NORTH CAROLINA JOURNAL OF LAW & TECHNOLOGY
VOLUME 20, ISSUE ON.2: MAY 2019

CONTROVERSY IN HEALTH CARE: A HARD LOOK AT NORTH CAROLINA'S CERTIFICATE OF NEED LAWS

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As health care costs continue to rise in the United States, patients are frequently exposed to unaffordable and unpredictable medical bills. In North Carolina, diagnostic imaging services such as MRI scans can cost patients more than a month's income. In response to this, physicians like Dr. Singh of Winston-Salem, North Carolina, have attempted to part ways with major hospitals in order to offer quality medical procedures at lower, transparent prices. In states like North Carolina, however, Certificate of Need ("CON") requirements prevent them from doing so by denying entities the ability to purchase major medical equipment or to open new facilities. Although CON programs were intended to lower health care spending when first implemented in the 1970s, the federal government has long-since declared these laws ineffective and even detrimental to health care spending and health care quality in the United States. However, CON programs have remained in effect in many states due to powerful lobbying and legislative resistance to reform. State CON programs, no matter the goals behind them, function to insulate incumbent providers from competition and allow those providers to set prices for services at arbitrarily high rates. In 2018, Dr. Singh filed a law suit against the North Carolina Department of Health and Human Services alleging that North Carolina's CON statute violates his personal rights to economic substantive due process and equal protection under the North Carolina Constitution, as well as the state's constitutional prohibition on monopolies and exclusive emoluments. North Carolina's judicial branch has the opportunity to decide this case based on the traditional deference given to the state when applying the rational basis test, or by looking at the evidence presented and perhaps concluding that it does not support a finding of rationality.

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I. INTRODUCTION

Imagine a scenario in which your physician says that you need a Magnetic Resonance Imaging ("MRI") scan. This trip to the doctor may have been caused by a car accident, a fall, or unusual abdominal pain. You were not expecting to need an MRI at any point in the foreseeable future. Can you afford to have the scan? How much will it cost? Who do you ask to find out?

These are questions that the average patient in the United States faces in a health care system known for its high prices,[1] opaque insurance practices, hidden fees, and general lack of transparency.[2]

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[1] *See* Jamie Ducharme, *The U.S. Spends Twice as Much on Health Care as Other High-Income Countries*, TIME (Mar. 13, 2018), http://time.com/5197347/us-health-care-spending/.

[2] *See* Lucas Laursen, *How Efficiency Experts Lowered Health Care Prices at One U.S. Hospital*, FORTUNE (Aug. 22, 2018),

They are also questions that physicians like Winston-Salem, North Carolina surgeon, Dr. Gajendra Singh,[3] see patients struggling with in a state where the median annual household income is $50,320, and the average per capita income is only $28,123 per year.[4] How should you respond when your patient explains that the MRI scan you ordered cost more than a month of her wages?[5] The scan was necessary to treat the patient's physical problems, but between the cost of the scan after insurance, the hospital facility fee, administration fees, and physician fees, she is buried in debt.[6]

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http://fortune.com/2018/08/22/healthcare-system-knee-replacement-costs/ (explaining that lack of transparency in health care costs has been a driving factor behind the rising cost of health care).

[3] *Surgeon Gajendra Singh and Attorney Josh Windham Explain Challenge to N.C. CON Law*, CAROLINA J.: VIDEO (Nov. 28, 2018, 7:15 AM), https://www.carolinajournal.com/video/surgeon-gajendra-singh-and-attorney-josh-windham-explain-challenge-to-n-c-con-law/ [hereinafter Carolina Journal Video].

[4] *QuickFacts: North Carolina*, U.S. CENSUS BUREAU, https://www.census.gov/quickfacts/fact/table/nc/INC110217#INC110217 (last visited Jan. 22, 2019).

[5] *See* Carolina Journal Video, *supra* note 3.

[6] Because insurance coverage is not streamlined in the United States, the percentage that insurance covers can vary dramatically from patient to patient. If a patient needs an MRI before she has reached her deductible, she is responsible for all expenses incurred prior to meeting that deductible amount. After reaching the plan's deductible (the amount of which varies per plan) then, depending on the plan, the patient will either be responsible for a copayment or coinsurance (a fixed percentage of the cost based on the plan) until she reaches the plan's out-of-pocket maximum, at which point the insurance company is responsible for additional covered expenses. Out-of-Pocket Maximums in 2019 are capped at $6,750 for individuals and $13,500 for families. *See* Stephen Miller, *2019 HSA Limits Rise, IRS Says*, SHRM (Nov. 15, 2018), https://www.shrm.org/resourcesandtools/hr-topics/benefits/pages/2019-hsa-contribution-limits-rise-irs-says.aspx. Additionally, where a patient goes for a particular service is a huge variable for cost. Patients must be aware of their networks, and whether the facilities they choose charge multiple fees for the same service, which is the case with hospitals. Some insurers refuse to cover outpatient diagnostic imaging performed in hospitals altogether because they are charged so much more than if the same service were rendered at a free-standing center. *See* Lydia Ramsey, *The Cost of an MRI Can Vary by Thousands Depending on Where You Go*, BUS. INSIDER (Mar. 28, 2017, 11:12 AM), https://www.businessinsider.com/how-much-an-mri-costs-by-state-2017-3. Insurance issues aside, there are still millions of uninsured Americans. For

Plagued by these concerns, Dr. Singh decided that there had to be a better way to provide care to his community.[7] He founded Forsyth Imaging Center with the goal of providing X-rays, echocardiograms, ultrasounds, CT scans, and MRI scans to his patients at prices they can afford.[8] Chief among his priorities was eliminating the practice of charging multiple fees for the same scans.[9] Patients can see the price beforehand (prices are displayed prominently online and in the office), use cash or insurance, apply for a zero percent financing program, and if a patient finds lower prices elsewhere, Forsyth will not only match that price, but will take an additional fifty dollars off of the total cost of the service.[10] Dr. Singh's financial goals with regard to the imaging center are simply to make enough money to cover the overhead costs and pay his staff, and to provide patients with quality imaging at the lowest possible price.[11] As it stands today, however, a North Carolina law is preventing Dr. Singh from realizing his vision of affordable diagnostic imaging and is keeping prices high for North Carolinians in need.

North Carolina is one of thirty-five states with a statute that requires certain health care facilities to obtain a certificate of need ("CON")[12] for many health care-related pursuits that involve new

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example, one study found North Carolina's uninsured rate rose to 15 percent by the close of 2017. *See* Dan Witters, *Uninsured Rate Rises in 17 States in 2017*, GALLUP (May 9, 2018), https://news.gallup.com/poll/233597/uninsured-rate-rises-states-2017.aspx.

[7] *See North Carolina CON*, INST. FOR JUST., https://ij.org/case/north-carolina-con/ (last visited Feb. 1, 2019).

[8] *See id.*

[9] *See* Complaint at 7–9, Singh v. N.C. Dep't of Health and Human Servs., No. 18CV009498 (N.C. Super. Ct. July 30, 2018), 2018 WL 5307689 [hereinafter Complaint].

[10] *See id.* at 9; *see also Price List*, FORSYTH IMAGING CTR., http://forsythimaging.com/price-list.html (last visited Feb. 1, 2019).

[11] *See* Carolina Journal Video, *supra* note 3.

[12] This paper uses the term "certificate of need" or "CON" because it deals with North Carolina law. However, this term is used generally to refer to the state practice of regulating the health care market by limiting supply on the basis of "need" or "necessity" and is intended to include other iterations used by different states.

construction, expansion, or the purchase of medical equipment.[13] North Carolina has one of the most comprehensive and heavily regulated CON statutes in the United States today, and the red tape often prevents physicians like Dr. Singh from providing affordable care to patients.[14] North Carolina's CON statute currently prohibits Dr. Singh from purchasing an MRI scanner for his imaging center unless the state issues his office a certificate of need,[15] but he is currently barred from even applying for one.[16] Under the statute, the state is responsible for determining an area's projected "need" for certain medical equipment and facilities and then incorporating that into the State Medical Facilities Plan.[17] Because the 2018 state plan did not designate a need for an additional MRI scanner in Forsyth County, where Dr. Singh's office is located, he was unable to submit an application.[18]

Even if he could apply for the MRI-CON, the application process is prohibitively expensive, and there is a very low likelihood that he would succeed in securing the certificate for his office, despite having a business model that aims to reduce prices and promote transparency for patients.[19] This is because his

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[13] *See* N.C. GEN. STAT. §§ 131E-175–131E-181 (2018) (listing all health care facility activities that require a certificate of need in North Carolina).

