[ORAL ARGUMENT NOT YET SCHEDULED]
No. 18-5299

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

IPSEN BIOPHARMACEUTICALS, INC.

Plaintiff-Appellant,

v.

ALEX MICHAEL AZAR, II, IN HIS OFFICIAL CAPACITY AS SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,

Defendants-Appellees.

On Appeal from the U.S. District Court for the District of Columbia
Civil Action No. 1:16-cv-02372
(Hon. Dabney L. Friedrich)

Brief of Amicus Curiae the Chamber of Commerce of the United States of America in Support of Plaintiff-Appellant

Daryl Joseffer
Michael B. Schon
U.S. CHAMBER LITIGATION CENTER
1615 H. St NW
Washington, DC 20062

Ruthanne M. Deutsch
Hyland Hunt
R. Craig Kitchen
DEUTSCH HUNT PLLC
300 New Jersey Ave. NW
Suite 900
Washington, DC 20001
(202) 868-6915
rdeutsch@deutschhunt.com

Counsel for The Chamber of Commerce of the United States of America

INITIAL BRIEF: February 4, 2019

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. Parties and Amici

All parties and amici appearing before the district court and this Court are listed in Appellant's brief apart from the Chamber of Commerce of the United States of America, appearing as amicus in this brief.

B. Ruling Under Review

Appellant's brief accurately references the ruling at issue.

C. Related Cases

This case has not previously been before this Court or any other court. Counsel is not aware of any related case pending before this Court or any other court.

/s/*Ruthanne M. Deutsch*
Ruthanne M. Deutsch

CORPORATE DISCLOSURE STATEMENT

Under Rule 26.1 of the Federal Rules of Appellate Procedure and D.C. Circuit Rule 26.1, amicus curiae the Chamber of Commerce of the United States of America submits the following corporate disclosure statement:

The Chamber of Commerce of the United States of America is a nonprofit, tax-exempt organization incorporated in the District of Columbia. The Chamber has no parent corporation, and no publicly held company owns 10% or more of its stock.

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CMS	Centers for Medicare and Medicaid Services
APA	Administrative Procedure Act
AMP	Average Manufacturer Price

INTEREST OF AMICUS CURIAE[†]

The Chamber of Commerce of the United States of America ("Chamber") is the world's largest business federation. It represents 300,000 direct members and indirectly represents more than three million businesses and professional organizations of every size, in every sector, and from every geographic region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber often files amicus curiae briefs in cases that raise issues of concern to the nation's business community.

This is such a case. The Chamber's membership includes businesses engaged in commerce throughout the nation, subject to the reach of every federal agency. Like Ipsen, some of those members are subject to the authority of the Centers for Medicare and Medicaid Services ("CMS") as participants in the Medicaid drug-rebate program. More broadly, the Chamber would like to ensure that the Administrative Procedure Act's bedrock promise of judicial review is kept for review of agency decisions, like the one here, that are final and consequential in everything but name. The Chamber has a keen interest in ensuring that agencies not

[†] No counsel for a party authored this brief in whole or in part, and no person other than amicus curiae, its members, or its counsel contributed money that was intended to fund this brief's preparation or submission. *See* Fed. R. App. P. 29(a)(4)(E). The Chamber filed its notice of its intent to participate as amicus curiae on January 31, 2019. All parties have consented to the filing of this brief.

be allowed to use informal processes to insulate otherwise final actions from judicial review, and that its members can get appropriate, timely judicial review of agency action that affects them.

SUMMARY OF ARGUMENT

I. The district court's rigid finality inquiry conflicts with the Supreme Court's and this Court's repeated admonition that courts must take a flexible and pragmatic approach in assessing finality. To start, the district court focused on the specific facts of various prior, outdated circuit cases, while giving short shrift to the holdings of more recent Supreme Court and Circuit precedent on point. But "[n]othing in [this Court's] case law suggests the law of final agency action is confined to the specific facts of prior circuit cases." *Friedman v. FAA*, 841 F.3d 537, 543 (D.C. Cir. 2016). Worse still, the district court discerned a bright-line requirement for finality—that the agency's decision have independent sanction or coercive effect—found nowhere in governing precedent. The law, in fact, is just the opposite; the APA "provides for judicial review of all final agency actions, not just those that impose a self-executing sanction." *Sackett v. EPA*, 566 U.S. 120, 129 (2012).

