FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

YAKIMA VALLEY MEMORIAL HOSPITAL, a Washington nonprofit corporation, *Plaintiff-Appellant*, v. WASHINGTON STATE DEPARTMENT OF HEALTH; MARY C. SELECKY, in her official capacity as Secretary of the Washington State Dept. of Health, *Defendants-Appellees*, and YAKIMA HMA, LLC, DBA Yakima Regional Medical and Cardiac Center, *Intervenor-Defendant*.	No. 12-35652 D.C. No. 2:09-cv-03032-EFS OPINION

Appeal from the United States District Court
for the Eastern District of Washington
Edward F. Shea, District Judge, Presiding

Argued and Submitted
June 4, 2013—Seattle, Washington

Filed September 23, 2013

Before: M. Margaret McKeown and Sandra S. Ikuta, Circuit Judges, and Cormac J. Carney, District Judge.[*]

Opinion by Judge McKeown

SUMMARY[**]

Constitutional Law

Affirming the district court's summary judgment, the panel held that Washington State Department of Health Certificate of Need regulations did not violate the dormant Commerce Clause.

The regulations provided that hospitals without on-site cardiac surgical facilities could perform elective percutaneous coronary interventions, which are nonsurgical procedures used to treat coronary heart disease, only if they obtained a Certificate of Need demonstrating sufficient need in the region to support an annual minimum volume. The panel held that the regulations did not violate the dormant Commerce Clause, which prohibits states from discriminating against interstate commerce, because the impact on interstate commerce, if any, was highly attenuated, and did not outweigh the safety benefits of the regulations.

[*] The Honorable Cormac J. Carney, District Judge for the U.S. District Court for the Central District of California, sitting by designation.

[**] This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

COUNSEL

James L. Phillips (argued), Miller Nash LLP, Seattle, Washington, for Plaintiff-Appellant.

Pamela Anderson (argued) and Richard A. McCartan, Assistant Attorneys General, Olympia, Washington, for Defendants-Appellees.

OPINION

McKEOWN, Circuit Judge:

This appeal involves a constitutional challenge under the Commerce Clause to Washington State Department of Health ("Department") Certificate of Need ("Certificate") regulations. In particular, the challenge targets regulations related to scheduled, or "elective," percutaneous coronary interventions ("PCIs"), which are nonsurgical procedures used to treat coronary heart disease. Hospitals without on-site cardiac surgical facilities may perform elective PCIs only if they obtain a Certificate demonstrating sufficient need in the region to support an annual minimum volume. Yakima Valley Memorial Hospital ("Memorial") claims the requirement that elective PCIs be performed only at hospitals that have a minimum annual volume of 300 procedures lacks a reasonable basis and that its putative benefits, including safety, are outweighed by the burdens it places on interstate commerce, thus violating the dormant Commerce Clause. We disagree. The impact on interstate commerce, if any, is highly attenuated, and does not outweigh the safety benefits of the regulations. We affirm the district court's dismissal of Memorial's claims at summary judgment.

BACKGROUND

PCI, a nonsurgical procedure used to treat coronary heart disease, includes balloon stenting and angioplasty. The procedure involves removing arterial plaque, thereby clearing out obstructed coronary arteries and ameliorating the effects of heart disease. Elective PCIs are performed when the patient is stable and no medical emergency requires immediate action. Washington law requires healthcare providers to obtain a Certificate[1] in order to offer certain facilities and services, including elective PCIs. Wash. Rev. Code § 70.38.105. Before 2007, only hospitals that had on-site surgical facilities were permitted to perform elective PCIs. In 2007, the state legislature directed the Department to promulgate elective PCI regulations for hospitals that, like Memorial, do not otherwise perform on-site cardiac surgery. *Id.* § 70.38.128. Factors to be considered included, among others, "access to care, patient safety, [and] quality outcomes . . . ." *Id.*

The Department worked with Health Management Associates ("HMA"), an operator of acute-care hospitals, on

