

# The Lithotripsy Game in North Carolina: A New Technology Under Regulation and Deregulation\*

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## I. THE STAKES IN THE GAME—REWARDS OF A NEW TECHNOLOGY

Every few years, it seems, an expensive new medical technology tests the ability of the health care system to assess its efficacy, safety, and cost-effectiveness and to allocate resources so that patients receive optimal treatment at reasonable cost. Resembling in this respect earlier diagnostic imaging technologies, extracorporeal shock wave lithotripsy (ESWL) is a recent technological breakthrough that has captured the attention of health planners and policymakers.<sup>1</sup> This noninvasive procedure, which employs equipment costing up to \$2.7 million per installed unit, is revolutionizing the treatment of urinary stones.<sup>2</sup>

ESWL appears to be a highly desirable technology from every standpoint. Not only does it achieve excellent results with lower complication

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<sup>1</sup>For formal technology assessments of ESWL, see NATIONAL CENTER FOR HEALTH SERVICES RESEARCH & HEALTH CARE TECHNOLOGY ASSESSMENT, U.S. DEP'T OF HEALTH & HUMAN SERVICES, EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY (ESWL) PROCEDURES FOR THE TREATMENT OF KIDNEY STONES (1985); OFFICE OF TECHNOLOGY ASSESSMENT, UNITED STATES CONGRESS, EFFECTS OF FEDERAL POLICIES ON EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY (1986); Farrell, *Percutaneous Ultrasound Procedures for the Treatment of Kidney Stones*, 1986 INT'L J. TECH. ASSESSMENT HEALTH CARE 152; Health and Public Policy Committee, American College of Physicians, *Lithotripsy*, 103 ANNALS INTERNAL MED. 626 (1985). For other recent descriptions and evaluations, see Mueller, *Extracorporeal Shock Wave Lithotripsy of Ureteral Stones: Clinical Experience and Experimental Findings*, 135 J. UROLOGY 831 (1986); Riehle, *Extracorporeal Shock Wave Lithotripsy for Upper Urinary Tract Calculi: One Year's Experience at a Single Center*, 255 J. A.M.A. 2043 (1986); Webb, *Extracorporeal Shock Wave Lithotripsy and Percutaneous Renal Surgery*, 58 BRIT. J. UROLOGY 1 (1986).

<sup>2</sup>In ESWL, electrohydraulic shock waves shatter kidney stones into small fragments so that they can be passed naturally by the patient. Chaussy & Schmiedt, *Shock Wave*

rates than invasive therapies,<sup>3</sup> but even given the high cost of "lithotrippers," it may cost less per treatment than the surgical procedures it replaces.<sup>4</sup> Margaret Heckler, Secretary of Health and Human Services, called attention to both the medical benefits and the cost savings of ESWL when she announced the approval of the first lithotripter by the Food and Drug Administration (FDA) in 1984.<sup>5</sup>

Although there is virtually no question that ESWL is highly efficacious and extremely safe, it has created significant problems for the health care system. In particular, early and widespread recognition of the potential benefits of ESWL put intense and sudden pressure on those processes that society has installed to evaluate medical technology and to guide the health care system's development. State certificate-of-need (CON)<sup>6</sup> regulators were put in the position of being able to award very big prizes to a very few. Entrepreneurial urologists and hospitals, playing for large stakes, pushed the regulatory system very hard. In cases where the regulators stood firm, they were in the potentially awkward position

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*Treatment for Stones in the Upper Urinary Tract*, 10 UROLOGIC CLINICS N. AM. 743 (1983). Prior to the procedure, the patient is anesthetized to keep him pain-free and immobilized while shocks are administered. Finlayson & Thomas, *Extracorporeal Shock-Wave Lithotripsy*, 101 ANNALS INTERNAL MED. 387, 388 (1984). The patient is then placed into a tub of water over a shock-wave generator. A two-axis x-ray system is used to locate the stone and the shock-wave generator is adjusted so that the shock-waves are focused on the stone. Approximately 1300 shocks are administered during the average one-hour procedure.

A lithotripter currently costs approximately \$1.7 million, not including the costs of installation, which can add an additional \$1 million to the price. American Hosp. Ass'n, *Lithotripters: Noninvasive Devices for the Treatment of Kidney Stones*, 6 HOSP. TECHNOLOGY SERIES: GUIDELINE REPORT 15, 19 (1985). *But see infra* note 15 (stating that several U.S. companies are exploring the manufacture of lower cost lithotripters).

<sup>3</sup>Surgical lithotomy has an associated mortality rate of 0.8 percent, R. SMITH & D. SKINNER, *COMPLICATIONS OF UROLOGIC SURGERY AND MANAGEMENT* 102 (1976), whereas ESWL has a complication rate of less than one percent with virtually no associated mortality, Finlayson & Thomas, *supra* note 2, at 388.