[14] *See* Katherine Restrepo, *Certificate of Need*, JOHN LOCKE FOUND., https://www.johnlocke.org/policy-position/certificate-of-need-laws/ (last visited Feb. 1, 2019) (discussing the North Carolina CON statute and its ranking among the states for the amount of laws included within it).

[15] N.C. GEN. STAT. § 131E-178 (2018); *see also* Complaint, *supra* note 9, at 2.

[16] *See* Complaint, *supra* note 9, at 2, 11.

[17] N.C. GEN. STAT. §§ 131E-176(25) to 177(1)–(6) (2018).

[18] *See* DIV. OF HEALTH SERV. REG., N.C. DEP'T OF HEALTH AND HUMAN SERVS., 2018 STATE MEDICAL FACILITIES PLAN 150–51 (2017), https://www2.ncdhhs.gov/dhsr/ncsmfp/2018/2018smfp.pdf.

[19] *See* N.C. GEN. STAT. § 131E-182 (2018) (showing non-refundable application fees). *But see* Complaint, *supra* note 9, at 33 ("Simply submitting an application would cost Dr. Singh approximately $45,000 ($5,000 for the non-refundable application fee, and about $40,000 to compile a successful MRI-CON application). And because CON applications are almost always highly competitive, it would likely cost Dr. Singh an additional $400,000 to litigate his CON application through to the end . . . .").

competitors[20] can challenge both his application and the state's finding of "need" for an additional scanner throughout the application process.[21] The statute not only allows challenges at the agency level, but also grants challengers automatic standing to request judicial review of agency certificate of need decisions in the North Carolina Court of Appeals.[22] Although a loophole in the law currently allows Dr. Singh to rent a scanner two days per week, he does so at exorbitant prices that are not financially compatible with his goal of offering access to affordable care.[23] It is time for states to

[20] *See* Complaint, *supra* note 9, at 31 (indicating that all of the MRI machines in Forsyth County at present are owned by two multi-billion-dollar hospital groups).

[21] N.C. GEN. STAT. § 131E-188(b) (2018).

[22] *Id*.; *see also* Complaint, *supra* note 9, at 25–27 ("All appeals from final decisions in contested-case proceedings must be taken directly to the North Carolina Court of Appeals within 30 days of written notice of the decision."). Because of the scarcity of "need" determinations, the process is extremely competitive. *Id.* at 26. The administrative portion of a contested application can take up to 270 days alone. *Id.* at 25. Competitors have every incentive to contest and potentially litigate, which ultimately makes the process one that can only be successfully navigated by entities with the most financial resources. *Id.* at 26–27; *see also* U.S. DEP'T OF HEALTH AND HUMAN SERVS., U.S. DEP'T OF TREASURY & U.S. DEP'T OF LABOR, REFORMING AMERICA'S HEALTHCARE SYSTEM THROUGH CHOICE AND COMPETITION 56 (2018), https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf [hereinafter *Choice and Competition*] ("[I]ncumbent firms may use CON laws to thwart or delay entry or expansion by new or existing competitors. CON programs have also facilitated anti-competitive agreements among competitors." (footnote omitted)); *see, e.g.*, Katherine Restrepo, *North Carolina's Certificate of Need Law is One Reason Why Health Care Costs in Charlotte Are So High*, JOHN LOCKE FOUND. (June 15, 2016), https://www.johnlocke.org/update/health-care-update-north-carolinas-certificate-of-need-law-is-one-reason-why-health-care-costs-in-charlotte-are-so-high/ (describing a law suit against a Charlotte, NC hospital group alleging violations of the Sherman Antitrust Act for contractually prohibiting insurance companies from incentivizing subscribers to find lower cost service providers).

[23] *See* Complaint, *supra* note 9, at 18, 29, 31 (indicating that renting a mobile MRI machine is approximately $2,600 to $3,000 per day, plus administrative fees). This is not tied into any assessment of the safety or quality of his office, as an entity is required to meet those standards regardless of whether they rent equipment or own it. *Id.* at 29–30.

reexamine their CON statutes in light of illogical results that conflict with the legitimate goals of health care reform.

This Recent Development will look at certificate of need programs through the lens of the recent complaint filed by Dr. Singh in the Wake County Superior Court, in order to examine the economics, ethics, and outcomes behind certificate of need programs. By analyzing the constitutional arguments presented in that complaint in light of elevated state interest in matters of public health, this Recent Development will explore the question of whether the courts or the legislature are better suited to make meaningful changes to the CON scheme. As it stands, the CON program in North Carolina risks impeding innovative treatment styles and potentially provides a safe haven for health care monopolies. Ultimately, judicial deference to the state's police power will require opponents of CON to reframe the issue as an arbitrary legal restraint on constitutionally protected economic rights rather than as a "matter of public health."

Part II of this Recent Development will explain the basic theory behind certificate of need laws and will provide a brief history of the CON regime at both the state and federal levels. Part III addresses the real-world application issues that states face as a result of CON laws. This part will assess research results and theoretical errors, as well as the shifting policy goals used to justify certificate of need programs. Part IV will look specifically at North Carolina, which has one of the most expansive CON statutes in the United States, and yet is the only state whose Supreme Court has declared a CON statute to be in violation of the state constitution. Part V looks at the interplay between public health, the state police power, and judicial deference at both the federal and the state levels. The Recent Development concludes by considering the constitutional issues raised in Dr. Singh's complaint in light of North Carolina's judicial precedents regarding the CON statute, substantive due process, and state prohibitions on monopolies.

II. INTERESTING IN THEORY: THE HISTORY OF CERTIFICATE OF NEED PROGRAMS

Certificate of need statutes first emerged on the health care scene in the 1960s as programs that potentially offered cost-containment solutions.[24] New York was the first state to enact a CON program in 1964, with a handful of states following in its footsteps that year, and many more in the years to come.[25] The original state laws generally applied solely to hospitals and long-term care facilities, requiring the government to assess whether there was need for new facilities prior to the start of construction.[26] Due to the particularities of the health care market following World War II, there was tremendous incentive to create new facilities, but relatively few ways for government to influence what the private sector built and where.[27] This created a fear of redundancy in some areas and a lack of available resources in others. Through CON programs, state governments saw a method to control and direct health care facilities' resources and spending, and to prevent unnecessary duplication of health care costs.[28]

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[24] *See* Emily Whelan Parento, *Certificate of Need in the Post-Affordable Care Act Era*, 105 KY. L.J. 201, 209–10 (2017) ("In most instances, the government allows market forces to determine the appropriate supply of a product, and consumers to purchase the amount of that product that meets their needs. However, the market for healthcare services is not a normal market, and it is this recognition that led to the development of health planning authorities and ultimately to CON programs." (footnote omitted)).

[25] *See id.*; *see also* John D. Blum, *Finding a New Regulatory Pathway for the Old Labyrinth of Health Planning*, 19 ANNALS HEALTH L. 213, 214 (2010) (noting that Rhode Island, Maryland, and California also enacted CON programs in 1964). North Carolina's original CON law was enacted in 1971. Determination of Need for Medical Care Facilities, 1971 N.C. Sess. Laws 1164 (codified at N.C. GEN. STAT. §§ 90-289–291) (repealed 1973).

[26] *See* Joshua Tinajero, *The Need to Repeal Certificate of Need Laws to Improve America's Health Care System: A Dormant Commerce Clause Analysis*, 37 J. LEGAL MED. 597, 598 (2017) (arguing that parties should challenge CON under the Commerce Clause by arguing that CON laws facially and functionally discriminate against out-of-state competitors).

[27] *See* Parento, *supra* note 24, at 210 (explaining the regulatory issues following the enactment of the Hill-Burton Act of 1946).

[28] *See id.*; *see also* Patrick John McGinley, *Beyond Health Care Reform: Reconsidering Certificate of Need Laws in a "Managed Competition" System*, 23 FLA. ST. U. L. REV. 141, 155 (1995).

During this period, health care theorists suggested that there was "a direct correlation between capacity and utilization; when combined with the availability of third-party reimbursement, oversupply of resources will create its own demand for excessive use."[29] In other words, because of the provider reimbursement practices used by insurance companies during this period, in which providers were paid based on their cost per service plus a percentage of additional profit, there was no incentive for facilities and providers to closely monitor costs.[30] For example, policymakers believed that by artificially controlling the amount of hospital beds, all of the beds in existing facilities would remain filled and profitable. Furthermore, those beds would not be wasted on patients whose conditions did not require in-patient hospitalization, but who nevertheless might be hospitalized anyway by physicians and hospitals looking to increase their profits.[31] Additionally, policymakers feared that if the supply of available beds increased, lower demand per facility would cause the price of the empty beds to be passed onto those patients (and their corresponding insurance plans) actually occupying beds in any given facility.[32]

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[29] *See* Parento, *supra* note 24, at 210–11. This is known as "Roemer's Law" or the "Roemer Effect," named for Milton Roemer, a health policy theorist who first noted the relationship. *See* McGinley, *supra* note 28, at 155 ("In short, [the Roemer Effect says] the effect of excess supply of health services is the 'manufacture' of demand.").

