priced product directly to covered entities and their child sites only. Covered entities will not be eligible to purchase Eli Lilly and Company products at the 340B ceiling price for shipment to a contract pharmacy.
>
> Covered entities that do not have an in-house pharmacy may contact 340B@lilly.com regarding the exception process to designate a contract pharmacy location.

Eli Lilly & Co., *Limited Distribution Plan Notice for Eli Lilly and Company Products*, 340B Health, (Sept. 1, 2020), https://www.340bhealth.org/files/200901_Eli_Lilly_and_Company_Limited_Distribution_Plan_Public_Notice.pdf.

56. Lilly's September 1, 2020, limited distribution plan "grant[s] an exception to the limited distribution program described above for Lilly insulin products," subject to several conditions not stated in the 340B statute:

- Any and all 340B eligible patients will be able to acquire their Lilly insulins through the contract pharmacy at the 340B price (typically $.03 per 3 mL pen or $.10 per 10 mL vial) at the point-of-sale;
- Neither the covered entity nor the contract pharmacy marks-up or otherwise charges a dispensing fee for the Lilly insulin;
- No insurer or payer is billed for the Lilly insulin dispensed; and,
- The covered entity provides claim-level detail (CLD) demonstrating satisfaction of these terms and conditions.

Id.

57. Immediately thereafter, the Plaintiff Covered Entities confirmed that Lilly no longer offered several of its drugs at or below the 340B ceiling price if they attempted to purchase the drug to ship to an address for one of their contract pharmacies.

58. On or around September 2, 2020, in response to a reporter's inquiry regarding Lilly's actions to refuse to honor 340B contract pharmacy arrangements, HRSA provided the following response:

> HRSA is not posting [Lilly's September 1] letter at this time as HRSA is considering whether manufacturer policies, including Lilly's, violate the 340B statute and whether sanctions may apply. Under section 340B(a)(1) of the Public Health Service Act (PHSA), a manufacturer participating in the 340B Program must offer its covered outpatient drugs for purchase at or below the 340B ceiling price. Those sanctions could include, but are not limited to, civil monetary penalties pursuant to section 340B(d)(1)(B)(vi) of the PHSA.
>
> The 340B statute does not specify the mode by which 340B drugs may be dispensed. However, the Agency believes contract pharmacies serve a vital function in covered entities' ability to serve underserved and vulnerable populations, particularly as many covered entities do not operate in-house pharmacies. Without comprehensive regulatory authority, HRSA has only limited ability to issue enforceable regulations to ensure clarity in program requirements across all the interdependent aspects of the 340B Program.
>
> We believe that manufacturers that refuse to honor contract pharmacy orders could significantly limit access to 340B-discounted drugs for many underserved and vulnerable populations who may be located in geographically isolated areas and rely on contract pharmacies as a critical point of access for obtaining their prescriptions. To this end, HRSA continues to strongly encourage all manufacturers to sell 340B priced drugs to covered entities directly and through contract pharmacy arrangements.

Bronwyn Mixter, *BREAKING: HRSA Is Investigating Whether Manufacturer Policies to Restrict 340B Pricing at Contract Pharmacies Violates Statute,* 340B Report (Sept. 2, 2020), https://340breport.substack.com/p/breaking-hrsa-is-investigating-whether.

59. Nevertheless, on information and belief, neither HRSA nor the Secretary took any enforcement action against Lilly to enforce the 340B statutory requirements to honor contract pharmacy arrangements.

B. Sanofi-Aventis U.S. LLC

60. On or around July 28, 2020, drug manufacturer Sanofi issued letters to 340B covered entities, including Plaintiffs Matthew 25 and Cempa, directing the covered entities to provide all of their claims data for 340B drugs purchased through contract pharmacies to a system called the 340B ESP program, which is operated by Second Sight Solutions, a Sanofi-designated vendor. Sanofi's letter stated that it would no longer honor contract pharmacy arrangements for covered entities that refuse to comply:

> Sanofi is requiring 340B covered entities to register with 340B ESP™ and begin providing 340B claims data by October 1, 2020. 340B covered entities that elect not to provide 340B claims data will no longer be eligible to place Bill To / Ship To replenishment orders for Sanofi products dispensed through a contract pharmacy. All 340B covered entities will continue to be able to purchase Sanofi products at the 340B price when shipped to an address registered on the 340B covered entity database as a parent or child site.

Letter from Gerald Gleeson, Vice President & Head, Sanofi US Market Access Shared Services, SanofiAventis U.S. LLC (July 2020), http://www.avitapharmacy.com/blog/wp-content/uploads/2020/09/Sanofi-Letter.pdf.

61. In response to the announcements from Lilly and Sanofi, on or around July 30, 2020, the trade association American Hospital Association wrote a letter to the Secretary urging him to act against Lilly and Sanofi. Letter from Thomas P. Nickels, Exec. Vice President, Am. Hosp. Ass'n, to Alex M. Azar II, Sec'y, HHS (July 30, 2020), https://www.aha.org/system/files/media/file/2020/07/aha-urges-hhs-take-action-against-drug-manufacturers-for-limiting-distribution-340b-drugs-letter-7-30-2020.pdf. On information and belief, the Secretary neither responded to the letter nor took the requested action.

C. AstraZeneca

62. On or around August 17, 2020, drug manufacturer AstraZeneca issued letters to 340B covered entities, including the Plaintiff Covered Entities, stating that it would no longer honor most 340B contact pharmacy arrangements effective October 1, 2020:

> Beginning on October 1, 2020, AstraZeneca plans to adjust this approach such that AstraZeneca only will process 340B pricing through a single Contract Pharmacy site for those Covered Entities that do not maintain their own on-site dispensing pharmacy.
>
> To implement this new approach, AstraZeneca will stop processing 340B chargebacks for all 340B Contract Pharmacy arrangements effective October 1, 2020. Any 340B Covered Entity that does not have an outpatient, on-site dispensing pharmacy should contact AstraZeneca to arrange for a Contract Pharmacy of its choice to be eligible to receive 340B pricing on behalf of the Covered Entity.