<sup>4</sup>The primary cost saving of ESWL comes from a reduction in the length of hospital stay. *FDA Approves Lithotripter for Kidney Stone Shattering*, 253 J. A.M.A. 620 (1985) [hereinafter *FDA Approves Lithotripter*]. An uncomplicated surgical lithotomy requires an average stay of one to three weeks. Castaneda-Zuniga, *Nephrostolithotomy: Percutaneous Techniques for Urinary Calculus Removal*, 134 AM. J. RADIOLOGY 721, 724 (1982). The newer technique of percutaneous nephrolithotomy requires four to eight days of hospitalization. *Id.* ESWL patients currently remain in the hospital only three days on average, and it is anticipated that ESWL will eventually be performed on an outpatient basis. *FDA Approves Lithotripter, supra*, at 620-21.

<sup>5</sup>U.S. DEP'T OF HEALTH & HUMAN SERVICES, HHS NEWS 2 (Dec. 19, 1984) (statement by Margaret M. Heckler, Secretary of Health & Human Services).

<sup>6</sup>Certification of need is a legislatively mandated process whereby health care providers and institutions must obtain approval from a state agency before making large capital expenditures or instituting costly new services. *See infra* notes 12-15 and accompanying text.

of giving the winners valuable monopolistic franchises and depriving the losers of patients and significant income.<sup>7</sup> Where the regulatory system gave way, the possibility of overinvestment in duplicative facilities raised the specter of excessive costs, overuse of ESWL, and neglect of alternative therapies when they might be medically indicated.<sup>8</sup> Although ESWL is a striking development in itself, much of its interest for policymakers lies in the lessons it teaches about the overall health care system and its ability to allocate resources and accommodate technological change.

ESWL has had a particularly significant impact on urologic practice in North Carolina. That state lies in the center of the so-called "stone belt," an area of the country where urinary stones are particularly common.<sup>9</sup> North Carolina urologists are thus heavily committed to the treatment of urinary stones, devoting an estimated fifteen to twenty percent of their professional work to this condition.<sup>10</sup> Hospitals, too, obtain significant income from urinary stone patients, and this business has been widely shared by all hospitals. ESWL thus posed an economic threat to both urologists and hospitals in North Carolina. If treatment of stones in the kidney and upper urinary tract were suddenly concentrated in a small number of lithotripsy centers, the impact on the providers losing that business would be substantial. The appearance of this new technology in North Carolina also threatened to accentuate a flow of patients away from community hospitals into the state's few, but strategically located, academic medical centers. A major "town/gown" conflict thus quickly developed as community urologists sought to keep their patients out of the academic institutions, which allegedly did not always return patients to the care of their original doctors.

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<sup>7</sup>See, e.g., *Michigan News Briefs*, United Press International, Feb. 11, 1986 (reporting that Michigan Department of Public Health had ordered Michigan's two largest hospitals not to bill patients for ESWL until they received CON approval); *New Kidney Stone Crushing Technique Studied*, United Press International, April 26, 1985 (stating that Virginia Health Commissioner announced his intent to "guard against unnecessary proliferation" of lithotripters despite the increasing number of applications for certificates of need for lithotripters).

<sup>8</sup>See, e.g., Freifeld, *The Rush to Crush*, FORBES, March 11, 1985, at 170, 171 (stating that in Chicago, health planners had succumbed to provider pressures in approving more lithotripters than were necessary).

<sup>9</sup>See Brown, *Living in the Stone Belt Can Be Dangerous to Your Kidneys*, Durham Morning Herald, Jan. 13, 1987, at A9, col. 1. Apparently because of dietary factors, residents of southeastern states have a higher incidence of calculi of the kidney and ureter than other U.S. citizens. *Id.* In 1984, the incidence of kidney stones in North Carolina was 29.9 per 10,000 population contrasted with the mean incidence among states of 16.4 cases per 10,000 population. Sierakowski, *The Frequency of Urolithiasis in Hospital Discharge Diagnoses in the United States*, 15 INVESTIGATIVE UROLOGY 438, 440 (1978).

<sup>10</sup>Personal communication with John L. Weinerth, M.D., Associate Professor, Division of Urology, Duke University (July 1986).

Although the struggle to capture the North Carolina ESWL market is interesting in itself as a spectator sport, there are more important reasons to focus on the North Carolina experience. First, the operation of the CON system was tested in significant ways, yielding lessons for students of this form of regulation. Second, the method of paying urologists for lithotripsy received an unusual degree of attention, highlighted by a clash between practicing urologists and Blue Cross and Blue Shield of North Carolina (NCBCBS) over the proper professional fee. This controversy yields some lessons about how business is done in a state that has yet to see many of the vaunted benefits of competition in health care<sup>11</sup> and suggests some serious questions about the role of Blue Cross and Blue Shield plans in forestalling such competition not only in North Carolina but in the nation as a whole. Finally, the North Carolina story has recently culminated, for reasons that will appear, in the repeal of CON requirements for lithotripters, thus presenting everyone—but especially NCBCBS—with a future challenge. This Article thus includes a discussion of what must happen now in the deregulated North Carolina market (and wherever else deregulation is tried) if the right number of lithotripters are to be appropriately located and properly used. Although it is far from clear that North Carolina is ready for deregulation of a single technology of this kind, the lessons drawn from the North Carolina experience may suggest to other states the merits of general deregulation and the urgency of encouraging the competitive developments that would permit it.