[30] *See* Parento, *supra* note 24, at 226; *see also* McGinley, *supra* note 28, at 184–86 (explaining how managed care health care models have changed the reimbursement structure since the 1980s, rendering CON statutes not only redundant, but detrimental to cost saving).

[31] *See* Maureen K. Ohlhausen, *Certificate of Need Laws: A Prescription for Higher Costs*, 30 ANTITRUST 50, 50–51 (2015). Ohlhausen explains another iteration of the theory using competing hospitals A, B, and C. Hospital A gets an expensive, brand-new MRI machine, so patients want to go to hospital A to use the new machine instead of the old machines at hospitals B and C. Because of this, hospitals B and C both buy new MRI machines. According to the theory, now none of the hospitals has enough patients who require scans to recoup the cost of the machine. *Id.*

[32] *See, e.g.*, In re Certificate of Need for Aston Park Hosp., Inc., 282 N.C. 542, 549 (1973) ("[Defendants contend] that the overhead cost of vacant beds must be absorbed by the patients in the occupied beds and, consequently, the effect of excess hospital bed capacity will be less efficient service to patients at greater cost.").

This idea seemed reasonable to legislators at the time, and it had the strong support of the American Hospital Association, who lobbied tirelessly on behalf of CON regimes.[33] In 1974, Congress took things a step further by passing the National Health Planning and Resource Development Act ("NHPRDA"), a key component of which was a mandate to all states, requiring them to enact legislation establishing CON programs or else lose significant amounts of federal funding for state-wide and local programs.[34] Unsurprisingly, forty-nine states (many of which already had CON statues) fell in line with the federal mandate.[35]

Despite their rapid adoption throughout the United States, CON programs quickly began to show signs that they were not all the government hoped they would be. For example, a 1979 study found that while the hospital bed growth rate slowed between 1968 and 1972, the average cost per patient per day actually rose.[36] The national expenditures on health care continued to increase exponentially, with the Department of Health and Human Services reporting that in 1982, the country's annual health care spending had reached $332 billion, which was 10.5 percent of the gross national product.[37] In particular, expenditures on hospital care skyrocketed from $52.4 billion in 1974 to approximately $230.1 billion in 1989.[38]

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[33] *See* Ohlhausen, *supra* note 31, at 51. Ohlhausen suggests it is not surprising that the AHA and other hospital groups lobbied, and continue to lobby, for CON programs which heavily restrict new competitors from entering into the health care market. *Id.*

[34] National Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641, 88 Stat. 2225 (1975) (originally codified at 43 U.S.C. §§ 300k–300n-5) (repealed 1986).

[35] *See* Chad A. Heiman, *Shifting Purpose: Why Iowa's Certificate of Need Law is a Form of Economic Protectionism for Certain Iowa Health Care Providers and Should be Repealed*, 104 IOWA L. REV. 385, 393 (2018) (explaining that because of the threat to cut funding, every state had adopted a CON program by 1980 with the exception of Louisiana).

[36] *See* Lauretta Higgins Wolfson, *State Regulation of Health Facility Planning: The Economic Theory and Political Realities of Certificates of Need*, 4 DEPAUL J. HEALTH CARE L. 261, 269–70 (2001) (providing a thorough explanation of the federal government's early repeal of the CON mandate).

[37] *Id.* (marking the first time that national health care costs had exceeded 10 percent of the gross national product).

[38] McGinley, *supra* note 28, at 157.

Members of Congress, dismayed by the law's failure to control health care costs, noted that the regulatory structure of many CON programs was "a hindrance to flexible response by health care providers," and that the application process was "burdensome, costly and cause[d] needless delays."[39] Unsurprisingly, Congress repealed the NHPRDA in 1986, and the federal government now strongly advises against the use of CON programs.[40] However, to this day there are still CON programs in thirty-five states and the District of Columbia.[41]

III. FLAWED IN PRACTICE: THE DISAPPOINTING RESULTS AND EVOLVING JUSTIFICATIONS FOR STATE CON STATUTES

The reasons behind the failure of many states to repeal their CON laws range from legitimate concerns about the unique nature of the health care market to the more cynical fact that CON programs have the wholehearted support of the wealthiest special interest groups, which have political influence in state legislatures.[42]

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[39] Wolfson, *supra* note 36, at 270–71 (quoting U.S. Rep. Thomas DeLay). See 132 CONG. REC. 1460 (1986) for DeLay's full remarks.

[40] *See, e.g.*, Joint Statement of the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice on Certificate-of-Need Laws and South Carolina House Bill 3250 (Jan. 11, 2016), https://www.ftc.gov/system/files/documents/advocacy_documents/joint-statement-federal-trade-commission-antitrust-division-u.s.department-justice-certificate-need-laws-south-carolina-house-bill-3250/160111ftc-doj-sclaw.pdf [hereinafter Joint Statement]. The FTC and the Antitrust Division of the DOJ have strongly opposed certificates of need as anti-competitive practices that shield incumbent providers from the competition that would normally induce innovation, improvement, and lower costs. *Id.* at 6–7. These federal entities are also critical of CON programs because they delay entry into the market and make entry more expensive. *Id.*

[41] *See* Richard Cauchi & Ashley Nobel, *CON-Certificate of Need State Laws*, NAT'L CONF. OF ST. LEGISLATURES, http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx (last updated Feb. 28, 2019).

[42] *See* Parento, *supra* note 24, at 231–32 (discussing the long-standing belief amongst stakeholders that wealth, influence, connections, and resources play a much bigger role than public policy concerns in the certificate of need process); *see also* Ohlhausen, *supra* note 31, at 51 ("Government actors respond to political pressure, often exerted by special interests that seek to place their own, narrow interests ahead of the general public welfare."); Matthew D. Mitchell, *Do Certificate-of-Need Laws Limit Spending?* 16–20 (Mercatus Ctr., Geo. Mason U., Working Paper, 2016), https://www.mercatus.org/system/files/mercatus-

CON programs have also continued to thrive because the health care market is extremely complex and opaque, making it difficult to decisively establish a cause and effect relationship between these laws and the exorbitant amount of money the United States spends on health care.[43] Additionally, the policy goals of CON programs have shifted over the years, in order to justify their continued use.[44] Furthermore, CON laws simply are not well known to the general public, so it is not an issue that constituents write to their legislators about or expect to be debated *ad nauseam* on the campaign trail. Despite the various justifications for their continued use, certificate of need programs have fundamental theoretical flaws that produce results which tend to negate those justifications.

A. *The Economics Behind Certificate of Need Requirements*

CON laws represent a level of market regulation that is relatively rare in the American economy and would probably not be accepted outside of the notoriously complex health care market. Setting aside the legal question of whether state police power should extend this far in the name of "public health," it is important to address how these laws affect the market from an economic perspective. In her harsh criticism of CON programs, Federal Trade Commissioner Maureen Ohlhausen points out that "CON laws actively restrict new entry and expansion [of the health care market]. They displace free market competition with regulation and tend to help incumbent firms amass or defend dominant market positions."[45] By artificially restricting the supply of health care services, the government is

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mitchell-con-healthcare-spending-v1a.pdf (discussing how various economic models function under CON and suggesting that the non-normative "interest-group model" is an explanation for the persistence of CON statutes, regardless of their functionality and desirability).

[43] *See, e.g.*, Thomas Stratmann & Jacob W. Russ, *Do Certificate-of-Need Laws Increase Indigent Care?* 16 (Mercatus Ctr., Geo. Mason U., Working Paper No. 14-20, 2014), https://www.mercatus.org/publication/do-certificate-need-laws-increase-indigent-care.

[44] *See* Parento, *supra* note 24, at 226–30. For example, although originally envisioned as a predominantly economic strategy, over the years pro-CON policymakers have extended their purpose to include policy goals like improving health care quality and increasing access to charitable services. *Id.*

[45] Ohlhausen, *supra* note 31, at 52.

likely driving prices up and stifling the innovation that comes with a competitive free market.[46]

It is absolutely true that the health care market is a different animal than most commercial markets for a number of reasons. Unlike the typical consumer of goods, "consumers" of health care often have little or no knowledge about the services they purchase, and they frequently have little walk-away power due to health concerns.[47] Generally, health care consumers are sick patients who have no medical background with which to determine if a medical service is rendered properly or is necessary for a particular condition.[48] Additionally, insurance providers tend to insulate health care consumers from the actual cost of care, making it incredibly difficult for a consumer to weigh the cost against the benefit of treatment.[49] Beyond this, "[i]t is difficult for patients to hold providers accountable for cost comparisons because of the scarcity of price information" and the extreme variation in cost from one insurance plan to another.[50] Proponents of CON programs often point to these aspects of the health care market to support the legislation, but the inherent lack of transparency in health care is exactly why competition, or some other means of controlling pricing, is vital to the health care market.[51] Transparency and "well-proven and socially beneficial forces of free market competition"[52] are crucial to a patient's ability to make financially sustainable health care decisions, absent a single-payor or universal health care system.

