

Nelson Mullins

Nelson Mullins Riley & Scarborough LLP
Attorneys and Counselors at Law
151 Meeting Street / Sixth Floor / Charleston, SC 29401-2239
Tel: 843.853.5200 Fax: 843.722.8700
www.nelsonmullins.com

Susannah Knox
Tel: 843.534.4414
susannah.knox@nelsonmullins.com

July 20, 2016

RECEIVED

JUL 22 2016

SC Court of Appeals

The Honorable Jenny Abbott Kitchings
Clerk of Court
South Carolina Court of Appeals
Post Office Box 11629
Columbia, SC 29211

RE: Presbyterian Hospital-York, LLC and Amisub of South Carolina, Inc. d/b/a
Piedmont Medical Center d/b/a Fort Mill Medical Center, Petitioners v. South
Carolina Department of Health and Environmental Control and The Charlotte-
Mecklenburg Hospital Authority d/b/a Carolinas Medical Center-Fort Mill,
Respondents
Appellate Case No. 2015-000056
Our File No. 05946/01509

Dear Ms. Kitchings:

Pursuant to South Carolina Rule of Appellate Procedure 208(b)(7), please find the enclosed supplemental authority relevant to the above-referenced appeal. *Colon Health Centers of America v. Hazel*, 813 F.3d 145 (4th Cir. 2016), was decided by the Fourth Circuit in January of this year, after briefs were submitted to the South Carolina Court of Appeals in this case. Respondents respectfully submit that *Colon Health* is “pertinent and significant” to this matter in the following respects:

1. In *Colon Health*, the Fourth Circuit upheld Virginia’s Certificate of Need (“CON”) law against a Dormant Commerce Clause challenge, both facially and as-applied to the appellant in that case.
2. The Fourth Circuit rejected the appellant’s argument that protecting existing providers was equivalent to favoring in-state interests. *Id.* At 154-55. *See* Respondent’s Brief, Sections II.A.1, II.B.1, III.A.
3. The Fourth Circuit upheld the constitutionality of CON programs that “reduc[e] competition in highly profitable operations,” thereby providing “existing hospitals with

July 20, 2016
Page 2

the revenue they need not only to provide indigents with care, but also to support money-losing but nonetheless important operations like trauma centers and neonatal intensive care units.” *Colon Health*, 813 F.3d at 157. See Respondent’s Brief, Sections II.A, II.B.1, III.A.

4. The Fourth Circuit reaffirmed that the *Pike* “undue burden” balancing test should be performed with great deference to the legislature. *Colon Health*, 813 F.3d at 155-56. See Respondent’s Brief, Section III.B.

Thank you for considering this important Fourth Circuit precedent on the Dormant Commerce Clause as it relates to this matter.

Very truly yours,

A handwritten signature in black ink, appearing to read "Susannah Knox". The signature is written in a cursive, flowing style.

Susannah Knox

SRK
Enclosures

cc: Douglas M. Muller, Esq.
Trudy H. Robertson, Esq.
E. Brandon Gaskins, Esq.
Ashley C. Biggers, Esq.
Vito M. Wicevic, Esq.
Stuart M. Andrews, Jr., Esq.
Daniel J. Westbrook, Esq.

813 F.3d 145
United States Court of Appeals,
Fourth Circuit.

COLON HEALTH CENTERS OF AMERICA, LLC;
Washington Imaging Associates–Maryland, LLC,
d/b/a Progressive Radiology, Plaintiffs–Appellants,

v.

Bill HAZEL, in his official capacity as Secretary of Health and Human Resources; Bruce Edwards, in his official capacity as Chair of the Virginia State Board of Health; James E. Edmondson, Jr., in his official capacity as member of the Virginia State Board of Health; Steven R. Escobar, in his official capacity as member of the Virginia State Board of Health; M. Catherine Slusher, in her official capacity as member of the Virginia State Board of Health; Amy Vest, in her official capacity as member of the Virginia State Board of Health; Eric O. Bodin, in his official capacity as Director of the Office of Licensure and Certification; John W. Seeds, in his official capacity as member of the Virginia State Board of Health; Marissa Levine, in her official capacity as the State Health Commissioner; Bradley Beall, in his official capacity as member of the Virginia State Board of Health; Theresa Middleton Brosche, in her official capacity as member of the Virginia State Board of Health; Megan C. Getter, in her official capacity as member of the Virginia State Board of Health; Henry N. Kuhlman, in his official capacity as member of the Virginia State Board of Health; Honorable Faye Prichard, in her official capacity as member of the Virginia State Board of Health; Benita Miller, in her official capacity as member of the Virginia State Board of Health; Peter Boswell, in his official capacity as Director of the Division of Certificate of Public Need; Tom East, in his official capacity as member of the Virginia State Board of Health; Linda Hines, in her official capacity as member of the Virginia State Board of Health; Honorable Mary Margaret Whipple, in her official capacity as member of the Virginia State Board of Health, Defendants–Appellees.

Shenandoah Independent Practice Association, Inc.; Shenandoah Surgeons LLC; Christopher Koopman, Research Fellow, The Mercatus Center at George Mason University; Matthew Mitchel, Senior Research Fellow, The Mercatus Center at George Mason University; Thomas Stratmann, University Professor of Economics and Law, Department of Economics, George Mason University; Robert Graboyes, Senior Research Fellow, Mercatus Center at George Mason University; Jake Russ, Graduate Fellow, Mercatus Center at George Mason University; James Bailey, Assistant Professor of Economics, Department of Economics and Finance, Creighton University, Amici Supporting Appellants, The Virginia Hospital & Healthcare Association; The Virginia Health Care Association; The State of Washington; The State of Arizona; The State of Hawaii; The State of Mississippi; The State of Vermont, Amici Supporting Appellees.

No. 14–2283.

Argued: Dec. 10, 2015.

Decided: Jan. 21, 2016.