## II. THE CON GAME—WINNER TAKE ALL

State CON laws were intended to contain costs and make the development of the health care system more rational by requiring prior state approval before major capital expenditures could be made and new health services could be introduced.<sup>12</sup> Because prevention of duplication

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<sup>11</sup>See *infra* notes 45-63 and accompanying text.

<sup>12</sup>See, e.g., P. JOSKOW, *CONTROLLING HOSPITAL COSTS: THE ROLE OF GOVERNMENT REGULATION* (1981); D. SALKEVER & T. BICE, *HOSPITAL CERTIFICATE-OF-NEED CONTROLS: IMPACTS ON INVESTMENT, COSTS, AND USE* 11-24 (1979); Bovbjerg, *Problems and Prospects for Health Planning: The Importance of Incentives, Standards and Procedures in Certificate of Need*, 1978 UTAH L. REV. 83, 84-90; Havighurst, *Regulating Health Facilities and Services by "Certificate of Need,"* 59 VA. L. REV. 1143, 1155-69 (1973). Like other states, North Carolina has enacted a CON law, N.C. GEN. STAT. § 131E-175 to 191 (Supp. 1985), pursuant to the National Health Planning Resource and Development Act of 1974, Pub. L. No. 93-641, 88 Stat. 2225, 2584-645 (codified as amended at 42 U.S.C. § 300k-n (1982)). An earlier North Carolina CON law was held invalid under the state constitution. *In re Certificate of Need for Aston Park Hosp., Inc.*, 282 N.C. 542, 193 S.E.2d 729 (1973). Before creating the present statute, the state resisted, unsuccessfully, the subsequent federal compulsion to enact a CON statute meeting federal specifications. See *North Carolina ex rel. Morrow v. Califano*, 445 F. Supp. 582 (E.D.N.C. 1977), *aff'd mem.*, 435 U.S. 962 (1978).

is a key regulatory goal, these laws create a powerful incentive for providers to put any promising new technology, tried or untried, in place as quickly as possible; once CON approval is obtained, there is a strong regulatory barrier to entry by competitors until the market expands enough to support a second facility without appreciable harm to the first. Even if the first mover purchases costly first-generation equipment, it will be protected against competition from a later applicant offering to provide the same service for less.<sup>13</sup> The convoluted rationale for protecting inefficient providers from price competition in this way is not addressed here,<sup>14</sup> but it is notable that one effect of this form of regulation is to encourage early investment by relieving the proponent of the concern that his investment will be devalued when more efficient technology becomes available. This point is of present interest because other lithotripsy devices that are now under development are expected to cost substantially less than the devices currently being installed.<sup>15</sup>

North Carolina providers began jockeying for CON's soon after the announcement of plans for introducing the lithotripter into the United States from Europe, where it was first developed. Indeed, an application to offer ESWL in North Carolina was filed one month before Dornier-

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<sup>13</sup>*Cf.* C. HAVIGHURST, DEREGULATING THE HEALTH CARE INDUSTRY 195-202, 214-22, 345-53 (1982) (noting the protectionist tendencies of CON regulation with respect to such desirable cost-saving innovations as home health care, HMO's, and ambulatory surgical facilities).

<sup>14</sup>*Id.* at 277-85 (explaining and criticizing the thinking behind protectionist regulation).

<sup>15</sup>In addition to Dornier-System, the manufacturer of the first device approved in the United States, at least four U.S. companies are exploring the manufacture of lithotripters. The first of these to begin clinical testing was Medstone International, Spartanburg, South Carolina. As of May 1985, Medstone had obtained FDA investigational device exemptions for five sites. American Urologic Ass'n, *Report to the Executive Committee of the AUA: Ad Hoc Committee to Study the Safety and Clinical Efficacy of the Current Technology of Percutaneous Lithotripsy and Noninvasive Lithotripsy* 20 (May 16, 1985) [hereinafter *Report to the Executive Committee*]. The Medstone lithotripter uses a fluid-filled bag for the acoustic interface; with the Dornier device, the patient is placed in a tub. The estimated cost of the Medstone lithotripter is about \$800,000, about half the cost of the Dornier device.

Two other firms have conducted *in vivo* studies in animals. International Biomedics, Inc., of Issaquah, Washington, uses a laser-driven shock wave generator and water-filled chest waders for the acoustic interface. *Id.* Another lithotripter, being developed by Dr. Fray Marshall and colleagues at the Johns Hopkins Medical Center, also uses a fluid-filled bag but differs from others in using ultrasound rather than x-rays for imaging. *Id.* at 21. The anticipated cost of the Hopkins device is between \$250,000 and \$500,000. The SD-3 lithotripter, being developed by Northgate Research, Inc., of Plattsburg, New York, was only in the *in vitro* investigational stage in 1985. *Id.* at 20. The cost of this device, if perfected, is estimated to be only \$250,000.

