No. 14-2283

In the United States Court of Appeals for the Fourth Circuit

COLON HEALTH CENTERS OF AMERICA, LLC, et al.,
Plaintiffs-Appellants,

v.

BILL HAZEL, et al.,
Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA AT ALEXANDRIA

BRIEF OF SCHOLARS OF ECONOMICS AND SCHOLARS OF LAW AND ECONOMICS AS *AMICI CURIAE* IN SUPPORT OF APPELLANTS

Jared M. Bona
Aaron R. Gott, *Of Counsel*
BONA LAW P.C.
4275 Executive Square
Suite 200
La Jolla, CA 92037
(858) 964-4589
jarod.bona@bonalawpc.com
aaron.gott@bonalawpc.com

Attorneys for Amici Curiae

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INTERESTS OF *AMICI CURIAE*

Amici curiae are scholars of economics and scholars of law and economics, all of whom have devoted significant academic attention to health economics and the effects of certificate-of-need regulation. *Amici* thus have a strong interest in ensuring that this Court's approach reflects an accurate understanding of the economic effects of CON programs.

Amici teach that a public policy program should be measured by its effects rather than its intentions or justifications. A review of the relevant economic literature concerning CON programs demonstrates that scant evidence supports the claim that these laws achieve their intended goals of controlling costs or increasing indigent care.

While *amici* believe the district court was incorrect to assert that Virginia's certificate of public necessity program creates local benefits in the form of cost control and increased levels of indigent care, *amici* do not take a position on the ultimate question of whether the program violates the dormant commerce clause.

Both parties to this appeal have consented in writing to the filing of this *amici curiae* brief.

Amici are:

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

SUMMARY OF ARGUMENT

Argument 1. Empirical evidence in economic literature does not support the conclusion that CON programs achieve their goal of controlling costs. Those studies that do provide support are based upon CON programs more generally, not Virginia's particularly onerous CON program, which require approval for low-cost devices. Recent studies show that CON programs, particularly in states with more stringent CON requirements, actually increase costs.

Argument 2. Though CON programs may have achieved some level of cross-subsidization of indigent care in the past, more recent studies have failed to show any meaningful cross-subsidization. Changes to the market—increased competition—now prevent cross-subsidization across patient groups.

ARGUMENT

Virginia's certificate-of-need (CON) law limits the entry or expansion of healthcare providers by requiring approval from the state prior to a provider entering new markets or making changes to existing capacity. The wide adoption of certificate-of-need

programs by states has provided ample opportunity to assess their effectiveness. And while Virginia's CON program is particularly onerous and uniquely anticompetitive, *see Colon Health Centers of Am., LLC v. Hazel*, 733 F.3d 535, 546 (4th Cir. 2013), academic consensus finds little evidence to support the speculated benefits of certificate-of-need programs.

When certificate programs were implemented, they were defended as providing two primary benefits: cost control and cross subsidization of indigent care. First, proponents claim that by restricting market entry and expansion through certificate programs, states might reduce overinvestment in facilities and equipment, thereby controlling the cost of health care. Second, they tout the potential to increase indigent care through what economists refer to as a "cross-subsidization."

The district court accepted these benefits and found they were "neither speculative nor rare." Op. at 16. Overwhelming and longstanding academic consensus, however, suggests that these putative benefits are entirely speculative and unsupported by evidence. Section I provides a brief history of CON programs.

Section II reviews the literature concerning the effectiveness of these programs as a cost-control measure. Section III demonstrates that certificate programs do not increase indigent care.

I. THE HISTORY OF CERTIFICATES OF NEED

CONs are a state invention. The first CON program was adopted by the state of New York in 1964 as a way to strengthen regional health planning programs by creating a process for prior approval of certain capital expenditures.[1] Between 1964 and 1974, twenty-six other states adopted CON programs.[2] Virginia was among those twenty-six states, with the creation of its Certificate of Public Need (COPN) program in 1973. The passage of the National Health Planning and Resources Development Act of 1974, which made certain federal funds contingent on the enactment of CON programs, provided a strong incentive for the remaining states to implement CON programs. In the seven years following this incentive, nearly every state without a CON

1. James Simpson, *State Certificate-of-Need Programs: The Current Status*, 75 AMERICAN JOURNAL OF PUBLIC HEALTH 1225 (1985).

2. *Id.*

program took steps to adopt certificate-of-need statutes. By 1982 every state except Louisiana had some form of a CON program.

By 1988, however, eleven states had either repealed their CON programs or allowed them to expire, and other states had either raised their review thresholds or otherwise reduced the scope of their CON review. Today, thirty-six states and the District of Columbia maintain a CON program.

