Exhibit 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ABBVIE INC., Plaintiff, v. **ROBERT F. KENNEDY, JR.**, in his official capacity as Secretary of the U.S. Department of Health and Human Services, *et al.*, Defendants.	Case No. 1:26-cv-01190-RDM Judge Randolph D. Moss

BRIEF OF *AMICI CURIAE* THE AMERICAN HOSPITAL ASSOCIATION, AMERICA'S ESSENTIAL HOSPITALS, NATIONAL ASSOCIATION OF CHILDREN'S HOSPITALS INC. D/B/A CHILDREN'S HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Regulations

Other Authorities

INTEREST OF *AMICI CURIAE*[1]

The **American Hospital Association** ("AHA") leads, represents, and serves nearly 5,000 member hospitals, health systems, and other healthcare organizations and 43,000 individual members with the mission of advancing the health of all individuals and communities. Through representation and advocacy, the AHA strives to ensure that its members' perspectives and needs are heard in national health policy development, legislative, and regulatory debates. More than 2,000 of the AHA's member hospitals and health systems participate in the 340B program.

America's Essential Hospitals is dedicated to high-quality care for all people, including those who face social and financial barriers. Consistent with this mission, the association's more than 400 members provide a disproportionate share of the nation's uncompensated care, with three-quarters of patients uninsured or covered by Medicare or Medicaid.

The **National Association of Children's Hospitals, Inc., d/b/a Children's Hospital Association** is the nation's leading advocate for children's health, uniting more than 200 children's hospitals to improve care and amplify impact. Through a unique combination of pediatric-specific expertise, data, and networking, the Children's Hospital Association drives informed and actionable progress from care to policy.

The **Association of American Medical Colleges** is dedicated to improving the health of people everywhere through medical education, healthcare, medical research, and community collaborations. Its members include all 163 LCME-accredited medical schools; nearly 500 academic health systems and teaching hospitals; and more than 70 academic societies.

[1] Pursuant to Local Civil Rule 7(o)(5) and Federal Rule of Appellate Procedure 29(a)(4)(E), counsel for *amici curiae* certify that no counsel for a party authored this brief in whole or in part, and no person other than the *amici*, their members, or their counsel made a monetary contribution to this brief's preparation or submission.

The **American Society of Health-System Pharmacists** ("ASHP") is the largest association of pharmacy professionals in the United States. ASHP advocates and supports the professional practice of pharmacists in hospitals, health systems, ambulatory care clinics, and other settings spanning the full spectrum of medication use. For over 80 years, ASHP has championed innovation in pharmacy practice, advanced education, and professional development, and has served as a steadfast advocate for members and patients.

Amici's members include disproportionate share hospitals that serve a high number of low-income, uninsured, or Medicaid-eligible patients; children's hospitals; critical access hospitals; and cancer hospitals. All of these types of members participate in the 340B program and have an acute interest in preserving their rights under its governing law and regulations and preventing participating drug manufacturers from commandeering the program to roll back the statutorily mandated discounts. Additionally, many of *Amici*'s 340B members operate on very thin (or negative) margins and would therefore face an immediate impact from Plaintiff AbbVie Inc. ("AbbVie") limiting the definition of patient to restrict access to the 340B program.

INTRODUCTION

Using a fabricated dispute over the scope of audits, AbbVie asks this Court to override the Department of Health and Human Services' statutory authority over the 340B program and rewrite the agency's longstanding definition of "patient." But if AbbVie succeeds here in shrinking that definition, hospitals in rural and other underserved communities will be forced to reduce healthcare services or eliminate them altogether. This is not, therefore, an abstract legal dispute over the meaning of "patient." Much is at stake for real patients.

Much is at stake for the 340B Program, too. "Congress vested authority to oversee compliance with the 340B Program in HHS and assigned no auxiliary enforcement role to" program participants. *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 117 (2011). But if

AbbVie is allowed to sidestep agency procedures and maneuver this case into federal court, it will wrest control over the program away from HHS.