Synopsis

Background: Out-of-state medical providers brought action against Virginia government officials, claiming that the requirement to obtain a certificate of need (CON) to establish or expand medical facilities and services violated the dormant aspect of the Commerce Clause. The United States District Court for the Eastern District of Virginia, Claude M. Hilton, Senior District Judge, 2012 WL 4105063, granted defendants' motion to dismiss for failure to state a claim. Providers appealed. The Court of Appeals, Wilkinson, Circuit Judge, 733 F.3d 535, reversed and remanded. On remand, the District Court, 2014 WL 5430973, granted summary judgment to defendants. Providers appealed.

Holdings: The Court of Appeals, Wilkinson, Circuit Judge, held that:

[1] the CON requirement did not discriminate against out-of-state medical providers in its purpose;

[2] the CON requirement did not have a discriminatory effect on out-of state medical providers; and

[3] the burden of the CON requirement on interstate commerce was not clearly excessive to the putative local benefits.

Affirmed.

West Headnotes (16)

[1] **Commerce**

↔ Regulation and conduct in general;
particular businesses

The implicit or “dormant” constraint of the Commerce Clause is driven primarily by concerns over economic protectionism, that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors. U.S.C.A. Const. Art. 1, § 8, cl. 3.

Cases that cite this headnote

[2] **Commerce**

↔ Regulation and conduct in general;
particular businesses

When a state statute discriminates against interstate commerce, it will be struck down unless the discrimination is demonstrably justified by a valid factor unrelated to economic protectionism. U.S.C.A. Const. Art. 1, § 8, cl. 3.

Cases that cite this headnote

[3] **Commerce**

↔ Regulation and conduct in general;
particular businesses

While discrimination simply means differential treatment of in-state and out-of-state economic interests that benefits the former and burdens the latter, not all economic harms or anti-competitive choices can or should be remedied through

application of the dormant Commerce Clause. U.S.C.A. Const. Art. 1, § 8, cl. 3.

Cases that cite this headnote

[4] **Commerce**

↔ Regulation and conduct in general;
particular businesses

Under the prevailing framework for dormant Commerce Clause claims, courts must chart a narrow course between rebuffing attempts of states to advance their own commercial interests by curtailing the movement of articles of commerce and generally supporting their right to impose even burdensome regulations in the interest of local health and safety. U.S.C.A. Const. Art. 1, § 8, cl. 3.

Cases that cite this headnote

[5] **Commerce**

↔ Powers Remaining in States, and
Limitations Thereon

In analyzing a dormant Commerce Clause claim, courts are not bound by the name, description or characterization given to a law by the legislature or the courts of the State; instead the principal focus of inquiry must be the practical operation of the statute, since the validity of state laws must be judged chiefly in terms of their probable effects. U.S.C.A. Const. Art. 1, § 8, cl. 3.

Cases that cite this headnote

[6] **Commerce**

↔ Preferences and Discriminations

The discrimination test of a dormant Commerce Clause claim can be described as both flexible and finite: courts are afforded some latitude to determine for themselves the practical impact of a state law, but in doing so they must not cripple the States' authority under their general police powers to regulate matters of legitimate local concern. U.S.C.A. Const. Art. 1, § 8, cl. 3.

Cases that cite this headnote

[7] **Commerce**

↔ Preferences and Discriminations

A state statute may discriminate against interstate commerce in one of three ways: facially, in its practical effect, or in its purpose. U.S.C.A. Const. Art. 1, § 8, cl. 3.

Cases that cite this headnote

[8] **Commerce**

↔ Preferences and Discriminations

A measure that discriminates between in-state and out-of-state economic interests is virtually per se invalid under the Commerce Clause, and will survive strict scrutiny only if it advances a legitimate local purpose that cannot be adequately served by reasonable nondiscriminatory alternatives. U.S.C.A. Const. Art. 1, § 8, cl. 3.

Cases that cite this headnote

[9] **Commerce**

↔ Subjects and regulations in general

Health

↔ Validity

Virginia requirement that a medical provider obtain a certificate of need (CON) to establish or expand medical facilities and services did not discriminate against out-of-state medical providers in its purpose, and thus did not violate the dormant Commerce Clause, where Virginia's CON regime, similarly to that in place in many other states, was designed to prevent overinvestment in and maldistribution of health care facilities, and the CON requirement serviced an array of legitimate public purposes including improving health care quality by discouraging the proliferation of underutilized facilities, enabling underserved and indigent populations to access necessary medical services, and encouraging cost-effective consumer spending. U.S.C.A. Const. Art. 1, § 8, cl. 3; West's V.C.A. § 32.1–102.1 et seq.

Cases that cite this headnote

[10] **Commerce**

↔ Subjects and regulations in general

Health

↔ Validity

Virginia requirement that a medical provider obtain a certificate of need (CON) to establish or expand medical facilities and services did not have a discriminatory effect on out-of-state medical providers, and thus did not violate the dormant Commerce Clause, where the approval rates for applications submitted by in-state and by out-of-state firms considered by the Virginia Department of Health were virtually identical at just under 85%, and there was no appreciable difference in the time in-state and out-of-state providers obtained permits, with the process taking between 154 and 167 days for both in-state and out-of-state providers. U.S.C.A. Const. Art. 1, § 8, cl. 3; West's V.C.A. § 32.1–102.1 et seq.

Cases that cite this headnote

[11] **Commerce**

↔ Local matters affecting commerce

Pike balancing, used to assess whether a law's incidental burdens on interstate commerce is clearly excessive in relation to its putative local benefits, as would violate the dormant Commerce Clause, frequently requires judges to make highly subjective calls, as weighing or quantifying a law's benefits and burdens may be a very subtle exercise. U.S.C.A. Const. Art. 1, § 8, cl. 3.

Cases that cite this headnote

[12] **Constitutional Law**

↔ Expediency

Judges are ill-equipped to second-guess the empirical judgments of lawmakers concerning the utility of legislation.

Cases that cite this headnote

[13] **Commerce**

↔ Local matters affecting commerce

In identifying the putative local benefits to be weighed against incidental burdens on interstate commerce, on a dormant Commerce Clause challenge to a state law which was not a plain attempt at local protectionism, a court applies a rational basis standard of review. U.S.C.A. Const. Art. 1, § 8, cl. 3.