Because lower cost second-generation devices may become available, hospitals may be hesitant about purchasing costly first-generation equipment. See *The Race for Competing Lithotripters Heats Up*, HOSPITALS, July 20, 1986, at 30; *Lithotripsy: Hospitals Take a Wait and See Attitude*, HOSPITALS, May 20, 1986, at 75.

System GmbH, the German manufacturer of the original lithotripter, filed its initial application for FDA approval of the device on February 22, 1984. This application—by North Carolina Baptist Hospital in Winston-Salem, which is associated with The Bowman Gray School of Medicine of Wake Forest University—was approved in June 1984, six months before the FDA approved the Dornier device.<sup>16</sup> A second application—by Carolina Lithotripsy, Ltd., a limited partnership of forty-two North Carolina urologists—was also filed before the FDA acted. This Fayetteville-based partnership was organized by Dr. William Jordan,<sup>17</sup> who had gone to Germany at an early date to learn the procedure and get a jump on the market when lithotripters finally became marketable in the United States.<sup>18</sup>

The forehandedness of these CON applications was impressive because FDA approval of a new technology normally takes several years.<sup>19</sup> However, in this case, the FDA, recognizing the potential benefits of the lithotripter and its extensive testing and use in West Germany, acted with extraordinary rapidity,<sup>20</sup> approving the device on December 19,

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<sup>16</sup>See Letter from William Vaughn, Chief, Certificate of Need Section, Division of Facility Services, N.C. Dep't of Human Resources, to John Lynch, President, North Carolina Baptist Hospitals (June 29, 1984). Dr. David McCullough, Chairman of the Division of Urology at Bowman Gray School of Medicine of Wake Forest University, explained that Bowman Gray urologists decided to pursue CON approval early because they were aware of the results of ESWL testing in Europe and believed that ESWL's potential benefits made it the "wave of the future." Personal communication with David McCullough, M.D. (Jan. 1987).

<sup>17</sup>See Carolina Lithotripsy, Ltd., Certificate of Need Application 1-5 (July 12, 1984); see also *Big Lithotripter Venture Helps Out Small NC Hospital*, HOSPITALS, May 20, 1986, at 76 (discussing the Fayetteville, N.C., partnership of urologists that purchased a lithotripter to be installed at Highsmith-Rainey Memorial Hospital).

<sup>18</sup>Personal communication with William Jordan, M.D. (July 1985).

<sup>19</sup>Currently, the FDA estimates that the median approval time for devices since 1976 has been approximately 8-1/2 months. Kahan, *Premarket Approval Versus Premarket Notification: Different Routes to the Same Market*, 39 FOOD DRUG COSMETIC L.J. 510, 518 (1984). This median is misleading, however, as an indication of the review time for truly new devices. Approximately 60% of the premarket applications (PMAA's) received by the FDA are not for new devices but for devices regulated under transitional provisions applicable to devices formerly regulated as new drugs. *Id.* at 518 n.44 (citing 21 U.S.C. § 360j(1)(1) (1982)). The review time for these transitional devices, e.g., sutures and contact lenses, is generally very short. *Id.* In addition, many PMAA's are returned to the sponsor for additional data, and this time is not counted in the FDA's statistics. *Id.* at 518. Economist Henry Grabowski, a student of drug and device regulation, believes that truly new medical devices will be subject to an average approval time approximately equal to that for new drugs. Personal communication with Henry Grabowski, Professor of Economics, Duke University (July 1985). The FDA has taken an average of 35 months following the filing of a new drug application (analogous to a PMAA) to approve new drugs. H. GRABOWSKI & J. VERNON, *THE REGULATION OF PHARMACEUTICALS: BALANCING THE BENEFITS AND RISKS* 23 (1983).

<sup>20</sup>The FDA approved extracorporeal shock wave lithotripsy for general use less than one year after the commencement of clinical trials in the United States. This was unusually

1984.<sup>21</sup> Carolina Lithotripsy's CON for a lithotripter, scheduled to be located in a Fayetteville hospital, was issued one day later.<sup>22</sup>

Applications by other North Carolina providers followed quickly upon the first CON awards and the FDA action. Stone Institute of the Carolinas, a Charlotte-based partnership of urologists, applied for a CON in August 1984, and got its approval in January 1985.<sup>23</sup> North Carolina Memorial Hospital in Chapel Hill, an adjunct of the medical school of the University of North Carolina, received CON approval in May 1985.<sup>24</sup> Unsuccessful applicants included St. Joseph's Hospital of

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rapid action. *See supra* note 19. One commentator argued, however, that the FDA's approval of lithotripsy was not fast enough, and that the FDA's delay in approving lithotripsy caused many kidney stone patients, especially those who were high-risk surgical candidates, to suffer. Gieringer, *The FDA's Bad Medicine*, 33 POL'Y REV. 71, 71 (1985).