There is another side to the argument, of course. While CON-supporters acknowledge that certificate of need laws might be unnecessary in a single-payor system, they argue that in the current

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[46] *Id.* at 51 ("Normally, if you want the price of something to decline, creating an artificial shortage of it is not the way to achieve that. There is no clear reason to expect that the basic laws of supply and demand would not apply . . . .").

[47] *See, e.g.*, Wolfson, *supra* note 36, at 262–64.

[48] *See id.*

[49] *See id.*

[50] *See id.* at 263.

[51] *See* Parento, *supra* note 24, at 206 ("[C]onsumption of healthcare services cannot be viewed as similar to consumption of a normal consumer product—most healthcare services are ordered for patients . . . .").

[52] Ohlhausen, *supra* note 31, at 52.

American health care system, the statutes provide much needed regulation and limit the effects of capitalism in the health care market.[53] Fear of a free-market approach to health care is legitimate because people need health care to be consistently affordable and accessible.[54] Although it is hard to find supporters of CON statutes, it is not difficult to find instances where, for example, hospitals have been forced to close their doors or have taken substantial economic hits due to competition from ambulatory surgical centers, which reduce their substantial out-patient surgery revenue.[55] This is particularly troublesome when a struggling hospital serves a rural area where patients have limited options for care. CON program proponents argue that ambulatory surgical centers "cherry-pick" patients with the best insurance, often excluding Medicaid beneficiaries.[56] Unlike hospital emergency rooms, these surgery centers are not required by federal law to accept patients regardless of their insurance status.[57] These are substantial concerns, but data

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[53] Mark Taylor, *States Scrutinizing Certificate of Need Programs*, HFMA (Feb. 17, 2017), *reprinted in* KENTUCKIANS FOR MORE HEALTHCARE OPTIONS (Feb. 18, 2017), http://www.kyhealthnow.org/state-scrutinizing-certificate-need-programs/ (citing retired state agency CON consultant, John Steen).

[54] See Blum, *supra* note 25, for a well-rounded assessment of the need for health planning and the problems with the current efforts to regulate through CON programs.

[55] *See, e.g.*, United States *ex rel.* Drakeford v. Tuomey Healthcare Sys., 675 F.3d 394 (4th Cir. 2012) (holding that a scheme devised to make up for loss of business to ambulatory surgical centers violated the Stark Law).

[56] *See* Matthew Glans, *Research & Commentary: Certificate of Need Laws Limit Access to Rural Hospitals*, HEARTLAND INST. (Feb. 26, 2016), https://www.heartland.org/publications-resources/publications/research--commentary-certificate-of-need-laws-limit-access-to-rural-hospitals?source=policybot.

[57] Federal law under the Emergency Medical Treatment and Labor Act of 1986 ("EMTALA") was enacted as a response to a practice among hospitals called "patient dumping," in which uninsured or underinsured patients were transferred from one hospital to another (usually from a private hospital to a public one) for non-medical reasons. In larger cities it was not infrequent in the 1980s for patients to arrive at public hospitals in the back of cabs in medically unstable condition. *See* BARRY R. FURROW ET AL., THE LAW OF HEALTH CARE ORGANIZATION AND FINANCE 178 (Barry R. Furrow et al. eds., 8th ed. 2018).

has consistently failed to show that certificate of need laws do anything to alleviate them.[58]

Undoubtedly, some measure of market regulation is needed, but CON regimes have not been effective solutions. Two 2016 studies of the economics behind CON programs stressed that although the health care market is certainly different from traditional markets, the basic theory of supply and demand still applies.[59] In a supply-and-demand model, restrictions on supply will never reduce per unit cost.[60] "[Supply restriction] *might* reduce overall healthcare expenditures . . . . But although reducing per unit cost is a worthy goal, it is far from obvious that reducing overall expenditures [in this manner] is desirable."[61] Normally, a supply restriction causes the per unit price of a good or service to rise, while that increased cost causes the quantity consumed to fall; thus, it is quite possible that when these are balanced, overall expenditure will be lower.[62]

However, there are two key problems with focusing on the reduction of overall health care expenditure. First, due to the third-party payor health insurance system in the United States, it is likely that even as supply restrictions cause per unit prices to increase, the quantity of services consumed will not fall as expected because consumers are unaware of that increased cost.[63] Of course, patients still pay for these increased health care costs indirectly, through higher insurance premiums or taxes, but there is a disconnect because a patient does not experience this as a price increase of the medical service itself.[64] The less price-aware the average consumer

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[58] *See* discussion *infra* Section III.B; *see also* Blum, *supra* note 25, at 216–18 ("All too often, regulation is a response to market failures or abuses, but without strategic planning backing regulatory responses, such interventions are stop gap measures that often only incite abuses in other areas of the delivery system.").

[59] *See* Mitchell, *supra* note 42, at 6; *see also* James Bailey, *Can Health Spending Be Reined in through Supply Constraints?: An Evaluation of Certificate-of-Need Laws* 9 (Mercatus Ctr., Geo. Mason U., Working Paper, 2016), https://www.mercatus.org/system/files/Bailey-CON-v1.pdf (discussing the economic theories used to analyze CON programs).

[60] Mitchell, *supra* note 42, at 5.

[61] *Id*.

[62] *Id*.

[63] *Id.* at 7.

[64] *Id.*

is, the more off-balance the demand model will be, so the supply restriction is just as likely to increase overall expenditure as it is to reduce it.[65] Second, if overall expenditures do decrease, "they do so only by restricting the availability of services, limiting consumer choice, and reducing consumer welfare."[66] In other words, the only way CON programs successfully achieve lower health care spending is if they succeed at restricting health care utilization enough to compensate for the increase in per-service price.

The root of the issue, and a key factor that sets health care apart from other markets is that people are always going to need medical care, regardless of the price. If prices disincentivize people from seeking preventive care or needed medical treatment, the temporary expense saved is likely to turn into a larger expense down the line.[67] While issues like "moral hazard" are present in the health care market,[68] patients typically get medical care at the direction of physicians.[69] Even with the push towards consumer-driven health care, patients cannot make fiscally responsible medical decisions if they do not have access to pricing information until after the services are rendered.[70] The degree to which CON requirements contribute to higher pricing only exacerbates these health care market-specific quirks. CON laws have not accomplished what they set out to do, at least in part because they have incentivized monopolistic practices

[65] *Id.*

[66] *Id.*

[67] *See* Ateev Mehrotra et al., *Promise and Reality of Price Transparency*, NEW ENG. J. MED. 1348, 1350 (2018) (explaining the complications with "consumer driven health care," and pointing out that methods like imposing high deductibles may decrease overall spending, but the reduction comes from patients simply declining to seek care because of the price).

[68] *See* Bailey, *supra* note 59, at 12–14 (referencing the insurance concept of moral hazard, a theory observed in the health insurance industry that people who have insurance typically use more services and take more risk).

[69] *See* Mehrotra et al., *supra* note 67, at 1351 ("Patients also value staying within the same health system to ensure that their care is coordinated, and if their physician recommends a given facility for a test or another clinician for a referral, patients are loath to override that recommendation simply on the basis of price.").

[70] *Id.* at 1348–51.

without regulating prices in a market where utilization reduction can only go so far to cut costs.[71]

B. *Justifying Certificate of Need Laws: Lofty Goals and Realistic Results*

As mentioned above, states initially established CON programs to combat the consequences of the "cost-plus" method of provider reimbursement, in which physicians and hospitals received more insurance money the more they spent per patient.[72] Today, however, most indemnity and cost-plus contracts have been replaced by managed care organizations ("MCOs"), which negotiate reimbursement rates contractually with provider networks.[73] Medicaid has also largely transitioned from traditional fee-for-service models to managed care networks, alleviating the risk that providers will not accept Medicaid.[74] This shift has removed much of the early justification for enacting CON statutes because managed care employs both supply-side and demand-side controls aimed to reduce costs.[75] Largely because of this radical shift in the structure of the health care market, alternate policy goals have emerged to

[71] Reduction in utilization of health care will always have practical limitations, the first being that people rely on health care in its myriad forms to live. Secondly, from a more economic standpoint, insurance prices impose artificial caps on patient costs. Utilization reduction efforts in modern insurance plans such as high cost-sharing often do not combat this because the costs of services have become so high that a patient can reach a high deductible with one service. *See id.* at 1350–51.