At bottom, AbbVie is challenging HHS guidance that has been in place for 30 years. It does so on the basis of a letter, sent by an agency sub-component before the completion of the statutorily mandated audit and Administrative Dispute Resolution ("ADR") process, reiterating a definition of "patient" that AbbVie has known about for all 30 of those years. Having provided 340B discounts for millions of patient prescriptions during that time, AbbVie almost certainly could have brought suit during those 30 years, but it never did. *Amici* do not know why AbbVie chose to challenge that definition now. But we do know that the letter on which it rests its entire basis for suit (*see* Compl. ¶ 145) does not allow AbbVie to sue in federal court *before* the audit and ADR processes are completed. *See Oregon Health & Sci. Univ. v. Engels*, 2025 WL 1707630, at *6 n.6 (D.D.C. June 17, 2025) ("UWMC emphasizes a November 12, 2024 letter from HRSA . . . . But this correspondence does not change the Court's analysis: HRSA reminding Plaintiffs of their statutory duties for eligibility does not transform a preliminary, procedural decision into a definitive one.").

There are several problems with AbbVie's attempt to rewrite the rules of the 340B program in this unusual procedural posture. On the merits, the agency's interpretation of "patient" reflects the best reading of the statute, is grounded in subject-matter expertise and reasoned analysis, and is entitled to meaningful weight. *See Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 402 (2024) ("In an agency case in particular, the court will go about its task with the agency's 'body of experience and informed judgment[]' . . . at its disposal."). AbbVie's attempt to replace that reading with a convoluted definition utterly divorced from the text of the 340B statute has no legal merit.

But AbbVie's more immediate legal infirmity is that its requests are not ripe, and its rush to this Court deprives safety-net healthcare providers of vital due process afforded to them by the 340B statute. As explained below, AbbVie is asking this Court to set aside the statutory process by which HHS may hear disputes between drug companies and safety-net medical providers arising out of 340B audits. By circumventing this process and attempting to retroactively apply a new definition of "patient," AbbVie would deny the affected safety-net providers their opportunity to be heard regarding the validity of any audit. This Court should decline to interfere in that statutory process unless and until AbbVie has followed the statutorily mandated procedure to allow for covered entity input and factual development of AbbVie's claims.

BACKGROUND

I. The 340B Program and Its Audit Process

Congress enacted the 340B Drug Pricing Program in 1992 to give safety-net healthcare providers (known as "covered entities") access to prescription drugs at significantly discounted prices. Pub. L. No. 102-585 § 602 (1992). The savings from these discounts 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, pt. 2, at 12 (1992).

Congress gave the Secretary of HHS, who acts through his designee the Health Resources and Services Administration ("HRSA"), control over the administration of the 340B program. *Astra USA, Inc.*, 563 U.S. at 114; 42 U.S.C. § 256b. The Secretary's responsibilities include entering into agreements with drug manufacturers that govern their participation in the 340B program, certifying covered entities, and conducting program compliance reviews on both covered entities and drug manufacturers. 42 U.S.C. § 256b(a)(1), (a)(7), (d). Critically for this case, the Secretary also is required by statute to establish procedures "relating to the number, duration, and scope of audits" of covered entities that drug manufacturers may permissibly conduct on records

that "directly pertain to the covered entity's compliance" with 340B's prohibitions against duplicate discounts and resale of drugs to anyone other than a patient of the covered entity (commonly referred to as "diversion"). 42 U.S.C. § 256b(a)(5)(C).

HRSA first established such procedures in 1996 and clarified them in 2011 and 2013. 61 Fed. Reg. 65,406-13 (Dec. 12, 1996); HRSA, 340B Drug Pricing Program Notice, Release No. 2011-3 (Nov. 21, 2011); HRSA, 340B Drug Pricing Program Notice, Release No. 2012-1.1 (Feb. 8, 2013). As to the number and duration of drug manufacturer audits, HRSA determined that a covered entity should only be subject to one audit at a time and that an audit "shall be limited to an audit period of one year and shall be performed in the minimum time necessary with the minimum intrusion on the covered entity's operations." 61 Fed. Reg. at 65,409-10. As to scope, HRSA required that a manufacturer wishing to conduct an audit "submit an audit workplan," which HRSA reviews "for reasonable purpose and scope" that "directly pertain[s] to the potential 340B violation(s)." *Id.* Through these provisions, HRSA prevents drug companies from weaponizing audits to harass safety-net hospitals and deter them from participating in the 340B program.