One reason for the FDA's relatively speedy approval of ESWL was the extensive testing of the procedure in Europe before it was introduced in the United States. The FDA had agreed to base its approval largely on the European data. The FDA's National Center of Devices and Radiological Health will generally consider foreign data in support of premarket approval if the studies appear valid and if the rights, safety, and welfare of the research subjects were not violated. Shapiro, *Legal Aspects of Premarket Approval of Medical Devices*, 38 FOOD DRUG COSMETIC L.J. 205, 211 (1983). Although the Center has not relied solely on foreign data in the past, the FDA has recently proposed to allow approval of new drugs based solely on foreign clinical data. *See* 47 Fed. Reg. 46,643 (1982). In an interview, attorney Joseph Onek, who represented Dornier-System in the FDA application process, said that testing centers in the United States were able rapidly to confirm the results of the extensive testing completed in Europe. Personal communication with Joseph Onek (July 1985). At the time that FDA began to evaluate the lithotripter, it had been used in Germany for five years. Gieringer, *supra* at 71. U.S. testing began less than one year prior to FDA approval. Nearly 2,000 of the 10,000 or so treatments worldwide had been performed in the United States. U.S. DEP'T OF HEALTH & HUMAN SERVICES, *News Release*, HHS NEWS 2 (Dec. 19, 1984).

Onek also explained that Dornier was slow in introducing the lithotripter to the U.S. market. By the time it was introduced, urologists, nephrologists, and others knew about the lithotripter and its advantages and were anxious to obtain the device. Another factor that may have led to more rapid approval of lithotripsy was the lower per-patient cost of the procedure. Onek was of the opinion that although relative cost-effectiveness is not an explicit criterion for approval, FDA officials were aware of and motivated by the lower costs associated with lithotripsy.

<sup>21</sup>FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVICES, SUMMARY OF SAFETY AND EFFECTIVENESS DATA: DORNIER LITHOTRIPTER, MODEL HM3 20 (1985).

<sup>22</sup>*See* Letter from Susanne Moulton, Chief, Certificate of Need Section, Division of Facility Services, N.C. Dep't of Human Resources, to William Jordan, M.D., Partner, Carolina Lithotripsy, Ltd. (Dec. 20, 1984).

<sup>23</sup>*See* Letter from Jack Brinson, Project Analyst, and Susanne Moulton, Chief, Certificate of Need Section, Division of Facility Services, N.C. Dep't of Human Resources to Orion Finklea, President, The Stone Institute of the Carolinas, Inc. (Jan. 28, 1985).

<sup>24</sup>Letter from Nancy Bres Martin, Project Analyst, and Susanne Moulton, Chief, Certificate of Need Section, Division of Facility Services, N.C. Dep't of Human Resources to Jane Rhoe-Jones, Acting Director of Planning, North Carolina Memorial Hospital (May 30, 1985).

Asheville<sup>25</sup> and Duke University Medical Center in Durham;<sup>26</sup> the CON applications for both facilities were denied because other facilities were deemed sufficient to serve patients in their respective service areas.<sup>27</sup>

A fifth lithotripter slipped into the state through a crack in the regulatory defenses. A CON application by physician-owned Piedmont Urinary Stone Center, Inc. (Piedmont), which proposed the installation of a lithotripter in a Winston-Salem hospital, was reviewed together with the application of Bowman Gray's North Carolina Baptist Hospital. Piedmont's application was denied because only one service was deemed necessary in the Winston-Salem/Greensboro area and the CON agency preferred that such a service be associated with an academic institution.<sup>28</sup> Piedmont then proposed, however, to install a lithotripter in an outpatient facility unconnected with a hospital and successfully applied to the CON agency for a ruling that the CON statute did not apply to capital investments in major medical equipment to be installed in physicians' offices.<sup>29</sup> Although the legislature quickly moved to close this loophole by extending CON regulation to lithotripters "regardless of ownership or location,"<sup>30</sup> Piedmont's plans were unaffected, and its lithotripter is currently operating in Winston-Salem.

As in the comparative hearing pitting the Piedmont physician group against Bowman Gray's Baptist Hospital, the town/gown conflict was evident throughout the struggles over the provision of ESWL in North Carolina. The next two CON's went to physician groups that had filed their applications well before the other academic institutions. Subse-

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<sup>25</sup>Letter from Dudley Stallings, Project Analyst, and Susanne Moulton, Chief, Certificate of Need Section, Division of Facility Services, N.C. Dep't of Human Resources, to Les Brown, Director of Planning and Development, St. Joseph's Hospital (Aug. 27, 1985).

<sup>26</sup>Certificate of Need Section, Division of Facility Services, N.C. Dep't of Human Resources, Required State Agency Findings, Disapproval of CON for Extracorporeal Shock Wave Lithotripter, St. Joseph's Hospital 2-3 (Aug. 27, 1985).

