# United States Court of Appeals

**FOR THE DISTRICT OF COLUMBIA CIRCUIT**

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Argued September 9, 2019 Decided December 3, 2019

No. 18-5299

IPSEN BIOPHARMACEUTICALS, INC.,
APPELLANT

v.

ALEX MICHAEL AZAR, II, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *ET AL.*,
APPELLEES

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Appeal from the United States District Court
for the District of Columbia
(No. 1:16-cv-02372)

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*Jeffrey S. Bucholtz* argued the cause for appellant. With him on the briefs were *John D. Shakow* and *Nikesh Jindal*.

*Ruthanne M. Deutsch*, *Hyland Hunt*, *R. Craig Kitchen*, *Daryl L. Joseffer*, and *Michael B. Schon* were on the brief for *amicus curiae* the Chamber of Commerce of the United States of America in support of plaintiff-appellant.

*Matthew J. Glover*, Attorney, U.S. Department of Justice, argued the cause for appellees. With him on the brief was *Abby C. Wright*, Attorney. *Alisa B. Klein*, Attorney, and *R. Craig Lawrence*, Assistant U.S. Attorney, entered appearances.

Before: HENDERSON, MILLETT and WILKINS, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* HENDERSON.

KAREN LECRAFT HENDERSON, *Circuit Judge*:

This appeal arises out of Ipsen Biopharmaceuticals, Inc.'s challenge to the designation by Centers for Medicare and Medicaid Services (CMS)—a part of the United States Department of Health and Human Services—of the pricing information Ipsen must report to CMS for a drug that it manufactures. The sole issue on appeal is whether a series of letters CMS sent Ipsen constitutes final agency action under the Administrative Procedure Act (APA), 5 U.S.C. § 704. As explained *infra*, we believe Ipsen has plausibly argued that receipt of the letters significantly increased its risk of a statutory civil penalty being levied for "knowingly provid[ing] false information." 42 U.S.C. § 1396r-8(b)(3)(C)(ii). This increased risk is a "legal consequence" sufficient to make the agency action final under the second prong of the test enunciated by the United States Supreme Court in *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997). Accordingly, we reverse the judgment of the district court and remand the case for further proceedings.

## I. BACKGROUND

Ipsen's appeal implicates the details of the self-reporting scheme contained in the Medicaid drug-rebate program. Medicaid is a co-operative federal and state program, the federal side of which is administered by CMS. *See* 42 U.S.C. § 1396 *et seq*. In order to participate in the Medicaid program, a drug manufacturer is obligated to enter into an agreement with CMS to provide rebates to states that elect to pay for outpatient prescription drugs. The rebate a manufacturer must provide is

calculated in two parts. Both parts use the average price (the AMP) that the manufacturer charges a wholesaler for the drug. The base rebate is the greater of 1.) the difference between the drug's AMP and the lowest price offered during the most recent past quarter and 2.) 23.1 % of the AMP. The additional rebate, paid on top of the base rebate, is calculated by subtracting the inflation-adjusted AMP for each dosage form and strength of the drug when it was first sold to wholesalers (described by Ipsen as the "base date AMP") from the AMP for the same dosage and strength during the quarter in which the rebate is calculated. The manufacturer calculates the total per-unit rebate and reports it to the participating states, which then use the information to prepare invoices sent to and paid by the manufacturer. The statute provides for civil penalties for manufacturers that "knowingly provide[] false information" related to the rebate calculation, including a civil penalty of up to $100,000 for each item of false information. *See* 42 U.S.C. § 1396r–8(b)(3)(B)–(C). Judicial review of a rebate calculation is limited to review of enforcement proceedings brought by CMS. *See* 42 U.S.C. § 1320a–7a(e); *see generally* 42 U.S.C. § 1396r–8.

Ipsen first introduced Somatuline Depot Injection in 2007 and, accordingly, calculated a base date AMP for the drug at that time. In 2014 Ipsen sought and obtained a new FDA approval for Somatuline ED, an outpatient prescription drug, it asserts, that is entitled to calculation of its own base date AMP.[1] Ipsen by letter notified CMS to this effect. Before receiving a response, Ipsen reported the new base date AMP to CMS. CMS responded to Ipsen's letter several months later, indicating that Ipsen was not entitled to calculate a new base

[1] The record does not allow us to determine the precise impact of Ipsen's preferred calculation. Presumably, Ipsen's base date AMP is higher, resulting in a lower additional rebate owed to the states.

date AMP. The letter further instructed Ipsen that "the baseline data for [Somatuline ED] must be changed to reflect the original baseline data of Somatuline Depot." Ipsen sent a second letter, iterating its position and requesting a meeting. The letter prompted a response by CMS's Director of the Division of Pharmacy repeating CMS's view that a new base date AMP was not warranted because Somatuline ED had received FDA approval under a supplemental new drug application number based on the new drug application number of Somatuline Depot. The Director's letter expressly stated that it was not "a final agency action or even an initial determination on a reimbursement claim."