Cases that cite this headnote

[14] **Commerce**

↔ Subjects and regulations in general

Health

↔ Validity

The burden on interstate commerce of Virginia's statutory requirement for medical providers obtain a certificate of need (CON) to establish or expand medical facilities and services was not clearly excessive in relation to its putative local benefits, and thus the CON requirement did not violate the dormant Commerce Clause on *Pike* balancing, despite contention that the requirement reduced competition which allowed entrenched incumbents to exert market power and charge inefficiently high prices, where the State claimed that the CON requirement boosted healthcare quality, ensured underserved and indigent populations had access to medical care, and maintained a geographic distribution of health care facilities. U.S.C.A. Const. Art. 1, § 8, cl. 3; West's V.C.A. § 32.1-102.1 et seq.

Cases that cite this headnote

[15] **Commerce**

↔ Powers Remaining in States, and Limitations Thereon

The party challenging a state law under the dormant Commerce Clause bears the burden of proving that the burdens placed

on interstate commerce outweigh the local benefits. U.S.C.A. Const. Art. 1, § 8, cl. 3.

Cases that cite this headnote

[16] **Commerce**

↔ Powers Remaining in States, and Limitations Thereon

Courts enforcing the dormant Commerce Clause were never intended to cut the States off from legislating on subjects relating to the health, life, and safety of their citizens. U.S.C.A. Const. Art. 1, § 8, cl. 3.

Cases that cite this headnote

Attorneys and Law Firms

*148 ARGUED: Darpana Sheth, Institute for Justice, Arlington, Virginia, for Appellants. *149 Stuart Alan Raphael, Office of the Attorney General of Virginia, Richmond, Virginia, for Appellees. ON BRIEF: Robert J. McNamara, William H. Mellor, Mahesha P. Subbaraman, Institute for Justice, Arlington, Virginia, for Appellants. Mark R. Herring, Attorney General, Cynthia V. Bailey, Deputy Attorney General, Christy W. Monolo, Assistant Attorney General, Carly L. Rush, Assistant Attorney General, Farnaz F. Thompson, Assistant Attorney General, Trevor S. Cox, Deputy Solicitor General, Office of the Attorney General of Virginia, Richmond, Virginia, for Appellees. Milad Emam, Wiley Rein LLP, Washington, D.C., for Amici Shenandoah Independent Practice Association and Shenandoah Surgeons LLC. Jared M. Bona, Aaron R. Gott, Bona Law P.C., La Jolla, California, for Amici Scholars of Economics and Scholars of Law and Economics. Robert W. Ferguson, Attorney General, Alan D. Copey, Deputy Solicitor General, Richard A. McCartan, Senior Counsel, Office of The Attorney General of Washington, Olympia, Washington; Mark Brnovich, Attorney General, Office of the Attorney General of Arizona, Phoenix, Arizona; Douglas S. Chin, Attorney General, Office of the Attorney General of Hawaii, Honolulu, Hawaii; Jim Hood, Attorney General, Office of the Attorney General of Mississippi, Jackson, Mississippi; William H. Sorrell, Attorney General, Office of the Attorney General of Vermont, Montpelier, Vermont, for Amici States of

Washington, Arizona, Hawaii, Mississippi and Vermont. James J. O’Keeffe, IV, Johnson, Rosen & O’Keeffe, LLC, Roanoke, Virginia; Jamie Baskerville Martin, Jeremy A. Ball, Jennifer L. Ligon, McCandlish Holton, Richmond, Virginia, for Amici Virginia Hospital & Healthcare Association and Virginia Health Care Association.

Before WILKINSON, KING, and WYNN, Circuit Judges.

Opinion

Affirmed by published opinion. Judge WILKINSON wrote the opinion, in which Judge KING and Judge WYNN joined.

WILKINSON, Circuit Judge:

Virginia’s certificate of need (CON) program governs the establishment and expansion of certain medical facilities inside the state. In this case two providers of medical imaging services, Colon Health Centers of America and Progressive Radiology, argue that the CON law unconstitutionally violates the dormant aspect of the Commerce Clause. The district court held that the certificate requirement neither discriminated against nor placed an undue burden on interstate commerce, and granted summary judgment to the Commonwealth. For the reasons that follow, we affirm.

I.

A.

Much of the background and many of the claims in this case have been set forth in our prior opinion. See *Colon Health Centers of Am., LLC v. Hazel*, 733 F.3d 535 (4th Cir.2013). Virginia is one of thirty-six states that requires medical service providers to obtain a “certificate of public need” in order to establish or expand operations within its borders. Va.Code Ann. §§ 32.1–102.1 *et seq.*; 12 Va. Admin. Code §§ 5–220–10 *et seq.* Virginia’s CON program applies to most health care capital expenditures, including investments in new computed tomographic (CT) and magnetic resonance imaging (MRI) facilities. See Va.Code Ann. § 32.1–102.2. It does not, however, cover the “[r]eplacement of existing equipment.” *Id.* at § 32.1–102.1. The program requires that an applicant show a sufficient

public need for its proposed venture in the relevant geographic area. Virginia asserts that this preapproval *150 mechanism helps prevent the redundant accretion of medical facilities, protect the economic viability of existing providers, promote indigent care, and assist cost-effective health care spending.

Firms that seek to obtain a certificate of need must file their completed applications with the Department of Health and the appropriate regional health planning agency. *Id.* at § 32.1–102.6. Applicants pay a fee of one percent of the project’s expected capital cost, but no less than \$1,000 and no more than \$20,000. 12 Va. Admin. Code § 5–220–180(B). The submissions are grouped into subcategories based on project type and evaluated in a process called “batching.” The code mandates that the review process be completed within 190 days of the start of the applicable batch cycle. Va.Code Ann. § 32.1–102.6.

Five regional health planning agencies across the state are charged with conducting, within 60 days, initial investigations into their respective regions’ applications. During this stage of review the agencies must hold a public hearing in the vicinity of the proposed investment site, where interested individuals and local governing bodies may submit comments to assist the agencies in their evaluations. After examining the data and reviewing the testimony before them, the agencies are directed to provide the Department of Health with their recommendations to approve or deny each application. *Id.*

The Department, concurrently with the regional health planning agencies, reviews the completed applications upon the commencement of the appropriate batch cycle. The Department is required to assess whether an informal fact-finding conference is warranted. Such a proceeding will be held if the Department independently determines that it is necessary or if an intervening party demonstrates that good cause exists to conduct it. Va.Code Ann. § 32.1–102.6(E). The date on which the record closes on the application varies depending on whether an informal fact-finding conference is conducted.

