

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE**

THE AMERICAN HOSPITAL
ASSOCIATION, THE MAINE HOSPITAL
ASSOCIATION, EASTERN MAINE
MEDICAL CENTER, NATHAN LITTAUER
HOSPITAL & NURSING HOME, UNITY
MEDICAL CENTER, and DALLAS
COUNTY MEDICAL CENTER,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., Secretary of the
U.S. Department of Health and Human
Services, THOMAS J. ENGELS,
Administrator, Health Resources and Services
Administration, THE HEALTH RESOURCES
AND SERVICES ADMINISTRATION, THE
UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES, and
THE UNITED STATES OF AMERICA,

Defendants.

Case No. 1:26-cv-00515-LEW

**PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
MOTION TO INTERVENE**

TABLE OF CONTENTS

INTRODUCTION	1
LEGAL STANDARD.....	4
ARGUMENT	4
I. PhRMA Is Entitled To Intervene As Of Right.....	4
II. Alternatively, PhRMA Should Be Permitted To Intervene Under Rule 24(b).	9
CONCLUSION.....	10

TABLE OF AUTHORITIES

Page(s)

Cases

<i>Allco Renewable Energy Ltd. v. Haaland</i> , Nos. 21-cv-11171, 21-cv-11390, 2022 WL 18033002 (D. Mass. Jan. 7, 2022).....	10
<i>Am. Hosp. Ass’n v. Kennedy</i> , 164 F.4th 28 (1st Cir. 2026).....	2, 8
<i>Am. Hosp. Ass’n v. Kennedy</i> , No. 25-cv-00600, 2025 WL 3677386 (D. Me. Dec. 18, 2025).....	2, 6
<i>B. Fernández & Hnos., Inc. v. Kellogg USA, Inc.</i> , 440 F.3d 541 (1st Cir. 2006).....	7
<i>Berger v. N.C. State Conf. of the NAACP</i> , 597 U.S. 179 (2022).....	6
<i>Conservation L. Found. v. Mosbacher</i> , 966 F.2d 39 (1st Cir. 1992).....	<i>passim</i>
<i>Cotter v. Mass. Ass’n of Minority L. Enf’t Officers</i> , 219 F.3d 31 (1st Cir. 2000).....	6, 7
<i>Daggett v. Comm’n on Governmental Ethics & Election Pracs.</i> , 172 F.3d 104 (1st Cir. 1999).....	4
<i>Dinner Table Action v. Schneider</i> , 2025 WL 604885 (D. Me. Feb. 25, 2025)	9
<i>Driftless Area Land Conservancy v. Huebsch</i> , 969 F.3d 742 (7th Cir. 2020)	1, 6
<i>Mass. Food Ass’n v. Mass. Alcoholic Beverages Control Comm’n</i> , 197 F.3d 560 (1st Cir. 1999).....	6, 7
<i>Melone v. Coit</i> , 100 F.4th 21 (1st Cir. 2024).....	3, 10
<i>United States v. Munsingwear, Inc.</i> , 340 U.S. 36 (1950).....	2

<i>Wal-Mart Stores, Inc. v. Tex. Alcoholic Beverage Comm’n</i> , 834 F.3d 562 (5th Cir. 2016)	6
--	---

Statutes and Regulation

42 U.S.C. § 256b(a)(1).....	5
42 U.S.C. § 1320f-2(a)(3)	5
42 U.S.C. § 1320f-2(d)	5
<i>Notice Regarding 340B Rebate Model Pilot Program</i> , 91 Fed. Reg. 48,883 (Aug. 3, 2026)	5

Rules

Fed. R. Civ. P. 24.....	4
-------------------------	---

Other Authorities

Boehringer Ingelheim, Comment Letter on Request for Information: 340B Rebate Model Pilot Program (April 20, 2026), https://www.regulations.gov/comment/HRSA-2026-0001-2323	8
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INTRODUCTION

Pharmaceutical Research and Manufacturers of America (PhRMA) moves to intervene as a defendant. PhRMA is an association that represents the country's leading innovative biopharmaceutical research companies. Its members include eight of the ten companies whose plans were approved by the Health Resources & Services Administration (HRSA) for participation in the 340B Rebate Model Pilot Program (Pilot Program).¹ *See* Ex. 1 (Stansel Decl.) ¶ 13.