Ipsen responded to the second letter by filing suit. CMS moved for summary judgment, arguing that it had taken no final agency action to trigger judicial review under the APA. *See* 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."). The district court agreed and granted summary judgment to CMS. Ipsen timely appeals pursuant to 28 U.S.C. § 1291.

## II. ANALYSIS

We review the district court's grant of summary judgment de novo. *See Grunewald v. Jarvis*, 776 F.3d 893, 898 (D.C. Cir. 2015). The APA permits judicial review of "final agency action" only. *See* 5 U.S.C. § 704. "Agency actions are final if two independent conditions are met: (1) the action marks the consummation of the agency's decisionmaking process . . . and (2) it is an action by which rights or obligations have been determined, or from which legal consequences will flow." *Soundboard Ass'n v. FTC*, 888 F.3d 1261, 1267 (D.C. Cir. 2018) (internal alterations and quotation marks omitted)

(quoting *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997)).[2] The parties agree that only the second condition is in dispute.

The Supreme Court has indicated that determining whether "legal consequences will flow" from an agency action is a "pragmatic" inquiry. *U.S. Army Corps of Eng'rs v. Hawkes Co.*, 136 S. Ct. 1807, 1815 (2016) (citing *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967)). We recently clarified that "[i]n characterizing the inquiry as pragmatic, we do not take the Court to be encouraging some sort of common-sense approach" but rather "[w]e take it as counseling lower courts to make *Bennett* prong-two determinations based on the concrete consequences an agency action has or does not have as a result of the specific statutes and regulations that govern it." *Cal. Comtys. Against Toxics v. EPA*, 934 F.3d 627, 637 (D.C. Cir. 2019).

In *Sackett v. EPA*, the Supreme Court delineated one way an agency action could interact with a statutory scheme to cause a legal consequence. 566 U.S. 120 (2012). There, the Court considered whether an EPA administrative compliance order issued to landowners was a "final agency action." The compliance order recited the EPA's decision that the landowners' property contained wetlands and that the landowners had violated the Clean Water Act, 33 U.S.C. § 1311, by discharging fill material into those wetlands. It commanded the landowners to "immediately . . . undertake activities to restore the Site." *Sackett*, 566 U.S. at 125. The order was not self-executing—the EPA had to initiate a separate enforcement action in order to penalize the

[2] Although Ipsen argues that the *Bennett* conditions are properly viewed as disjunctive, not conjunctive, it acknowledges that our Circuit precedent settles this issue. *See Soundboard*, 888 F.3d at 1267 (*Bennett* conditions are conjunctive).

landowners for violating the statute. Nonetheless, the Court held that "legal consequences . . . flow[ed]" from the order because, *inter alia*, issuance of the order meant that the landowners faced higher penalties in a future enforcement proceeding than they would have had the EPA not issued the order. *Id*. at 126.

We recently applied *Sackett* in *Rhea Lana, Inc. v. DOL*, a case in which the Department of Labor twice notified a company that one of its practices violated the Fair Labor Standards Act. 824 F.3d 1023 (D.C. Cir. 2016). The second letter noted that the statute provided for a civil penalty for any "repeated or willful violations of" the statute and warned that "[i]f at any time in the future [the company] is found to have violated [the relevant provisions], it will be subject to such penalties." *Id*. at 1026. We held that the warning met *Sackett*'s articulation of "legal consequences" resulting therefrom. *Id*. at 1032.

Ipsen analogizes the consequences of the CMS letters it received to the consequences of the agency communications in *Sackett* and *Rhea Lana*. It emphasizes that the Medicaid statute provides for penalties against manufacturers that "knowingly provide[] false information." *See* 42 U.S.C. § 1396r-8(b)(3)(C)(ii). Ipsen argues that "legal consequences . . . flow[ed]" from the letters because they increased the probability that in the future it could be found to have "knowingly" supplied false information.