[1] Earlier federal laws from the 1970s, now repealed, required states to pass Certificate laws in order to qualify for federal healthcare funding. Certificate laws allowed state health agencies to determine the need for certain health services in each geographic area and to license only needed services. *Cmty. Psychiatric Ctrs. Of Or., Inc. v. Grant*, 664 F.2d 1148, 1149–50 (9th Cir. 1981) (describing Congress' creation of "areawide 'health systems agencies' . . . to oversee and assist state agencies in planning and in the operation of state health programs," including state certificate of need programs for offering new institutional health services). Washington law requires Certificates for any "specialized service that meets complicated medical needs of people and requires sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care." Wash. Rev. Code § 70.38.025(14).

an "independent evidence-based review of the circumstances under which elective [PCIs] should be allowed in Washington at hospitals that do not otherwise provide on-site surgery." The September 2007 HMA report stated that "[e]lective PCI[s] should not be performed in hospitals without on-site surgery," and recommended limiting approval to "program[s] that serve[] a community or population with a fully documented pattern of unmet need." The report also recommended that elective PCIs should be performed only at hospitals that had a minimum annual volume of 300 procedures, noting that the "optimal" annual volume was 400 or more. The report recognized, however, that "[p]ublications suggest or recommend minimum volumes ranging from >200, 400, 500, to even 600."

After receiving the HMA report, the Department met with numerous additional stakeholders, who advised the Department that hospitals with on-site surgery facilities preferred a 400-PCI minimum, while those without on-site facilities favored a 200-PCI minimum. The final regulations elected the midpoint between the two positions: only hospitals that can demonstrate that they will perform at least 300 PCIs annually will receive a Certificate permitting them to perform elective PCIs. Wash. Admin. Code § 246-310-720(1). The regulations apply statewide and do not single out or target particular facilities.

Only one hospital in the Yakima Valley area has on-site surgery facilities: Yakima Regional Medical and Cardiac Care Center ("Regional"). Regional is a for-profit hospital owned by a Florida corporation. As a holder of a PCI Certificate, it performs both elective and emergency PCIs. Regional requires a 20–30% prepayment before performing an elective PCI, and it will not perform an elective PCI

without adequate reimbursement. In contrast, Memorial is a nonprofit hospital that serves both uninsured and insured residents of Yakima Valley. Unlike Regional, Memorial would perform an elective PCI on an uninsured patient. In 2009, Regional performed 338 elective and emergency PCIs and Memorial performed 132 emergency PCIs.

In February 2011, Memorial filed an application for a Certificate to perform elective PCIs. The Department denied the application, finding that Memorial had not demonstrated a need for a second elective PCI program in the relevant planning area. Memorial is unlikely to secure a PCI Certificate until sometime around 2022, when the Yakima Valley market's projected unmet need will exceed 300 procedures.

In its complaint, Memorial alleged that the PCI regulations are an unreasonable restraint of trade in violation of the Sherman Act, 15 U.S.C. § 1, and unreasonably discriminate against interstate commerce in violation of the dormant Commerce Clause and 42 U.S.C. § 1983. The district court previously granted the Department's motion for judgment on the pleadings, and on a prior appeal of that ruling, we upheld the dismissal of the Sherman Act claims, but reversed and remanded for further proceedings on the constitutional claim. *Yakima Valley Mem'l Hosp. v. Wash. State Dep't of Health* ("*Yakima I*"), 654 F.3d 919 (9th Cir. 2011).

On remand, the Department moved for summary judgment, arguing that under the dormant Commerce Clause, Memorial could not show that the burden imposed on interstate commerce by the 300 minimum volume standard "is clearly excessive in relation to the putative local benefits."

Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970). We review de novo the district court's grant of the Department's motion. *See Universal Health Servs., Inc. v. Thompson*, 363 F.3d 1013, 1019 (9th Cir. 2004).

ANALYSIS

The Commerce Clause of Article I, § 8 of the United States Constitution empowers Congress to "regulate Commerce . . . among the several States." Courts have long read a negative implication into the clause, termed the "dormant Commerce Clause," that prohibits states from discriminating against interstate commerce. *See Dep't of Revenue of Ky. v. Davis*, 553 U.S. 328, 337 (2008). "The modern law of what has come to be called the dormant Commerce Clause is driven by concern about 'economic protectionism—that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors.'" *Id.* at 337–38 (quoting *New Energy Co. of Ind. v. Limbach*, 486 U.S. 269, 273–74 (1988)).