II. CERTIFICATE OF NEED PROGRAMS ARE AN INEFFECTIVE COST-CONTROL MEASURE

A. Early research found no evidence of cost control

While the goal of these programs was primarily cost control, many early studies of these laws generally found no evidence of reduced investment by hospitals,[3] nor did these early studies find evidence of cost control.[4] As early as 1976, scholars were

3. Fred J. Hellinger, *The Effect of Certificate-of-Need Legislation on Hospital Investment.* 13 INQUIRY: A JOURNAL OF MEDICAL CARE ORGANIZATION, PROVISION AND FINANCING 187 (1976); *see also* David S. Salkever & Thomas W. Bice *The Impact of Certificate-of-Need Controls on Hospital Investment*, 54 THE MILBANK MEMORIAL FUND QUARTERLY. HEALTH AND SOCIETY 185 (1976).

4. Frank A. Sloan & Bruce Steinwald, *Effects of Regulation on Hospital Costs and Input Use*, 23 JOURNAL OF LAW AND ECONOMICS 281 (1980); *see also* Frank A. Sloan, *Regulation and the Rising Cost of Hospital Care*, 63 THE REVIEW OF ECONOMICS AND STATISTICS 479 (1981); Paul L. Joskow, *The Effects of Competition and Regulation on Hospital Bed Supply and the Reservation Quality of the Hospital*, 11 BELL JOURNAL OF ECONOMICS 421(1980); Paul L.

concluding that CON programs had little effect on hospital investments, with one study concluding that there is "no empirical evidence to suggest that [certificate-of-need legislation] has decreased investment."[5] Another empirical study, conducted in 1979, found that CON laws were not reducing the total dollar volume of hospital investments but were altering its composition.[6] Restricting investments through CON programs simply drove hospitals to increase investments in other services and equipment.

Moreover, other early studies found no evidence that CON programs controlled costs. A 1980 study published in the *Journal of Law and Economics* found that CON regulations fail to control costs.[7] Examining 1,228 nonfederal, short-term general hospitals from 1970 through 1975, the authors concluded that:

> Our evidence suggests that, as a group, regulatory programs did not meaningfully contain hospital costs during the first half of the 1970s. The results are consistent with three alternative views: (a) the regulations examined in this study do not have the capability of controlling hospital costs; (b) the

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Joskow, CONTROLLING HOSPITAL COSTS: THE ROLE OF GOVERNMENT REGULATION (1981).

5. Hellinger *supra* note 3, at 192.
6. *See* Salkever & Bice, *supra* note 3.
7. *See* Sloan & Steinwald, *supra* note 4.

> regulations are effective, but our empirical approach was inappropriate to capture these effects; or (c) the regulations are potentially effective, but the time period studied was not long enough or was too soon after implementation in most cases for these effects to have become measurable. We feel that the first explanation is far more likely than the third and leave it to readers to judge the second.[8]

This finding that CON laws fail to control costs was confirmed by other studies conducted during this time.[9] These results were one driving factor behind the federal government's repeal of the CON incentive program in the 1980s.[10] By 1988, eleven states had either repealed their CON programs or allowed them to expire, and other states had either raised their review thresholds or otherwise reduced the scope of their CON review. Analyzing the differences in health care markets during this time, a staff report of the Bureau of Economic Analysis at the Federal Trade Commission estimated that significantly relaxing the regulations

8. *Id.* at 82.

9. *See* Sloan, *supra* note 4; Joskow, *supra* note 4; Joskow, *supra* note 4.

10. *See* Christopher Koopman & Thomas Stratmann, *Certificate-of-Need Laws: Implications for Virginia* (Mercatus on Policy, Mercatus Center at George Mason University, Arlington, VA, February 2015), http://mercatus.org/sites/default/files/Koopman-Certificate-of-NeedVA-MOP_1.pdf.

did not increase costs, but would instead lower costs by 1.4 percent.[11]

B. More recent examinations of CON laws have found mixed results.

While states continued to implement CON programs over the three decades since the federal repeal of CON requirements, scholars have continued to examine the effects these programs. The results of this more recent research has been mixed. For example, a 1998 study found that while CON laws may appear to have a limited cost-control effect, removing these laws in several states was not associated with a surge in hospital spending.[12] Other studies—commissioned by Chrysler, Ford, and General Motors—found that employee health care costs during the periods examined were higher in states without CON laws compared with those in states with CON laws.[13] However, this issue certainly is

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11. Daniel Sherman, *The Effect of Certificate-of-Need Laws on Hospital Costs: An Economic Policy* Analysis, STAFF REPORT OF THE BUREAU OF ECONOMICS, FEDERAL TRADE COMMISSION (January 1988), https://www.ftc.gov/sites/def ault/files/documents/reports/effect-state-certificate-need-laws-hospital-costs-economic-policy-analysis/232120.pdf.