We agree. Within the framework of the "specific" statutory and regulatory scheme involved here, *California Communities*, 934 F.3d at 637, and in view of the character of the agency action at issue, that increased risk of prosecution and penalties constitutes a "legal consequence" under *Bennett* for four reasons.

First, the letter refutes any colorable argument Ipsen might have in an enforcement action that it was acting without knowledge of CMS's position. Under the relevant statute, "knowingly" means that "a person, with respect to an act, has actual knowledge of the act, acts in deliberate ignorance of the act, or acts in reckless disregard of the act, and no proof of specific intent to defraud is required." 42 C.F.R. § 1003.110. Here, CMS takes the position that the CMS letter would be "relevant evidence" in a future determination regarding whether Ipsen would be subject to enhanced penalties for a "knowing" or "willful" violation of the Social Security Act. *See Tr. of Oral Arg.* at 41–47, *Ipsen Biopharmaceuticals v. Azar*, No. 18-5299 (D.C. Cir. Sept. 9, 2019).[3] CMS also conceded that it has brought an enforcement action against another drug manufacturer under 42 U.S.C. § 1396r-8(b)(3)(C)(ii) for "knowingly provid[ing] false information" when that company allegedly "misrepresented the Average Sales Price of at least one of its products to CMS." Govt 9/13/2019 Ltr at 1-2.

Perhaps CMS believed its position would not constitute "legal consequences" under *Bennett* because of our dictum in *Soundboard*, indicating that an FTC staff attorney letter, even if "could be [used as] evidence of willfulness," would not satisfy *Bennett*'s second prong. *See* 888 F.3d at 1273. But this case differs from *Soundboard* in one critical respect. In

[3] CMS draws our attention to the fact that in district court Ipsen argued that it could not be found to have "knowingly provid[ed] false information," notwithstanding receipt of the letters because "its position reflects . . . a reasonable, good-faith interpretation on a novel issue." This statement, CMS suggests, undermines Ipsen's argument that the letters produced legal consequences because it concedes that the letters did not automatically subject Ipsen to civil penalties. Although Ipsen conceded that the letters would not automatically result in penalties, it nonetheless maintains that the letters "increased its risk of facing penalties."

*Soundboard*, the FTC staff attorney letter did not meet *Bennett's* first prong because it was not the consummation of the agency's decision-making. ***Id.*** at 1269-71. As a result, the *Soundboard* letter was not an authoritative statement of the agency's views. The Supreme Court has indicated that such informal advice is insufficient, as a matter of law, to establish a "knowing" or "willful" violation of a statute or regulation pursuant to a theory that the regulated party should have been "warned away from the view that it took." *See Safeco Ins. Co. of America v. Burr*, 551 U.S. 47, 69-70 & n.19 (2007). Following *Safeco*, we have held, in the False Claims Act context, that "knowledge" of falsity was not established where the government could point to "informal guidance" only, not "the necessary 'authoritative guidance,'" as evidence "to warn a regulated defendant away from an otherwise reasonable interpretation it adopted." *U.S. ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 289 (D.C. Cir. 2015) (quoting *Safeco*, 551 U.S. at 70 & n.19). At the same time, we noted that even if a regulated party adopts a "reasonable" interpretation of an "ambiguous" statute, it can nonetheless be deemed liable for knowingly making a false statement if it "had been warned away from that interpretation" by authoritative agency guidance. ***Purcell,*** 807 F.3d at 288.

When further pressed about the permissible use of the letter at oral argument, CMS asserted that using the letter as "relevant evidence" against Ipsen did not result in a legal consequence because, unlike in *Rhea Lana*, there is no "regulation on the books," *see* 824 F.3d at 18 n.3, that announces that any future action contrary to the agency's position will be deemed willful by the agency. *Tr. of Oral Arg.* at 54–58. But that is a distinction without a difference. In *Rhea Lana*, we held that, if the regulation was "capable of a reading rendering the letter a stand-alone trigger for willfulness penalties," it "render[ed] Rhea Lana a candidate for civil

penalties." Therefore the agency's letter was final agency action because it "establish[ed] legal consequences." 824 F.3d at 21. The outcome in *Rhea Lana* turned on the legal consequence of the letter in that case and CMS cannot avoid the legal consequence of the letter in this case by arguing that here the legal consequence does not count because it results from the application of settled caselaw rather than from a published regulation**.** The CMS letter could be potentially dispositive proof in an enforcement action, consistent with *Safeco* and *US ex rel Purcell*, because "knowingly" means "that a person, with respect to an act, has actual knowledge of the act, acts in deliberate ignorance of the act, or acts in reckless disregard of the act, and no proof of specific intent to defraud is required," and that is of legal consequence under *Bennett*. *See* 42 C.F.R. § 1003.110.