After an audit is conducted, "[t]he manufacturer shall submit the audit report to the covered entity," and the covered entity has 30 days to provide its response. 61 Fed. Reg. at 65,410. If the covered entity and manufacturer dispute the audit findings, they may proceed to HHS's ADR process. *Id.* Per the 340B statute, a manufacturer must conduct an audit of a covered entity before initiating the ADR process. 42 U.S.C. § 256b(d)(3)(B)(iv); *see also* 42 C.F.R. § 10.21(a)(2). Once that ADR process commences, a covered entity is provided with additional opportunities to submit information in its defense and to request reconsideration of an adverse decision. 42 C.F.R. §§ 10.21(e)(1), 10.23(c), 10.24.

It is ultimately up to the Secretary to determine—"after notice and hearing"—whether a covered entity has engaged in conduct that violates the 340B program's prohibitions on duplicate discounts and resale of drugs. 42 U.S.C. § 256b(a)(5)(D). This mandatory notice and hearing is vital for covered entities because a finding of a violation means the "covered entity shall be liable to the manufacturer" to repay all 340B discounts received on the drugs at issue in the violation. 42 U.S.C. § 256b(a)(5)(D). The Secretary also can choose to impose sanctions for violations on covered entities, including civil monetary penalties payable to drug manufacturers, removal from the 340B program, and referral to other federal enforcement authorities. 42 U.S.C. § 256b(d)(2)(B)(v). Given that 340B discounts can reduce the price of certain drugs by thousands of dollars for just one 30-day supply, a finding of an unintentional violation involving even a small number of drugs could have grave financial consequences for a safety-net healthcare provider.

II. AbbVie's Pre-Audit Efforts to Manufacture This Litigation

AbbVie alleges that it "identified concerning purchase data" from Barrio Comprehensive Family Health Care Center, Inc. ("Barrio") and Mount Sinai Hospital ("Mount Sinai") in 2024. Compl. ¶ 13. In early 2025, AbbVie sent Barrio and Mount Sinai similar letters demanding answers to more than 40 questions from each covered entity. Compl. Ex. 1 pp. 32-36, Ex. 5 pp. 31-36. Both covered entities agreed to meet with AbbVie in good faith to discuss its questions. Compl. Ex. 1 p. 40; Ex. 5 p. 41. Both covered entities also responded to AbbVie's inquiries in writing. Compl. Ex. 1 pp. 62-121; Ex. 5 pp. 48-49, 66-69, 92-96, 126-29. For example, Mount Sinai explained that AbbVie's alleged duplicate discount claims—which AbbVie continues to cite as its basis for wanting to audit Mount Sinai, Compl. ¶¶ 151-52—"emanated from the deficiencies with the external ESP program that AbbVie required [Mount Sinai] to use, not the Mount Sinai system,"

and that such claims were "only paid once."[2] Compl. Ex. 5 p. 48; *see also* pp. 68-69, 95-96.[3] Mount Sinai also expressly confirmed that "Mount Sinai follows the HRSA patient definition for 'eligible patient.' In fact we incorporated the HRSA definition verbatim into our policy. There are no qualifications or deviations whatsoever." Compl. Ex. 5 p. 41; *see also* p. 123. AbbVie only answered these covered entities' efforts to provide responsive information with long lists of follow-up questions. Compl. Ex. 1 pp. 40-41, 123-27; Ex. 5 pp. 41-42, 71-72, 98-103. For Mount Sinai, these questions almost always arrived on Friday nights, even when Mount Sinai had responded to the previous set early in the week. Compl. Ex. 5 pp. 98, 100-02, 109. Eventually, after Mount Sinai pointed this out, AbbVie stopped responding altogether.

AbbVie submitted audit requests for Barrio and Mount Sinai to HRSA on June 27, 2025, and July 2, 2025, respectively. Compl. ¶¶ 139, 163. As AbbVie admits, HRSA has not prevented AbbVie from carrying out those audits. *E.g.*, Compl. ¶¶ 145, 172. Indeed, HRSA expressly told AbbVie on September 18, 2025, that it was "not denying AbbVie the opportunity to audit Mt. Sinai or Barrio in accordance with the work plan submitted." *Id*.

Nor did HRSA prospectively refuse to take action on any findings from AbbVie's audits. HRSA simply told AbbVie that, "to the extent findings result from AbbVie's application of a patient definition that is *inconsistent with the longstanding 1996 Guidelines and the 340B statute*, [HRSA's Office of Pharmacy Affairs] will not be able to impose corrective actions." Compl. Ex. 4 (emphasis added). In other words, in accordance with its statutory obligations, HRSA informed

[2] Mount Sinai also provided AbbVie with copies of correspondence regarding issues with AbbVie's mandatory claim platform, 340B ESP. Compl. Ex. 5 pp. 131-39. After months of follow-up from Mount Sinai, 340B ESP still had not set up a call with AbbVie about the issues.