The code instructs that a certificate may not be issued unless the State Health Commissioner “has determined that a public need for the project has been demonstrated.” *Id.* at § 32.1–102.3(A). The Commissioner’s decision is due forty-five days after the record closes, but that period may be extended by an additional twenty-five

days. *Id.* at § 32.1–102.6(E). In making his assessment, the Commissioner must consider a number of factors, although no single factor is dispositive. *Id.* at § 32.1–102.3(B)(1)–(8). For example, the Commissioner evaluates “[t]he extent to which the proposed service or facility will provide or increase access to needed services for residents of the area to be served,” and “[t]he relationship of the project to the existing health care system of the area to be served, including the utilization and efficiency of existing services or facilities.” *Id.* at § 32.1–102.3(B)(1),(5). An application is considered approved and a certificate is granted if the Commissioner fails to issue a decision within seventy days after the closing of the record.

Constructing new facilities or augmenting existing operations without a certificate of need is a Class 1 misdemeanor, punishable by fines of up to \$1,000 for each day a service provider is in violation of the statute. *Id.* at § 32.1–27.1. Applicants and other interested persons dissatisfied with the Commissioner's decision may seek judicial review under the Virginia Administrative Procedure Act. *See id.* at § 32.1–24.

B.

Appellants Colon Health Centers and Progressive Radiology are out-of-state medical providers who wish to establish, *151 through the use of private funds, specialized MRI and CT services in Virginia. Appellants challenged the constitutionality of the CON program, claiming that it violates the dormant Commerce Clause as well as the Fourteenth Amendment's Equal Protection, Due Process, and Privileges or Immunities Clauses. The district court dismissed appellants' suit under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief may be granted. *Colon Health Centers of Am., LLC v. Hazel*, No. 1:12CV615, 2012 WL 4105063, at *11 (E.D.Va. Sept. 14, 2012).

On appeal, we affirmed the dismissal of appellants' Fourteenth Amendment claims, reversed the dismissal of the dormant Commerce Clause claim, and remanded the case for further factual development on the Commerce Clause issue. *Colon Health*, 733 F.3d at 539. After careful consideration of the parties' arguments, we made clear that this case is one of “heightened importance,” and

emphasized the “fact-intensive quality” of the dormant Commerce Clause analysis. *Id.* at 545.

The district court conducted an extensive discovery process on remand, and ultimately granted summary judgment in favor of the Commonwealth. J.A. 1509–27. Colon Health and Progressive Radiology now urge us to reverse that decision on two grounds. First, appellants argue that Virginia's CON requirement violates the dormant Commerce Clause by discriminating against interstate commerce in both purpose and effect. Second, appellants contend that even if the program does not unconstitutionally discriminate, it nevertheless violates the dormant Commerce Clause because it places an undue burden on interstate commerce. We address each of these arguments in turn.

II.

A.

[1] The general framework of the law in this area is well settled. The Commerce Clause gives Congress the power “[t]o regulate Commerce ... among the several States.” U.S. Const. art. I, § 8, cl. 3. Although by its terms the clause speaks only of congressional authority, “the [Supreme] Court long has recognized that it also limits the power of the States to erect barriers against interstate trade.” *Dennis v. Higgins*, 498 U.S. 439, 446, 111 S.Ct. 865, 112 L.Ed.2d 969 (1991) (quoting *Lewis v. BT Inv. Managers, Inc.*, 447 U.S. 27, 35, 100 S.Ct. 2009, 64 L.Ed.2d 702 (1980)). This implicit or “dormant” constraint is driven primarily by concerns over “economic protectionism—that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors.” *New Energy Co. of Ind. v. Limbach*, 486 U.S. 269, 273–74, 108 S.Ct. 1803, 100 L.Ed.2d 302 (1988).

[2] [3] [4] To that end, the Supreme Court has instructed that “[t]he principal objects of dormant Commerce Clause scrutiny are statutes that *discriminate* against interstate commerce.” *CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 87, 107 S.Ct. 1637, 95 L.Ed.2d 67 (1987) (emphasis added). “[W]hen a state statute [] discriminates against interstate commerce, it will be struck down unless the discrimination is demonstrably justified by a valid factor unrelated to economic protectionism.” *Yamaha Motor Corp. v. Jim's Motorcycle, Inc.*, 401 F.3d

560, 567 (4th Cir.2005) (quoting *Wyoming v. Oklahoma*, 502 U.S. 437, 454, 112 S.Ct. 789, 117 L.Ed.2d 1 (1992)). While discrimination “simply means differential treatment of in-state and out-of-state economic interests that benefits the former and burdens the latter,” *Or. Waste Sys., Inc. v. Dep’t of Envtl. *152 Quality of State of Or.*, 511 U.S. 93, 99, 114 S.Ct. 1345, 128 L.Ed.2d 13 (1994), not all economic harms or anticompetitive choices can or should be remedied through application of the dormant Commerce Clause. See *Brown v. Hovatter*, 561 F.3d 357, 363 (4th Cir.2009). Under the prevailing framework courts must chart a narrow course between “rebuff[ing] attempts of states to advance their own commercial interests by curtailing the movement of articles of commerce ... [and] generally supporting their right to impose even burdensome regulations in the interest of local health and safety.” *H.P. Hood & Sons, Inc. v. Du Mond*, 336 U.S. 525, 535, 69 S.Ct. 657, 93 L.Ed. 865 (1949).