[72] *See* discussion *infra* Part I.

[73] *See* FURROW ET AL., *supra* note 57, at 63. MCOs contract with providers to create networks for their subscribers to use at discounted rates. *Id.* They further attempt to control costs through frequent utilization review, capitation payment models, integrated delivery systems, cost-sharing, and reference pricing. *Id.* at 63–70. MCOs have experienced some success at reducing costs over the years, but generally health care spending continues to rise. *Id.* at 63; *see also* McGinley, *supra* note 28, at 161–74 (explaining that CON programs and managed care or managed competition are incompatible).

[74] *Medicaid Transformation*, N.C. DEP'T OF HEALTH & HUMAN SERVS., https://www.ncdhhs.gov/assistance/medicaid-transformation (last visited Mar. 6, 2019).

[75] *See* FURROW ET AL., *supra* note 57, at 62–75.

justify retaining CON programs.[76] These include: (1) increasing charitable care; (2) ensuring access to care (including rural access to care); and (3) increasing the quality of care.[77]

There is nothing unusual about this list. In fact, a health care policy that does not include each of these goals would be suspect. What is unusual, however, is that studies find either a negative or a neutral correlation between CON programs and desired policy outcomes when data is compared between CON states and non-CON states.[78] Most recently, researchers at the Mercatus Center have conducted several thorough studies regarding the efficacy of CON programs. When assessing patient accessibility to diagnostic imaging in CON states compared to non-CON states, they found that states with CON programs typically have fewer non-hospital services,[79] reduced overall numbers of providers,[80] and reduced availability of imaging services.[81] The same study also found that states requiring certificates of need for diagnostic imaging equipment generally had higher numbers of residents who travel out of state to receive services.[82] The data also showed that states with CON requirements file fifty-one percent more hospital claims (as opposed to non-hospital claims) for diagnostic imaging services than non-CON states.[83]

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[76] See, e.g., Parento, *supra* note 24, at 223–30 for a comprehensive analysis of these policy justifications.

[77] *Id.*

[78] *See, e.g.*, Thomas Stratmann & Matthew C. Baker, *Are Certificate-of-Need Laws Barriers to Entry?: How They Affect Access to MRI, CT, and PET Scans* 19–20 (Mercatus Ctr., Geo. Mason U., Working Paper, 2016), https://www.mercatus.org/system/files/Stratmann-CON-Barriers-to-Entry.pdf.

[79] *See, e.g.*, *id.* at 17.

[80] *Id.* at 17–19 (showing statistically significant differences at the ten percent level for all non-hospital services and indicating that this is some evidence that non-hospital providers may be reduced because they are barred from market entry by CON requirements).

[81] *Id.*

[82] *Id.* at 20.

[83] *Id.* at 16–17 ("For the MRI utilization regressions, the point estimate on MRI-CONs implies that in states with these CON regulations, 51 percent more MRI claims are filed by hospitals than by other providers, as compared with states without these regulations. That finding is consistent with the hypothesis that the MRI-CONs benefit hospitals relative to other providers."). CT and PET scan data

Another study produced statistically significant results indicating that states with CON statutes are consistently associated with fewer rural hospitals.[84] Additionally, studies have suggested that CON laws have negative correlations with the overall quality of care,[85] as well as with the accessibility of care in general.[86] Research findings have also indicated that no statistically significant implications exist regarding CON programs' effect on the provision of charitable care, not to mention relying on CON programs to provide care to the uninsured, which has drawn harsh criticism from scholars in the field.[87] Although these findings in no way suggest

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show similar trends. *Id.* at 17. This is particularly concerning when considering the previously mentioned elevated expense of hospital services.

[84] *See* Thomas Stratmann & Christopher Koopman, *Entry Regulation and Rural Health Care: Certificate-of-Need Laws, Ambulatory Surgical Centers, and Community Hospitals* 15–17 (Mercatus Ctr., Geo. Mason U., Working Paper, 2016), https://www.mercatus.org/system/files/Stratmann-Rural-Health-Care-v1.pdf (stressing that the stated purpose for regulating ASCs under CON programs is because of the claim that these centers take away outpatient business from hospitals, leading to economic peril for rural hospitals, but in reality states with ASC-CON requirements have both fewer rural ASCs and fewer rural hospitals).

[85] *See, e.g.*, *id.* (indicating that of all measures in this study, the largest statistical difference found is in deaths following serious post-surgery complication, where there is an average of six more deaths per 1,000 patient discharges in CON states than in non-CON states). Regulation through CON programs can affect health outcomes in more direct ways too—for example, in Virginia a newborn died after a complication resulted in early delivery that required a high tech NICU. The baby was delivered at a hospital without this equipment, having applied for and been denied a CON to expand its neonatal unit due to lack of "need." There was a hospital six miles away with the specialty equipment, but the only ambulance that could transport the baby safely was out on another call. Eric Boehm, *How Virginia's Hospital Licensing Laws Led to an Infant's Death*, REASON (Jan. 25, 2017), https://reason.com/archives/2017/01/25/virginia-certificate-of-need-hospital.

[86] *See* Stratmann & Russ, *supra* note 43, at 10–11, 14 (explaining that the regression analyses showed that states with CON programs have 99 fewer hospital beds per 100,000 people than those without CON programs, and when controlling for only CONs that regulate acute hospital beds, those states have an average of 133 fewer beds per 100,000).

[87] *See* Ohlhausen, *supra* note 31, at 52–53 (suggesting that the competition insulation benefits for incumbent providers are unevenly distributed based on arbitrary factors, like area population, that have nothing to do with how much indigent care is provided, and that a better way to insure the provision of indigent

that repealing or reforming CON regulation is the miracle cure-all for our ailing health care system, they certainly illustrate that the perceived benefits of CON programs do not outweigh the harm they cause to people like Dr. Singh and his patients. Though a state may indicate a "rational" basis behind a law, if after fifty years, the law does not yield the desired results and continues to encroach upon the rights of citizens, courts should intervene to uphold those rights.[88]

IV. NORTH CAROLINA'S COMPLEX RELATIONSHIP WITH CERTIFICATE OF NEED

North Carolina has a complicated history with its CON program. Today, the state has one of the most comprehensive CON statutes in the United States.[89] The average state with a CON program regulates approximately fourteen categories of medical services while North Carolina's statute regulates twenty-five separate categories of health care facilities and medical equipment.[90] Additionally, North Carolina's CON program is stringently enforced.[91] Despite consistent efforts in the state legislature, attempts to reform the

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care would be for states to directly fund it); *see also* Parento, *supra* note 24, at 224–25 ("[I]ncumbents argue that the guarantee of restricted competition allows them to negotiate *higher* prices with private insurance companies, thereby conferring a larger profit margin, which allows for more resources to provide care to poorer patients without insurance."). Studies have not shown a statistically significant difference in the amount of indigent care actually provided by hospitals in CON states compared to non-CON states, however. *Id.* at 225; *see also* Stratmann & Russ, *supra* note 43, at 14, 30 (looking at uncompensated care as the sum of hospital-level uncompensated care in a state divided by the number of beds in the reporting hospitals).

[88] *See* discussion *infra* Part V.

[89] *See* CHRISTOPHER KOOPMAN & THOMAS STRATMANN, CERTIFICATE-OF-NEED LAWS: IMPLICATIONS FOR NORTH CAROLINA 2 (Mercatus Ctr., Geo. Mason Univ., 2015), https://www.mercatus.org/system/files/Koopman-Certificate-of-Need-NC-MOP_1.pdf ("North Carolina's CON program currently regulates 25 different services, devices, and procedures, which is much more than the national average.")

[90] N.C. GEN. STAT. § 131E-177(4) (2018).