The Pilot Program approvals obtained by PhRMA's members are a direct object of Plaintiffs' Complaint in this case. The Prayer for Relief asks the Court to "enter orders providing ... that HRSA's approvals of the drug companies' plans are permanently enjoined as unlawful and invalid." Dkt. 1 at 140. That request demonstrates that the manufacturers and their approvals are the "real targets of the suit," just as the manufacturers are "subjects of the regulatory plan" created by HRSA. *Conservation L. Found. v. Mosbacher*, 966 F.2d 39, 43 (1st Cir. 1992).

Because the Plaintiffs' Complaint seeks "[c]hanges in the rules" that, if ordered by the Court, would "affect the proposed intervenors' business, both immediately and in the future," precedent from this Circuit and elsewhere shows that PhRMA and the other proposed intervenors are entitled to intervene as of right. *Id.* Indeed, the Seventh Circuit described intervention by holders of challenged government permits as "a paradigmatic case for intervention as of right." *Driftless Area Land Conservancy v. Huebsch*, 969 F.3d 742, 744, 749 (7th Cir. 2020) ("The

¹ PhRMA requests that Rule 24(c)'s responsive pleading requirement be waived or deferred until Federal Defendants are ordered to answer the Complaint, as no party will be prejudiced. *See Peaje Invs. LLC v. García-Padilla*, 845 F.3d 505, 515 (1st Cir. 2017) (recognizing flexibility in Rule 24(c)'s requirements, absent prejudice to any party).

plaintiffs cite no appellate case, and we know of none, that affirmed a denial of intervention in similar circumstances.”).

It is particularly important for PhRMA to participate in this case, because the prior round of litigation shows that the government’s representation of the manufacturers’ interests may be inadequate. *See Mosbacher*, 966 F.2d at 44 (“An intervenor need only show that representation may be inadequate, not that it is inadequate.”). In the earlier litigation, this Court denied motions by PhRMA and several manufacturers to intervene, finding, in the earliest stages of that case, no “tangible basis” for questioning the adequacy of the government’s representation of the movants’ interests. *Am. Hosp. Ass’n v. Kennedy*, No. 25-cv-00600, 2025 WL 3677386, at *4 (D. Me. Dec. 18, 2025) (citation omitted), *vacated*, No. 25-2237, 2026 WL 2913956 (1st Cir. Sep. 25, 2026).² But that conclusion was drawn on a limited record. Subsequent events demonstrate that the government’s representation was inadequate with respect to the *merits* of the dispute, the *injuries* suffered by the manufacturers, and—clearest of all—the *remedy* consented to by the government.

Merits. The government waived in this Court arguments that PhRMA had sought to advance concerning the legal sufficiency of HRSA’s decisional process. The appeals court declined to excuse the government’s waiver and refused to consider those arguments. *See Am. Hosp. Ass’n v. Kennedy*, 164 F.4th 28, 35–36 (1st Cir. 2026).

² The First Circuit dismissed the appeal as moot and vacated the order denying intervention under *United States v. Munsingwear, Inc.*, 340 U.S. 36 (1950). The appeals court observed: “If a future district court denies the Manufacturers’ requests to intervene, that ruling. . . would be subject to immediate appellate review. And if time is of the essence, the Manufacturers could seek review of a denial of intervention on an expedited basis.” 2026 WL 2913956, at *2 n.2. PhRMA accordingly requests a swift determination on its intervention motion.

Injury. The First Circuit deemed the government uninjured and unable to represent the financial harms the manufacturers would suffer from the injunction imposed by this Court; and moreover, the government downplayed the manufacturers’ financial injuries. *Id.* at 37.