The Supreme Court and this Court have reaffirmed—in decisions of recent vintage—that agency action is final when, as here, it leaves a regulated party with a Hobson's choice: change its business practice to conform to the agency's definitive legal pronouncement, or continue that practice and risk serious penalties in a future

enforcement proceeding. *Sackett*, 566 U.S. at 127; *Rhea Lana, Inc. v. Dep't of Labor*, 824 F.3d 1023, 1030 (D.C. Cir. 2016). When there is "no entitlement to further agency review," and nothing left to do but "wait for the Agency to drop the hammer," *Sackett*, 566 U.S. at 127, an agency's action is final.

CMS's letter informed Ipsen that in the agency's view, the statute required Ipsen to report Somatuline ED as if it were the original Somatuline. Ipsen's refusal to change its reporting behavior to conform to that interpretation would expose Ipsen to the risk of a charge of "knowingly provid[ing] false information," 42 U.S.C. § 1396r-8(b)(3)(C)(ii), in a future enforcement proceeding. This exposure to potentially increased liability alone suffices to make CMS's decision final. *See Sackett*, 566 U.S. at 129; *Rhea Lana*, 824 F.3d at 1025.

Beyond that, CMS's letter is also final under *U.S. Army Corps of Eng'rs v. Hawkes Co.*, 136 S. Ct. 1807 (2016) because it denies Ipsen safe harbor from the knowing violation provision of the statutory scheme. Had CMS agreed that Ipsen was correctly using a new base date AMP for Somatuline ED, then CMS would have no plausible claim that Ipsen was knowingly providing false information. Put another way, a letter agreeing that Ipsen was correctly calculating the data it reported would grant Ipsen safe harbor from the statutory provision imposing penalties on manufacturers who "knowingly provide false information." It follows that CMS's letter here, which disagrees with Ipsen's calculation, amounts to a denial of that safe

harbor. And the creation or denial of a safe harbor is also by itself a legal consequence making CMS's letter final. *Id.* at 1814.

II. The presumption of judicial review forms the bedrock of the Administrative Procedure Act ("APA"), ensuring that regulated entities have a chance to test the lawfulness of agency action without risking financial ruin.

The decision below imperils that principle by providing a roadmap for agencies to evade judicial review by simply issuing final decisions through nominally informal letters containing definitive legal directives with real consequences. This sounds hyperbolic, but the decision at issue came from the head of the relevant subunit of the agency on reconsideration of informal advice given by agency staff; consists of an unambiguous interpretation of a generally applicable statutory term; marks the consummation of the agency's decisionmaking process on that legal issue; tells the regulated party to comply with the agency's view; and threatens substantial penalties for failure to comply. Under the district court's decision, such an action is unreviewable so long as the agency issues its decision by letter and omits explicit threat of an enforcement action. Yet no further agency review is contemplated or available, and the administrative process, short of enforcement, is over.

If affirmed, the district court's ruling would encourage other agencies to similarly mask definitive legal pronouncements backed by the risk of future sanction

as informal advice. That would force regulated entities—although convinced the agency has made an unlawful or arbitrary and capricious decision—to make the painful choice of either running the gauntlet of enforcement proceedings and penalties to get judicial review or acquiesce to the agency's approach immediately, with no hope of judicial review.

Faced with that choice, many a regulated party might choose to conform to the agency's dictate, even with serious concerns about its legality, because the ruinous sanctions possible in a future enforcement proceeding could make the benefit of judicial review so late in the game not worth the cost. The result: mistaken and unlawful agency actions go uncorrected, by following a roadmap that insulates from judicial review definitive legal pronouncements with real consequences, from judicial review. Affirming the district court's ruling would flout the APA's promise.

ARGUMENT

I. THE DISTRICT COURT'S RIGID INSISTENCE THAT AGENCY ACTION IS NOT FINAL UNLESS IT COERCES IMMEDIATE BEHAVIORAL CHANGE IS AT WAR WITH THE PRAGMATIC NATURE OF THE FINALITY INQUIRY AND MISREADS THE SUPREME COURT'S AND THIS COURT'S PRECEDENT.