Letter from Odalys Caprisecca, Exec. Dir., Strategic Pricing & Operations, AstraZeneca PLC (Aug. 17, 2020), http://www.avitapharmacy.com/blog/wp-content/uploads/2020/09/AstraZeneca-Retail-Communication-340B-Final.pdf.

63. On information and belief, AstraZeneca ceased offering 340B pricing on drugs dispensed at contract pharmacies on October 1, 2020.

D. Novartis

64. Like Sanofi, Novartis sent letters to the Plaintiff Covered Entities requesting them to register in the 340B ESP program by October 1, 2020, which would require them to provide all claims data related to 340B drugs dispensed to the Plaintiff Covered Entities' patients at contract pharmacies. Letter from Daniel Lopuch, Vice President Novartis Managed Mkts. Fin., Novartis Pharmaceuticals Corp. (Aug. 17, 2020). Novartis stated that all 340B covered entities will be required to register for 340B ESP and "provide 340B claims data originating from [contract pharmacy] utilization in order to receive 340B reimbursements [for contract pharmacy drugs] from Novartis." *Id.*

E. Responses to Manufacturer Actions

65. On or around July 16, 2020, the 340B Coalition, a group of national trade associations whose members are 340B covered entities, wrote to the Secretary urging him to act against Lilly. Letter from the 340B Coal., to Alex M. Azar II, Sec'y, HHS (July 16, 2020), https://www.dropbox.com/s/2m4mjvtx1dwpkyu/340B%20Coalition%20Letter%20to%20HHS%2007.16.2020.pdf?dl=0. On information and belief, the Secretary neither responded to the letter nor took the requested action.

66. On or around August 19, 2020, the trade association National Association of Chain Drug Stores issued a letter to the Secretary urging him to act against Lilly, Sanofi, and AstraZeneca for their refusals to honor 340B contract pharmacy arrangements. Letter from Steven C. Anderson, President & Chief Exec. Officer, Nat'l Ass'n of Chain Drug Stores, to Alex M. Azar II, Sec'y, HHS (Aug. 19, 2020), https://strategichealthcare.net/wp-content/uploads/2020/08/NACDS-letter.pdf. On information and belief, the Secretary neither responded to the letter nor took the requested action.

67. On or around September 14, 2020, 243 Members of the U.S. House of Representatives, including both Democratic and Republican members and spearheaded by leadership of the committees with oversight jurisdiction over HHS and HRSA, issued a letter to the Secretary urging him to act against Lilly, Sanofi, and AstraZeneca considering their refusals to honor 340B contract pharmacy arrangements. Letter from David B. McKinley *et al*., Members of Cong., to Alex M. Azar II, Sec'y, HHS (Sept. 14, 2020), https://mckinley.house.gov/uploadedfiles/congressional_member_340b_letter_to_azar_9.14.20.pdf. On information and belief, the Secretary neither responded to the letter nor took the requested action.

68. By letter dated September 11, 2020, Plaintiff RWC-340B wrote to the Secretary and encouraged the agency to act against Lilly, Sanofi, Novartis, and AstraZeneca due to their refusals to honor 340B contract pharmacy arrangements. Letter from Shannon Stephenson, President, RWC-340B, to Alex M. Azar II, Sec'y, HHS (Sept. 11, 2020), https://www.rwc340b.org/wp-content/uploads/2020/09/Letter-to-HHS-on-Mfr-Actions-from-RWC340B-9-11-2020.pdf. In its letter, RWC-340B stated that it required HRSA's assistance, in part, because HRSA never implemented ADR regulations as required by statute. *Id*. RWC-340B requested that HRSA assess CMPs against Lilly, Sanofi, Novartis, and AstraZeneca. *Id*. RWC-340B stated that it "would construe lack of enforcement by HHS prior to October 1, 2020 as an indication that HHS has refused this request." *Id*. Nevertheless, the Secretary neither responded to the letter nor took the requested action.

69. By letter dated September 21, 2020, the HHS General Counsel responded to a letter from Lilly dated September 8, 2020, requesting a pre-enforcement advisory opinion on whether Lilly's "new unilateral policy" on 340B contract pharmacies "would subject Lilly to sanctions." Letter from Robert P. Charrow, Gen. Counsel, Office of the Sec'y, HHS, to Anat Hakim, Senior Vice President & Gen. Counsel, Eli Lilly & Co. (Sept. 21, 2020), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hhs-eli-lilly-letter.pdf. The HHS General Counsel stated as follows:

> As we have indicated in earlier correspondence, although the Health Resources and Services Administration ("HRSA") has significant initial concerns with Lilly's new policy, it continues to review that policy and has yet to make a final determination as to any potential action. Correspondingly, Lilly cannot and should not view the absence of any questions from the government as somehow endorsing Lilly's policy especially when this Department is leading the government's response to the COVID-19 pandemic.