Remedy. The government consented to vacatur of the Pilot Program and the manufacturers’ approvals in settling with Plaintiffs, thus accepting the very outcome that the manufacturers attempted to avoid as intervenors. This settlement occurred after the manufacturers sought to argue that the appropriate remedy would be remand *without* vacatur—relief that would have allowed the Pilot Program to take effect while the agency addressed the Court’s conclusion that the agency action adopting the Program was inadequately explained.

Alternatively, the Court should grant permissive intervention under Rule 24(b), consistent with precedent affirming such grants when a party seeks to defend its own federal program approvals. *Melone v. Coit*, 100 F.4th 21, 28–29 (1st Cir. 2024) (deeming it “obvious” that the permit-holder “has significant interests at stake in this litigation and that the outcome may impair its ability to protect those interests”). PhRMA seeks to do just that on behalf of its members, and to offer an industry-wide perspective on the Pilot Program, the flaws in Plaintiffs’ broadside attack on HRSA’s ability to pilot rebate models, and the consequences of an order enjoining the Program.

While Plaintiffs will likely argue that granting intervention will unduly complicate the suit, that argument should not bear weight. Plaintiffs brought this suit to attack the manufacturers’ approvals and thus have no cause to contend manufacturers should be precluded from participating as parties to defend those approvals and their related business interests. PhRMA’s intervention will not delay proceedings. PhRMA wants a swift resolution that will affirm its members’ right to rely on their approvals and allow HRSA to gain experience with rebate models. To the extent

concerns about litigation complexity arise, the Court may use its ordinary case-management tools to address them.

LEGAL STANDARD

Rule 24(a)(2) permits intervention as of right upon a timely motion when the movant has an interest in the action that may be impaired and is not adequately represented by existing parties. On the final element, “[a]n intervenor need only show that representation *may* be inadequate, not that it is inadequate.” *Mosbacher*, 966 F.2d at 44 (emphasis added). Alternatively, Rule 24(b) permits intervention where the movant shares a common question of law or fact with the action and intervention will not unduly delay or prejudice the parties. *See* Fed. R. Civ. P. 24.

ARGUMENT

I. PhRMA Is Entitled To Intervene As Of Right.

PhRMA’s motion is timely, its members’ approvals are directly at risk, and the government may not adequately represent PhRMA’s interests.

A. PhRMA’s Motion Is Timely.

Plaintiffs filed their complaint and motion for temporary restraining order on October 9, 2026. *See* Dkts. 1, 2. PhRMA has moved to intervene on October 15. That is unquestionably timely under Rule 24. *See, e.g., Daggett v. Comm’n on Governmental Ethics and Election Pracs.*, 172 F.3d 104, 109 (1st Cir. 1999) (intervention motion filed within two weeks of complaint “easily met” Rule 24’s timeliness requirement).

B. PhRMA And Its Members Have Significant, Protectable Interests In This Case.

1. PhRMA seeks to protect both its members’ existing approvals and their interest in the development of future rebate models. First, this suit directly threatens federal approvals that eight

PhRMA members have secured. *See* Dkt. 1 § Prayer for Relief (asking to “set aside” the approvals). If Plaintiffs prevail, PhRMA’s members will lose the ability to implement their authorized plans. They thus have the “direct, not contingent” interest Rule 24 requires: they “are the real targets of the suit and are the subjects of the regulatory plan” Plaintiffs challenge. *Mosbacher*, 966 F.2d at 43. This interest alone justifies intervention.

