CHAPTER 8: MISCELLANEOUS SUBJECTS

I. CERTIFICATES OF NEED

Introduction. State certificate of need (CON) programs generally prevent firms from entering certain areas of the health care market unless they can demonstrate to state authorities that there is an unmet need for their services. Upon making such a showing, prospective entrants receive from the state a CON allowing them to proceed.[1] Proving that unmet need to state authorities is sometimes expensive and time-consuming.[2] Industry representatives, as well as legal, economic, and academic experts on the health care industry, spoke on the subject of CON at the Hearings on a panel discussing Quality and Consumer Protection: Market Entry (June 10).[3]

Many CON programs trace their origin to a repealed federal mandate. The National Health Planning and Resources Development Act of 1974[4] offered states powerful incentives to enact state laws implementing CON programs.[5] By 1980, all states except Louisiana had enacted CON programs.[6] Congress repealed the federal law in 1986, but a substantial number of states continue to maintain CON programs,[7] "although often in a loosened form compared to their predecessors."[8]

The Agencies believe that CON programs can pose serious competitive concerns that generally outweigh CON

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[1] *See* JOHN MILES, 2 HEALTH CARE & ANTITRUST LAWS: PRINCIPLES AND PRACTICE § 16:1, at 16-2, 16-5 to 16-6 (2003) (noting that CONs under the federal Health Planning Act required providers to "obtain state approval – a 'certificate of need' – before spending set amounts on capital investments or adding new health care services"); James F. Blumstein & Frank A. Sloan, *Health Planning and Regulation Through Certificate of Need: An Overview*, 1978 UTAH L. REV. 3; Randall Bovbjerg, *The Importance of Incentives, Standards, and Procedures in Certificate of Need*, 1978 UTAH L. REV. 83; Clark C. Havighurst, *Regulation of Health Facilities and Services by "Certificate of Need"*, 59 VA. L. REV. 1143 (1973).

[2] *See* Keith B. Anderson, Certificate of Need Regulation of Health Care Facilities, FTC Staff Prepared Statement Before North Carolina State Goals and Policy Board 7 n.17 (Mar. 6, 1989).

[3] Complete lists of participants on these and other panels are available *infra* Appendix A and in the Agenda, *at* http://www.ftc.gov/ogc/healthcarehearings/completeagenda.pdf.

[4] Pub. L. 93-641, 88 Stat. 2225 (1975) (codified at 42 U.S.C. §§ 300k-300n-5), *repealed*, Pub. L. 99-660, § 701, 100 Stat. 3799 (1986).

[5] MILES, *supra* note 1, § 16:1, at 16-2.

[6] *See, e.g.*, Morrisey 6/10 at 146; *On Certificate of Need Regulation: Hearing on H.B. 332 Before the Senate Comm. On Health and Human Services* (Ohio 1989) (Statement of Mark D. Kindt, FTC Regional Director) (noting that by 1980, all states except Louisiana had enacted CON legislation) [hereinafter Kindt].

[7] *See* Davenport-Ennis 5/29 at 113-14; Morrisey 6/10 at 146 (noting that by 2002, about 36 states and the District of Columbia retained CON programs in some form); MILES, *supra* note 1, § 16:2, at 16-9 (stating that "CON laws remain in many states and the District of Columbia"). Quite recently, Florida exempted from CON new adult open-heart surgery and angioplasty programs at general hospitals and the addition of beds to existing hospital structures. Fla. Bill SJ 01740 (effective July 1, 2004), *amending* FLA STAT. ch. 408.036, .0361 (2003).

[8] MILES, *supra* note 1, § 16:1, at 16-2 to 16-3. *See also* Len M. Nichols et al., *Are Market Forces Strong Enough to Deliver Efficient Health Care Systems? Confidence is Waning*, 23 HEALTH AFFAIRS 1, 11 (Mar./Apr. 2004) (noting that CON programs "eroded through the 1990s").

programs' purported economic benefits. Where CON programs are intended to control health care costs, there is considerable evidence that they can actually drive up prices by fostering anticompetitive barriers to entry. Other means of cost control appear to be more effective and pose less significant competitive concerns. The Report analyzes each of these points in turn below.