[5] [6] Recognizing this difficulty, the Supreme Court has advised courts in this context to “eschew[] formalism for a sensitive, case-by-case analysis.” *W. Lynn Creamery, Inc. v. Healy*, 512 U.S. 186, 201, 114 S.Ct. 2205, 129 L.Ed.2d 157 (1994). In other words, courts are “not bound by [t]he name, description or characterization given [the law] by the legislature or the courts of the State.” *Colon Health*, 733 F.3d at 546 (quoting *Hughes v. Oklahoma*, 441 U.S. 322, 336, 99 S.Ct. 1727, 60 L.Ed.2d 250 (1979)). “The principal focus of inquiry must be the practical operation of the statute, since the validity of state laws must be judged chiefly in terms of their probable effects.” *Lewis*, 447 U.S. at 37, 100 S.Ct. 2009; see also *Yamaha*, 401 F.3d at 568. The discrimination test can thus be described as both flexible and finite: Courts are afforded some latitude to determine for themselves the practical impact of a state law, but in doing so they must not cripple the States’ “authority under their general police powers to regulate matters of legitimate local concern.” *Maine v. Taylor*, 477 U.S. 131, 138, 106 S.Ct. 2440, 91 L.Ed.2d 110 (1986) (internal quotation marks omitted).

B.

[7] [8] A state statute may discriminate against interstate commerce in one of three ways: “facially, in its practical effect, or in its purpose.” *Envtl. Tech. Council v. Sierra Club*, 98 F.3d 774, 785 (4th Cir.1996). A discriminatory measure is “virtually *per se* invalid,”

and will survive strict scrutiny only if it “advances a legitimate local purpose that cannot be adequately served by reasonable nondiscriminatory alternatives.” *Or. Waste Sys.*, 511 U.S. at 99, 114 S.Ct. 1345 (internal quotation marks omitted).

Here, the parties are in agreement that Virginia’s CON law is not facially discriminatory. The program applies to all firms establishing or expanding covered health care operations within the state, and makes no distinction between in-state and out-of-state service providers. See, e.g., Va.Code Ann. § 32.1–102.6 (“[t]o obtain a certificate for a project,” every applicant, regardless of geographic location, “shall file a completed application”).

[9] Appellants do, however, maintain that the CON program discriminates in both purpose and effect. With regard to purpose, they note that the law is intended to “protect the economic viability of existing [service] providers” by impeding the development of new medical facilities. Appellants’ Br. at 41 (citing 12 Va. Admin. Code § 5–230–30 (“[t]he [CON] program discourages the proliferation of services that would undermine the ability of essential community providers to maintain their financial viability”). Because current health care firms are categorically in-state entities, the argument goes, the primary goal of the certificate requirement is to shelter those providers from competition at the expense of out-of-state businesses seeking entry into the market.

*153 That argument misses the main point. Certificate-of-need regimes—in place in many states across this country—are designed in the most general sense to prevent overinvestment in and maldistribution of health care facilities. See Laretta H. Wolfson, *State Regulation of Health Facility Planning: The Economic Theory and Political Realities of Certificates of Need*, 4 DePaul J. Health Care L. 261, 262 (2001). Indeed, as we discuss in greater detail below, Virginia’s program serves an array of legitimate public purposes: improving health care quality by discouraging the proliferation of underutilized facilities, enabling underserved and indigent populations to access necessary medical services, and encouraging cost-effective consumer spending. See *infra* part III.B. Appellants may be dissatisfied with the Virginia General Assembly’s policy choices in this complex field, but we cannot discern a sinister protectionist purpose in this straightforward effort to bring medical care to all the citizens of the Commonwealth in the most efficient and

professional manner. We thus turn our attention to the issue of discriminatory effect.

[10] Appellants allege that in practice Virginia's CON program "systematically advantages established in-state providers at the expense" of new, primarily out-of-state firms. Appellants' Br. at 13–14. Specifically, appellants claim that the CON application process impermissibly grants current Virginia firms the authority to thwart the market entrance of out-of-state providers in three ways. First, the code allows interested parties to request an informal fact-finding conference so that the merits of a particular application can be further scrutinized. See Va.Code Ann. § 32.1–102.6. This authorization, according to appellants, can significantly lengthen the administrative review period and increase the costs and uncertainty borne by applicants. Second, the intervention proviso also grants local firms, who may be in competition with an applicant, the power to stymie the process through an adversarial presentation at conference. Appellants assert that despite the "informal" label, fact-finding conferences "often resemble full-blown litigation" and "[a]pplicants regularly retain counsel." Appellants' Br. at 10. Finally, appellants argue that the process gives a structural edge to established interests: Because applications are grouped and reviewed in batches, "Virginia-based entities [can] submit competing applications [within the appropriate batch cycle] in order to block applications they want to see denied." *Id.* at 13.

We are unconvinced by appellants' arguments. In order to prove discriminatory effect, appellants must demonstrate that Virginia's CON law, "if enforced, would negatively impact interstate commerce to a greater degree than intrastate commerce." *Colon Health*, 733 F.3d at 543 (quoting *Waste Mgmt. Holdings, Inc. v. Gilmore*, 252 F.3d 316, 335 (4th Cir.2001)). "The fulcrum of this inquiry will be whether the certificate requirement erects a special barrier to market entry by non-domestic entities." *Id.* at 546. Here, the Commonwealth's expert, Dr. John Mayo, revealed that over a fourteen-year period ending in January 2014, "approval rates for applications submitted by in-state and by out-of-state firms considered by the Virginia Department of Health [were] virtually identical" at just under eighty-five percent. J.A. 142–43. The State's expert also reported that obtaining a certificate took the same length of time for both in-state and out-of-state applicants—154 to 167 days. *Id.* at 143. In short, both the application process and its end result in Virginia

showed no appreciable difference in the treatment of in-state and out-of-state entities. This in contrast to programs that revealed marked disparities in the handling of in-state and *154 out-of-state applications. See, e.g., *Walgreen Co. v. Rullan*, 405 F.3d 50, 56 (1st Cir.2005) (in which "[o]ver fifty percent of out-of-Commonwealth entities [were] forced to undergo the entire administrative process compared to less than twenty-five percent of local applicants").

Appellants, for their part, condemn the state expert's approach. They argue that "the district court erred by crediting the Commonwealth's expert's decision to base his analysis entirely on whether a particular entity was legally incorporated in Virginia or elsewhere." Appellant's Br. at 51. According to appellants, "the inquiry should be practical, rather than formal, and established service providers in Virginia should be counted as 'in-state' regardless of their state of legal incorporation." *Id.* at 52.