12. Christopher J. Conover and Frank A. Sloan, *Does Removing Certificate-of-Need Regulations Lead to a Surge in Health Care Spending?* 23 JOURNAL OF HEALTH POLITICS, POLICY AND LAW 455 (1998).

13. Mark J. Gendregski, *CON Testimonial Notes for DaimlerChrysler Corporation* (March 19, 2002), http://www.ciclt.net/ul/sgh/CON%20Endorsem

not settled, and other more recent studies reach contrary findings. For example, a 2010 study published in the *Journal of Healthcare Finance* found no evidence that CON laws are associated with reduced hospital costs, but instead found that stringent CON programs increase costs by five percent.[14]

C. Cost control is not supported by sufficient academic consensus

Virginia's claim that its COPN law implements cost control as a local benefit is not just "entirely speculative," it is improbable. *See Medigen of Kentucky, Inc. v. Pub. Serv. Comm'n of W. Virginia*, 985 F.2d 164, 167 (4th Cir. 1993) (finding no basis for entirely speculative benefits unsupported by the record). The literature does not support a conclusion that the presence of CON laws generates any reduction in hospital investments and spending. In particular, many of the earliest studies examining the effects of CON laws, such as Virginia's CON program, found

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ent.pdf; Ford Motor Company, *Relative Costs Data v. Certificate of Need (CON) for States in Which Ford has a Major Presence* (2000) http://ushealthpolicygateway.com/wp-content/uploads/2009/07/mi-con-appendixj-l.pdf; General Motors, *Statement of General Motors Corporation on the Certificate of Need (CON) Program in Michigan* (February 12, 2002) http://ushealthpolicygateway.com/wp-content/uploads/2009/07/mi-con-appendixj-l.pdf.

14. Patrick A. Rivers, et. al., *The Effects of Certificate-of-Need Regulation on Hospital Costs*, 36 JOURNAL OF HEALTH CARE FINANCE 1 (2010).

no evidence of reduced spending. Moreover, the more recent literature has remained mixed, and lacks any consensus to support the conclusion that CON programs are an effective cost-control measure. The literature that does provide support to CON programs generally does not support any conclusion that CON restrictions on low-cost medical devices achieve these cost control objectives.

III. VIRGINIA'S CON DOES NOT INCREASE INDIGENT CARE

While there is little evidence to support the claim that certificates of need are an effective cost-control measure, many states continue to justify these programs using the rationale that CON regulations increase the provision of health care for the poor. To achieve this, fourteen states—including Virginia—include some explicit requirement regarding charity care within their

respective CON programs.[15] This is what economists have come to refer to as a "cross subsidy."[16]

The theory supporting cross-subsidization through CON programs is straightforward. By limiting the number of providers that can enter a particular practice and by limiting the expansion of incumbent providers, CON laws effectively give a limited monopoly privilege to providers that receive approval in the form of a certificate of need. As a result, approved providers can charge higher prices than would be possible under truly competitive conditions. The hope is that providers will use these enhanced profits to cover the losses from providing otherwise unprofitable, uncompensated care to the poor. In effect, those who can pay are charged higher prices to subsidize those who cannot.

At one point the idea that a state could cross-subsidize through its CON laws may have been borne out by the data, since some

15. Thomas Stratmann & Jacob Russ, *Do Certificate-of-Need Laws Increase Indigent Care?* (Working Paper No. 14-20, Mercatus Center at George Mason University, Arlington, VA, July 2014), http://mercatus.org/publication/do-certificate-need-laws -increase-indigent-care; Virginia's charity care requirement can be found at VA. CODE ANN. § 32.1-102.3.

16. Richard Posner, *Taxation by Regulation*, 2 BELL JOURNAL OF ECONOMICS AND MANAGEMENT SCIENCE 22 (1971); Gerald Faulhaber, *Cross-Subsidization: Pricing in Public Enterprises*, 65 AMERICAN ECONOMIC REVIEW 966.

early studies did find evidence that cross-subsidization was occurring. For example, studies have found evidence of *quid pro quo* cross-subsidization: those hospitals that provided the most indigent care had a higher probability of winning approval for certificates of need.[17] Other studies confirmed the presence of cross-subsidization as well.[18]

More recent research, however, does not find evidence that cross-subsidization is still occurring.[19] Two literature surveys concluded that although cross-subsidization may have been

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17. Ellen S. Campbell & Gary M. Fournier, *Certificate-of-Need Deregulation and Indigent Hospital Care*, 18 JOURNAL OF HEALTH POLITICS, POLICY AND LAW 905 (1993); Gary M. Fournier & Ellen S. Campbell, *Indigent Care as Quid Pro Quo in Hospital Regulation*, 79 REVIEW OF ECONOMICS AND STATISTICS 669 (1997).