Id. The HHS General Counsel also criticized Lilly for implementing its unilateral policy during a public health emergency:

> [W]e believe that the timing of your pricing changes is, at the very least, insensitive to the recent state of the economy. Although the economy is rebounding at a record rate, the unemployment and under-employment rates are still temporarily higher than at the beginning of the year due to COVID-19. Many Americans and many small businesses have had difficulty making ends meet. Lilly, on the other hand, seems to be enjoying an outstanding year. The price of Lilly's stock has increased by more than 11 percent since January 1, 2020, reflecting, among other things, the fact that your company's comprehensive income jumped from $1.414 billion during the second quarter of 2019 to $1.615 billion for the second quarter of 2020, an increase of more than 14 percent.
>
> In contrast, during this same period, most health care providers, many of which are covered entities under section 340B, were struggling financially and requiring federal assistance from the Provider Relief Fund established by the CARES Act. Many continue to struggle and depend on emergency taxpayer assistance. It is against this backdrop that you are effectively increasing the prices of 10 mg and 20 mg Cialis by more than 500,000 percent and have done the same for other drugs in your portfolio.

Id. The HHS General Counsel closed by warning that a False Claims Act "suit against Lilly is a potential consequence in the event that Lilly knowingly violates a material condition of the program that results in over-charges to grantees and contractors." *Id*.

VII. Facts Related to Plaintiffs' Contract Pharmacy Arrangements

A. RWC-340B

70. RWC-340B "is a national organization of HIV/AIDS health care clinics and service providers that receive funding under the Ryan White CARE Act, either through a primary grant or subgrant, and participate as covered entities in the federal 340B Drug Discount Program." RWC-340B, *Ryan White Clinics For 340B Access*, https://www.rwc340b.org/ (last visited Oct. 9, 2020).

71. Approximately 1.2 million people are currently living with HIV/AIDS in the United States. RWC-340B, *Value of Ryan White Providers and Impacts Associated with Resource Reduction*, 2 (Sept. 2020), https://www.rwc340b.org/wp-content/uploads/2020/09/RWC340B-White-Paper-FINAL.pdf. Ryan White clinics provide

critical support to this vulnerable population, serving over half a million individuals by furnishing "HIV primary medical care, medications, and support services for underserved and uninsured" to people living with HIV/AIDS. *Id.* at 2-3.

72. Patients of Ryan White clinics are particularly vulnerable. They are "more likely to have less than a high school education, live in poverty, and be homeless" than people living with HIV/AIDS who are not treated in Ryan White clinics. *Id.* at 6.

73. Patients at Ryan White clinics, however, achieve better overall outcomes than patients in other settings of care. Patients at Ryan White clinics are more likely to achieve HIV viral suppression than patients seen elsewhere. *Id.* at 4. Viral load suppression can result in an undetectable level of HIV in a patient's blood, reducing the risk of transmission. *Id.* Ryan White clinics increased the rate of viral suppression from 69.5% in 2010 to 87.1% in 2018, which is far higher than the 62.7% suppression in all people living with HIV/AIDS. *Id.* at 4-5. The success of Ryan White clinics is due, in part, to their higher rates of mental health, substance abuse, and case management services. *Id.* at 6-7.

74. The savings from 340B drugs is critically important to Ryan White clinics. Without 340B savings, these clinics would have to cut services such as case management, dieticians, vaccines, and substance abuse assistance. *See id.* at 8. Loss of these services would create higher risks of severe illnesses in people living with HIV/AIDS and lead to increased health care expenses. *Id.*

75. Losing contract pharmacy arrangements would be devastating to Ryan White clinics. HRSA's database of 340B providers shows that 75% of Ryan White clinics have contract pharmacy arrangements. *See* HRSA, *Welcome to 340B OPAIS*, https://340bopais.hrsa.gov/ (last visited Oct. 9, 2020). For many Ryan White clinics, contract

pharmacy arrangements are the primary, or even sole, path to 340B discounts. Loss of these discounts would jeopardize services provided by Ryan White clinics and irreparably harm the very vulnerable patients they serve.

B. Matthew 25

76. Matthew 25 provides health care services to approximately 487 people living with HIV/AIDS in Kentucky and Indiana. Approximately 58% of Matthew 25's patients have incomes at or below the federal poverty level, and another 22% of patients have incomes between 101% and 200% of the federal poverty level. Matthew 25 provides comprehensive outpatient and case management services to its clients. These case management services assist clients to coordinate their healthcare and support services and to encourage adherence to drug regimens and routine healthcare. Matthew 25 also provides outpatient and specialty medical care and support services for women, infants, children, and youth living with HIV/AIDS.

77. Matthew 25 funds its services with Ryan White CARE Act grants. Matthew 25 uses 340B savings to provide health care and non-health care services to patients that are not funded in whole or part by grants:

- Physicians that oversee the nurse practitioners who are the primary caregivers at its clinics;
- A "retention specialist" whose expertise is in retaining HIV/AIDS patients in care, thus reducing or completely suppressing their viral load and the chance of spreading the HIV infection;
- A "linkage navigator" whose expertise is in linking patients living with HIV/AIDS, and particularly those individuals who have been recently diagnosed, with appropriate treatment providers and support services;

- A food pantry at each of its locations that also delivers food as needed;
- Transportation for Ryan White patients to receive medical care;
- Advice on, and linkage to, low-income housing;
- Outreach to encourage testing for individuals at high risk of contracting HIV/AIDS; and
- Linguistic services for individuals who do not speak English as a first language.

78. Matthew 25 does not operate an in-house retail pharmacy and obtains 340B discounted drugs exclusively through contract pharmacy arrangements. Matthew 25 has 340B contract pharmacy arrangements with Coordinated Care Network ("CCN"), Curant Health Florida LLC and Curant Health Georgia LLC (collectively "Curant Health"). Both CCN and Curant Health specialize in providing pharmaceuticals to treat HIV/AIDS. CCN and Curant Health provide these services through mail order. Prior to October 1, 2020, Matthew 25 purchased drugs from AstraZeneca through these contract pharmacy arrangements. Since October 1, 2020, Matthew 25 has not been able to purchase 340B discounted drugs from AstraZeneca.