The consequences of losing those approvals underscore that interest. Section 340B of the Public Health Service Act requires manufacturers to offer discounted pricing, while the Medicare Drug Price Negotiation Program requires manufacturers to make available select drugs at a “maximum fair price” (MFP). *See* 42 U.S.C. §§ 256b(a)(1), 1320f-2(a)(3). When both programs apply, the manufacturer is not required to give both discounts. Instead, federal law requires the manufacturer to provide only one discount—the one that yields the lower price. *Id.* § 1320f-2(d). The Pilot Program is intended to allow manufacturers to review claims data before providing the 340B price and thereby to prevent duplicate discounts. *See* Ex. 1 ¶¶ 15, 18. Without the Program, PhRMA members risk duplicate discounts totaling billions of dollars or federal penalties for failing to timely provide the required price. *Id.*

Further, PhRMA and its members have an interest in the Pilot Program’s future implications. HRSA plans to use Program data “to inform future policy considerations related to program integrity and compliance,” including possible “broader application” of rebates. *Notice Regarding 340B Rebate Model Pilot Program*, 91 Fed. Reg. 48,883, 48,890, 48,893 (Aug. 3, 2026). PhRMA has advocated that rebate models should be available for all 340B purchases. *See* Ex. 1 ¶ 22. Halting the Pilot would deprive HRSA of evidence relevant to that broader option.

2. These interests readily satisfy Rule 24’s interest requirement. In *Mosbacher*, the First Circuit held that fishing groups were entitled to intervene in a suit challenging a federally approved fishery plan because changes to the plan would affect their businesses “both immediately and in the future.” 966 F.2d at 43; *see also Mass. Food Ass’n v. Mass. Alcoholic Beverages Control Comm’n*, 197 F.3d 560, 566 (1st Cir. 1999) (assuming that trade association satisfied interest requirement where its “members were subject to the very ... regulation challenged”). Similarly, the Seventh Circuit called a suit seeking to invalidate government permits “a paradigmatic case for intervention as of right” by the permit holders. *Driftless*, 969 F.3d at 744; *see also Wal-Mart Stores, Inc. v. Tex. Alcoholic Beverage Comm’n*, 834 F.3d 562, 569 (5th Cir. 2016) (association could intervene to protect members’ interests as intended beneficiaries of challenged rules).

The next requirement—potential impairment of PhRMA’s interests—is also satisfied here. The First Circuit has held that “even a small threat” to an intervenor’s interests suffices. *Cotter v. Mass. Ass’n of Minority L. Enf’t Officers*, 219 F.3d 31, 35 (1st Cir. 2000). Here, plaintiffs’ claims directly threaten significant harm to PhRMA members’ approvals, and to their financial interests.

C. The Government May Not Adequately Represent PhRMA’s Interests.

PhRMA has also shown that the representation of the existing parties “may be inadequate.” *Mosbacher*, 966 F.2d at 44. This Court previously denied intervention on the basis that PhRMA and the manufacturers had offered no “tangible basis” for questioning the adequacy of the government’s representation. *Am. Hosp. Ass’n*, 2025 WL 3677386, at *4. Subsequent events underscore why the government may not adequately represent manufacturers’ interests here.

Rule 24(a)(2) “promises intervention to those who bear an interest that may be practically impaired or impeded” unless existing parties adequately represent that interest. *Berger v. N.C.*

State Conf. of the NAACP, 597 U.S. 179, 195 (2022). The burden of showing inadequate representation is “minimal” where a private party asserts interests that are “related” to those “of an existing government party” but not “identical,” because the government must “bear in mind broader public-policy implications.” *Id.* at 195–96. And, although courts in this Circuit sometimes presume that the government will adequately defend its own actions, that presumption is rebuttable. *See Mass. Food Ass’n*, 197 F.3d at 567. Further, where the proposed intervenor has a “tangible and substantial stake,” its burden of showing inadequate representation is “lighter” than if its interest were “thin and widely shared.” *B. Fernández & Hnos., Inc. v. Kellogg USA, Inc.*, 440 F.3d 541, 546 (1st Cir. 2006). PhRMA’s members seek to preserve their own approvals and avoid substantial financial losses.