An agency's action, regardless of formality, constitutes "final agency action" subject to judicial review under the APA, 5 U.S.C. § 704, when it "mark[s] the consummation of the agency's decisionmaking process," and is an act "by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (internal quotations and citations omitted). In *Bennett*, the Supreme Court reaffirmed the longstanding "pragmatic approach" to finality. *U.S. Army Corps of Eng'rs v. Hawkes Co.*, 136 S. Ct. 1807, 1815 (2016). Under that "pragmatic and flexible" approach, *Rhea Lana, Inc. v. Dep't of Labor*, 824 F.3d 1023, 1027 (D.C. Cir. 2016) (internal quotations omitted), CMS's letter easily satisfies both of *Bennett*'s prongs.

A. The first prong need not detain this Court long. CMS's concession that its decision marked the end of its decisionmaking process suffices. *See Hawkes*, 136 S. Ct. at 1813–14 (agency's action satisfied *Bennett*'s first prong when agency conceded issue); *Rhea Lana*, 824 F.3d at 1027 (same). And CMS conceded *Bennett*'s first prong with reason—the letter is "firm and conclusive," *Barrick Goldstrike Mines, Inc. v. Browner*, 215 F.3d 45, 50 (D.C. Cir. 2000), and reflects CMS's "settled

agency position," *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1022–23 (D.C. Cir. 2000), on an issue of statutory construction. The letter denies reconsideration and provides for no more review. There is no "entitlement to further agency review" unless CMS decides "to drop the hammer" by instituting enforcement proceedings. *Sackett*, 566 U.S. at 127. The letter thus marks the end of CMS's decisionmaking process.[2]

Accepting CMS's concession that this action ends its decisionmaking process makes sense: the agency's relevant subunit head, on reconsideration of an initial staff determination, offered the agency's last word on the legal question at issue. That belies any agency *ipse dixit* that its decision is non-final. Accepting self-serving agency boilerplate would allow agencies to insulate their decisions from judicial review by mere say-so. All the agency need do is place its decisions in form letters styled as non-final advice. Judicial review evaded so easily would contravene the "strong presumption" of judicial review of administrative action. *Mach Mining, LLC v. EEOC*, 135 S. Ct. 1645, 1651 (2015).

Even if agency boilerplate about a decision's finality were relevant in some cases, the Court need not address the issue here. The district court—and CMS, given

[2] This alone may be enough to end the finality inquiry. Whether *Bennett's* two steps are independently necessary aspects of finality was explicitly left open in *Hawkes*, see 136 S. Ct. at 1813 n.2 (leaving open question of whether "an agency action that satisfies only the first [prong] may also constitute final agency action").

its concession—did not rely on the boilerplate to suggest that CMS had not reached the consummation of its decisionmaking process. That is likely because, as Ipsen rightly notes, Appellant Br. 37 n.7, CMS's boilerplate is irrelevant to the subject matter of CMS's letter and was likely included by mistake. The language relates to reimbursement claims not at issue. Self-serving agency boilerplate should never be dispositive of finality. Here, because the letter's boilerplate is plainly inapposite to the substance of agency's legal position that the letter announced, there is all the more reason for the Court to ignore this boilerplate language.

B. After leaving *Bennett's* first prong unresolved despite CMS's concession, the district court then failed to correctly assess *Bennett*'s second prong.

1. In assessing whether legal consequences flowed from CMS's letter, the court surveyed a host of cases, lamenting the lack of bright-line rules to determine finality. But the upshot of the court's analysis of largely-outdated cases was imposition of its own flawed bright line: that an agency decision is not final if it lacks independent coercive effect, such as a self-executing sanction. *See* Op. 8 (JA__) (heavily relying on whether CMS's letter had "*binding* effects on Ipsen") (emphasis in original); *id.* at 12 (JA__) (concluding that CMS's letter failed to satisfy *Bennett*'s second prong because it "does not force Ipsen to alter its business model or day-to-day practices").

The district court's wooden insistence that, to be final, an agency action must dictate immediate compliance has no basis in precedent and demands a rigid approach when the finality inquiry should instead be "pragmatic and flexible." *Rhea Lana*, 824 F.3d at 1027 (internal quotations omitted). Under the correct approach, agency action satisfies *Bennett*'s second prong—despite not having independent coercive effect—when it requires the regulated party either to "comply with the [agency] requirement and incur the [associated] costs . . . or . . . follow [its] present course and risk prosecution." *Abbott Labs. v. Gardner*, 387 U.S. 136, 152 (1967) (citation omitted).