<sup>27</sup>Letter from Nancy Bres Martin, Project Analyst, and Robert Fitzgerald, Assistant Director, Certificate of Need Section, Division of Facility Services, N.C. Dep't of Human Resources, to William Anlyan, M.D., Chancellor of Health Affairs, Duke University Medical Center (May 30, 1986).

<sup>28</sup>See Letter from Everette Jenkins, Assistant Chief, Certificate of Need Section, Division of Facility Services, N.C. Dep't of Human Resources, to Keith Christian, President, CV, Inc. (July 17, 1984).

<sup>29</sup>See Declaratory Ruling, *In re* Request for Declaratory Ruling by Piedmont Stone Center, P.A., Piedmont Stone Joint Venture, and Carolina Medicorp., Inc. (Mar. 28, 1985); Letter from Jack Brinson, Project Analyst, Certificate of Need Section, Division of Facility Services, N.C. Dep't of Human Resources, to Charles Hauser, Agent, Piedmont Stone Center (Apr. 9, 1985).

<sup>30</sup>The amended statute required that all persons obtain a certificate of need prior to the acquisition of a lithotripter "regardless of ownership or location." N.C. GEN. STAT. §§ 131E-176(16)g, 178(a) (Supp. 1985). On the policy implications of regulating capital equipment in physician offices, see C. HAVIGHURST, *supra* note 13, at 205-10.

quently, Memorial Hospital in Chapel Hill succeeded despite its presence in the same service area as the Fayetteville group, in part because it asserted educational and research needs.<sup>31</sup> (Duke, ironically, was unable to make this argument because it already possessed a lithotripter for research use, which was exempt from the CON requirement, and therefore sought only authority to offer a clinical service for compensation).<sup>32</sup> Perhaps in an effort to defuse opposition from community urologists, Memorial and Baptist hospitals made special arrangements whereby the former could obtain privileges to admit and treat ESWL patients. The claims of community urologists, asserted in a number of applications and challenges against the academic centers, included concern for the convenience of patients, the financial security of community hospitals, and the increasing dominance of the academic institutions.<sup>33</sup>

Although the CON regulators stood firm against exceeding a total of five lithotripters in the state, certain powerful interests were unhappy with the outcome of the CON process, which resulted in inconvenience for citizens in the western part of the state and left one prestigious institution (Duke) barred from charging for the use of a lithotripter already in place. Several legislators took up the cause of Duke and St. Joseph's Hospital in Asheville and explored the possibility of legislation that would bypass the CON agency. Because North Carolina, unlike some states, does not allow "special legislation" favoring named private interests,<sup>34</sup> it was necessary to write the exception in generic terms that bespoke a plausible legislative objective. In about two days' time, a bill was written and passed by the House of Representatives defining conditions for exemption that only Duke and St. Joseph's could meet.<sup>35</sup> Shortly thereafter, however, the Senate took a different view, and both

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<sup>31</sup>See North Carolina Memorial Hospital, Certificate of Need Application, Attachment 3, 5 (Dec. 11, 1985).

<sup>32</sup>See Certificate of Need Section, Division of Facility Services, N.C. Dep't of Human Resources, Required State Agency Findings, Disapproval of Conversion of Research Lithotripter to Clinical Use, Duke University, 6 (May 30, 1986).

<sup>33</sup>See, e.g., Letter from Raymond Joyner, Chairman, Dep't of Urology, Durham County General Hosp., to Susanne G. Moulton, Chief, Certificate of Need Section, Division of Facility Services, N.C. Dep't of Human Resources (Jan. 31, 1985).

<sup>34</sup>See N.C. CONST. art. II, § 24; cf. *Commissioner of Public Health v. Bessick M. Burke Memorial Hosp.*, 366 Mass. 734, 323 N.E.2d 309 (1975) (upholding constitutionality of exemptive legislation applied to CON); D. ALTMAN, R. GREENE & H. SAPOLSKY, *HEALTH PLANNING AND REGULATION* 28, 53, 186-87, 200-01 (1981) (discussing special legislation exempting named private interests from CON in Massachusetts).

<sup>35</sup>Oliver & Andrews, *House OKs Bill to Let Duke Use Kidney-Stone Machine*, Durham Morning Herald, July 2, 1986, at 1B, col. 2. Many other states have discovered that technocratic regulation of the health care industry frequently gives way whenever it becomes necessary to offend powerful interests that can effectively appeal to political leaders for assistance. See D. ALTMAN, R. GREENE, & H. SAPOLSKY, *supra* note 34, at 26-31, 153, 177-87, 202-10, 233-36 (noting ways providers circumvent the certificate of need process).

houses, in a surprising move, finally decided to repeal altogether the CON requirement for lithotripters and ESWL services.<sup>36</sup>

This sudden deregulatory move by North Carolina has somewhat startling implications. Many states, no longer bound by federally imposed requirements to maintain CON laws, have cut back on such regulation.<sup>37</sup> Although a few states have repealed their CON laws altogether,<sup>38</sup> most have maintained controls over large capital investments in hospital-based facilities, ostensibly on the theory that capital-intensive institutional services are least amenable to allocation by market forces.<sup>39</sup> North Carolina's deregulation of ESWL, which obviously was not the product of a well-considered policy judgment, is peculiar in that it preserves the basic scheme of comprehensive regulation but makes an exception for a technological development of the kind that most observers would agree is a prime candidate for regulatory allocation.