We find no error in the approach taken by the district court. It was plainly reasonable for the State's expert to consider an entity's state of incorporation in demarcating the boundary between in-state and out-of-state applicants. The district court noted simply that "state of incorporation is relevant to whether an entity is an out-of-state business discriminated against by Virginia's regulatory scheme." J.A. 62. And indeed it is relevant. Not only is the state of incorporation an easily applied criterion. By choosing to incorporate within a particular state, a corporation opts to identify itself with both state law and state process in a way that an out-of-state corporation does not. James D. Cox & Thomas Lee Hazen, 1 TREATISE ON THE LAW OF CORPORATIONS § 3:2 (3d ed. 2015) ("In selecting the state of incorporation, the [corporation] makes a decision not only as to the relevant statutory law but also as to the case law that will govern all corporate questions, including the duties of the corporation's officers and directors and the rights of its stockholders").

Appellants further contest the district court's decision on the ground that the court "improperly credited the testimony of [the Commonwealth's] expert over [their expert's analysis]." Appellants' Br. at 56. They argue that their expert established that the "Virginia law undisputedly and expressly favors granting CONs to entities that have previously completed projects" in the state. Appellants' Br. at 55 (citing 12 Va. Admin. Code §

5-230-60). In other words, appellants' expert concluded that the certificate requirement discriminates in favor of incumbent health care providers at the expense of new, predominantly out-of-state firms.

We reject appellants' argument as a matter of law, for incumbency bias in this context is not a surrogate for the "negative[] impact [on] interstate commerce" with which the dormant Commerce Clause is concerned. *Colon Health*, 733 F.3d at 543. The dormant Commerce Clause is exclusively designed to address the "differential treatment of in-state and out-of-state economic interests that benefits the former and burdens the latter." *Granholm v. Heald*, 544 U.S. 460, 472, 125 S.Ct. 1885, 161 L.Ed.2d 796 (2005) (internal quotation marks omitted). Thus, what appellants label as an impermissible foray into a battle of the experts is a simple recognition of the fact that incumbency is not the focus of the dormant Commerce Clause.

Allowing incumbency to serve as the proxy for in-state status would be a risky proposition. One can be, for example, an incumbent recipient of some state contractual benefit without necessarily being an in-state resident. In fact, the vitality of interstate commerce relies upon the ability of one state to have some allegedly incumbent companies of another state provide its citizens with needed goods and services. As the district court explained, "[u]nder [appellants'] view, the success rate of new *155 out-of-state applicants should be measured against the success rate of new in-state applicants combined with every previously-successful entity currently operating in Virginia. This approach tips the scales in favor of new out-of-state applicants; it does not provide an accurate depiction of whether Virginia's [] program discriminates against interstate commerce." J.A. 1523.

Finally, appellants specify that one-hundred percent of CT scanner and MRI machine manufacturers are located outside the state of Virginia. Appellants' Br. at 31. Because medical imaging manufacturers are by definition out-of-state entities, appellants assert that "the burdens of Virginia's CON requirement are anything but evenhanded." *Id.* at 32. But that point is easily turned around. We think it axiomatic that there can be no discrimination in favor of in-state manufacturers when there are no manufacturers in the state. How are we to properly assess, for example, "whether the certificate requirement erects a special barrier to market entry by

non-domestic entities," *Colon Health*, 733 F.3d at 546, when there is no domestic business with which to compare those non-domestic entities?

We do not doubt that appellants are frustrated by the state legislature's decision to impose a certificate requirement in this area. However, we will not take the potentially limitless step of striking down every state regulatory program that has some alleged adverse effect on market competition. We live in such an interconnected economy that for any regulation some effects are almost bound to be felt out of state. To accept appellants' arguments "would broaden the negative Commerce Clause beyond its existing scope," *United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 348, 127 S.Ct. 1786, 167 L.Ed.2d 655 (2007) (Scalia, J., concurring), such that "the States' power to engage in economic regulation would be effectively destroyed." See *Am. Motors Sales Corp. v. Div. of Motor Vehicles*, 592 F.2d 219, 224 (4th Cir.1979).

III.

A.

Even where a law does not facially, in effect, or purposefully discriminate against interstate commerce, we have in past cases undertaken a second analytical step, asking whether any of the law's incidental burdens on interstate commerce might still be "clearly excessive in relation to [its] putative local benefits." *Sandlands C&D LLC v. Cty. of Horry*, 737 F.3d 45, 53 (4th Cir.2013) (quoting *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142, 90 S.Ct. 844, 25 L.Ed.2d 174 (1970)). Our previous opinion in this case was skeptical of *Pike's* balancing test. We noted that the "discriminatory effects test represents [a] superior framework of analysis" and that the *Pike* approach "is often too soggy to properly cabin the judicial inquiry or effectively prevent the district court from assuming a super-legislative role." *Colon Health*, 733 F.3d at 546. Because it so often casts judges into disputes involving subjective or technically difficult decisions properly committed to the discretion of state legislatures, *Pike* balancing risks an unwarranted expansion of the judicial function.

[11] *Pike* balancing frequently requires judges to make highly subjective calls. "[W]eighing or quantifying" a law's

benefits and burdens may be “a very subtle exercise.” *Dep’t of Revenue of Ky. v. Davis*, 553 U.S. 328, 354, 128 S.Ct. 1801, 170 L.Ed.2d 685 (2008). The exercise is complicated by the difficulty of determining by what criteria benefits and burdens ought to be assessed. Sometimes “[i]t is a *156 matter not of weighing apples against apples, but of deciding whether three apples are better than six tangerines.” *Id.* at 360, 128 S.Ct. 1801 (Scalia, J., concurring). Making that decision often in turn requires one to “decid[e] which interest is more important”—a policy call of the kind ordinarily entrusted to representative government. *Id.*

[12] Judges are, for better or worse, not often economists or statisticians. We are ill-equipped to “second-guess the empirical judgments of lawmakers concerning the utility of legislation.” *CTS Corp.*, 481 U.S. at 92, 107 S.Ct. 1637. Simply put, there are cases in which “the Judicial Branch is not institutionally suited to draw reliable conclusions of the kind that would be necessary ... to satisfy a *Pike* burden.” *Davis*, 553 U.S. at 353, 128 S.Ct. 1801. The Supreme Court still “generally leave[s] the courtroom door open to plaintiffs invoking the rule in *Pike*,” *Davis*, 553 U.S. at 353, 128 S.Ct. 1801, and so we proceed to the merits of appellants’ argument. We do so only after recognizing our own institutional limitations, however, and only after giving due deference to the body whose primary responsibility it is to judge the benefits and burdens of Virginia legislation: the Virginia legislature.