[91] *See* Restrepo, *supra* note 14 (providing an overview of CON laws in North Carolina); *see also* KOOPMAN & STRATMANN, *supra* note 89 (explaining that while North Carolina's policy is among the strictest, it also presents the state legislature and the Department of Health and Human Services with an opportunity to "reverse course" and make a notable change).

statute have largely been unsuccessful.[92] Although it ranks third among the nation's most restrictive CON statutes, North Carolina has the distinction of being the only state whose Supreme Court has ruled that a CON program is in violation of the state constitution.[93]

A. *The CON Law That Almost Wasn't: The North Carolina Supreme Court Decision in* Aston Park

The North Carolina Generally Assembly enacted the state's first CON law in 1971. That same year, Aston Park Hospital applied for a certificate of need to build a new, larger facility in the Asheville area.[94] The governing state agency denied the hospital's application, on the grounds that the new facility "would be an unnecessary and weakening duplication of services and undesirable dilution of physicians' time in treating patients at widely separated hospitals."[95] When the CON statute was enacted, the state designated a need for 94 additional hospital beds in the area, but 90 of those were already approved to be provided by another hospital whose plans were finalized prior to the passage of the CON statute.[96] Aston Park

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[92] *See e.g.*, Dan Way, *Certificate of Need May Be on the Chopping Block, Again*, CAROLINA J. (Mar. 28, 2017, 4:00 AM), https://www.carolinajournal.com/news-article/certificate-of-need-may-be-on-the-chopping-block-again/ (discussing a 2017 Senate Bill aimed at phasing out the CON statute). Certificate of Need reform has been a strangely partisan issue, with republicans traditionally in favor of deregulation. This mirrors typical health care debates, in which conservative-leaning politicians (in both parties) push for managed competition, whereas liberals are in favor of government regulation of the health care market, but CON laws do not actually seem to achieve desired policy goals. If the government controlled the pricing of services in addition to restriction through CON programs it would certainly be a more typical ideological debate such as the free-market versus universal health care discussion. As it stands now, however, CON programs favor large hospital incumbents and do not control how much those certificate holders charge for services.

[93] *See* Robert M. Anderson, *The Judiciary's Inability to Strike Down Healthcare Service Certificate of Need Laws Through Economic Substantive Due Process: A Call for Legislative Action*, 2 CHARLESTON L. REV. 703, 720 (2008).

[94] In re Certificate of Need for Aston Park, 282 N.C. 542, 542–43 (1973).

[95] *Id.* at 543 (quoting the explanation given to Aston Park Hospital by the North Carolina Medical Care Commission, which then served the role that the State Health Planning and Development Agencies would take on after the passage of NHPRDA).

[96] *Id.*

challenged the state decision on the grounds that the statute violated Article I, Sections 1, 19, 32, 34, and Article II, Section 1 of the North Carolina Constitution.[97]

After hearing the hospital's argument, the North Carolina Supreme Court struck down the 1971 CON statute as unconstitutional, carefully distinguishing a certificate of need requirement from the state's legitimate interest in enacting licensing requirements that govern facility quality and safety standards.[98] While the court did not address each constitutional violation separately, it concluded that "the Constitution of [North Carolina] does not permit the Legislature to authorize a state board or commission to forbid persons, with the use of their own property and funds, to construct adequate facilities" merely because there is a fear that competition might adversely affect other hospitals.[99]

Regarding Article I, Sections 32 and 34, (North Carolina's constitutional prohibitions on exclusive emoluments and monopolies, respectively) the court expressed that, although the health care market is quite different to other markets in some respects, "[the court] know[s] of no reason to doubt its similarity thereto in its response to the spur of competition."[100] The court expanded on this by clarifying that in industries like public utilities, where competition is undesirable, "the State has undertaken to protect the public from the customary consequences of monopoly by making the rates and services of the certificate holder subject to regulation and control by the Utilities Commission."[101] Under the CON regime, however, no such rate regulation existed, and the artificial creation of monopolies could not be reconciled with their constitutional prohibition.[102] The court also specifically delved into a due process analysis under Article I, Section 19, concluding:

> [I]t is necessary to a valid exercise of the police power that the proposed restriction have a reasonable and substantial relation to the evil it purports to remedy. We find no such reasonable relation between the

[97] *Id.*
[98] *Id.*
[99] *Id.* at 549.
[100] *Id.*
[101] *Id.* at 550.
[102] *Id.* at 549.

> denial [of Aston Park's CON application] . . . and the promotion of the public health.[103]

The court ultimately held that the certificate of need statute had violated Aston Park Hospital's substantive due process rights, guaranteed by the North Carolina Constitution, in addition to the anti-monopoly and anti-exclusive emoluments clauses.[104]

It is not often a state's highest court holds a statute in violation of so many constitutional principles, but Congress ultimately rendered the judgment in *Aston Park* moot when it enacted NHPRDA in 1974.[105] In *Morrow v. Califano*,[106] North Carolina sued to challenge the provision of the federal statute which mandated that state legislatures enact CON laws.[107] The state argued that the mandate represented an unconstitutional interference with the North Carolina Constitution and the state's legislative process; thus, the state contended that it was overly coercive and violated the principles of state sovereignty and federalism.[108] The District Court for the Eastern District of North Carolina rejected those arguments, concluding the federal government action was constitutional.[109]

Although the North Carolina Supreme Court has never actually overruled its decision in *Aston Park*, the state legislature enacted a new CON statute in 1977 pursuant to the federal mandate in NHPRDA.[110] "The *Morrow* decision, thus, merely confirmed the legislature's federally endorsed circumvention of *Aston Park*."[111] Despite the outcome of North Carolina's attempt to challenge the

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[103] *Id.* at 551.

[104] *Id.* at 550–52.

[105] National Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641, 88 Stat. 2225 (1975) (originally codified at 43 U.S.C. §§ 300k–300n-5) (repealed 1986); *see also* discussion *infra* Part II.

[106] 445 F. Supp. 532 (E.D.N.C. 1977), *aff'd mem.*, 435 U.S. 962 (1978).

[107] *Id.* at 533.

[108] *See id.*

[109] *Id.* at 534 ("We perceive nothing unconstitutional either in the purposes of the Act or in the condition thereby attached to health grants made to the States under federal health programs.").

[110] *See* Joshua A. Newberg, *In Defense of* Aston Park*: The Case for State Substantive Due Process Review of Health Care Regulation*, 68 N.C. L. Rev. 253, 260 (1990).

[111] *Id.*

constitutionality of certificate of need laws in the 1970's, some scholars believe that, absent the federal mandate, CON laws should now be challenged under a substantive due process analysis.[112]

B. *North Carolina's CON Statute Today*

Perhaps to counteract the *Aston Park* court's assertion that CON programs did not reasonably relate to the promotion of public health, the preamble to the current North Carolina CON statute states several grounds that directly link it to the state's legitimate interest in the furtherance of public health.[113] These include controlling the cost, utilization, and distribution of health care facilities to guarantee equal access to services; reducing the duplication and unnecessary use of medical services; and alleviating the "enormous economic burden on the public."[114] With this strong public health justification for the statute, the legislature clearly sought to implicate the state's police power, potentially deterring future constitutional challenges to the law.[115]

In addition to setting forth the types of activities it regulates, the statute also establishes the criteria that will be considered upon review of an application.[116] The list is extensive, and one can easily understand how an entire industry has grown around CON application consulting, without which the average physician could never hope to satisfactorily address all of the criteria listed.[117] In Dr.

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[112] *See generally id.* (suggesting that in instances representing a "legislative failure," courts are justified in engaging in substantive due process review of economic legislation, and that state courts with elected judges are particularly positioned to take on this role when action is called for); *see also* Anderson, *supra* note 93 (explaining the judiciary's unwillingness to interfere in certificate of need-related issues, and advocating for a shift back to means-ends scrutiny for economic substantive due process issues).

[113] *See* N.C. GEN. STAT. § 131E-175 (2018).

[114] *Id.*

[115] *See* LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT 131–38 (2d ed. 2008) (explaining the state public health powers in the modern constitutional era).

[116] N.C. GEN. STAT. § 131E-183 (2018).

[117] *See* Complaint, *supra* note 9, at 23 (alleging that, because of the extensive review criteria, a CON applicant must hire a team of experienced consultants and economic specialists to successfully generate the data, plans, and projections required); *see also, e.g.*, *North Carolina: Certificate of Need (CON) Overview*,

Singh's case, for example, he alleges that the price of preparing an MRI-CON application would cost him around $40,000 in pre-application consulting fees and would probably take many months to complete.[118] Among other things, an application must identify the population to be served and demonstrate the need for the services within that population, specifically highlighting any minority groups to be served.[119] An applicant must also show that her proposal is the most fiscally sound by providing financial and operational projections, showing availability of resources and qualified personnel, and demonstrating that any enhanced competition will have a positive impact upon cost effectiveness, quality, and access of the services proposed.[120]

The requirements themselves, while burdensome, seem to reflect sound public health goals. However, even upon successfully meeting all of the requirements, an applicant is still more likely to be rejected than not, particularly for MRI-CONs.[121] In his complaint, Dr. Singh alleges that the state's "competitive-review" system is responsible for this because it allows NCHHS to reject applications simply because another application is chosen to fill that area's "need."[122] The review system also gives competitors a 30-day period to submit comments and exhibits challenging the representations made in the application.[123] Dr. Singh's complaint also indicates that the scarcity of new "need" determinations for fixed MRI scanners ensures that MRI-CONs are always subject to competitive review, and typically the application is the subject of several challenges from competitors during the 30-day window.[124] If the agency

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RES. & PLAN. CONSULTANTS, LP, https://www.rpcconsulting.com/certificate-of-need/north-carolina/ (last visited Mar. 9, 2019).