79. Loss of contract pharmacy services would devastate the many services that Matthew 25 currently finances with 340B savings. Matthew 25 would have to reduce the services that it provides to its patients, and Matthew 25 will have to reduce the number of its employees or contractors who are responsible for the services listed in paragraph 77. These changes will result in reduced services to Matthew 25's patients and consequent implications for their health.

C. Cempa

80. Cempa serves patients in Chattanooga, Tennessee and also operates a mobile clinic that serves patients in the greater Chattanooga area. Cempa participates in the 340B program both as an FQHC-LA and as a Ryan White Clinic. Cempa provides health care services regardless of the patient's ability to pay and charges for services on a sliding fee scale according to the patient's financial resources. Cempa also operates a program in which it subsidizes retail drugs dispensed to uninsured individuals whose income is at or below 200% of the federal poverty level. If such a patient is uninsured, Cempa pays the full cost of the patient's drugs, and if the patient is insured, Cempa pays the copayment for those drugs.

81. Cempa does not operate an in-house retail pharmacy. Cempa obtains 340B discounted drugs solely through contract pharmacy arrangements. Cempa has multiple contract pharmacy relationships, including arrangements for its FQHC-LA, mobile unit, and Ryan White Clinic. Cempa purchased 340B discounted drugs from the four Drug Companies before they halted 340B sales through contract pharmacy arrangements.

82. If Cempa loses 340B savings from its contract pharmacy purchases, its program to subsidize drugs for low-income patients will be imperiled. The cost of drugs dispensed to uninsured individuals will rise dramatically, and the saving from 340B purchases will no longer be available for these subsidies.

COUNT I
Declaratory Judgment

83. Plaintiffs reallege and incorporate by reference paragraphs 1–82 as if fully set forth below.

84. Plaintiffs request a declaration pursuant to 28 U.S.C. § 2201 that they are entitled to purchase and dispense drugs at 340B discounts through arrangements with contract pharmacies.

85. The 340B statute directs the Secretary to execute PPAs with manufacturers that "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." 42 U.S.C. § 256b(a)(1). The 340B statute contains no exemption permitting pharmaceutical manufacturers to restrict 340B sales based upon the delivery location of the drugs.

86. The 340B statute includes covered entity organizations, including Ryan White CARE Act grantees and FQHC-LAs, that lack in-house pharmacies. *See id.* § 256b(a)(4)(D). Congress therefore intended that an in-house pharmacy is not a condition for participation in the 340B program. Congress therefore also intended that, as a condition of participation in Medicaid and Medicare Part B, pharmaceutical manufacturers must provide 340B pricing to covered entities that order through third-party agents, such as contract pharmacies.

87. The Secretary has consistently, and correctly, interpreted the 340B statute to require manufacturers to honor 340B contract pharmacy arrangements. In 1996, the Secretary interpreted the statute to entitle covered entities to purchase at 340B discounts through contract pharmacies:

> The statute is silent as to permissible drug distribution systems. There is no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself. It 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.
>
> It 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.

Contract Pharmacy Notice, 61 Fed. Reg. at 43,549.

88. The Secretary has consistently, and correctly, stated that his contract pharmacy guidance interprets preexisting statutory requirements. *Id.* at 43,550; Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. at 10,273.

89. The Secretary's CMP regulation defines an "instance of overcharging" as "any order for a covered outpatient drug, by NDC, which results in a covered entity paying more than the ceiling price . . . ." 42 C.F.R. § 10.11(b). An order "includes any order placed directly with a manufacturer or through a wholesaler, authorized distributor, or ***agent***." *Id.* § 10.11(b)(1) (emphasis added). Contract pharmacies serve as agents of 340B covered entities. Contract Pharmacy Notice, 61 Fed. Reg. at 43,550.

90. Therefore, a manufacturer that charges a covered entity more than the 340B ceiling price for a drug ordered via a contract pharmacy has overcharged the covered entity in violation of the 340B statute, 42 U.S.C. § 256b, and the 340B CMP regulation, 42 C.F.R. § 10.11.

COUNT II
Violation of Due Process

91. Plaintiffs reallege and incorporate by reference paragraphs 1–90 as if fully set forth below.

92. Congress unambiguously required the Secretary to issue ADR regulations no later than September 19, 2010. 42 U.S.C. § 256b(d)(3). The Secretary has missed that deadline by over ten years.

93. The Secretary represented to the Supreme Court in 2011 that the Secretary would issue ADR regulations, leading the Court to hold that 340B covered entities do not have a private right of action against drug manufacturers. *Astra*, 563 U.S. at 116.

94. The Secretary has, therefore, left the Plaintiff Covered Entities with no recourse to vindicate their rights under the 340B statute and the CMP regulation to receive 340B discounts through contract pharmacy arrangements other than the intervention of this Court.

95. By failing to implement ADR as Congress mandated and as the government represented to the Supreme Court, and by failing to take action on its own initiative to enforce the 340B statute's requirements on manufacturers to honor contract pharmacy arrangements, the Secretary has deprived the Plaintiff Covered Entities of their protected property interests under the Due Process Clause of the Fifth Amendment to the U.S. Constitution, and thereby Defendant has deprived the Plaintiff Covered Entities of their procedural due process rights.

96. Covered entities must be permitted to pursue complaints under the ADR process for overcharges against manufacturers that refuse to honor contract pharmacy arrangements. The Secretary has deprived covered entities of any opportunity to pursue such complaints.

97. By failing to implement ADR regulations as Congress mandated and as the government represented to the Supreme Court it would, and by failing to take action on its own initiative to enforce the 340B statute's requirements on manufacturers to honor contract pharmacy arrangements, the Secretary has caused substantial and irreparable harm to Plaintiffs and all 340B covered entities with contract pharmacy arrangements, as well as to their patients.