The first inquiry under the dormant Commerce Clause is whether the law treats in-state and out-of-state economic interests differently, in which case it "it is virtually *per se* invalid." *Or. Waste Sys., Inc. v. Dep't of Envtl. Quality of State of Or.*, 511 U.S. 93, 99 (1994). The regulations here do not facially discriminate against out-of-state interests, but instead act "evenhandedly," with, at best, only "incidental" impacts on interstate trade. *Hughes v. Oklahoma*, 441 U.S. 322, 336 (1979) (internal quotation marks omitted). Regulations with incidental impacts are analyzed under the balancing test set forth in *Pike*:

> Where the statute regulates even-handedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits. If a legitimate local purpose is found, then the question becomes one of degree. And the extent of the burden that will be tolerated will of course depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities.

397 U.S. at 142 (internal citation omitted).

The Supreme Court has further emphasized that "a state's power to regulate commerce is at its zenith in areas traditionally of local concern" and that "regulations that touch upon safety . . . are those that 'the Court has been most reluctant to invalidate.'" *Kassel v. Consol. Freightways Corp. of Del.*, 450 U.S. 662, 679 (1981) (citation omitted) (quoting *Raymond Motor Transp., Inc. v. Rice*, 434 U.S. 429, 443 (1978)).

I. THE MINIMUM PROCEDURE REQUIREMENT DOES NOT BURDEN INTERSTATE COMMERCE

The PCI regulations do not treat in-state and out-of-state actors differently, nor are they an even-handed law that incidentally makes it harder for out-of-state actors to do business in the state. Instead, the practical upshot of the regulations is to restrict one in-state hospital—Memorial—from expanding its PCI business, which ends up going to

Regional, another in-state hospital.[2] Our prior opinion noted that Memorial's allegations involved the impact on interstate commerce and directed the district court to apply the *Pike* balancing test, but made no finding about the significance of the alleged burden. *Yakima I*, 654 F.3d at 932 ("The ultimate question of whether the PCI regulations survive *Pike* scrutiny is not before us."). The district court correctly interpreted our holding and on remand inquired into the downstream impact of the PCI regulations on interstate commerce. Accepting as true Memorial's arguments and evidence, the burden on interstate commerce is obviously too minor and remote to create a "substantial burden" under *Pike*.

We recently considered the dormant Commerce Clause in relation to a California statute prohibiting licensed opticians from offering prescription eyewear at the same location as eye examinations. *Nat'l Ass'n of Optometrists & Opticians v. Harris*, 682 F.3d 1144, 1147–48 (9th Cir. 2012). Looking to *Exxon Corp. v. Governor of Md.*, 437 U.S. 117, 128 (1978), we held that "there is not a significant burden on interstate commerce merely because a nondiscriminatory regulation precludes a preferred, more profitable method of operating in a retail market." *Optometrists*, 682 F.3d at 1153. The decision of whether a nondiscriminatory regulation nevertheless significantly burdens interstate commerce depends "on the interstate *flow of goods*, not on where the retailers were incorporated, what the out-of-state market shares of sales and profits were, or whether competition would be affected by the statute." *Id.* The same analysis

[2] Although it is not dispositive, we note that Regional is owned by an out-of-state entity, and Memorial's challenge reverses the traditional dormant Commerce Clause framework where an out-of-state entity challenges a law that disadvantages it relative to in-state competitors.

applies here. What is really at issue is the shifting of business from one competitor to another, not a burden on interstate commerce. The regulations do not "impair the free flow of materials and products across state borders." *Id*. at 1155. As in *Optometrists*, a significant burden on interstate commerce does not exist simply because the nondiscriminatory PCI regulations affect the structure of the market. *Id.*