[118] Complaint, *supra* note 9, at 23. The $40,000 is on top of the application fee, as well as the cost of hiring an attorney to navigate the challenges that will likely arise once the CON application has been submitted. *Id.*

[119] N.C. GEN. STAT. § 131E-183(3) (2018).

[120] *Id.*

[121] *See* Complaint, *supra* note 9, at 26–27.

[122] *See id*. at 24 (citing N.C. GEN. STAT. § 131E-183(a)(1)).

[123] N.C. GEN. STAT. § 131E-185(a1)(1) (2018).

[124] *See* Complaint, *supra* note 9, at 26 ("Given the scarcity of new need determinations for fixed MRI scanners and the adversarial nature of these proceedings, qualified providers eager to offer new services to patients are forced

approves an application, these challenges continue in the form of administrative hearings and potentially litigation in the state court system.[125] Dr. Singh argues that MRI-CONs are extremely valuable because they confer the "tremendous economic advantage that comes with holding exclusive legal rights to own and operate [MRI] scanners" in a particular service area.[126] This incentivizes incumbent MRI-CON holders to challenge all new CONs in the area.[127]

V. IS *FORSYTH IMAGING* THE NEXT *ASTON PARK*?

The complaint filed by Dr. Singh against the North Carolina Department of Health and Human Services requests that the court grant the plaintiff declaratory and injunctive relief, on the grounds that North Carolina's CON statute violates the state's constitution. Specifically, the complaint alleges violations under the following provisions: (1) the anti-monopoly clause of Article I, Section 34; (2) the exclusive emoluments clause in Article I, Section 32; (3) the substantive due process guarantee in Article I, Section 19 (Law of the Land clause); and (4) the equal protection guarantee in Article I, Section 19.[128] Essentially, the alleged constitutional violations mirror those which persevered against the CON statute forty-six years ago in *Aston Park*.[129]

Since that time, however, there have been no successful constitutional challenges to the statute. The judicial branch has continuously upheld state CON programs as a legitimate exercise of the state's police power, through which states have an inherent authority to enact and enforce laws to protect and promote "the

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to aggressively compete with one another—not in the marketplace [by lowering rates and providing top quality services], but in the CON-application process.").

[125] N.C. GEN. STAT. § 131E-188 (2018). Following administrative hearings, "[a]ny affected person who was a party in a contested case hearing shall be entitled to judicial review of all or any portion of any final decision . . . . The hearing shall be to the Court of Appeals . . . ." *Id.* § 131E-188(b).

[126] Complaint, *supra* note 9, at 26.

[127] *Id.* ("[I]ncumbent MRI providers frequently file written comments and petitions for contested-case hearings in an attempt to stonewall the introduction of new, competing MRI scanners.").

[128] *Id.* at 34–38.

[129] *See id.*; *see also* In re Certificate of Need for Aston Park, 282 N.C. 542, 546 (1973).

health, safety, morals, and general welfare of the people."[130] Laws enacted for the advancement or the preservation of public health are likely to survive most constitutional challenges in both federal and state courts, as this type of government action exemplifies a compelling state interest.[131] Public health, in particular, brings to the forefront an inherent ideological tension in the United States between the desire for limited government and the idea that our government should protect the health and wellbeing of its citizens.[132] This conflict reflects the tendency of public health laws to clash with individual liberties that are considered most fundamental to an American way of life. Because of that struggle, it is all the more important for courts to engage with these cases.

A. *North Carolina's Law of the Land Clause Will Not Invalidate the State's CON Statute*

Dr. Singh and the Forsyth Imaging Center allege that the CON requirement, both on its face and as applied, violates the substantive due process and equal protection rights guaranteed by the North Carolina Constitution's Law of the Land Clause.[133] The complaint asserts that because "the MRI-CON requirement lacks a real and substantial (or even a rational) relationship to protecting the health or safety of North Carolina patients," it violates Dr. Singh's substantive due process right to freely participate in the health care market without being subjected to "arbitrary, irrational, and protectionist legislation."[134] The equal protection allegation challenges the statute on the grounds that it makes an arbitrary distinction between CON-holders and providers without a CON because whether a provider is permitted to own an MRI scanner under the law is not based on that provider's ability to provide safe and affordable MRI scans.[135] Although these claims reflect

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[130] *See* Michael R. Ulrich, *Law and Politics, an Emerging Epidemic: A Call for Evidence-Based Public Health Law*, 42 AM. J.L. & MED. 256, 260 (2016) (quoting GOSTIN, *supra* note 115).

[131] *See* GOSTIN, *supra* note 115, at 141–42.

[132] *See* Ulrich, *supra* note 130, at 261–62 (expressing this tension between the social compact theory and the theory of limited government).

[133] N.C. CONST. art. I, § 19; *see* Complaint, *supra* note 9, at 36–38.

[134] *See* Complaint, *supra* note 9, at 36–37.

[135] *Id.* at 37–38.

seemingly logical reasoning, neither are likely to succeed because of the relationship between the judicial branch and the state police power. In balancing the economic liberty interest with the state's interest in "public health," courts hearing this case will apply rational basis review, which is notoriously deferential to the legislature.[136] Under a rational basis test, modern courts generally refuse to consider the actual rationale behind a particular policy or its effectiveness, curtailing the substantive analysis of claims like Dr. Singh's.[137]

Although it is unlikely that the Law of the Land Clause challenge will succeed here, this case does present the judiciary with an occasion to reconsider the level of deference actually required when adjudicating matters of public health, as well as whether this case fits into that category. In what is regarded as the foundational public health law case, *Jacobson v. Massachusetts*,[138] the Supreme Court recognized that a state has the authority to limit individual liberty to the extent necessary to promote public health and safety, including enforcing mandatory vaccinations, quarantines, and other measures that would otherwise be considered a gross abuse of power.[139] That said, state police power, while substantial, is not unlimited. The *Jacobson* opinion, considered settled doctrine since 1905, "established a floor of constitutional protection for individual rights, including five standards of judicial review: necessity, reasonable methods, proportionality, harm avoidance, and

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[136] *See* GOSTIN, *supra* note 115, at 137–40 ("Rationality review almost always results in a finding that police power regulation is constitutional."). The reason behind the application of rational basis review instead of a stricter level of scrutiny is that courts since the *Lochner* era have designated economic liberty interests to be non-fundamental in most cases, and this case does not implicate discrimination against a protected class like race, sex, national origin, or disability. *Id.*; *see also* Anderson, *supra* note 93, at 730 (explaining that certificate of need laws will survive the rational basis standard for economic substantive due process).

[137] *See* GOSTIN, *supra* note 115, at 138–39 ("Scientific evidence is the raison d'être of public health action, Yet, in a rational basis review, the state is not obligated to produce scientific evidence. 'A legislative choice is not subject to courtroom fact finding and may be based on rational speculation unsupported by evidence or empirical data.'").

[138] 197 U.S. 11 (1905).

[139] *Id.* at 24–25.

fairness."[140] However, the judicial branch has largely determined that a traditional rational basis review of substantive due process and equal protection challenges to CON statutes is appropriate.[141]

Courts do not make factual inquiries under rational basis review, and certainly do not explore whether legislation is based on peer-reviewed, scientific, or economic evidence.[142] Although the judicial branch claims that the legislature is best situated to address matters of public policy, nothing ensures that the legislature's public policy determinations have any rational relation to the ends they intend to achieve. "This lowest standard of review does not force public health authorities to justify their actions by demonstrating a significant risk and showing the intervention is likely to ameliorate that risk; nor does it usually require authorities to justify targeting particularly vulnerable or unpopular groups."[143] Although there are dangers of an overly powerful judiciary, the same is true for the legislature. Courts should be willing to analyze all of the facts presented, particularly when liberty interests are at stake.

Although the North Carolina Supreme Court has indicated that the guaranteed protections of the state constitution are intended to be interpreted broadly compared to those in the Federal Constitution,[144] in *Hope—A Women's Cancer Center, P.A. v. North Carolina*,[145] the North Carolina Court of Appeals did not apply any heightened scrutiny when reviewing the plaintiff's economic

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[140] GOSTIN, *supra* note 115, at 130–31.

[141] *Id.* at 138–39.

[142] *Id.* at 139; *see also* Ulrich, *supra* note 130.

[143] GOSTIN, *supra* note 115, at 140.