Mosbacher and *Cotter* are illustrative. Both establish that, when litigation threatens a concrete privilege conferred by the government on a private party, any presumption is readily rebutted. In *Mosbacher*, fishing groups sought to defend a federally approved fishery plan. 966 F.2d at 40. The First Circuit found inadequate representation because the government’s judgments were “necessarily constrained by [its] view of the public welfare,” while the fishermen viewed their interests in a “different, perhaps more parochial light.” *Id.* at 44. Further, the government had—contrary to the fishermen’s interests—accepted a consent decree providing virtually all the relief the plaintiffs sought. *Id.* In *Cotter*, minority police officers sought to defend promotions on grounds the police department had reason to resist: that its existing promotional tests were deficient. 219 F.3d at 35–36. That “likelihood of conflict or divergence between the intervention applicants and the named defendants” satisfied the adequate-representation factor. *Id.* at 36.

The prior Pilot Program litigation shows that both concerns apply. As in *Cotter*, the government and manufacturers advanced different defenses. The manufacturers argued that HRSA’s approvals were informal adjudications requiring only limited explanation. *See* Proposed Intervenor’s Opp’n Br. at 11–12, *Am. Hosp. Ass’n*, No. 25-cv-00600, Dkt. 72. The government asserted judicially unreviewable discretion over 340B rebates—a view at odds with PhRMA members’ interests in judicial review of HRSA’s actions. When the government raised the informal-adjudication argument on appeal, the First Circuit held the government had waived the argument. *See Am. Hosp. Ass’n*, 164 F.4th at 35–36.

The parties also diverged on the financial consequences of an injunction. PhRMA and the manufacturers emphasized, with substantiating evidence, that rebates were the best and most reliable means of deduplicating discounts. *See* Proposed Intervenor’s Opp’n Br. at 13–15. In denying the government’s stay request, the First Circuit stated that the government could not show irreparable injury because the costs of the injunction would not fall on the government. “Rather, the primary cost of any delay” would fall on the manufacturers, who were not parties. *Am. Hosp. Ass’n*, 164 F.4th at 37. The court also credited the government’s assertion that “manufacturers have alternative methods” of addressing duplicate discounts—a point PhRMA and the other movants sought to rebut, but were denied the opportunity to do so. *Id.* As the record shows, PhRMA and the other movants were correct: due to the absence of a rebate model, one manufacturer paid out millions of dollars *per week* in duplicate discounts in early 2026. *See* Boehringer Ingelheim, Comment Letter on Request for Information: 340B Rebate Model Pilot Program, at 2 (April 20, 2026), <https://www.regulations.gov/comment/HRSA-2026-0001-2323>.

And as in *Mosbacher*, the government ultimately agreed to relief adverse to the manufacturers. PhRMA had urged remand without vacatur if the Court found the Pilot Program unlawful. *See* Proposed Intervenor’s Opp’n Br. at 20. The government did not request that remedy in its initial briefing (it did so only belatedly, after the hearing). *See* Notice at 1, *Am. Hosp. Ass’n*, No. 25-cv-00600, Dkt. 85. After the Court entered a preliminary injunction and the First Circuit denied a stay, the government agreed with Plaintiffs to vacate the Pilot Program and the manufacturers’ approvals. *See* Judgment at 2, *Am. Hosp. Ass’n*, No. 25-2237 (1st Cir. Sept. 25, 2026). PhRMA, a non-party, had no opportunity to oppose that relief. *Cotter*, *Mosbacher*, and prior events establish that the government may not adequately represent PhRMA’s interests here.

II. Alternatively, PhRMA Should Be Permitted To Intervene Under Rule 24(b).

PhRMA also meets the requirements for permissive intervention under Rule 24(b): PhRMA’s defenses share common questions with this action, its participation will help fully develop the issues, and intervention will not unduly delay resolution or prejudice the parties.