Just so here. Ipsen must comply with CMS's dictate to use the original base date AMP when reporting drug-pricing data for Somatuline ED, a change in business practice that would require Ipsen to pay higher rebates. Or Ipsen may keep using an independent base date AMP, risking civil penalties should CMS ever institute enforcement proceedings. This Court can go all the way back to *Frozen Food Express v. United States*, 351 U.S. 40 (1956), to find judicial review available in such a scenario. There, the Supreme Court determined that an order was final even though it "'had no authority except to give notice of how the [agency] interpreted' the relevant statute, and 'would have effect only if and when a particular action was brought against a [regulated party].'" *Hawkes*, 136 S. Ct. at 1815 (quoting *Abbott Labs*., 387 U.S. at 150).

Later cases reaffirm this point: a non-tentative agency pronouncement of its legal view that insists on compliance but does not contemplate immediate enforcement proceedings is final agency action subject to judicial review. *See Hawkes*, 136 S. Ct. at 1815. Even a pronouncement that "would have effect *only if and when* a particular action was brought" is immediately reviewable when it mandates a change in behavior by industry to avoid the risk of enforcement. *Abbott Labs.*, 387 U.S. at 150 (emphasis added). "[T]he APA provides for judicial review of all final agency actions, not just those that impose a self-executing sanction." *Sackett v. EPA*, 566 U.S. 120, 129 (2012).

CMS's two-page letter—issued after nearly a year of deliberation by the responsible senior official who reconsidered a preliminary staff decision—satisfies *Bennett*'s second prong under these cases. The letter breaks new legal ground. It definitively construes the statutory scheme. And it forces Ipsen to decide between acquiescing to CMS's decision and paying more in rebates to make its drugs available to Medicaid patients, or risking significant civil penalties by maintaining its current course. So, as in *Hawkes* and *Frozen Food*, Ipsen faces no certain "administrative or criminal proceeding . . . for failure to conform to the [agency decision] itself." *Hawkes*, 136 S. Ct. at 1815; *see also Frozen Food*, 351 U.S. at 44–45. Rather, prosecutorial discretion is involved. But Ipsen does risk "significant . . . civil penalties" should CMS bring an enforcement action. *Hawkes*,

136 S. Ct. at 1815. That "dilemma" of having to conform to CMS's unreviewed decision or risk "serious penalties attached to noncompliance" is enough, by itself, to satisfy *Bennett*'s second prong. *Abbott Labs.*, 387 U.S. at 152–53.

If the district court's decision is affirmed, and CMS's letter here deemed non-final, Ipsen's only way to obtain judicial review would be to violate CMS's directive and await enforcement. But that provides no basis for eschewing review now. *E.g.*, *Hawkes*, 136 S. Ct. at 1815; *Abbott Labs.*, 387 U.S. at 153. "The possibility that the agency might not bring an action for penalties, or, if it did, might not succeed in establishing the underlying violation did not rob the administrative order in *Sackett* of legal consequences, nor does it do so here." *Rhea Lana*, 824 F.3d at 1032 (citing *Sackett*, 132 S. Ct. at 1372).

Nor does the fact that Ipsen may self-report drug-pricing data without the agency's blessing—given how this regulatory scheme works—deprive the letter of final effect. Ipsen self-reports in the shadow of CMS's power, at any time, to subject Ipsen to audit, 42 U.S.C. § 1396r-8(b)(3)(A)–(B), impose civil penalties for late reporting and knowingly providing false information, *id.* § 1396r-8(b)(3)(B)–(C), or terminate Ipsen's Medicaid participation, *id.* § 1396r-8(b)(4)(B)(i). Termination can happen before parties are even afforded a hearing. *See id.*

Although CMS's letter did not directly contemplate an enforcement proceeding, it directed Ipsen to discontinue using a new base date AMP for