B.

[13] While the Supreme Court applies a “virtual *per se* rule of invalidity” to enforce the dormant Commerce Clause against plain attempts at local protectionism, laws which do not so discriminate face only “less strict scrutiny.” *Wyoming v. Oklahoma*, 502 U.S. 437, 454–55 & n. 12, 112 S.Ct. 789, 117 L.Ed.2d 1 (1992). In identifying the “putative local benefits” to be weighed against incidental burdens on interstate commerce, *Pike*, 397 U.S. at 142, 90 S.Ct. 844, we therefore apply a rational basis standard of review. *Colon Health*, 733 F.3d at 535.

[14] Virginia advances a number of legitimate interests in support of its CON program. First, it argues that the CON program boosts healthcare quality. The Virginia Health Department’s designee Erik Bodin noted in deposition testimony that by reducing excess medical capacity, the

CON program may “increase the quality of the care that’s being provided because the expertise of the people using the equipment and interpreting the results is higher.” J.A. 639. A subcommittee of the Virginia General Assembly similarly found that “studies provide strong evidence that quantity and quality are closely related and experience and practice with complex procedures are assumed to increase skill and improve expertise.” J.A. 210. In other words, practice makes perfect, or at least familiarity with sophisticated medical devices is to be preferred to only infrequent use of them. In this regard, the CON program helps ensure that new entrants do not overly dilute the market and thereby prevent medical personnel from practicing and performing procedures on a regular basis.

Second, the CON program may help underserved and indigent populations access needed medical care. Certificates of need may be granted on the condition that the recipients provide a certain level of indigent care each year. Va.Code Ann. § 32.1–102.4(F); Va.Code Ann. § 32.1–102.2(C). And applicants for certificates of need have at least on occasion “use[d] their performance of charity care [] at a rate higher than the average as a factor in why they should be approved” in the first place. J.A. 640–41 (Bodin Dep.). The impact of all this may be substantial—possibly “in excess” of “several hundred million dollars” of care for needy patients each year. *Id.* at 634–35. Such additional care would *157 be impressive in any state, but it may be all the more so in Virginia, which has few public hospitals, principally the University of Virginia and Virginia Commonwealth University Medical Centers. Without the assistance of private caregivers serving indigent patients, service at least in part motivated by the CON program, those hospitals might be even more burdened than they already are.

A related purpose of the CON program is geographical in nature. For reasons not difficult to discern, medical services tend to gravitate toward more affluent communities. The CON program aims to mitigate that trend by incentivizing healthcare providers willing to set up shop in underserved or disadvantaged areas such as Virginia’s Eastern Shore and far Southwest. “In determining whether” to issue a certificate, for example, Virginia considers “the effects that the proposed service or facility will have on access to needed services in areas having distinct and unique geographic, socioeconomic,

cultural, transportation, or other barriers to access to care.” Va.Code Ann. § 32.1–102.3(B)(1).

The CON program may also aid underserved consumers in a more indirect fashion. By reducing competition in highly profitable operations, the program may provide existing hospitals with the revenue they need not only to provide indigents with care, but also to support money-losing but nonetheless important operations like trauma centers and neonatal intensive care units. Appellants' expert agreed in his deposition that full-service hospitals have “long been in the practice of cross-subsidizing unprofitable services with the profits from those that are profitable.” J.A. 392. It is perhaps no accident that the CON applicants in this case sought to open standalone gastroenterology and radiology facilities, not new community health centers. Concerns that such practices could drain needed revenue from more comprehensive general hospitals providing necessary though unprofitable services are not irrational.

Finally, Virginia argues that the CON program furthers its legitimate interest in reducing capital costs and the costs to consumers of medical services. By preventing untoward increases in excess capacity, Virginia contends, the CON program can reduce the healthcare system's overall costs. Excess capacity means that those extra hospital beds and additional medical equipment must pay for themselves, thereby generating pressure for hospital stays and diagnostic tests that patients really do not need. See Brief for Va. Hospital & Healthcare Ass'n & Va Health Care Ass'n (“Hospitals' Brief”) at 21. And a former Virginia Secretary of Health and Human Resources has observed that Virginia experienced a significant increase in expenditures for equipment and new services when it partially deregulated its health care sector between 1989 and 1992. J.A. 211. It again is not irrational for Virginia or any other state to credit its own prior experience with deregulation.

C.

[15] Appellants “bear[] the burden of proving that the burdens placed on interstate commerce outweigh” the aforementioned local benefits. *LensCrafters, Inc. v. Robinson*, 403 F.3d 798, 805 (6th Cir.2005). While they advance a number of arguments, we find none persuasive. Several in particular warrant discussion.

First, appellants attack the wisdom of the CON program. They argue that it is “a relic of a failed federal policy” that once encouraged these sorts of programs, Appellants' Br. at 7, and that the application process imposes “[e]xtraordinary costs ... in terms of time and money.” *Id.* at 9. *158 Appellants also refer to a report of the Federal Trade Commission and the U.S. Department of Justice, which found in 2004 that CON programs “are not successful in containing healthcare costs” and “pose serious anticompetitive risks that usually outweigh their purported economic benefits.” J.A. 1153.

At the heart of appellants' argument is the basic economic maxim that barriers to entry like CON programs may reduce competition and thereby allow entrenched incumbents to exert market power and charge inefficiently high prices. Like Virginia's legitimate state interest arguments, we do not find appellants' countervailing argument to be unreasonable. The points noted above, however, might be more persuasively made before the Virginia General Assembly, not a panel of unelected federal judges. The battle between laissez fairists and regulators is as old as the hills. The fighting, however, is more often over economics and politics than over law. Legislators, not jurists, are best able to compare competing economic theories and sets of data and then weigh the result against their own political valuations of the public interests at stake.