18. David Dranove et. al., *How Do Hospitals Respond to Negative Financial Shocks? The Impact of the 2008 Stock Market Crash*, NBER WORKING PAPER 18853 (2013); Jennifer L. Troyer, *Cross-Subsidization in Nursing Homes: Explaining Rate Differentials Among Payer Types,* 68 SOUTHERN ECONOMIC JOURNAL 750 (2002); Guy David et.al., *Do Hospitals Cross Subsidize?* NBER WORKING PAPER 17300 (2011).

19. Austin B. Frakt, *How Much Do Hospitals Cost Shift? A Review of the Evidence*, 89 Milbank Quarterly 90 (2011); Austin B. Frakt, *The End of Hospital Cost Shifting and the Quest for Hospital Productivity*, 49 Health Services Research 1 (2014); Vivian Y. Wu, *Hospital Cost Shifting Revisited: New Evidence from the Balanced Budget Act of 1997*, 10 INTERNATIONAL JOURNAL OF HEALTH CARE FINANCE AND ECONOMICS 61 (2010); Dranove et. al., *supra* note 18; Chapin White, *Contrary to Cost-Shift Theory, Lower Medicare Hospital Payment Rates for Inpatient Care Lead to Lower Private Payment Rates,* 32 HEALTH AFFAIRS 935 (2013); Chapin White & Vivian Y. Wu, *How Do Hospitals Cope with Sustained Slow Growth in Medicare Prices?*, 49 HEALTH SERVICES RESEARCH 11 (2014).

possible in the past, changes in the market no longer allow this to occur.[20] In particular, other scholars have found that the market has become too competitive to allow hospitals to continue cross subsidizing between patient groups.[21]

Using state-level hospital data and the most comprehensive CON-regulation database to date, a recent empirical study into the connection between CON laws and cross-subsidization found no evidence of higher levels of indigent care in states that have CON programs compared to those that do not.[22] They do find, however, that CON laws are associated with fewer hospital beds per capita and with fewer facilities with MRI machines per capita.

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20. Austin B. Frakt, *How Much Do Hospitals Cost Shift? A Review of the Evidence*, 89 Milbank Quarterly 90 (2011); Austin B. Frakt, *The End of Hospital Cost Shifting and the Quest for Hospital Productivity*, 49 Health Services Research 1 (2014).

21. Vivian Y. Wu, *Hospital Cost Shifting Revisited: New Evidence from the Balanced Budget Act of 1997*, 10 INTERNATIONAL JOURNAL OF HEALTH CARE FINANCE AND ECONOMICS 61 (2010); David Dranove et. al., *How Do Hospitals Respond to Negative Financial Shocks? The Impact of the 2008 Stock Market Crash*, NBER WORKING PAPER 18853 (2013); Chapin White, *Contrary to Cost-Shift Theory, Lower Medicare Hospital Payment Rates for Inpatient Care Lead to Lower Private Payment Rates,* 32 HEALTH AFFAIRS 935 (2013); Chapin White & Vivian Y. Wu, *How Do Hospitals Cope with Sustained Slow Growth in Medicare Prices?*, 49 HEALTH SERVICES RESEARCH 11 (2014).

22. Thomas Stratmann & Jacob Russ, *supra* note 15.

CONCLUSION

Since their inception, CON programs have been defended on the grounds that they either control costs or increase health care for the poor. However, there is little evidence to conclude that this is actually occurring. In the early days, CON programs may have been an effective tool to restrict the supply of regulated medical services, but many early studies found that they had little effect on hospital investments. A review of the more recent literature finds that programs such as Virginia's CON are an ineffective cost-control measure and an unsuccessful tool for increasing care for the poor. In fact, such restrictions appear to decrease access to care by reducing the number of hospital beds per capita and the number of hospitals with MRI machines per capita. Moreover, the academic literature examining CON programs looks at their entirety and not the effects of any individual CON regulation pertaining to any particular device or service. In this regard, the literature provides no support that CON restrictions on medical imaging devices achieve the intended goals that traditionally justify such programs.

Respectively submitted and dated: March 30, 2015

/s/ Jarod M. Bona
Jarod M. Bona
Aaron R. Gott, *Of Counsel*
BONA LAW P.C.
4275 Executive Square
Suite 200
La Jolla, CA 92037
(858) 964-4589
jarod.bona@bonalawpc.com
aaron.gott@bonalawpc.com