Somatuline ED. A.R. 33–34 ((JA__—__) (upholding initial directive that "the baseline data for [Somatuline ED] must be changed," A.R. 6 (JA __). CMS's letter is thus best read as directing Ipsen to comply. Or else. Because CMS "articulate[d] an unequivocal position . . . and expect[ed] regulated entities to alter their primary conduct to conform to that position, the agency has voluntarily relinquished the benefit of postponed judicial review." *Ciba-Geigy Corp. v. EPA,* 801 F.2d 430, 436 (D.C. Cir. 1986). Given the "pragmatic and flexible" nature of the finality inquiry, the mere fact that CMS's letter did not *force* Ipsen to do anything is irrelevant. It is enough that, if Ipsen "does not conform to [CMS's] view in fulfilling its reporting obligation," it could be "subject to an enforcement action and fines" at some point. *Barrick Goldstrike*, 215 F.3d at 47–48.

2. Undue reliance on the letter's lack of a self-executing sanction was not the district court's only mistake; it also dismissed the burden CMS's letter imposed on Ipsen as "less significant than in cases like *Frozen Food* and other cases, where potential criminal liability existed" because Ipsen faced "only civil enforcement mechanisms." Op. 12 (JA__). That is wrong twice over. For one thing, under both Supreme Court and D.C. Circuit precedent, exposure to additional *civil* liability is a "legal consequence" satisfying *Bennett*'s second prong. *See Sackett*, 566 U.S. at 126, 129; *Rhea Lana*, 824 F.3d at 1025. For another, CMS's letter, like the agency decision in *Hawkes*, denies Ipsen a safe harbor from liability. That, too, constitutes

a legal consequence satisfying *Bennett*'s second prong. *See Hawkes*, 136 S. Ct. at 1814.

Before CMS's decision, Ipsen had to worry about monetary penalties only for late reporting of data. That is because Ipsen based its decision to use a new base date AMP for Somatuline ED on a good-faith reading of the statutory scheme. If CMS had never issued a decision, Ipsen could not have plausibly been accused of *knowingly* providing *false* information; at most, if the agency were to disagree with Ipsen's reading, the information provided could be called inaccurate or based in part on a mistake. But after CMS's letter, issued at Ipsen's request, Ipsen is on notice of the agency's view that using a new base date AMP for new drugs approved through supplemental New Drug Application violates the Social Security Act. Ipsen believes that interpretation is wrong. But under the district court's ruling, Ipsen has no right to challenge it. And if Ipsen persists in using the new base date AMP for its new drug, it may face liability for "knowingly provid[ing] false information." 42 U.S.C. § 1396r-8(b)(3)(C)(ii).

This "exposure to [knowing]-violation penalties apparently resulting from receipt of [CMS's] advice" is a "legal consequence within the meaning of *Bennett v. Spear*, just as exposure to double penalties made EPA's compliance order legally consequential in *Sackett.*" *Rhea Lana*, 824 F.3d at 1030. That such penalties are contingent on a future enforcement proceeding does not matter. "The possibility that

the agency might not bring an action for penalties or, if it did, might not succeed in establishing the underlying violation," does not deprive CMS's letter of finality. *Id.* at 1032. And given *Sackett* and *Rhea Lana*, the district court's discounting of any penalties here as "only civil" and not "criminal" Op. 12 (JA__), was flat wrong.[3]

3. *Hawkes* provides yet another reason CMS's letter satisfies *Bennett*'s second prong. There, the Supreme Court evaluated an agency decision that either could have created a five-year safe harbor from enforcement proceedings and limited potential liability for a regulated entity, or could have denied that safe harbor and limitation. *Hawkes*, 136 S. Ct. at 1814. That is just like CMS's letter, viewed pragmatically against the statutory provision imposing civil penalties and the possibility that CMS could have issued a letter agreeing with Ipsen.

[3] The district court mistakenly ignored Ipsen's exposure to potential additional liability because Ipsen purportedly conceded that CMS's letter lacked such an effect. Op. 10 (JA__). Not so. Ipsen merely expressed its belief that continued data reporting based on a good-faith statutory interpretation would not qualify as a knowing violation. D.E. 18 at 6 n.1 (JA__). But Ipsen also recognized that CMS's letter increased Ipsen's risk of facing penalties. *Id*. at 6 ("the *risk* of enforcement action is enough") (emphasis in original). And the agency itself never disclaimed its power to impose civil penalties. D.E. 35 at 14 (JA__). That Ipsen could raise defenses in a civil penalty action—including that CMS's interpretation at issue in this case is arbitrary and contrary to law, as well as the argument that its good-faith reliance on a reasonable interpretation precludes a finding of a "knowing" violation even if CMS's interpretation were ultimately upheld—does not change the reality that CMS's letter renders Ipsen at least "a candidate" for enforcement action. *Rhea Lana*, 824 F.3d at 1032.