[3] AbbVie never claimed to Mount Sinai or in its Complaint that it actually paid any of these purportedly duplicated claims more than once.

AbbVie that it could not enforce audit findings that allege wrongdoing for permitted conduct. *See* 42 U.S.C. § 256b(a)(5)(D).

Despite being authorized to do so, AbbVie has chosen not to audit Barrio or Mount Sinai in the ten months since HRSA's September 2025 letter. AbbVie chose not to move forward with the audits even though it admits that "auditing a covered entity is a precondition for a manufacturer to file an ADR claim and thereby obtain enforcement of diversion or duplicate discounting findings." Compl. ¶ 48.

AbbVie filed this action on April 8, 2026, asking this Court to, among other things, 1) "Declare that HRSA's determination regarding what constitutes a 'patient of the entity,' as reflected in its September 18 letter refusing to enforce findings from AbbVie's audit requests as proposed, and as that determination applies to Barrio Comprehensive Family Health Care Center, Inc. and The Mount Sinai Hospital, is unlawful under the APA and the 340B statute," 2) "Declare that the interpretation of 'patient of the entity' set forth in AbbVie's audit requests reflects the best meaning of the term as it is used in the 340B statute," and 3) "Authorize AbbVie to audit Barrio and Mount Sinai using the correct statutory understanding of 'patient of the entity,' as set forth in AbbVie's audit requests." Compl. Prayer for Relief ¶¶ 1, 5, 6. In other words, AbbVie is asking this Court to declare the agency's own interpretation of its governing statute unlawful, substitute AbbVie's preferred definition of "patient" in its place, and then authorize AbbVie to retrospectively audit covered entities under that new standard. But AbbVie's manufactured, unripe lawsuit is a transparent attempt to avoid the path Congress prescribed: conduct audits, make allegations, allow covered entities their opportunity for notice and a hearing, obtain a final agency determination, and then challenge that determination through the ordinary course.

The government defendants moved to dismiss this case on June 16, 2026, arguing that AbbVie lacks standing, AbbVie's claims are not ripe, the HRSA letters AbbVie seeks to challenge are not final agency action, and AbbVie's challenge is unreviewable because audit enforcement decisions are committed to agency discretion by law. Dkt. 13. AbbVie's opposition to that motion is due on July 28, 2026. Dkt. 16; 6/22/2026 Minute Order.

ARGUMENT

This Court should reject AbbVie's effort to rewrite the definition of "patient" through litigation rather than the appropriate agency-directed administrative process. At least two separate flaws warrant that result. *First*, this case is premature because AbbVie has declined to complete the mandatory audits that would allow for the development of a factual record. *Second*, AbbVie's attempt to retrospectively apply a new definition of "patient" to a hospital's prior conduct, without allowing that hospital to contest that definition in the audit and ADR processes, raises serious constitutional concerns. This Court should decline to allow these kinds of procedural end-runs and dismiss AbbVie's Complaint.

I. AbbVie's Claims Are Not Ripe.

AbbVie's Complaint should be dismissed because it cannot satisfy the "threshold inquiry" of ripeness. *In re Aiken Cnty.*, 645 F.3d 428, 434 (D.C. Cir. 2011); *see also* Dkt. 13 at 13-15. The ripeness doctrine guards courts, "through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies," and serves "to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way." *Nat'l Park Hosp. Ass'n v. Dep't of Interior*, 538 U.S. 803, 807-08 (2003) (quoting *Abbott Lab'ys v. Gardner*, 387 U.S. 136, 148-49 (1967)). Both prongs of the ripeness inquiry—"(1) the fitness of the issues for judicial decision and (2) the hardship to the parties of withholding court consideration"—counsel in favor of dismissal here. *Id.* at 808.

The government persuasively explains why (1) AbbVie's claim "depends on a chain of contingencies that may never materialize"; (2) "[w]ithholding review also causes AbbVie no cognizable hardship," and (3) why the fact that this "dispute may present a purely legal question about statutory interpretation does not change the analysis." Dkt. 13 at 14-15. Each of those reasons is sufficient for this Court to find this case unripe. But there are even more reasons that this Court should bear in mind.

