

United States Court of Appeals For the First Circuit

No. 25-2237

AMERICAN HOSPITAL ASSOCIATION; ST. MARY'S REGIONAL MEDICAL CENTER;
MAINE HOSPITAL ASSOCIATION; NATHAN LITTAUER HOSPITAL AND NURSING
HOME; UNITY MEDICAL CENTER; DALLAS COUNTY MEDICAL CENTER,

Plaintiffs, Appellees,

v.

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

Defendants,

ABBVIE INC.; ASTRAZENECA PHARMACEUTICALS LP; PHARMACYCLICS LLC;
BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; NOVO NORDISK INC.;
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Interested Parties, Appellants.

Before

Montecalvo, Howard, and Thompson,
Circuit Judges.

JUDGMENT

September 25, 2026

Two federal initiatives to reduce drug costs threatened to impose duplicative discount obligations on drug manufacturers: (1) the 340B Program, which allows safety-net providers to purchase drugs at reduced "ceiling price[s]," 42 U.S.C. § 256b; and (2) the Medicare Drug Price Negotiation Program, which requires the Secretary of the Department of Health and Human Services to negotiate "maximum fair prices" that Medicare pays for certain drugs. *Id.* §§ 1320f(a)(3), (c)(2), 1320f-2(a). To address this concern, the Health Resources and Services Administration ("HRSA"), an agency within the Department of Health and Human Services (the "Department"), created a program to help manufacturers avoid having to pay duplicative discounts

(the "Pilot Program"). See 340B Program Notice, 90 Fed. Reg. 36,163 (Aug. 1, 2025) (corrected notice issued at 90 Fed. Reg. 38,165 (Aug. 7, 2025)). The Pilot Program required providers to pay the full price for certain drugs up front and then claim a rebate from the manufacturer to align the net purchase price with the applicable discount program.

I.

Appellants AbbVie Inc. and its subsidiary Pharmacyclics LLC (collectively "AbbVie"), AstraZeneca Pharmaceuticals LP ("AstraZeneca"), Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer"), Novo Nordisk Inc. ("Novo Nordisk"), and Pharmaceutical Research and Manufacturers of America are pharmaceutical manufacturers and a related industry trade association respectively (collectively the "Manufacturers") who supported the Pilot Program because it allowed them to more effectively deduplicate their discount obligations. AbbVie, AstraZeneca, Boehringer, and Novo Nordisk were also approved to participate in the Pilot Program beginning on January 1, 2026.

Appellees, the American Hospital Association, the Maine Hospital Association, and four individual hospitals (collectively the "Association"), represent healthcare providers who had to pay higher upfront prices for certain drugs under the Pilot Program.

The Association sued the United States, the Department, HRSA, and certain government officials in the United States District Court for the District of Maine seeking to enjoin the Pilot Program under the Administrative Procedure Act ("APA"). The Manufacturers moved to intervene in defense of the Pilot Program. See Fed. R. Civ. P. 24. The district court denied intervention but allowed the Manufacturers to participate as amici curiae.

After the district court granted a preliminary injunction and this court denied the government's request for a stay pending appeal, the Association and the government jointly moved for vacatur and remand of the Pilot Program. The district court granted that motion, vacated the Pilot Program and HRSA's approvals of nine manufacturer applications to participate in the Pilot Program, and remanded the matter to the Department. The government has not appealed the district court's vacatur order.

II.

While the matter remained pending, the Manufacturers appealed the district court's denial of their intervention motions. See R & G Mortg. Corp. v. Fed. Home Loan Mortg. Corp., 584 F.3d 1, 7 (1st Cir. 2009) ("[A]n order denying a motion to intervene is immediately appealable."). We can only address this appeal, however, if our jurisdiction to do so is secure under Article III. Redfern v. Napolitano, 727 F.3d 77, 82 (1st Cir. 2013).

A.

Federal courts exercise jurisdiction over "cases" and "controversies." U.S. Const. art. III, § 2, cl. 1. A case must present a "live" dispute "that will have a real effect on real parties in interest." Bos. Bit Labs, Inc. v. Baker, 11 F.4th 3, 8 (1st Cir. 2021) (emphasis omitted). "[I]f a case loses its live-controversy character at any point in the proceedings, the mootness doctrine generally stops us from pumping new life into the dispute (regardless of how fascinating the party's claims are) by ousting the federal courts of jurisdiction and requiring us to dismiss the case." Id. (citation modified).

Here, the district court's vacatur and remand of the Pilot Program caused the intervention dispute to become moot. The goal of the Manufacturers' intervention motions was to take an active role in defending the Pilot Program. That goal became unattainable when the district court vacated the Pilot Program with the government's consent. At that point, the Pilot Program was stripped of its legal effect and there was nothing left for the Manufacturers to defend. See Gulf of Me. Fisherman's All. v. Daley, 292 F.3d 84, 88 (1st Cir. 2002) (replacement of one regulation with another mooted challenge to first regulation because it was "no longer in effect"). And because the government is not seeking to restore the Pilot Program on appeal, there is no justiciable controversy in which the Manufacturers can intervene, and no effective relief that this court can grant. See id. Accordingly, this appeal is moot.

B.