Take the safe-harbor-creation possibility first. The legal effect of CMS's letter, had it agreed that Ipsen was correctly using an independent base date AMP for its new drug, would have been like the "negative JD" addressed in *Hawkes*. *Id.* at 1814. Such written agreement with Ipsen's reporting practices would have created a safe harbor from liability for knowing violations—Ipsen could not plausibly be charged with knowingly providing false information when it asked for and followed the agency's guidance on how to calculate the data provided. A letter agreeing with Ipsen, then, much like a negative JD, would "limit[] the potential liability a [regulated entity] faces." *Id*. That "effect[] is a 'legal consequence[]' satisfying the second *Bennett* prong." *Id.* (quoting *Bennett*, 520 U.S. at 178).

Viewed against the same backdrop, CMS's letter here—which announces CMS's definitive view that Ipsen is reporting inaccurate information—is like the "affirmative JD" in *Hawkes*. The letter could serve to *deny* Ipsen safe harbor from liability for knowing violations, vastly increasing the potential sanctions Ipsen could face. "It follows that" the letter, like "affirmative JDs[,] ha[s] legal consequences as well: [It] represent[s] the denial of the safe harbor" that CMS could have given Ipsen had CMS agreed with Ipsen's view. *Hawkes*, 136 S. Ct. at 1814.

In short, when CMS announces its last word on what constitutes a "covered outpatient drug" under the Social Security Act—no matter whether CMS agrees or disagrees with the drug manufacturer—that agency decision alters the legal

landscape for regulated entities like Ipsen just like the JDs did in *Hawkes*. *Bennett*'s second prong demands nothing more. *See Hawkes*, 136 S. Ct. at 1814 (quoting *Bennett*, 520 U.S. at 178) (omission in original) ("Because "'legal consequences . . . flow' from approved JDs, they constitute final agency action."); *see also id.* at 1817 (Kagan, J., concurring) (quoting *Bennett*, 520 U.S. at 178) (alteration in original) ("The creation of [a] safe harbor . . . is a 'direct and appreciable legal consequence[]' satisfying the second prong of *Bennett*.").

4. This Court may easily conclude that CMS's letter satisfies *Bennett*'s second prong based on the Hobson's choice Ipsen faced (comply with CMS's interpretation of the law or risk future sanctions), the "legal consequence" of exposure to knowing violation civil penalties, and the denial-of-a-safe-harbor analysis from *Hawkes.* But if any lingering doubts about finality remain, another practical consideration gets this case across the finish line.

Judicial review of CMS's letter "neither improperly intrude[s] into the agency's decisionmaking process nor squander[s] judicial resources through piecemeal review." *Nat'l Treasury Emps. Union v. FLRA*, 745 F.3d 1219, 1223 (D.C. Cir. 2014) (internal quotation marks and citation omitted). On the contrary, CMS's review process is over, as the agency has conceded. Providing for judicial review now would only improve the accuracy of the drug-pricing data that manufacturers must self-report, and aid all parties affected when CMS dictates a generally-

applicable change to reporting criteria for similarly-situated new drugs, by allowing for a judicial resolution of the self-reporting criteria required of manufacturers by law.

Consider how Ipsen proceeded—it voluntarily apprised the agency of how Ipsen was reporting drug-pricing data for Somatuline ED so it could get the agency's considered view on its reporting approach. CMS first responded to Ipsen informally—in an email from a Health Insurance Specialist, A.R. 6–8 (JA__–__)—and there announced a view contrary to Ipsen's. Ipsen did not then seek judicial review; having received the agency's preliminary guidance, Ipsen sought agency reconsideration by letter requesting the Office of General Counsel's review. A.R. 9–32 (JA__–___). Ipsen then had to wait a year before CMS reached the "consummation of its decisionmaking process" on the question presented.