COUNT III
VIOLATIONS OF THE ADMINISTRATIVE PROCEDURE ACT

98. Plaintiffs reallege and incorporates by reference paragraphs 1–97 as if fully set forth below.

99. The APA requires a court to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1).

100. The Secretary has unlawfully withheld and unreasonably delayed issuing ADR regulations within the deadline set by Congress. 42 U.S.C. § 256b(d)(3).

101. The Secretary has unlawfully withheld from the Plaintiff Covered Entities their rights to purchase drugs at 340B discounts.

102. The Secretary has unlawfully withheld from the Plaintiff Covered Entities their right to refunds from manufacturers that overcharged the Plaintiff Covered Entities by refusing to honor contract pharmacy arrangements. *Id*. § 256b(d)(1)(B)(ii).

103. The Secretary's refusal to enforce the Plaintiff Covered Entities' rights to purchase and dispense drugs at 340B discounts through contract pharmacy arrangements is arbitrary, capricious, an abuse of discretion, not based upon substantial evidence, and not in accordance with the law, in violation of the APA. 5 U.S.C. § 706(2)(A).

COUNT IV
MANDAMUS

104. Plaintiffs reallege and incorporates by reference paragraphs 1–103 as if fully set forth below.

105. The Secretary has a clear, nondiscretionary duty to promulgate ADR regulations. 42 U.S.C. § 256b(d)(3). The Plaintiff Covered Entities have a clear right to ADR procedures. *Id.* The Plaintiff Covered Entities have no adequate remedy available other than an order from this Court directing the Secretary to comply with Congress's mandate to issue ADR regulations.

106. The Secretary has a clear, nondiscretionary duty to ensure that manufacturers sell covered outpatient drugs to the Plaintiff Covered Entities at 340B prices. *Id*. § 256b. The Plaintiff Covered Entities have a clear right to purchase covered outpatient drugs at 340B prices.

Id. The Plaintiff Covered Entities have no adequate remedy available other than an order from this Court directing the Secretary to order pharmaceutical manufacturers that have executed PPAs to sell drugs to the Plaintiff Covered Entities at 340B discounts when purchased through contract pharmacies.

107. The Secretary has a clear, nondiscretionary duty to establish "procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers." *Id*. § 256b(d)(1)(B)(ii). The Plaintiff Covered Entities have a clear, nondiscretionary duty to procedures to obtain refunds for overcharges by manufacturers. *Id.* § 256b(d)(1)(B)(ii), (d)(3). The Plaintiff Covered Entities have no adequate remedy available other than an order from this Court directing the Secretary to establish procedures enabling the Plaintiff Covered Entities to secure refunds from manufacturers. *See Astra*, 563 U.S. at 113-14.

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully requests relief as follows:

1. A declaration that the Plaintiff Covered Entities are entitled to purchase and dispense covered outpatient drugs through contract pharmacies at 340B discounts;

2. An order from this Court directing the Secretary to promulgate ADR regulations within 60 days of the Court's order;

3. An order from this Court directing the Secretary to enforce the Plaintiff Covered Entities' right to purchase and dispense covered outpatient drugs via contract pharmacies at 340B discounts;

4. An order from this Court directing the Secretary to use his authority to order Lilly, Sanofi, AstraZeneca, and Novartis to refund overpayments owed to the Plaintiff Covered

Entities as a result of the refusal to sell covered outpatient drugs at 340B discounts to the Plaintiff Covered Entities when ordered via contract pharmacy arrangements;

5. An order from this Court directing the Secretary to use his authority to impose CMPs upon drug manufacturers Lilly, Sanofi, AstraZeneca, and Novartis unless and until they comply with the requirements of the 340B statute and honor contract pharmacy arrangements;

6. An order from this Court directing the Secretary to revoke the PPA of any pharmaceutical manufacturer that does not offer drugs at 340B discounts when ordered via contract pharmacy arrangements, thereby excluding drugs produced by such manufacturer from coverage under the Medicaid and Medicare Part B insurance programs.

7. An order from this Court awarding the Plaintiff Covered Entities the costs and fees incurred in this litigation and granting such other relief in law and/or equity as this Court may deem just and proper.

JURY DEMAND

Plaintiffs demand a jury trial on all issues triable by a jury as of right.

Respectfully submitted,

/s/ Ronald S. Connelly
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Dated: October 9, 2020

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
FLORENCE DIVISION

Genesis Health Care, Inc., Plaintiff, v. Alex M. Azar, II, *as Secretary of the United States Department of Health and Human Services*; George Sigounas, *as Administrator of the Health Resources and Services Administration*; and Krista Pedley, *as Captain in the United States Public Health Service and Director of the Office of Pharmacy Affairs in the Health Resources and Services Administration,* Defendants.	Civil Action No.: 4:19-cv-1531-RBH **ORDER**

This matter is before the Court for consideration of Defendants Alex M. Azar, II, George Sigounas, and Krista Pedley's ("Defendants") motion to dismiss for lack of subject matter jurisdiction, ECF No. 41, and motion to stay discovery, ECF No. 46. For the reasons discussed below, the Court will grant Defendants' motion to dismiss, thereby rendering Defendants' motion to stay discovery moot, and dismiss this case without prejudice for lack of subject matter jurisdiction.