Memorial attempts to meet its burden of showing an impact on interstate commerce by pointing to the interstate transactions it must forego because of the PCI regulations—recruiting out-of-state interventional cardiologists, purchasing supplies from out of state, and providing service to and receiving payment from out-of-state patients. But these meager allegations do not show that the challenged regulations impede those interstate transactions in general. These transactions are collateral to Memorial having the authorization to perform elective PCI procedures. It is uncontroverted that the 300-procedure minimum instead shifts PCI business, and associated interstate activity, from Memorial to Regional, which will perform elective PCIs in Memorial's place. Memorial's loss of business to Regional—whatever the consequence to *Memorial's* bottom line—does not itself burden interstate commerce. *See Exxon*, 437 U.S. at 127 (holding that "interstate commerce is not subjected to an impermissible burden simply because an otherwise valid regulation causes some business to shift from one interstate supplier to another"); *Optometrists*, 682 F.3d at 1153.

Memorial also argues that the PCI regulations burden interstate commerce by reducing the total number of PCIs performed. We credit Memorial's claim that the total number of potential PCIs in the area may be reduced because 25% of the area's population is uninsured and some of those

uninsured residents would come to Memorial for the procedure but are not eligible for treatment at Regional. Memorial did not estimate how many of these uninsured patients forego elective PCIs each year. However, regardless of the size of this potential unserved market, we agree with the district court that this speculative downstream impact is "highly attenuated" and that a reduction in the total number of elective PCIs performed in the Yakima Valley does not place a significant burden on interstate commerce.[3]

Although Supreme Court precedent recognizes the burden placed on individual entities arising from protectionist or discriminatory regulations, no such protectionist motive or effect exists here. *See Pike*, 397 U.S. at 145 (analyzing economic burden imposed by requirement that cantaloupes grown in Arizona be packed and processed there instead of in existing California facilities); and *Hunt v. Wash. State Apple Adver. Comm'n*, 432 U.S. 333, 350–54 (1977) (striking down law that burdened Washington apple producers in favor of North Carolina growers). Similarly, the absence of protectionist impact makes this case unlike *Walgreen v. Rullen*, 405 F.3d 50 (1st Cir. 2005), where the First Circuit struck down a facially nondiscriminatory Certificate law that in effect protected in-state incumbent pharmacies from out-of-state competition.

[3] We likewise reject Memorial's argument that the district court erred by failing to follow the instruction in *Pike* to consider alternatives with a lesser impact on interstate commerce. In *Optometrists* we concluded that "[b]ecause the challenged laws do not impose a significant burden on interstate commerce, it would be inappropriate for us to set them aside based on a conclusion that the State's purposes could be served as well with alternative laws." 682 F.3d 1157.

Not only are the challenged regulations nondiscriminatory, they are predicated on a safety-related purpose. *See Gen. Motors Corp. v. Tracy*, 519 U.S. 278, 306 (1997) ("[T]he Commerce Clause . . . was never intended to cut the States off from legislating on all subjects relating to the health, life, and safety of their citizens, though the legislation might indirectly affect the commerce of the country." (internal quotation marks omitted)); *City of Philadelphia v. New Jersey*, 437 U.S. 617, 623–24 (1978) ("[I]ncidental burdens on interstate commerce may be unavoidable when a State legislates to safeguard the health and safety of its people."). In sum, neither the economic impact on Memorial's own operations, nor the alleged downstream impact on uninsured patients, creates a substantial burden on interstate commerce.

II. THE MINIMUM PROCEDURE REQUIREMENT PROTECTS PUBLIC SAFETY

Our conclusion that the burden on interstate commerce is insignificant would normally end the constitutional inquiry. *See Optometrists*, 682 F.3d at 1155 ("If a regulation merely has an effect on interstate commerce, but does not impose a significant burden on interstate commerce, it follows that there cannot be a burden on interstate commerce that is 'clearly excessive in relation to the putative local benefits' under *Pike*."). Nonetheless, because Memorial claims that the safety benefits of the 300-PCI minimum are not just minimal, but illusory or nonexistent, we address this argument.

Memorial's argument is narrow, namely that the choice of a 300-PCI minimum over a 200-PCI minimum is constitutionally infirm. In Memorial's view, because no

study establishes a difference between its proposed 200-PCI minimum and the Department's 300-PCI standard, the choice of 300 was arbitrary and any benefit is illusory. We recognize that "the incantation of a purpose to promote the public health or safety does not insulate a state law from Commerce Clause attack," but the safety aspects here are neither illusory nor a fig leaf masking discrimination. *Kassel*, 450 U.S. at 670.