The consequences Ipsen claims to face in the future are not as certain as those in *Rhea Lana* or *Sackett*. We in *Rhea Lana* and the Supreme Court in *Sackett* accepted that the agency action alone was enough to subject the regulated parties to additional penalties in the event of an enforcement action. By contrast, Ipsen claims that the letters increase its *risk* of incurring penalties in a future enforcement proceeding—granted, a less certain consequence. Nonetheless, Ipsen does claim that its receipt of the letters will be *a* factor, if not *the* factor, in assessing penalties against it in a future enforcement proceeding. CMS conceded as much before us. *See Tr. of Oral Arg.* at 42 ("Well, again, the letter here would be evidence, or could be used as evidence in that adjudication . . . .").

Second, the self-reporting nature of the regulatory scheme gave the letter's command immediate and direct legal force. The regulatory scheme requires Ipsen to self-report pricing information to CMS each quarter as a condition of its participation in the Medicaid Rebate program. *See* 42 C.F.R.

§ 447.510; *see also* 42 U.S.C. § 1396r-8(b)(3). As soon as the letter issued, each and every one of the repeat submissions exposed Ipsen to potential civil penalties for each quarter. *See* 42 U.S.C. § 1396r-8(b)(3)(C) (a manufacturer "is subject to a civil penalty in an amount not to exceed $100,000 for each item of false information"). No further or intervening agency action is needed for the penalty risk and amount to start accumulating—the trigger is the issuance of the letter.

Third, as CMS itself acknowledges, there is no further agency action for Ipsen to invoke or to exhaust to plead its cause. Appeal is unavailable and there is no avenue for Ipsen to affirmatively seek relief. As CMS concedes, the agency's decisionmaking process is at the end. CMS has made its final decision and has told Ipsen that its rebate computations "must be changed," as the prior rebate amount is the only one that Ipsen (in CMS's view) can lawfully implement. The only potential next step is an agency enforcement action. *See Tr. of Oral Arg.* at 36–37 (Counsel for CMS: "[S]ometimes in self-reporting regimes it may be difficult for a regulated entity, like Ipsen, to get a final agency action short of CMS telling them please change this.").

As a result, the only thing standing between Ipsen and CMS's prosecution of it for financial penalties, and a possible expulsion from participation in the Medicaid Rebate program, *see* 42 U.S.C. § 1396r-8(b)(3)(C), (4)(B)(i), is the agency's exercise of prosecutorial discretion.[4] The regulatory scheme thus leaves Ipsen in a quandary: Either accept CMS's interpretation to avert civil penalties and the risk of exclusion

[4] *See Tr. of Oral Arg.* at 41 (Q: "[I]s there anything standing between [Ipsen] * * * and an enforcement action, other than prosecutorial discretion?" CMS Counsel: "No[.]").

from the Medicaid Rebate program or proceed in defiance of that risk, with penalties growing each quarter.

Fourth, agencies often communicate their interpretations of governing statutory and regulatory obligations or prohibitions to interested parties in letters and they do so without taking final agency action. In this case, however, the nature of the agency's letter went beyond simply announcing its interpretation of relevant statutory and regulatory language. The letter expressly applied CMS's interpretation of the governing law to the specific facts of Ipsen's case. *See* J.A. 45 (stating that the new factors Ipsen highlighted "do not meet the criteria for the establishment of new base date AMPs").[5] In that respect, the agency action at issue here closely resembles an individual adjudication, which is a well-recognized form of final agency action. *See Southwest Airlines Co. v. United States Dep't of Transp.*, 832 F.3d 270, 276 (D.C. Cir. 2016).

For the foregoing reasons, the judgment of the district court is reversed and the case is remanded for further proceedings consistent with this opinion.

*So ordered*.

[5] *See also Tr. of Oral Arg.* at 52 (CMS counsel stating that the letter "laid out our view of the law" and how it applied "to the facts provided").