Factual and Procedural History

Plaintiff is a nonprofit Federally Qualified Health Center ("FQHC") that provides comprehensive primary and preventative healthcare to patients regardless of their health insurance status and ability to pay. Amended Verified Petition for Judicial Review ("Amended Petition") ¶ 1. As a FQHC, Plaintiff is eligible to participate in the 340B Program, which is a drug pricing program managed by the Health Resources and Services Administration (HRSA), an agency within Department of Health and Human Services ("HHS"). *Id.* ¶ ¶ 9-10. The 340B Program allows the HHS Secretary to

enter into agreements with manufacturers of covered outpatient drugs in order to obtain discounts for covered entities, such as Plaintiff, that purchase these drugs for their patients. *Id*. ¶ 10. Plaintiff and other covered entities purchase covered outpatient drugs from manufacturers through wholesalers, and dispense these drugs at wholly-owned and contract pharmacies to individuals who qualify as a covered entity's patients under the 340B Program. *Id*. ¶ 11.

HHS may audit covered entities to evaluate compliance with the statutory requirements of the 340B Program. *Id*. ¶ 13. The Health Resources and Services Administration ("HRSA" or "the agency") is an agency within HHS and is responsible for administering the 340B Program. *Id*. ¶2. Within the HRSA, the Office of Pharmacy Affairs ("OPA") is responsible for conducting audits of covered entities like Plaintiff. *Id*. ¶ 14. In June 2017, OPA conducted a one-and-a-half day on-site audit (the Audit) of Plaintiff. *Id*. On February 14, 2018, OPA issued its Final Report containing its Audit findings. *Id.* ¶ 15. OPA found Plaintiff had "fail[ed] to comply with the statutory eligibility requirement of compliance with auditable records" and therefore, the agency made a preliminary determination that Plaintiff was no longer eligible to participate in the 340B Program and that Plaintiff was liable to manufacturers of covered outpatient drugs for purchases made while it was ineligible for 340B Program participation. *Id*.

On March 13, 2018, Tony R. Megna, Plaintiff's CEO, responded to the agency's Final Audit Report and objected to the Audit's findings. *Id*. ¶ 18. On June 26, 2018, the agency replied to Plaintiff's response and concluded Plaintiff's objections were without merit and Plaintiff was ineligible for participation in the 340B Program. *Id*. ¶ 19. Two days later, on June 28, 2018, Plaintiff filed a verified petition for judicial review and emergency motion to stay before this Court, in which Plaintiff asked this Court to, *inter alia*, impose a temporary stay halting the agency's determination that Plaintiff was

ineligible to participate in the 340B Program and declare Plaintiff eligible under the 340B Program. See ECF No. 1.

On August 23, 2018, this Court entered an Order noting Plaintiff had withdrawn its emergency motion to stay because Plaintiff had been provisionally readmitted to the 340B Program. ECF No. 10. The Court stayed this case at the request of both parties from August 24, 2018 to May 29, 2019 to allow the parties to attempt to resolve this matter without judicial intervention. While this case was stayed, on September 24, 2018, the agency vacated its decision to remove Plaintiff from the 340B Program and promptly reinstated Plaintiff into the 340B Program. Amended Complaint ¶ 22.

Despite HRSA vacating its decision and reinstating Plaintiff into the 340B Program, Plaintiff file a motion to amend its petition, emergency motion to stay, and petition for declaratory relief. *See* ECF No. 33. The Court denied Plaintiff's motion for a preliminary injunction and emergency motion to stay, but granted Plaintiff's motion to amend its petition. ECF No. 44. In the Amended Petition, Plaintiff sought an order from this Court: (1) directing "HRSA to retract any notification it may have provided to manufacturers that Plaintiff is ineligible under the 340B Program"[1], (2) "set[ting] aside HRSA's determinations pursuant to 5 U.S.C. § 706(2)(A)", and (3) declarative relief "concerning the plain wording of 42 U.S.C. § 256b(a)(5)(B)." ECF No. 33 at 25. After the Amended Petition was filed, on June 6, 2019, OPA voided the audit findings in their entirety, and informed Plaintiff that it "ha[d] no further obligations or responsibilities in regard to the audit, including any actions to submit a

[1] Although Plaintiff requested this relief in the Amended Petition, this request was made before the agency sent the June 6, 2019 letter informing Plaintiff that, in addition to restoring Plaintiff's eligibility for participation in the 340B Program, the agency was voiding the audit in its entirety. Furthermore, Plaintiff does not address this request for relief in its response to Defendants' motion to dismiss. The contents of the June 2019 letter combined with Plaintiff's silence on this issue in its subsequent filing strongly suggests to this Court that this issue has been resolved since the filing of the Amended Petition. Even assuming *arguendo* this issue has not been fully resolved, it is insufficient to change the Court's conclusion that it does not have jurisdiction over this matter as set forth herein. There is no final agency action to judicially review.

[Corrective Action Plan] or perform the actions outlined in the [Corrective Action Plan] previously submitted to OPA. ECF No. 41, Exhibit A.

Shortly after Plaintiff filed the amended petition, Defendants filed a motion to dismiss for lack of subject matter jurisdiction, ECF No. 41, and a motion to stay discovery, ECF No. 46, pending this Court's ruling on Defendants' motion to dismiss. Plaintiff has responded to both motions. See ECF Nos. 43, 47. Accordingly, both motions are ripe for decision before this Court.