First, as explained below, *Amici* do not believe that AbbVie could appropriately raise a challenge to HHS's 30-year-old definition of "patient" in the context of a retrospective audit; doing so would violate basic retroactivity principles. *See infra* Part II. But even if it could, "further factual development would 'significantly advance [the Court's] ability to deal with the legal issues presented.'" *Nat'l Park Hosp. Ass'n*, 538 U.S. at 812 (quoting *Duke Power Co. v. Carolina Env't Study Grp., Inc.*, 438 U.S. 59, 82 (1978)); *Delta Air Lines, Inc. v. Export-Import Bank of U.S.*, 85 F. Supp. 3d 250, 270 (D.D.C. 2015) (finding case unripe where questions of statutory interpretation could not be evaluated in a "factual vacuum"). While AbbVie abstractly alleges that it will not be able to conduct an appropriate audit, any reviewing court will be much better served by seeing the *actual* results of an *actual* audit before assessing AbbVie's claims regarding the definition of patient. Right now, it is unclear what AbbVie's definition even entails, as AbbVie's Complaint sets forth only its view of the "minimum" criteria and uses undefined terms like "legitimate healthcare service," "clinical practice standards," and "primary responsibility." Compl. ¶ 140. It similarly is unclear how AbbVie's proposed definition would impact various patient populations. Having an actual record of patients that AbbVie does not believe should qualify as "patients" under the statute would greatly assist the Court in evaluating whether AbbVie's definition could possibly constitute the single, best meaning of the term, including whether that definition is inconsistent

with the aims of the 340B statute. *See United States v. Barnes*, 295 F.3d 1354, 1364 (D.C. Cir. 2002) (a "statute should ordinarily be read to effectuate its purposes rather than frustrate them." (citation omitted)).

Second, although the government has explained why AbbVie would not suffer any hardship if this Court postponed consideration of its claim, it is worth emphasizing that any hardship caused by postponement must be "immediate and significant." *Devia v. N.R.C.*, 492 F.3d 421, 427 (D.C. Cir. 2007) (citation omitted). AbbVie's own actions prove it cannot come close to satisfying this standard. AbbVie waited seven months to even file suit once it received the OPA letter that AbbVie says gives rise to its claims—effectively conceding there is no immediate hardship. *See* Compl. Prayer for Relief (seeking relief as to September 18, 2025 letter in April 8, 2026 Complaint). AbbVie also has sought continuances since this suit has been pending, further indicating that there is no immediacy to its alleged harms. *E.g.*, Dkt. 16, 24. And AbbVie likely could have completed its audits and proceeded to the ADR process by the time that Defendants' motion to dismiss will be adjudicated, yet it has not moved forward in either forum. AbbVie should not now be permitted to skip that statutory audit-and-ADR process based on these hollow claims of hardship.

II. Adjudicating AbbVie's Unripe Claims Would Impermissibly Deprive 340B Program Participants, Including the *Amici*'s Member Hospitals, of Due Process Rights.

AbbVie's decision to skip the administrative process and sprint straight to federal court on the basis of a pre-audit letter from an agency sub-component also warrants dismissal because allowing this case to proceed would strip covered entities of their due process rights. Here, the covered entities that AbbVie would audit had no knowledge of AbbVie's purported patient definition when they submitted their claims to AbbVie and no ability to challenge that definition when AbbVie raised questions about it when seeking HRSA's approval to conduct an audit. Nor

can the covered entities challenge the definition in this case—Barrio and Mount Sinai are not parties here, even though they are parties to the underlying audits.