A. Rationale Behind CON Programs

CON programs had the major goal of controlling costs by restricting provider capital expenditures.[9] The forces of competition ordinarily limit excess supply, but, according to a panelist representing the American Health Planning Association, "[c]ompetition in health care is ... very different" than in other markets.[10] Congress appears to have shared this view in 1974; the passage of the Health Planning Act reflected a congressional belief that market failure plagued the health care market, resulting in "excess supply and needless duplication of some services."[11]

The system of cost-based reimbursement may have driven the problem that Congress sought to solve.[12] When many CON programs were established, government or private insurance paid health care expenses "on a retrospective cost reimbursement basis."[13] This, coupled with the general concern that patients would not be sufficiently price sensitive and would demand the perceived highest quality services, led to the fear that health care providers would expand their services – sometimes to the point of offering unnecessarily duplicative services – because they competed largely on only non-price grounds.[14]

Although cost-based reimbursement is much less common today, some contend that CON programs still have a role to play in the health care marketplace. Indeed, one panelist argued that in health care markets, "providers control the supply of services. Medical practitioners direct the flow of patients and therefore the demand for

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[9] *See* Piper 6/10 at 53; Morrisey 6/10 at 146 (noting that CON programs "were established in the '70s to help control health care costs"). *See also* MILES, *supra* note 1, § 16:1, at 16-4 ("[The primary role of the Health Planning Act was to regulate the supply of health care resources, particularly institutional services, by requiring a CON from the state before certain levels of capital expenditures could be made or new services introduced."); Kindt, *supra* note 6, at 2-3 (noting that a "key justification" for CON programs has been "the belief that health care providers, particularly hospitals, would undertake excessive investment in unregulated health care markets," driving up health care costs); PUBLIC HEALTH RESOURCE GROUP, CERTIFICATE OF NEED PROJECT REPORT 17-18 (2001).

[10] Piper 6/10 at 53-54 (observing that the main aim of CON programs is to limit "excess supply generating excess demand"). *See also* PUBLIC HEALTH RESOURCE GROUP, *supra* note 9, at 18.

[11] MILES, *supra* note 1, § 16:1, at 16-4.

[12] *See id.*

[13] Anderson, *supra* note 2, at 6. *See also* Davenport-Ennis 5/29 at 114 (noting that at the time, the federal government reimbursed health care expenses on a "cost-plus basis, which did not provide the cost control capability of today's prospective payment system").

[14] Morrisey 6/10 at 147; *see also* Davenport-Ennis 5/29 at 114 (noting that government officials intended CON to "retain rising health care costs, to prevent unnecessary duplication of resources and services, and [to] expand consumer access to quality health care services").

services."[15] In health care markets, he stated, "supply generates demand[,] putting traditional economic theory on its head."[16] Moreover, consumers lack the information to compare prices, he said.[17] Such problems can lead to an inefficient allocation of health care resources and higher health care costs, some state.[18]

Some commentators also suggest that CON programs can enhance health care quality and access.[19] One panelist, for example, stated that there are "few mechanisms" other than the CON process that promote "minimum patient volumes" that contribute, he stated, to better quality care.[20] CON regulation also can address cherry picking, preventing firms from, for example, converting cancer "medical practices to medical care facilities [that] divert well-insured patients [from] local hospital cancer programs" and "undermine[] the ability of essential community hospitals to provide a full array of oncology services to the entire community."[21]

B. Competitive Concerns that CON Programs Raise

Many have criticized CON programs for creating barriers to entry in the health care market.[22] As noted previously, CON

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[15] Piper 6/10 at 55.

[16] *Id.* at 62.