Standard of Review

A Rule 12(b)(1) motion to dismiss for lack of subject matter jurisdiction raises the fundamental question of whether a court has jurisdiction to adjudicate the matter before it. Fed. R. Civ. P. 12(b)(1). "Federal courts are courts of limited subject matter jurisdiction, and as such there is no presumption that the court has jurisdiction." *Pinkley, Inc. v. City of Frederick, Md.*, 191 F.3d 394, 399 (4th Cir. 1999). In deciding a motion under Rule 12(b)(1), the burden is on the plaintiff to show subject matter jurisdiction exists, and the Court is to "regard the pleadings' as mere evidence on the issue, and may consider evidence outside the pleadings without converting the proceeding to one for summary judgment." *Richmond, Fredericksburg & Potomac R.R. Co. v. United States*, 945 F.2d 765, 768 (4th cir. 1991) (citing *Adams v. Bain*, 697 F.2d 1213, 1219 (4th Cir. 1982)). "The moving party should prevail only if the material jurisdictional facts are not in dispute and the moving party is entitled to prevail as a matter of law." *Id.*

Discussion

Defendants move to dismiss this case in its entirety under Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction and mootness. ECF No. 41 at 2. Specifically, Defendants contend (1) this case was rendered moot by the agency's decision to void the audit in its entirety and there is no final

agency action under the APA for Plaintiff to challenge; (2) there is no case or controversy as required by Article III and Plaintiff is now seeking an impermissible advisory opinion; and (3) the Declaratory Judgment Act, 28 U.S.C. § 2201, does not provide an independent basis for this Court to exercise jurisdiction in this case.[2]

Defendants first allege this case should be dismissed pursuant to Fed. R. Civ. P. 12(b)(1) because there is no final agency action for Plaintiff to challenge under the APA and therefore, this case is moot. 5 U.S.C. § 702 of the APA provides that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of the relevant statute, is entitled to judicial review thereof." Other than agency action made specifically reviewable by statute, § 704 limits the APA's non-statutory right of judicial review to final agency action. 5 U.S.C. § 704 ("Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review.")[3]

The Supreme Court has set forth two elements that must be satisfied in order for an agency's action to be "final" for purposes of judicial review. "First, the action must mark the 'consummation' of the agency's decisionmaking process – it must not be of a merely tentative or interlocutory nature... [a]nd second, 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). "[A]n agency action may be considered 'final' only when the action signals the consummation of an agency's

[2] Defendants also assert that no constitutional claim lies against the agency or the Defendants in their official capacity because a *Bivens* action cannot lie against either the United States or against federal agents acting in their official capacities. *See Doe v. Chao*, 306 F.3d 170, 184 (4th Cir. 2002). Although the Court recognizes this is a correct statement of the law, the Court does not see its applicability in the instant case because Plaintiff has not asserted a *Bivens* claim. Therefore, the Court will decline to address this reason for dismissal discussed in Defendants' brief.

[3] As there is no private right of action to enforce agency action related to the administration of the 340B Program, Plaintiff seeks relief on the APA's general review provisions. 5 U.S.C. §§ 702, 704. *See Astra USA, Inc. v. Santa Clara County, Cal.*, 563 U.S. 110 (2011).

decisionmaking process *and* gives rise to legal rights or consequences." *COMSAT Corp. v. National Sci. Found.*, 190 F.3d 269, 274 (4th Cir. 1999). (italics in original).

In this case, the original final agency action was the agency's determination that Plaintiff was ineligible to continue participating in the 340B Program. It "marked the consummation of the agency's decisionmaking process" and was one from which "legal consequences will flow." *Bennett*, 520 U.S. at 178. At the time this action was filed, this was the final agency action Plaintiff sought to challenge in this Court, and this Court had jurisdiction to review the agency's decision declaring Plaintiff ineligible for participation in the 340B Program. However, after this action was filed, the agency voided the audit in its entirety and reinstated Plaintiff as a covered entity under the 340B Program. As Plaintiff readily admits in its response in opposition to the Defendants' motion to dismiss, "Defendants [decision to void the audit findings] provides Genesis retroactive relief from the immediate obligations imposed on Genesis by [the agency]." ECF No. 43 at 2. Plaintiff contends they are now "directly challenging the audit process in this action," but importantly, Plaintiff is not challenging the final result of the agency's process – the decision to void the audit and restore Plaintiff's eligibility to participate in the 340B Program. *Id*. at 3.

The difficulty with Plaintiff's contention is that the "audit process" is not a final agency action susceptible to judicial review under 5 U.S.C. § 704. Plaintiff insists that "absent judicial review, [the agency] will continue to incorporate its unlawful and narrower definition of 'patient' into its audit standards so that Genesis, as well as other covered entities, will continue to be subject [to the same standards]." ECF No. 43 at 3. The proper time to challenge this allegedly narrower definition of "patient" is when the definition is used in an audit that marks the completion of the agency's decisionmaking process and "affect[s] the legal rights of the relevant actors" and has "appreciable legal

consequences." *Bennett*, 520 U.S. at 178. The agency's decision to void the audit and restore Plaintiff's status as a covered entity in the 340B Program plainly fails to affect Plaintiff's legal rights - in fact, it restores Plaintiff's rights exactly as they were before the audit occurred. Therefore, the agency's decision to void the audit produced no "appreciable legal consequences" and is not a final agency action subject to review under the APA. See *id*. (discussing *Dalton v. Specter*, 511 U.S. 462 (1994); and *Franklin v. Massachusetts*, 505 U.S. 788 (1992).

Defendants next allege that, because there is no final agency action, there is no case or controversy as required by Article III and Plaintiff is now seeking an impermissible advisory opinion on the definition of the word "patient" in the event of a future audit. ECF No. 41 at 8. In a separate but related argument, Defendants contend the Declaratory Judgment Act does not provide an independent basis for this Court to exercise jurisdiction over this case. Plaintiff argues it "face[s] an ongoing and imminent threat of auditing and enforcement based on the Defendants' [alleged unlawful] auditing standards" and therefore this matter is still properly before the Court.