[144] *See* J. Michael McGuinness, *The Rising Tide of North Carolina Constitutional Protection in the New Millennium*, 27 CAMPBELL L. REV. 223, 238 (2005) (explaining potential for the North Carolina Constitution to be interpreted as having far more broad protections for individuals than the Federal Constitution while discussing Corum v. Univ. of N.C., 330 N.C. 761 (1992)) (citing State v. Ballance, 229 N.C. 764, 769 (1949)); *see also, e.g.*, Good Hope Health Sys. v. N.C Dep't of Health and Human Servs., 189 N.C. App. 534 (2008) (reviewing federal constitutional challenges to the agency's decision to revoke a CON it had previously awarded to a facility while the facility was arranging financing for construction). For a breakdown of relatively recent challenges to CON statutes in the federal courts under the Commerce Clause, see Parento, *supra* note 24, at 233–37.

[145] 203 N.C. App. 593 (2010).

substantive due process challenge to the CON statute.[146] In that case, the plaintiff challenged the state's denial of its application for a fixed breast MRI scanner to detect and treat breast cancer.[147] Although the court acknowledged the Law of the Land Clause was meant to "limit the state's police power to actions which have a *real or substantial* relation to the public health," it took an extremely permissive view when assessing "whether the means undertaken in the CON law are reasonable in relation to this purpose."[148] In applying the rational basis test, the court did not challenge the assertions of fact in the preamble to the CON statute, instead holding that the reasons for enacting the statute listed therein were legitimate, and it was reasonable for the legislature to believe that the statute would remedy them.[149] The court's attitude in *Hope* makes it doubtful that

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[146] *Id.* at 603 ("These constitutional protections have been consistently interpreted to permit the state, through the exercise of its police power, to regulate economic enterprises provided the regulation is rationally related to a proper government purpose." (quoting Poor Richard's Inc. v. Stone, 322 N.C. 61, 64 (1988))).

[147] *Id.* at 595.

[148] *Id.* at 602–03; *see id.* at 605 ("[F]inding the statute rationally related to a legitimate purpose where 'the legislature *could have* reasonably believed that the statute would promote [the] ends . . . .'") (quoting Armstrong v. N.C. State Bd. of Dental Exam'rs, 129 N.C. App. 153, 161–62 (1998)) (emphasis added)).

[149] *Id.* at 604–05. For perspective on how the Fourth Circuit treats federal constitutional challenges to CON statutes under a rational basis analysis, see Colon Health Ctrs. of Am. v. Hazel, 813 F.3d 145 (4th Cir. 2016). In *Colon Health Centers*, the Fourth Circuit rejected the out-of-state plaintiff's argument that the CON statute was indicative of economic protectionism, designed to benefit in-state economic interests by burdening out-of-state competition. *Id.* at 151. Pointing to the state's justifications for the statute, the court held that "[a]ppellants 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 [the] citizens . . . ." *Id.* at 153. Similar to the North Carolina Court of Appeals in *Hope*, the Fourth Circuit was completely unwilling to look into whether the state's justifications for the CON program were logical or supported by fact in any way, instead suggesting that the plaintiff present its factual findings regarding the anticompetitive risks and ineffectiveness of CON statutes to the Virginia General Assembly: "'There was a time' when courts 'rigorously scrutinize[d] economic legislation' and 'presumed to make such binding judgments for society.' 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." *Id.* at 158 (alteration in original) (citation omitted).

Dr. Singh's claims under Article I, Section 19 will do much to move the needle in the direction of invalidating the law.

It might be possible to reshape the issues, however, and convince a court that this statutory and regulatory regime does not reasonably relate to the state's legitimate public health concerns. If the context of the law shifts from a matter of public health to a purely economic constraint, Dr. Singh's case might be viewed as arbitrary government action that infringes on his rights without justification. This would require the court to take the evidence and results of the CON program into consideration when determining whether the CON statute passes the rational basis test.[150] While it is without question that the legislature has the inherent power to enact reasonable legislation to protect the health of citizens, it is important to remember that part of the judiciary's role is to check that power when it is being exercised in an irrational manner. Constitutional inquiries are not isolated from reality or facts, and courts can and should play a role in assessing whether there is reasoned logic behind laws that restrict individual liberties.

B. *North Carolina Judicial Review of Anti-Monopoly and Exclusive Emoluments Claims*

Dr. Singh's complaint challenges the constitutionality of North Carolina's CON programs on two additional and related grounds: the constitutional prohibitions against monopolies[151] and exclusive

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The court continues by asserting that to rule against the CON statute would be to undermine the state's police power, which is a fundamental aspect of the system of federalism. *Id.*

[150] In determining that law does not meet the legislature's public health ends, however, the court would need to tread carefully so as not to limit the General Assembly's ability to enact legislation that similarly infringes on the rights of citizens but does function to further the state's legitimate public health goals. *See generally* Blum, *supra* note 25 (explaining that while CON statutes have gotten lost along the way, they were enacted to address legitimate concerns, and rational, long-term health care planning and regulation is necessary in the American health care system).

[151] N.C. CONST. art. I, § 34 ("Perpetuities and monopolies are contrary to the genius of a free state and shall not be allowed."); *see also* Complaint, *supra* note 9, at 34.

emoluments.[152] There is less case law in this area, but both claims were successful in *Aston Park*.[153] Dr. Singh alleges that the MRI-CON program gives CON-holders a monopoly by awarding them the exclusive privilege of providing MRI services and denying all other providers from doing so.[154] The complaint insists that "[t]he purpose of the MRI-CON requirement is to protect incumbent MRI providers from competition" and that protectionism is not a legitimate basis for legally preventing Dr. Singh from providing safe and affordable MRIs to patients.[155] For the same reason, Dr. Singh argues that the CON statute violates the constitutional protection against exclusive emoluments for private actors.[156] Although these are compelling arguments, when taken with the results of CON programs, which do functionally shield incumbent providers from competition, it may be a stretch to argue that this was the intended purpose. In reviewing constitutional questions, the North Carolina Supreme Court presumes that laws enacted by the state's General Assembly are constitutional unless it determines that the law is unconstitutional beyond a reasonable doubt.[157] From the deference the North Carolina courts have shown to the state's policy goals listed in the statute's preamble, it seems like a court will dismiss this type of argument as baseless and plainly contradicted by the text of the statute.

VI. CONCLUSION

It is unclear whether the courts will engage with these issues in light of the substantial amount of deference given to the state when

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[152] N.C. CONST. art. I, § 32 ("No person or set of persons is entitled to exclusive or separate emoluments or privileges from the community but in consideration of public services."); *see also* Complaint, *supra* note 9, at 34.

[153] 282 N.C. 542, 551 (1973).

[154] Complaint, *supra* note 9, at 34.

[155] *Id.*

[156] N.C. CONST. art. I, § 32 ("No person or set of persons is entitled to exclusive or separate emoluments or privileges from the community but in consideration of public services."); *see also* Complaint, *supra* note 9, at 35 ("A CON granted to a private health-care provider is not a license or a contract to provide 'public services,' and private CON-holders are not state agents or employees.").

[157] *See, e.g.*, N.C. State Bd. of Educ. v. North Carolina, 814 S.E.2d 54, 60 (2018).

it asserts its police powers.[158] If the court contextualizes the issue as one of "public health," there is a substantial likelihood that the courts will decline to overturn the state law and will instead conclude that the legislative branch is best suited to decide on the proper course.[159] This will likely be the case, even if the plaintiff argues and sufficiently proves that the laws do not serve the public health function that they were intended to—or that they do the opposite of what was intended. The major problem such judicial deference presents is that not only would the plaintiff not succeed on the Article I, Section 19 claims, but also the anti-monopoly and exclusive emoluments violation claims would potentially suffer the same fate. The law tends to hold constitutional notions of equal protection and due process among the most sacred of our rights as Americans, so if such liberty interests give way to deference to the state's police power, then it is hard to think of other constitutional rights being upheld. However, if the court is willing to look at the issue from a different perspective, there is potential for Dr. Singh's claims to succeed. The idea that the legislative branch is the proper channel for change in policy is certainly legitimate, but the legislature has consistently failed to pass meaningful changes to CON. Furthermore, despite impacting the daily life of North Carolinians, the law is relatively obscure and is isolated from the political consciousness of voters. These elements suggest that it is time for state courts to consider taking a proactive role in determining whether the CON statute is a legitimate exercise of the state's police power.

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[158] *See* Newberg, *supra* note 110 (analyzing the possibility of another *Aston Park*-like ruling). *See generally* Anderson, *supra* note 93 (assessing the potential success or failure of an economic substantive due process argument in a modern court).

[159] *See* Anderson, *supra* note 93, at 721–22 (explaining that although the North Carolina Supreme Court has yet to examine the constitutionality of the reintroduced CON program with respect to economic substantive due process, the court's adoption of the rational basis standard will likely produce very different results from those seen in *Aston Park* in 1973).