Providing judicial review now preserves CMS's ability to issue the sort of workaday "advice" letters this Court has on occasion held were non-final. *See, e.g.*, *Holistic Candlers & Consumers Ass'n v. FDA*, 664 F.3d 940, 944 (D.C. Cir. 2012).[4]

[4] *Holistic Candlers* analyzed an informal agency advice letter that satisfied neither *Bennett* prong, so the district court was wrong to read it to foreclose review here. As CMS concedes, the agency has finished its decisionmaking process. In *Holistic Candlers*, the agency had more to do: "evaluate" submitted information—including a forthcoming response from manufacturers—to "decide whether your product may be legally marketed." 664 F.3d at 944–45. The warning letters were factbound too, evaluating each product's label to determine the product's lawfulness, *id.* at 942, and expressing "no position, unequivocal or otherwise," about the

But it also affords manufacturers like Ipsen the ability to challenge CMS's definitive legal interpretations without having to await costly enforcement proceedings (that may never occur) and risk substantial penalties. And because some drug manufacturers might conform to the agency's purportedly unreviewable decision rather than risk enforcement, providing judicial review now ensures that CMS's decisions do not evade review altogether. That result honors the "'strong presumption' favoring judicial review of administrative action." *Mach Mining*, 135 S. Ct. at 1651 (citation omitted).

Allowing judicial review also encourages other drug manufacturers in the Medicaid drug-rebate program to hew to Ipsen's diligent and transparent series of actions. A self-reporting regime works better if participants can seek the agency's advice whenever there is doubt about how to calculate the data reported, with the security that they will have the opportunity to challenge legal pronouncements they think are wrong, pre-enforcement. Such diligence ensures the data's accurate reporting in compliance with regulatory requirements. *See* 42 C.F.R. § 447.510 (duty to self-report pricing data and fix reporting errors as they arise). But if CMS's letter is not final—and thus is not reviewable—that might chill drug manufacturers from

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agency's regulatory authority, *id.* at 945. Here, by contrast, CMS's letter, is neither tentative nor factbound: It was issued by an agency subunit head, on reconsideration of initial staff advice, and expresses the agency's "unequivocal position," *id.* at 954, on statutory requirements, for not just Ipsen, but all similarly-situated drug manufacturers.

asking for CMS's view in future cases. Why risk potential knowing violation liability in a future enforcement action by seeking the agency's view when manufacturers need not get agency approval to report pricing data, and the agency's decision, even if mistaken, would be immune from judicial correction? This practical consideration reinforces the conclusion that CMS's letter is final—and thus reviewable—under the APA.

II. THE DECISION BELOW PROVIDES A ROADMAP FOR AGENCIES TO ISSUE INDUSTRY-TRANSFORMING RULES THAT ARE INSULATED FROM JUDICIAL REVIEW.

The consequences of the district court's ruling are far-reaching and extend beyond CMS and the facts here. If endorsed by this Court, the decision below shows other agencies how to issue definitive rules that coerce immediate compliance from industry on risk of ruinous penalties, yet evade judicial review. This Court should reverse to prevent copycat informal agency "guidance."

The APA's "basic presumption of judicial review" of agency action, *Weyerhaeuser Co. v. U.S. Fish & Wildlife Serv.*, 139 S. Ct. 361, 370 (2018), would be obliterated if courts accepted at face value an agency's *ipse dixit* that its definitive interpretation of the applicable statutory scheme, issued by the head of the relevant unit within the agency, was non-final. Yet that is exactly what the decision below invites. And many agencies could take up the invitation. CMS is hardly unique in its

use of informal guidance to communicate what the agency believes the law requires. Under the roadmap offered by the ruling below, there is effectively no substantive limit on how definitive and industry-transforming such "informal" guidance can be.

What's more, if their organic statutes are silent on this question (which most are), agencies that don't yet have similar regulations can take up the open invitation and delegate to staff the power to issue industry-wide interpretations of regulations, with real consequences, but free from judicial review. *Cf. Vt. Yankee Nuclear Power Corp. v. Nat. Res. Def. Council, Inc.*, 435 U.S. 519, 543–44 (1978) (agencies have authority to "fashion their own rules of procedure" when a statute does not specify what process to use). Such unfettered ability to enlarge the scope of executive authority harms the business community by encouraging agencies to adopt vague regulations that they can later interpret with binding force in practice, if not in name, while evading judicial review.