Because these issues involve intertwined doctrines of justiciability, the Court finds it necessary to begin with an overview of these doctrines. Article III of the United States Constitution limits the jurisdiction of federal courts to deciding "cases" and "controversies." U.S. Const. Art. III, § 2. "It has long been settled that a federal court has no authority 'to give opinions upon moot questions or abstract propositions, or to declare principles or rules of law which cannot affect the matter in issue in the case before it.'"[4] *Church of Scientology of Cal. v. United States*, 506 U.S. 9, 12 (1992) (quoting *Mills v.*

[4] The case-or-controversy requirement applies equally in actions seeking declaratory relief, such as the case at bar. *See Golden v. Zwickler*, 394 U.S. 103, 108 (1969). To satisfy the case-or-controversy requirement in an action seeking declaratory relief, "the facts alleged, under all circumstances, [must] show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Maryland Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941).

Green, 159 U.S. 651, 653 (1895)).

An actual controversy must exist at all stages of federal court proceedings. If events subsequent to the filing of the case resolve the dispute, the case should be dismissed as moot. *Pashby v. Delia*, 709 F.3d 307, 316 (4th Cir. 2013). "[M]ootness is the doctrine of standing in a time frame...[t]he requisite personal interest that must exist at the commencement of the litigation (standing) must continue throughout its existence (mootness)." *United States Parole Comm'n v. Geraght*, 445 U.S. 388, 397 (1980), quoting Henry Monaghan, Constitutional Adjudication: The Who and When, 82 Yale L.J. 1363, 1384 (1973)."Federal courts lack jurisdiction to decide moot cases because their constitutional authority extends only to actual cases or controversies." *Iron Arrow Honor Soc. v. Heckler*, 464 U.S. 67, 71 (1983). "A case is moot when the issues presented are no longer live or the parties lack a legally cognizable interest in the outcome." *City of Erie v. Pap's A.M.*, 529 U.S. 277, 287 (2000) (citation and internal quotations omitted); *Williams v. Ozmint*, 716 F.3d 801, 809 (4th Cir. 2013) (citation omitted).

A federal court has subject matter jurisdiction over a claim for declaratory relief if "(1) the complaint alleges an actual controversy between the parties of sufficient immediacy and reality to warrant the issuance of a declaratory judgment; (2) the court possesses an independent basis for jurisdiction over the parties (e.g., federal question or diversity jurisdiction); and (3) the court does not abuse its discretion in its exercise of jurisdiction." *Volvo Constr. Equip. N. Am. Inc. v. CLM Equip. Co.*, 386 F.3d 581, 592 (4th Cir. 2004). "[D]istrict courts possess discretion in determining whether and when to entertain an action under the Declaratory Judgment Act, even when the suit otherwise satisfies subject matter jurisdictional prerequisites." *Wilton v. Seven Falls Co.*, 515 U.S. 277, 282 (1995).

The Court begins with the first jurisdictional prerequisite, which is often called the "Constitutional inquiry" because a case "meets the actual controversy requirement [for declaratory

relief] only if it presents a controversy that qualifies as an actual controversy under Article III of the Constitution." *Volvo Constr. Equip. N. Am. Inc.*, 386 F.3d at 592. An actual controversy is one that is "definite and concrete, touching the legal relations of parties having adverse legal interests," "real and substantial," and one that seeks "specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical set of facts." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937)).

In the case at bar, the parties ceased to have a "definite and concrete" controversy when the agency decided to void its audit findings. The specific relief Plaintiff originally requested, to be restored as a "covered entity" in the 340B Program, has already been provided by the agency. At this time, the relief requested in Plaintiff's amended petition seeks to have this Court render exactly the type of impermissible advisory opinion contemplated by the Supreme Court in *MedImmune*. Because the case-or-controversy requirement is not satisfied in this case, this case is moot. *See Simmons*, 634 F.3d at 763.

There is, however, a well-recognized exception to the mootness doctrine for conduct "capable of repetition, yet evading review." *Fed. Election Comm'n v. Wisc. Right to Life, Inc.*, 551 U.S. 449, 462 (2007). This exception applies when "(1) the challenged action is in its duration too short to be fully litigated prior to cessation or expiration and (2) there is a reasonable expectation that the same complaining party will be subject to the same action again." *Id*.

Although Plaintiff does not cite any applicable case law or expound upon this argument in great detail, Plaintiff alludes to this doctrine several times in its response to Defendants' motion to dismiss. Plaintiff stated "Defendants' internal policies and procedures that formed the basis of the voided audit

are unlawful and clearly capable of repetition as to Genesis and/or any other 'covered entity' that [the agency] audits under its statutory authority." ECF No. 43 at 2. While Plaintiff contests the Defendants' allegedly narrower definition of the word "patient," Plaintiff does not otherwise specify what internal policies or procedures are unlawful, nor does Plaintiff explain how a future decision from the agency would "evade review." The present case is not one which was "too short,"rather, as Plaintiff admits in its brief, it is a case in which the initial challenged agency action was voided in its entirety. Plaintiff asserts "Defendants' unlawful and narrowed definition of 'patient' is still firmly incorporated into Defendants' audit standards," but there is no audit upon which Plaintiff can make such an allegation. ECF No. 43 at 2. Without an active audit that would allow this Court to review the agency's allegedly unlawful definition of "patient," this case is moot and the "capable of repetition, yet evading review" exception is inapplicable.

Conclusion

For the foregoing reasons, the Court **GRANTS** Defendants' motion to dismiss. Accordingly, Defendants' motion to stay discovery, ECF No. 46, is **MOOT**. Therefore, this case is **DISMISSED WITHOUT PREJUDICE** for lack of subject matter jurisdiction.

IT IS SO ORDERED.

Florence, South Carolina
December 18, 2019

s/ R. Bryan Harwell
R. Bryan Harwell
Chief United States District Judge