[17] *Id.* at 55 (noting, however, that consumers do "suffer under the ultimate increased costs in premiums and their taxes"). The same panelist also cited empirical studies suggesting that CON programs reduce health care costs, studies that another panelist questioned. *Compare* Piper 6/10 at 57-61, *and* Thomas R. Piper, *Comments Regarding Hearings on Health Care and Competition Law and Policy* 5-13 (Public Comment) (discussing these and other studies) [hereinafter Piper (public cmt)], *with* Loeffler 6/10 at 127 (questioning those studies), *and with* Piper 6/10 at 127-28 (responding to such questions). *See generally infra* notes 37-42, and accompanying text.

[18] *See, e.g.*, MILES, *supra* note 1, § 16:1, at 16-4 (describing Congress' concerns); Piper 6/10 at 62 (asserting that "[a]reas with more hospitals and doctors spend more on health care services per person"); PUBLIC HEALTH RESOURCE GROUP, *supra* note 9, at 11 ("Adding providers usually mean increases in costs."); *see also* Piper 6/10 at 126 (noting that the fact that the public fisc is at stake adds importance to the concern).

[19] PUBLIC HEALTH RESOURCE GROUP, *supra* note 9, at 5.

[20] Piper (public cmt), *supra* note 17, at 12 (noting, for example, that in CON-free states, "the percentage of patients that had surgery in low volume programs was three times higher than in states with CON regulation").

[21] Piper (public cmt), *supra* note 17, at 13-14; *see also* Piper 6/10 at 54 (noting that CON programs aim to overcome "market gaps and excesses like the avoidance of low-income populations and concentration of services in ... affluent areas"); Nichols et al., *supra* note 8, at 11 (stating that today "some states are considering reinstituting or reinvigorating [CON programs] in response to construction of physician-owned specialty facilities, which has posed a competitive threat to community hospitals"). *But see* Price 6/10 at 108 (would-be entrant denying allegation of "cherry picking"); Davenport-Ennis 5/29 at 115-16 (stating that CON programs restrict the supply of cancer treatment services such that "low-income, seriously ill, and rural patients" who do not live near a hospital or major medical center lose access to care).

[22] *See* Anderson, *supra* note 2, at 7; Hennessy 6/10 at 95, 99-100 ("CON protects incumbent providers . . . from competition" and is an "impediment to innovation [and] quality improvement" in health care); Blumstein & Sloan, *supra* note 1; Bovbjerg, *supra* note 1; Havighurst, *supra* note 1. The Commission has also noted the

regimes prevent new health care entrants from competing without a state-issued certificate of need, which is often difficult to obtain. This process has the effect of shielding incumbent health care providers from new entrants. As a result, CON programs may actually increase health care costs, as supply is depressed below competitive levels.[23]

Moreover, CON programs can retard entry of firms that could provide higher quality services than the incumbents.[24] By protecting incumbents, CON programs likewise can "delay[] the introduction and acceptance of innovative alternatives to costly treatment methods."[25] Similarly, CON programs' "[c]urtailing [of] services or facilities may force some consumers to resort to more expensive or less-desirable substitutes, thus increasing costs for patients or third-party payers. For example, if nursing home beds are not available, the discharge of patients from more expensive hospital beds may be delayed or patients may be forced to use nursing homes far from home."[26]

Empirical studies indicate that CON programs generally fail to control costs and can actually lead to increased prices.[27] Supporting this conclusion, some panelists offered examples of the anticompetitive effects of CON programs. One panelist, for example, noted that CON programs "artificially limit[]" access to cancer treatment, placing "vital therapies and technologies out of [consumers'] reach" in favor of "old technologies."[28] He stated that his practice's application to a state for a certificate of need to introduce improved cancer radiation technology faced opposition in June 2002 from all of the state's operators of existing radiation therapy equipment. One year later, at the time of his testimony in the Hearings, he noted that the state still had not approved the CON application.[29] By contrast, in a bordering state without a CON program, his practice was able to introduce new cancer-fighting technologies rapidly.[30] Another panelist stated that incumbent home health service providers in her state have, for 23 years, successfully opposed the CON application of her nursing service, thereby barring its entry and "keep[ing] the oligopoly in place."[31] The incumbents, she

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impact of CON programs on entry and firm behavior. *See In re* Hosp. Corp. of Am., 106 F.T.C. 361, 489-501 (1985).