Courts have granted permissive intervention in analogous circumstances. In *Dinner Table Action v. Schneider*, 2025 WL 604885, at *2 (D. Me. Feb. 25, 2025), for example, the court held that when a party “seek[s] to intervene to defend the” legality of a challenged state law, it “clearly ha[s] a ‘defense that shares with the main action a common question of law or fact.’” *Id.* (quoting Fed. R. Civ. P. 24(b)(1)(B)). The court granted intervention even though the proposed intervenors substantially agreed with the government, reasoning that their distinct perspective would help “fully develop[] the case.” *Id.* at *2–3. Amicus participation was insufficient because amici could not introduce arguments. *Id.* at *3. Here, PhRMA seeks to intervene to defend the Pilot Program approvals secured by its members. PhRMA can explain developments in the 340B Program,

including the impact of the MFP statute, and the need for the Pilot Program, from the perspective of manufacturers. PhRMA can also provide perspective on how the Pilot Program may inform broader adoption of rebate models under the 340B Program. These perspectives will aid the Court in assessing Plaintiffs’ challenge and the competing claims of irreparable harm.

An even closer parallel is *Melone*. There, Vineyard Wind sought to intervene to defend federal approvals for an offshore wind project. *Melone*, 100 F.4th at 27–28. The district court granted permissive intervention, and the First Circuit affirmed, noting “what was obvious—Vineyard Wind ‘has significant interests at stake in this litigation and . . . the outcome may impair its ability to protect those interests.’” *Id.* at 29.³

The same is true here. PhRMA’s members have significant interests in their federal approvals, and its prompt intervention will not prejudice any other party. PhRMA is prepared to adhere to any expedited schedule that the Court may adopt and to coordinate with other intervenors as appropriate. PhRMA has no interest in delaying this litigation; to the contrary, PhRMA’s interest is in a fast resolution that will allow members to implement their approved rebate plans.

CONCLUSION

For the forgoing reasons, the Court should grant PhRMA’s motion to intervene as of right or, in the alternative, for permissive intervention.

³ The district court denied Vineyard Wind intervention as of right without prejudice because Vineyard Wind’s concerns about inadequate representation, including a possible unfavorable settlement, were deemed speculative. *Allco Renewable Energy Ltd. v. Haaland*, 2022 WL 18033002, at *5–6 (D. Mass. Jan. 7, 2022). PhRMA’s concerns, by contrast, are grounded in past events, including a prior unfavorable settlement between plaintiffs and HRSA. *See supra* pp. 8-9.

Dated: October 15, 2026

Respectfully submitted,
/s/ Daniel L. Rosenthal

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was electronically filed with the Clerk of the Court via the Court's CM/ECF system, which sent notification of such filing to all counsel of record by electronic means.

/s/ Daniel L. Rosenthal
Daniel L. Rosenthal

EXHIBIT 1

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE**

THE AMERICAN HOSPITAL ASSOCIATION,
THE MAINE HOSPITAL ASSOCIATION,
EASTERN MAINE MEDICAL CENTER,
NATHAN LITTAUER HOSPITAL &
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ROBERT F. KENNEDY, JR., Secretary of the
U.S. Department of Health and Human Services,
THOMAS J. ENGELS, Administrator, Health
Resources and Services Administration, THE
HEALTH RESOURCES AND SERVICES
ADMINISTRATION, THE UNITED STATES
DEPARTMENT OF HEALTH AND HUMAN
SERVICES, and THE UNITED STATES OF
AMERICA,

Defendants.

Case No. 1:26-cv-00515-LEW

**DECLARATION OF JAMES C. STANSEL
IN SUPPORT OF PhRMA's MOTION TO INTERVENE**

I, James C. Stansel, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

1. I am Executive Vice President, General Counsel and Corporate Secretary of Pharmaceutical Research and Manufacturers of America (PhRMA). In this role, I supervise the work of PhRMA's law department, which supports PhRMA's public policy advocacy to represent its members' interests in matters before Congress, the Executive Branch, the courts, and state legislatures and regulatory agencies.

2. I have held this position since 2016. I have personal knowledge of the facts stated herein. If called as a witness in this matter, I could and would competently testify to each of the facts set forth below.

3. PhRMA is a voluntary nonprofit association organized and existing under the laws of the State of Delaware that represents the country's leading biopharmaceutical research companies.

4. PhRMA's members are the country's leading innovative biopharmaceutical companies, which are focused on developing innovative medicines that transform lives and create a healthier world. PhRMA advocates for public policies to ensure patients can access and afford medicines that prevent, treat, and cure disease. PhRMA member companies have invested more than \$900 billion in the search for new treatments and cures over the last decade, supporting nearly five million jobs in the United States.