The North Carolina experience reveals once again the political dimensions and debatable premises of CON regulation. Despite numerous objective studies of the question, CON regulation has never been shown to control health care costs.<sup>40</sup> Indeed, substantial evidence suggests that CON laws were put in place not primarily to control costs but to protect the most powerful existing institutions against competitors skimming profitable business<sup>41</sup> and to legitimize rapidly rising costs in the eyes of

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<sup>36</sup>See Lineberry, *Duke Lithotripter Use Gets Senate Approval*, Durham Morning Herald, July 12, 1986, at 1C, col. 5. Because North Carolina had not contracted with the federal government under section 1122 of the Social Security Act, 42 U.S.C. § 1320a-1 (1982), to perform planning services, leading to possible denial of Medicare reimbursement of capital costs, this legislative action removed all governmental constraints on the installation of lithotripters.

<sup>37</sup>Simpson, *Full Circle: The Return of Certificate of Need Regulation of Health Facilities to State Control*, 19 IND. L. REV. 1025 (1987).

<sup>38</sup>*Id.* at 1061, 1079-81.

<sup>39</sup>See C. HAVIGHURST, *supra* note 13, at 4-5. In the National Health Planning and Resources Development Amendments of 1979, Congress identified the provision of "inpatient health services and other institutional health services" as being particularly subject to the market failure that it viewed as necessitating CON regulation for new health facilities and services. Legislative findings accompanying the 1979 amendments stated that "the prevailing methods of paying for health services by public and private health insurers" make competition an unreliable allocative mechanism and singled out institutional services as most likely to be among those "for which competition does not or will not appropriately allocate supply." 42 U.S.C. § 300k-2(b)(i)-(2) (1982); see also H.R. Rep. No. 190, 96th Cong., 1st Sess. 51-54 (1979).

<sup>40</sup>See generally C. HAVIGHURST, *supra* note 13, at 63-74 (summarizing analytical and descriptive studies of CON's effect on costs); P. JOSKOW, *supra* note 12, at 138-68; Sloan, *The Track Record of Certificate-of-Need Programs* (paper presented at the third annual Health Policy Symposium, "The Role of Health Planning in a Competitive Environment," Vanderbilt University, May 15-16, 1986).

<sup>41</sup>"In North Carolina, improvement of the borrowing capacity of the hospitals—by protecting them from competition—was an explicit purpose" behind the enactment of the state's first CON law. Havighurst, *supra* note 12, at 1164 n.77 (citing Durham Morning

an increasingly concerned public.<sup>42</sup> Moreover, some have argued that the main effect of entry regulation has been to protect payers and providers from having to alter their traditionally nonadversarial relationships by embarking, respectively, on prudent buying and competitive selling of health services.<sup>43</sup> North Carolina's deregulation of lithotripsy suggests that legislative support for CON regulation is weakening and that the public is running out of patience with a regulatory scheme that protects established institutions.

The natural question that arises is what happens next in North Carolina. Unless the market conditions that were deemed to warrant CON regulation have changed or can now change readily, there may be a proliferation of unneeded, overutilized lithotripters. According to the scenario visualized by advocates of health planning and CON regulation, the public can expect to pay a high price and receive inappropriate, even unnecessary, medical care. Whether this vision will be fulfilled, however, depends upon those who pay for medical care and their willingness and ability to defend themselves against the predictable higher costs. Later discussion, following examination of payment issues that have already arisen in North Carolina, will consider what actions payers might take in this regard and the actual prospects for their taking them.<sup>44</sup> That discussion will also consider whether the scenario may instead fulfill the predictions of deregulation advocates, who argue that unlimited entry will trigger prudent purchasing and effective price competition among providers, creating a market deterrent to replace the barrier that CON regulation supposedly erected to the creation of technological overcapacity.

### III. PLAYING FOR MONEY

The active pursuit of CON's for ESWL facilities in North Carolina indicated that providers, particularly physicians, anticipated that the

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Herald, June 25, 1971, at 1C, col. 1). See also Payton & Powsner, *Regulation through the Looking Glass: Hospitals, Blue Cross, and Certificate-of-Need*, 79 MICH L. REV. 203, 255-56 (1980).

<sup>42</sup>Payton & Powsner, *supra* note 41, at 247-48. This source shows that the main proponents of CON regulation were not themselves interested in cost containment but stood to gain if the public could be satisfied that continued cost escalation was justified. They may even have anticipated the great political difficulty encountered by public regulators in saying "no" to "needs" asserted by reputable providers. See *supra* note 35; C. HAVIGHURST, *supra* note 13, at 25-52.

