NOT FOR PUBLICATION

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MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Plaintiff-Appellant, v. ELIZABETH LANDSBERG, in her official capacity as Director of the California Office of Statewide Health Planning and Development, Defendant-Appellee.	No. 21-16312 D.C. No. 2:17-cv-02573-MCE-KJN MEMORANDUM*

Appeal from the United States District Court
for the Eastern District of California
Morrison C. England, Jr., District Judge, Presiding

Argued and Submitted July 5, 2022
Honolulu, Hawaii

Before: WARDLAW, NGUYEN, and OWENS, Circuit Judges.

Pharmaceutical Research & Manufacturers of America (PhRMA) appeals the district court's denial of its motion for summary judgment. California Senate Bill 17 (SB 17), codified at California Health & Safety Code § 127677, requires

* This disposition is not appropriate for publication and is not precedent except as provided by Ninth Circuit Rule 36-3.

that pharmaceutical manufacturers provide California purchasers with advance notice of an increase in a pharmaceutical drug's wholesale acquisition cost (WAC) exceeding 16% over two years (the "advance notice" requirement) and a statement as to whether the increase in WAC is due to a change or improvement in the drug (the "disclosure" requirement). PhRMA challenges SB 17 as facially violating both the dormant Commerce Clause and the First Amendment. The district court certified its order for interlocutory review, specifically referencing its ruling denying the facial dormant Commerce Clause challenge. We granted PhRMA's petition for interlocutory appeal, vesting us with jurisdiction under 28 U.S.C. § 1292(b). We affirm, and do not reach PhRMA's First Amendment claim.[1]

The district court did not err in finding that genuine disputes of material fact exist as to whether SB 17 directly regulates interstate commerce. PhRMA argues that SB 17's advance notice requirement amounts to direct regulation of interstate commerce. *See* Cal. Health & Safety Code § 127677(b). "A local law directly regulates interstate commerce when it 'directly affects transactions that take place across state lines or entirely outside of the state's borders.'" *Rosenblatt v. City of*

[1] The district court's certification order does not mention PhRMA's First Amendment claim, and PhRMA did not request review of the First Amendment claim either at the district court or in its petition for interlocutory review before this court. While we have the discretion to review the district court's First Amendment holding as part of the certified order on appeal, *see Yamaha Motor Corp., U.S.A. v. Calhoun*, 516 U.S. 199, 205 (1996), we decline to exercise such discretion.

Santa Monica, 940 F.3d 439, 445 (9th Cir. 2019) (quoting *Daniels Sharpsmart, Inc. v. Smith*, 889 F.3d 608, 614 (9th Cir. 2018)). "[T]he 'practical effect' of a challenged statute is 'the critical inquiry' in determining whether that statute constitutes direct regulation." *S.D. Myers, Inc. v. City & Cnty. of San Francisco*, 253 F.3d 461, 467 (9th Cir. 2001) (quoting *Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989)).

The district court correctly determined that "PhRMA claims SB 17 directly impacts out-of-state drug prices but what that impact may actually be remains unclear." While PhRMA argues that the advance notice provision freezes drug prices nationwide, WAC is a nationwide list price set by manufacturers for each drug that does not reflect the final transaction price. In its opposition to summary judgment, California presented expert testimony that changes in WAC are not directly tied to changes in a drug's final transaction price. Additionally, while PhRMA correctly notes that WAC is sometimes used in negotiations of drug prices in federal Medicare reimbursement and state Medicaid reimbursement programs, California's experts explained that the frequency of WAC's use in these reimbursement formulas and WAC's precise effects in calculating reimbursement amounts remains unclear. With regard to private contractual negotiations, the district court correctly found that PhRMA provides no "explanation or examples as to how these market transactions will be impacted, especially since such contracts

involve negotiations on a wide array of factors, including rebates and discounts." And PhRMA fails to identify a single party unable to increase the WAC on a pharmaceutical drug due to SB 17's advance notice requirement.

In short, we currently lack the evidentiary record needed to determine whether SB 17 actually regulates interstate commerce in the pharmaceutical drug market.[2] On remand, PhRMA will have the opportunity to present such evidence. But, on this record, the district court did not err in determining that there are genuine disputes of material fact as to whether SB 17's practical effect is to directly regulate transactions in interstate commerce. *See Rosenblatt*, 940 F.3d at 445.

AFFIRMED AND REMANDED.

[2] The district court bypassed discovery and proceeded directly to summary judgment proceedings at PhRMA's request.