5. PhRMA's current members are Alkermes plc.; Amgen Inc.; Astellas Pharma; AstraZeneca; Bayer Corporation; Biogen; BioMarin Pharmaceutical Inc.; Boehringer Ingelheim Pharmaceuticals, Inc.; Bristol Myers Squibb; CSL; Daiichi Sankyo, Inc.; Eisai Inc.; Eli Lilly and Company; EMD Serono; Genentech; Genmab US, Inc.; Gilead Sciences, Inc.; GSK; Incyte Corporation; Ipsen Biopharmaceuticals, Inc.; Johnson & Johnson; Kyowa Kirin, Inc.; Lundbeck LLC; Merck & Co., Inc.; Neurocrine Biosciences, Inc.; Novartis Pharmaceuticals Corporation; Novo Nordisk Inc.; Otsuka America Pharmaceutical, Inc.; Pfizer Inc.; Sanofi; Stemline Therapeutics, Inc.; Sumitomo Pharma America; Takeda Pharmaceuticals USA, Inc.; and UCB, Inc.

6. PhRMA represents its members across the country concerning legislative, political, legal, and social issues in which the biopharmaceutical industry has an interest. PhRMA serves as the industry's principal policy advocate.

7. This lawsuit involves the 340B Drug Pricing Program (340B). 340B is a federal program that requires drug manufacturers to offer to sell certain drugs to "covered entities" at or below a specified statutory price. If manufacturers do not participate in 340B, the medicines they

manufacture are not eligible for reimbursement from the federal government under Medicare Part B or Medicaid.

8. As part of my job responsibilities, I am familiar with PhRMA members' participation in 340B.

9. Many of PhRMA's member companies listed above participate in 340B. Those manufacturers provide to covered entities deeply reduced-priced drugs as part of the program. One study has found that through their participation in 340B, PhRMA's members annually provide discounts worth at least \$79.5 billion. *See Adam Fein, The 340B Program Hit \$100 Billion in 2025: Has It Become Too Big to Reform?*, Drug Channels (July 15, 2026), <https://www.drugchannels.net/2026/07/the-340b-program-hit-100-billion-in.html>.

10. Because PhRMA's members participate in 340B, they are directly affected by the operation of the program and by the requirements for participation. Accordingly, as a representative of its members' interests, PhRMA has a clear stake in the proper operation and application of 340B.

11. This lawsuit specifically concerns the 340B Rebate Model Pilot Program (Pilot Program), which the Health Resources & Services Administration (HRSA) announced via Federal Register notice on August 3, 2026. *See Notice Regarding 340B Rebate Model Pilot Program*, 91 Fed. Reg. 48,883 (Aug. 3, 2026).

12. The Pilot Program allows an approved group of manufacturers to effectuate 340B price reductions on specified drugs through rebates to covered entities rather than upfront discounts. As part of my job responsibilities, I am familiar with the Pilot Program.

13. To date, HRSA has reviewed and approved rebate model plans under the Pilot Program that were proposed by the following PhRMA members: Amgen, Astellas, AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb, GSK, Merck, and Pfizer. *See HRSA, 340B Rebate Model Pilot Program: Approved manufacturer 340B Rebate Model plans*, <https://www.hrsa.gov/opa/340b-model-pilot-program>.

14. These manufacturers are eligible to participate in the Pilot Program, as presently designed, because each has one or more drugs that has been selected for the Inflation Reduction Act's (IRA) Medicare Drug Price Negotiation Program. The IRA requires covered manufacturers to offer a "maximum fair price" (MFP)—another statutorily mandated price reduction—on certain medicines. But the law explicitly states that a manufacturer need not provide both the MFP and 340B price reductions on the same prescription. And a manufacturer that fails to provide accurate pricing could face civil monetary penalties. *See* 42 U.S.C. § 1320f-6(a), (c).