The APA was crafted to "guard[] against excesses in rulemaking by requiring notice and comment," mandating that an agency invite public "comment on [a rule's] shortcomings . . . respond to their arguments, and explain its final decision." *Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1211 (2015) (Scalia, J., concurring) (citing 5 U.S.C. § 553(b)–(c)). If affording deference to an agency's interpretations of those regulations already creates incentives for an agency to "write substantive rules more broadly and vaguely, leaving plenty of gaps to be filled in later, using interpretive

rules unchecked by notice and comment," *id.* at 1212, imagine the consequences of allowing agencies to evade judicial review altogether simply by labeling their pronouncements "non-final guidance" and leaving the "final" determinations for enforcement proceedings.

In rigidly applying the finality inquiry, the district court's analysis allows agencies to thwart judicial review with the stroke of a pen, while regulated entities are coerced into immediate action through final rules cloaked as non-final advice. Such extreme deference to agency nomenclature is the polar opposite of the "clear and convincing indications" from Congress (not an agency), that the Supreme Court has demanded in other contexts to "foreclose review." *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1360 (2018) (internal quotation marks and citation omitted).

Through the head of the relevant unit, CMS changed the meaning of "covered outpatient drug" for the Medicaid drug-rebate program. CMS's letter thus affects all drug manufacturers who, like Ipsen, received FDA approval of a new drug through a supplemental new drug application. And CMS's letter, by the agency's own concession, marks its final word on the question. By its terms, the letter demands compliance with the agency's interpretation, A.R. 33–34 (JA__—__) (Ipsen must use original AMP because Ipsen's contrary interpretation "d[id] not warrant establishment of new base date AMPs for . . . Somatuline ED") and by implication (given the statutory scheme) contains a veiled threat of potential sanctions for refusal

to follow the agency's newly-announced rule. There was not a whiff of "voluntariness" in this directive. Nor does it matter that if there were no letter at all, industry would have to wait until after an enforcement action to challenge the agency's interpretation. "[S]uch a 'count your blessings' argument is not an adequate rejoinder to the assertion of a right to judicial review under the APA." *Hawkes*, 136 S. Ct. at 1816.

If affirmed, the ruling below would become this Court's precedent. All sorts of agencies would then have every incentive to issue definitive pronouncements of their regulatory power, with real legal consequences, yet shielded from judicial review unless a company runs the gauntlet of potential enforcement proceedings and penalties. Forcing this dilemma on regulated industry to obtain review—lose money or risk penalties—conflicts with the Supreme Court's and this Court's precedents. It also is bad for business and allows agencies to avoid accountability for mistaken or ill-considered actions, exactly what the APA was designed to protect against.

CONCLUSION

For these reasons, the district court's judgment should be reversed.

Respectfully submitted,

/s/ *Ruthanne M. Deutsch*

Daryl Joseffer
Michael B. Schon
U.S. CHAMBER LITIGATION CENTER
1615 H. St NW
Washington, DC 20062

Ruthanne M. Deutsch
Hyland Hunt
R. Craig Kitchen
DEUTSCH HUNT PLLC
300 New Jersey Ave. NW
Suite 900
Washington, DC 20001
(202) 868-6915
rdeutsch@deutschhunt.com

Counsel for Amicus Curiae the Chamber of Commerce of the United States of America

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CERTIFICATE OF COMPLIANCE

This amicus curiae brief is in 14-point Times New Roman proportional font and contains 5,293 words as counted by Microsoft Word, excluding the items that may be excluded. The brief thus complies with the type-face, style, and volume limitations set forth in Rule 29(a)(5) and 32(a)(5)–(7)(B) of the Federal Rules of Appellate Procedure.

/s/ *Ruthanne M. Deutsch*
Ruthanne M. Deutsch

February 4, 2019

CERTIFICATE OF SERVICE

I hereby certify that, on February 4, 2019, I served the foregoing amicus curiae brief upon all registered counsel by filing a copy of the document with the Clerk through the Court's electronic docketing system:

/s/ *Ruthanne M. Deutsch*
Ruthanne M. Deutsch