[23] *See* Anderson, *supra* note 2, at 7-8; Kindt, *supra* note 6, at 6-7.

[24] *See, e.g.*, Anderson, *supra* note 2, at 7-9; Kindt, *supra* note 6, at 6; *Hosp. Corp. of Am.*, 106 F.T.C. at 495 (opinion of the Commission) (stating that "CON laws pose a very substantial obstacle to both new entry and expansion of bed capacity in the Chattanooga market" and that "the very purpose of the CON laws is to restrict entry").

[25] Anderson, *supra* note 2, at 9; Kindt, *supra* note 6, at 6.

[26] Kindt, *supra* note 6, at 7.

[27] *See generally infra* notes 37-42, and accompanying text.

[28] Hennessy 6/10 at 92-93.

[29] *Id.* at 95-96; *see also id.* at 96-97 (noting similar opposition to application to introduce PET scanning to state with CON program).

[30] *Id.* at 95-98, 136.

[31] Price 6/10 at 101-10.

stated, charge more for comparable services than her service would.[32] The barrier to entry has likewise shielded incumbents from the need to offer improved and innovative services, she said.[33] As a result, some patients resort to services that "are not to their liking" or simply are not served at all.[34] Other panelists described how an incumbent used the CON process as a barrier to entry in a local surgical market,[35] and how a CON program restricted supply in a way that jeopardized patients' care.[36]

C. CON and Cost Control

Several panelists and commentators stated that CON programs generally fail to control costs.[37] Indeed, one panelist surveyed the empirical literature on the economic effects of CON programs and concluded that the "literature tends to conclude ... that CON has been ineffective in controlling hospital costs," and that, to the contrary, "[i]t may have raised costs and restricted entry."[38] Commentators stated that the reason that CON has been ineffective in controlling costs is that the programs do not put a stop to "supposedly unnecessary expenditures" but "merely redirect[] any such expenditures into other areas."[39] Thus, a CON rule that restricts capital investment in new beds does nothing to prevent

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[32] *Id.* at 105.

[33] *Id.* at 106.

[34] *Id.* at 102, 104 (reporting that she has spoken to "young people who have been lying in their own waste for three days with no one to come take care of them").

[35] Rex-Waller 3/27 at 58.

[36] Davenport-Ennis 5/29 at 115-21.

[37] *See* Hennessy 6/10 at 93-94 (stating that "CON is a failure as a cost containment tool" and that the premiums in Kansas and Missouri are generally the same, in spite of the fact that one state has a CON program and the other does not); Anderson, *supra* note 2, at 2-6 (summarizing empirical evidence and finding that CON fails to regulate costs); Kindt, *supra* note 6, at 3-5 (summarizing empirical studies on the economic effects of CON programs and concluding that "[t]here is near universal agreement among the authors [of studies on the economic effects of CON programs] and other health economists that CON has been unsuccessful in containing health care costs"); DANIEL SHERMAN, FEDERAL TRADE COMM'N, THE EFFECT OF STATE CERTIFICATE-OF-NEED LAWS ON HOSPITAL COSTS: AN ECONOMIC POLICY ANALYSIS (1988) (concluding, after empirical study of CON programs' effects on hospital costs using 1983-84 data, that strong CON programs do not lead to lower costs but may actually increase costs); MONICA NOETHER, FEDERAL TRADE COMM'N, COMPETITION AMONG HOSPITALS 82 (1987) (empirical study concluding that CON regulation led to higher prices and expenditures); KEITH B. ANDERSON & DAVID I. KASS, FEDERAL TRADE COMM'N, CERTIFICATE OF NEED REGULATION OF ENTRY INTO HOME HEALTH CARE: A MULTI-PRODUCT COST FUNCTION ANALYSIS (1986) (economic study finding that CON regulation led to higher costs, and that CON regulation did little to further economies of scale); *cf.* PUBLIC HEALTH RESOURCE GROUP, *supra* note 9, at 4 (noting that the "track record of the cost effectiveness of state CON programs is decidedly mixed," and that "[i]n some states, the of effectiveness is at least partially attributable to deficiencies in program operations and to political environments in which legislative or high-level executive branch intervention alters or affects CON decision-making"). *See also* David S. Salkever, *Regulation of Prices and Investment in Hospitals in the United States, in* 1B HANDBOOK OF HEALTH ECONOMICS, 1489-90 (A.J. Culyer & J.P. Newhouse eds., 2000) (concluding that "there is little evidence that [1970s-era] investment controls reduced the rate of cost growth," even though "inconsistent reports of constraining effects on numbers of beds and diffusion of some specialized services did appear").