15. The PhRMA members identified in Paragraph 13 above sought approval to use rebate models in the Pilot Program to assist in compliance with the IRA and to avoid other 340B duplicate discounting. Under the manufacturers' rebate models approved by HRSA, manufacturers will pay rebates to covered entities for 340B-eligible prescriptions within 10 days of receiving basic claims data that confirms each prescription's eligibility for the 340B discount. *See* 91 Fed. Reg. at 48,903.

16. The PhRMA members whose rebate programs were approved for the Pilot by HRSA have been preparing to implement their rebate programs. I understand that these preparations have required significant expenditures of time and money in designing the rebate model systems and applying for approval from HRSA.

17. The Pilot Program begins on January 1, 2027. The approved manufacturers likewise have obligations to offer the MFP on select drugs under the IRA beginning not later than January 1, 2027.

18. Absent the Pilot Program, PhRMA's members stand to lose billions of dollars. Berkeley Research Group has estimated that manufacturers could pay \$5.2 billion in duplicate 340B and MFP discounts in 2027 alone. *See* Berkeley Research Group, *Update on Effectuation of the Maximum Fair Price in 2026 and Outlook for 2027* at 2 (April 2026), https://media.thinkbrg.com/wp-content/uploads/2026/05/06130328/Effectuation-of-the-Maximum-Fair-Price-in-2026-and-Outlook-to-2027_5.6.26.pdf. In a prior report, Berkeley

Research Group noted that “every dispense subject to a duplicate discount will represent a financial loss to the manufacturer ... because the 340B discount and the MFP discount, when added together, exceed the drug’s list price.” Berkeley Research Group, *Implications for Duplication with the 340B Channel* at 2 (Oct. 2024), <https://media.thinkbrg.com/wp-content/uploads/2024/10/23161214/BRG-Implications-for-Duplication-with-the-340B-Channel-2024.pdf>.

19. In addition to these members selected for the Pilot Program, other PhRMA members have an interest in the Pilot.

20. As the agency explained, “HRSA will use data collected through the Pilot, including rebate submissions, denials, and dispute outcomes, to more effectively prevent duplicate discounts relative to existing mechanisms and to inform future policy considerations related to program integrity and compliance.” 91 Fed. Reg. at 48,890. The Pilot will “allow[] for the evaluation and adjustment of workflows and data exchange mechanisms based on actual experience prior to broader application.” *Id.* at 48,893.

21. Other PhRMA members who participate in the 340B Program, including those whose drugs have previously been selected for MFP negotiation or may be subjected to MFP obligations in later years, are strongly interested in pursuing rebate models in the future. *See* PhRMA, Request for Information: 340B Rebate Model Pilot Program and Request for Public Comment at 3 (April. 20, 2026), https://cdn.aglty.io/phrma/global/resources/import/pdfs/Rebate%20Notice%20PhRMA%20Comments_FINAL.pdf (urging that “a rebate model should be an option for all 340B drug purchases immediately, without first limiting implementation to a pilot”).

22. On behalf of these members, PhRMA has advocated that HRSA “work toward a broader rebate model that goes beyond IRA selected drugs, as operational and program integrity benefits of such a rebate approach apply broadly across the 340B program.” *Id.* As a result, these

members too have a strong interest in ensuring that the agency will be able to use the Pilot Program to review and study the efficacy of rebate models.

23. The agency's ability to study rebate models has particular practical importance because HRSA has adopted a legal position that a manufacturer may not use a rebate mechanism to deliver the 340B ceiling price without prior approval from HRSA, and to date courts have sustained HRSA's position on that point. *See, e.g., Novartis Pharmaceuticals Corporation v. Kennedy*, 182 F.4th 1027, 1038 (D.C. Cir. 2026). Those rulings underscore the importance for PhRMA's members that HRSA be able to obtain real-world information about the operation of rebate models.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. *See* 28 U.S.C. § 1746.

Executed on: October 13, 2026

/s/ James C. Stansel

James C. Stansel

Declarant