The Manufacturers argue that the intervention dispute avoids mootness because the issue is capable of repetition, yet evading review. This exception to the mootness doctrine "applies only in exceptional situations." City of Los Angeles v. Lyons, 461 U.S. 95, 109 (1983). The party invoking the exception must demonstrate that "(1) the challenged action is in its duration too short to be fully litigated prior to cessation or expiration, and (2) there is a reasonable expectation that the same complaining party will be subject to the same action again." Fed. Election Comm'n v. Wis. Right to Life, Inc., 551 U.S. 449, 462 (2007) (quoting Spencer v. Kemna, 523 U.S. 1, 17 (1998)); Redfern, 727 F.3d at 84.

At a minimum, the Manufacturers fail to demonstrate a reasonable expectation that a denial of their intervention rights will avoid judicial review in the future. They argue that the underlying litigation was active for less than three months, and that any repeat of such proceedings would preclude fulsome appellate review of their intervention rights.¹ But predicting how a second round of litigation might play out requires an impermissible amount of speculation. See Roe v. Healey, 78 F.4th 11, 23 (1st Cir. 2023) ("[T]o escape a finding of mootness, review-avoiding repetition must be reasonably expected."); Harris v. Univ. of Mass. Lowell, 43 F.4th 187, 194 (1st Cir. 2022) (theoretical possibility that challenged action might reoccur does not support application of

¹ We note that the Manufacturers did not file a notice of appeal in connection with the denial of intervention until after the district court preliminarily enjoined the Pilot Program. Am. Hosp. Ass'n v. Kennedy, No. 2:25-cv-00600, Dkt. 97 (D. Me. Dec. 30, 2025).

"capable of repetition, yet evading review" exception).

Although the government's decision to abandon its defense of the Pilot Program cut the litigation short this time, there is no indication that future litigation concerning a new drug rebate program would end so abruptly. If a new rebate program becomes the subject of litigation, the district court may find the new program to be APA compliant. The district court also may grant intervention before resolving any motions for injunctive relief. Either way, there would be no need for the Manufacturers to seek appellate review of a denial of their asserted intervention rights.² And regardless of how a future district court might rule with respect to preliminary relief, the government may not agree to vacatur of a future program as quickly as it did here. See Ctr. for Bio. Diversity v. Bureau of Land Mgmt., 69 F.4th 588, 596 (9th Cir. 2023) ("[D]enials of intervention will not typically evade review because they usually do not become moot before appellate review is complete"); Seneca Res. Corp. v. Township of Highland, 863 F.3d 245, 255 (3d Cir. 2017) (rejecting "speculative" argument that future litigation would become moot before putative intervenors could get court ruling on intervention); cf. W. Coast Seafood Processors Ass'n v. Nat. Res. Def. Council, Inc., 643 F.3d 701, 705 (9th Cir. 2011) ("The intervention controversy avoids review here only because [the agency] acquiesced in the court-ordered remedy by dismissing its appeal, not because the controversy is inherently limited in duration." (internal quotation marks omitted)). Accordingly, the intervention dispute in this case is not a suitable candidate for the "capable of repetition, yet evading review" exception.

C.

The parties agree that if this appeal is deemed moot, vacatur of the district court's intervention order is appropriate under United States v. Munsingwear, Inc., 340 U.S. 36, 39 (1950). Munsingwear vacatur "expunges an adverse decision that would be reviewable had th[e] case not become moot." Camreta v. Greene, 563 U.S. 692, 712 n.10 (2011).

We agree that the order denying intervention should be vacated. "A party who seeks review of the merits of an adverse ruling, but is frustrated by the vagaries of circumstance, ought not in fairness be forced to acquiesce in the judgment." U.S. Bancorp. Mortg. Co. v. Bonner Mall P'ship, 513 U.S. 18, 25 (1994). The Manufacturers fall into this category of litigants because their attempt to appeal the denial of intervention was frustrated by the government's acquiescence in the Pilot Program's vacatur -- i.e., they lost their ability to challenge the intervention order through the actions of the parties. The Manufacturers are thus appropriate candidates for the equitable remedy of vacatur insofar as it concerns the district court's ruling on intervention. See id. at 26 (considering whether party invoking Munsingwear bore responsibility for mootness).

² If a future district court denies the Manufacturers' requests to intervene, that ruling, as noted, would be subject to immediate appellate review. R & G Mortg. Corp., 584 F.3d at 7. And if time is of the essence, the Manufacturers could seek review of a denial of intervention on an expedited basis.

III.

The district court's order denying intervention is vacated and the appeal is dismissed.

By the Court:

Anastasia Dubrovsky, Clerk

cc: Hon. Lance E. Walker, Jennifer Lyons, Clerk, United States District Court for the District of Maine, Melissa A. Hewey, Karen L. Dunn, Jenifer N. Hartley, Lawrence Atkinson, Lindsay Feinberg, Maxwell A. Baldi, Jay S. Geller, Paul McDonald, Lucas L. Fortier, Matthew Scott Owen, Meredith M. Pohl, Nick Bell, Edward S. MacColl, William B. Schultz, Alyssa Howard, Jeffrey L. Handwerker, Jeffrey D. Talbert, Allon Kedem, Daniel L. Rosenthal, Corin R. Swift, Kwaku A. Akowuah, Meenakshi Datta, Thomas Ross Brugato, Alfred Cecil Frawley IV, Kevin F. King, Daniel Gerard Randolph