Memorial's position is weak and ignores the substantial evidence linking minimum requirements to safety and quality. The Department presented evidence that a facility's skills and competence and, accordingly, patient safety increase with the number of PCIs, although the exact point and rate at which those returns diminish is unclear ("Overall, high volume operators had better outcomes . . . in low-risk and high-risk patients."). The 2007 HMA report to the Department reviewed the relevant literature and recommended that "PCI programs in hospitals with and without on-site cardiac surgery should have minimum annual PCI volumes of >300 and an optimal annual volume of >400." The report stated that a "minimum annual volume of >300 was selected based on a balanced review of the literature. Publications suggest or recommend minimum volumes ranging from >200, 400, 500, to even 600. Most experts recommend that PCI programs with <200 be evaluated for closure. It is logical to recommend a minimum that exceeds the closure set point." Nothing suggests that the Department took anything other than a comprehensive, balanced view of the data, which, significantly, recommended closing facilities that fell below the 200 procedure threshold. Memorial is simply unhappy that the Department did not adopt the lowest minimum mentioned in the HMA report.

The extensive HMA report, which Memorial does not attack on the merits, distinguishes this matter from *Kassel*, the primary case that Memorial invokes. In *Kassel*, the Iowa regulation prohibited the use of particular large trucks (65-foot "double" or "twin" trailers) within Iowa's borders. 450 U.S. at 665. Iowa conceded that "it [could] produce no study that establishes a statistically significant difference in safety between the 65-foot double and the kinds of vehicles [Iowa] permits." *Id.* at 673. The Court struck down the statute given the economic burdens of either complying with the size regulations or re-routing interstate traffic around Iowa. *Id.* at 674. Unlike in *Kassel*, the data here show that the safety benefits of the 300-PCI minimum are not illusory. The Department had ample justification to conclude that, if a minimum volume of 400 is "safer" than a range of 200–400, a 300-PCI minimum is "safer" than a 200-PCI requirement, the minimum threshold under any recommendation.

Memorial further argues that the 300-PCI minimum was chosen to protect incumbent providers of PCI procedures instead of to meet a medical necessity. The Department held five meetings with stakeholders in the process of the PCI rulemaking. The stakeholders submitted a report in which incumbent providers recommended a 400-PCI minimum and providers seeking to provide elective PCIs recommended a 200-PCI minimum. The Department's adoption of a 300-PCI minimum—the midpoint between the two positions—does not suggest "regulatory capture" by the incumbents. We also note that the Department subsequently granted nine new PCI Certificates, eight of them in areas where there was already an incumbent provider, weakening any inference that the standard is designed to block the entry of new market participants.

Finally, Memorial claims that the 300-PCI minimum, which derives in part from American College of Cardiology Foundation ("ACCF") recommendations, should be invalidated because the Department does not uniformly mandate that hospitals adhere to those guidelines in various practice cases. This is an "apples to oranges" argument that does nothing to invalidate the Department's conclusion that a 300-PCI minimum has real safety benefits above a threshold of 200 PCIs.

Memorial offers no evidence that the benefits of the 300-PCI minimum are illusory or manufactured. In view of the substantial record supporting the safety requirement, we are loath to insert ourselves into the medical debate. As the Supreme Court has emphasized, "if safety justifications are not illusory, the Court will not second-guess legislative judgment about their importance in comparison with related burdens on interstate commerce." *Kassel*, 450 U.S. at 670 (internal quotation marks omitted); *see also Kleenwell Biohazard Waste and Gen. Ecology Consultants, Inc. v. Nelson*, 48 F.3d 391, 399–400 (9th Cir. 1995) (upholding nondiscriminatory regulation of solid waste disposal based on "ample evidence" that regulations protected the public).

CONCLUSION

Memorial did not establish that the challenged regulations burdened interstate commerce or that the putative safety benefits were illusory. We therefore affirm the district court's dismissal of all of Memorial's remaining claims.

AFFIRMED.