This is where the case's extremely unusual posture—an uncompleted audit of past behavior—intersects with Barrio's and Mount Sinai's constitutional rights. AbbVie is attempting to apply its new definition of patient to retrospective covered entity conduct (during an audit and ADR process that have not yet been completed). But doing so would be directly contrary to the "well-established" law "that a regulation that changes legal rights adversely cannot be applied retroactively." *Grant Med. Ctr. v. Burwell*, 204 F. Supp. 3d 68, 80 (D.D.C. 2016); *see Verizon Tel. Cos. v. FCC*, 269 F.3d 1098, 1109 (D.C. Cir. 2001) ("In a case in which there is a substitution of new law for old law that was reasonably clear, a decision to deny retroactive effect is uncontroversial." (internal quotation marks and citation omitted)); *AT&T v. FCC*, 454 F.3d 329, 332 (D.C. Cir. 2006) (noting same principle in context of agency adjudication). That is because "an agency cannot sanction an individual for violating the agency's rules unless the individual had 'fair notice' of those rules," and no one has fair notice of rules, like the one AbbVie seeks here, that have not been adopted or even announced. *SNR Wireless LicenseCo., LLC v. FCC*, 868 F.3d 1021, 1043 (D.C. Cir. 2017) (quoting *Gen. Elec. Co. v. EPA*, 53 F.3d 1324, 1328-29 (D.C. Cir. 1995)). AbbVie's request that it be permitted to audit Barrio and Mount Sinai for *past* 340B discount claims in accordance with its own newly invented definition of "patient"—and then pursue penalties based on its audit findings—thus impermissibly seeks to "increase a [covered entity's] liability for past conduct" that was entirely proper at the time in which it occurred. *Landgraf v. USI Film Prods.*, 511 U.S. 244, 280 (1994). Because neither HHS nor an ADR Panel could retroactively sanction covered entities for not complying with AbbVie's "patient" definition, AbbVie cannot ask this Court to do so here. *See Arkema Inc. v. EPA*, 618 F.3d 1, 9 (D.C. Cir.

2010); *AT&T*, 454 F.3d at 332. That, in turn, means that AbbVie is asking this Court to issue an advisory opinion on an abstract legal issue that could not be applied in the audit process below. *Devia*, 492 F.3d at 426 ("Institutional interests in deferring review here are high. . . . [T]hey also include avoiding the issuance of what could effectively become an advisory opinion."); *cf. Truckers United for Safety v. Mead*, 251 F.3d 183, 191 (D.C. Cir. 2001) (declining to issue an "advisory" opinion on the meaning of a statute when it could not be applied to a retrospective investigation). This Court should decline that invitation.

In addition, AbbVie's attempt to seek federal court review before the audit-and-ADR process is completed violates covered entities' procedural due process rights. The 340B statute requires that AbbVie conduct an audit as a prerequisite to seeking any enforcement action. 42 U.S.C. § 256b(d)(3)(B)(iv). It must then complete the ADR process, which requires that the covered entity be given notice and an opportunity to be heard. 42 U.S.C. § 256b(a)(5)(D). "When a statute dictates that parties receive notice and a hearing, the provision of those basic procedural rights is not left to be decided by administrative flexibility or discretion." *City of Kansas City, Mo. v. U.S. Dep't of Hous. & Urban Dev.*, 861 F.2d 739, 744 (D.C. Cir. 1988) (cleaned up and citation omitted). Similarly, private parties cannot be permitted to evade "the provision of those basic procedural rights." *See id*.

At the very least, these constitutional concerns raise their own serious ripeness problems. For this reason, this Court should heed Judge Leval's wise admonition:

> The ripeness principles . . . bear heightened importance when, as in the present case, the potentially unripe question presented for review is a constitutional question. If there is one doctrine more deeply rooted than any other in the process of constitutional adjudication, it is that we ought not to pass on questions of constitutionality . . . unless such adjudication is unavoidable.

Bronx Household of Faith v. Bd. of Educ. of City of N.Y., 492 F.3d 89, 114 (2d Cir. 2007) (Leval, J., concurring) (internal quotation marks omitted). Although the underlying "patient" definition question is not a constitutional one, AbbVie's attempted end-run around the statutory processes and attempt to retroactively apply that definition raises serious due process questions that need not be decided now given the many other reasons why this case is unripe. Consequently, this Court should "decline[] to jump ahead to make this premature adjudication." *Id*. at 123.

CONCLUSION

Defendants' motion to dismiss AbbVie's Complaint should be granted.

Dated: July 14, 2026

Respectfully Submitted,

/s/ Karen L. Dunn
Karen L. Dunn (D.C. Bar No. 1002520)
L. Rush Atkinson*
Lyle W. Gruby*
Jenifer N. Hartley*
DUNN ISAACSON RHEE LLP
401 9th Street, NW
Washington, DC 20004
(202) 240-2900
kdunn@dirllp.com
ratkinson@dirllp.com
lgruby@dirllp.com
jhartley@dirllp.com

Counsel for Amici Curiae

**Pro hac vice application forthcoming.*