[38] Morrisey 6/10 at 148-49, 152-53.

[39] Kindt, *supra* note 6, at 5.

hospitals from "add[ing] other kinds of fancy equipment" and using that to compete for consumers.[40]

As one commentator noted, "[t]he regulation of supply through mechanisms such as CON may have made sense when most reimbursement was cost-based and thus there was incentive to expand regardless of demand but they make much less sense today when hospitals are paid a fixed amount for services and managed care forces them to compete both to participate in managed-care networks and then for the plans' patients."[41] The policy justification of CON programs is particularly questionable given the number of evolving supply and demand-side strategies for controlling costs, including those outlined in Chapter 1.[42]

Conclusion. The Agencies believe that CON programs are generally not successful in containing health care costs and that they can pose anticompetitive risks. As noted above, CON programs risk entrenching oligopolists and eroding consumer welfare. The aim of controlling costs is laudable, but there appear to be other, more effective means of achieving this goal that do not pose anticompetitive risks. A similar analysis applies to the use of CON programs to enhance health care quality and access. For these reasons, the Agencies urge states with CON programs to reconsider whether they are best serving their citizens' health care needs by allowing these programs to continue.

II. STATE ACTION AND NOERR DOCTRINES

The state action and Noerr-Pennington doctrines curb competition law in order to promote important values, such as federalism and the right to petition the government for redress of grievances.[43] Inappropriately broad interpretations of these doctrines, however, can chill or limit competition in health care markets.[44] Industry representatives, as well as legal, economic, and academic experts on the health care industry, spoke at the Hearings on a panel discussing Competition Law and Noerr Pennington/State Action issues on June 11.[45]

A. State Action Doctrine

The state action doctrine precludes federal antitrust scrutiny of certain state (and state authorized) conduct. The state action doctrine is rooted in principles of federalism and respect for state sovereignty. As the Supreme Court stated in the seminal state

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[40] *Id.*

[41] MILES, *supra* note 1, § 16:1, at 16-3.

[42] *See, e.g.*, Kindt, *supra* note 6, at 8-11; Anderson, *supra* note 2, at 9-13 (same); Davenport-Ennis 5/29 at 121 (citing means other than CON programs "to regulate over-usage and over-referral"). *But see* PUBLIC HEALTH RESOURCE GROUP, *supra* note 9, at 11 (stating that "[m]anaged care companies have not created the competition and lower cost solutions originally expected of them").

[43] *See* Havighurst 6/11 at 30-32.

[44] *See, e.g.*, Robin E. Remis, *Health Care and the Federal Antitrust Laws: The Likelihood of a Harmonious Coexistence*, 13 J. CONTEMP. HEALTH L. & POL'Y 113, 123-25 (1996).

[45] Complete lists of participants on these and other panels are available *infra* Appendix A and in the Agenda, *at* http://www.ftc.gov/ogc/healthcarehearings/completeagenda.pdf.