Appellants' free market arguments also overlook the fact that the health care market has its own idiosyncrasies. Consumers, i.e. patients, often do not know the price of the medical service they receive until after it has been provided. Hospitals' Br. at 8. For many reasons, patients, some of whom are under intense time pressures and physical stress, face difficulties in assessing the quality of medical services as well. In this market, patients at all income levels often choose a provider with private insurance or the government footing the lion's share of the bill; they thus lack the normal incentives to shop for price. Providers are not free agents either. Squeezed by insurers, regulation, and obligations to provide indigent care at a financial loss, providers lack the customary freedom of a seller of services to set its price. Unprofitable but vital medical services do not reap providers the usual market rewards. *Id.* at 10. Many of the classic features of a free market are simply absent in the health care context, and that fact counsels caution when courts are urged to

dismantle regulatory efforts to counter perceived gaps and inefficiencies in the healthcare market.

[16] “There was a time” when courts “rigorously scrutinize[d] economic legislation” and “presumed to make such binding judgments for society.” *United Haulers*, 550 U.S. at 347, 127 S.Ct. 1786 (citing *Lochner v. New York*, 198 U.S. 45, 25 S.Ct. 539, 49 L.Ed. 937 (1905)). But this is no longer that time, and under rational basis review, reasonable debates such as this one are resolved in favor of upholding state laws. The states do, after all, play a crucial role in our constitutional scheme. To override their judgments casually would be to undermine a cornerstone of our federal system: the state police power. Courts enforcing the dormant Commerce Clause were “never intended to cut the States off from legislating on [] subjects relating to the health, life, and safety of their citizens.” *Sherlock v. Alling*, 93 U.S. 99, 103, 23 L.Ed. 819 (1876). That is their lifeblood, and we shall not constrict it here.

Appellants, to their credit, are not done. They charge that the entirety of Virginia’s evidence in support of its purported interests amounts to mere “hearsay and speculation, unsupported by any fact or expert testimony.” Appellants’ Br. at 40. They also contrast Virginia’s lack of expert testimony on the general effectiveness of CON programs with their expert’s declaration that “CON laws produce little or no real benefits even as they impose costs on taxpayers and patients.” J.A. 828.

*159 Appellants’ empirical arguments are, again, more suited to a legislature than a court. While we have held that the state interests considered in *Pike* balancing must not be “entirely speculative,” *Medigen of Ky., Inc. v. Pub. Serv. Comm’n of W. Va.*, 985 F.2d 164, 167 (4th Cir.1993), Virginia’s are not so here. The Commonwealth has supported them with reasonable argument and the record testimony of individuals well versed in the CON program’s aims. To require Virginia to submit expert testimony or provide bullet-proof empirical backing for every legislative judgment is a requirement bereft of any limiting principle. Most legislation, after all, relies on assumptions that can be empirically challenged. Were we to engage in an exhaustive empirical battle in, for starters, every dormant Commerce Clause case, there would be no end to judicial interference with legislation touching no

end of subject matters. Our federal system would end up as the loser.

The same reasoning explains why we reject appellants’ argument that Virginia should have to prove that benefits flow from the CON program’s “requirements for medical-imaging devices” in particular, and not just from the CON program in general. Appellants’ Br. at 39. That argument draws us deep into the weeds. Were we to allow device-by-device litigation over what medical equipment the CON program might constitutionally cover and what it might not, litigation would become the main arena and the undermining of legislation would have no end.

In *Department of Revenue of Kentucky v. Davis*, the Supreme Court rejected arguments similar to those made here. That case involved a challenge to a state method of taxing income earned from state and local bonds. Kentucky, along with forty other states, used a “differential tax scheme” in which interest income derived from bonds issued by the state and its subdivisions was not subject to a state income tax, even though interest income earned from the bonds of other states was taxable. *Davis*, 553 U.S. at 332–35, 128 S.Ct. 1801. The Court rejected the challenge to the law under *Pike*. It noted both the challengers’ argument that the law “blocks” other states from “access to investment” and “harms the national municipal bond market ... by distorting and impeding the free flow of capital,” and the countervailing possibility that the law might pose an “advantage ... for bonds issued by [] smaller municipalities,” who without it might lack “ready access to any other bond market.” *Id.* at 353–55, 128 S.Ct. 1801. Under such circumstances, *Pike* balancing lay beyond the judicial ken. *Id.* at 355, 128 S.Ct. 1801. As in the case before us, the “most significant” aspect of “these cost-benefit questions [was] not even the difficulty of answering them ... but the unsuitability of the judicial process” for “reaching whatever answers are possible at all.” *Id.* “[A]n elected legislature is the preferable institution for incurring the economic risks of any alteration in the way things have traditionally been done.” *Id.* at 356, 128 S.Ct. 1801. So too here.

D.

The Framers wisely aimed to “avoid the tendencies toward economic Balkanization that had plagued relations among the Colonies.” *Hughes*, 441 U.S. at 325–26, 99

S.Ct. 1727. Our jurisprudence has respected that fact. But every regulatory response to a complex economic problem is not ripe for a *Pike* balancing challenge. The healthcare market is infamously complicated, with patients, providers, insurers, government, and many others all attempting to come to terms over a particular service touching physical wellbeing and *160 sometimes even life itself. Here thirty-six states, some of whom appeared before us as *amici*, have some variety of CON program. Their combined ability to act as “laboratories for experimentation” in such a complex field warrants our respect. See *United States v. Lopez*, 514 U.S. 549, 581, 115 S.Ct. 1624, 131 L.Ed.2d 626 (1995) (Kennedy, J., concurring). Here Virginia has experimented not only by

creating a CON program, but by tweaking and modifying it over decades. None of the foregoing discussion proves that the Commonwealth's approach is the very best way to deliver its citizens quality healthcare. It may or may not be. It is anything but clear, however, that courts can lead the way in providing a better path. While we cannot say whether Virginia's program is ultimately wise, it most certainly is constitutional. The judgment is affirmed.

AFFIRMED

All Citations

813 F.3d 145

End of Document

© 2016 Thomson Reuters. No claim to original U.S. Government Works.