<sup>43</sup>The crucial observation of Payton & Powsner, *supra* note 41, is that CON laws perpetuated a financing system that served the interests of the dominant payers and providers. See also Havighurst, *supra* note 12, at 1156 ("Viewed in the light of possibilities for more fundamental changes in the market for insurance and health services, certificate-of-need laws may appear as conservative measures, designed to preserve the very institutions which create the problems to which they are addressed.').

<sup>44</sup>See *infra* notes 76-127 and accompanying text.

ESWL game would be highly profitable. However, what profits would be earned and to whom they would accrue would depend upon numerous factors, beginning with the policies and practices of the various payers and their ability to bargain for favorable rates of payment. The North Carolina experience featured a heated controversy over physician fees for lithotripsy as NCBCBS attempted to take a stand against the urologists' proposal that they receive an allowance for their services roughly equal to what they previously received when kidney stones were managed surgically. As explored further below, both the unusual effort made by NCBCBS and its failure to affect fees significantly are instructive.

The North Carolina experience with lithotripsy also focused attention on the economics of patient referrals from community physicians to ESWL centers. Although questions were raised about the ethical propriety of fees paid—ostensibly for follow-up services—by some centers to referring physicians, the discussion below shows that such payments may not be incompatible with fair play and appropriate outcomes in the lithotripsy game.

#### A. *The UCR Game—with the Blues' Chips*

When ESWL was first undertaken in North Carolina in 1985, NCBCBS had to set some limit on the urologists' professional allowance for the procedure.<sup>45</sup> Hospitals would be reimbursed their costs under the customary arrangement, but a limit on reimbursable physician fees had to be initially established by fiat because there was no "going rate" from which NCBCBS could derive a "usual, customary, and reasonable" (UCR) rate. Because no fee was yet either "usual" or "customary," NCBCBS turned to its Physician Advisory Committee for guidance on what would be "reasonable."

Largely on the strength of testimony by David F. Paulson, M.D., chief of the Division of Urology at Duke, NCBCBS's advisory committee determined that a fee in the range of \$350 to \$450 would be proper.<sup>46</sup>

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<sup>45</sup>Personal communication with William DeMaria, M.D., Medical Director, NCBCBS (Jan. 1987). See also MEDICAL ADVISORY PANEL OF THE HEALTH BENEFITS MANAGEMENT DIVISION, BLUE CROSS & BLUE SHIELD, FINANCIAL ANALYSIS OF EXTRACORPOREAL LITHOTRIPTER SERVICES, at .05 - .07 (discussing appropriate professional fee for ESWL). Under the typical NCBCBS contract, the patient patronizing a "participating" physician is assured that the physician will accept the plan's payment to him as payment in full (subject to any deductible or co-payment provided for); the plan's contract with the physician so provides and also sets a "UCR" limit on what the plan will pay. If the patient patronizes a "non-participating" doctor, the plan typically does not pay the physician directly but instead reimburses the patient for bills incurred up to a contractually specified limit (usually based on the UCR formula). See generally BLUE CROSS & BLUE SHIELD ASS'N, USUAL, CUSTOMARY AND REASONABLE: AN EXPLANATION FOR DOCTORS 1-3; BLUE CROSS AND BLUE SHIELD OF NORTH CAROLINA, COST CARE: A PARTICIPATING DOCTOR PAYMENT PLAN (1985).

<sup>46</sup>Personal communication with William DeMaria, M.D., Medical Director, NCBCBS (Jan. 1987).

This amount was considerably less than the customary surgical fee of \$1,500 to \$2,000 for an uncomplicated nephrolithotomy, which Carolina Lithotripsy proposed to charge.<sup>47</sup> The higher fee would accord with the general position taken by the ad hoc committee on lithotripsy of the American Urological Association (AUA).<sup>48</sup> This committee was then chaired, coincidentally, by another North Carolinian, William H. Boyce, M.D., former chairman of the Division of Urology at Wake Forest's Bowman Gray School of Medicine.<sup>49</sup> Obviously, Dr. Paulson had taken a position very much at odds with the interests of his professional colleagues in the state.<sup>50</sup>

On the merits of the fee issue, the AUA's view was that the urologist is required to possess special knowledge and to exercise special skills in ESWL and that the pre- and post-procedure responsibilities associated with ESWL are the same as with surgery.<sup>51</sup> In the contrary view of Dr. Paulson, the urologist's role in ESWL is merely to supervise the technician, a much less demanding and extensive service than a surgical procedure.<sup>52</sup> Adopting the latter view and recognizing that some additional charges for services before and after the procedure might also have to be paid, NCBCBS initially recognized \$450 as the limit of its payment responsibility for the procedure itself. In response, Carolina Lithotripsy

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<sup>47</sup>Personal communication with William Jordan, M.D. (July 1985). One urologist noted, however, that the professional fee for ESWL is only one element of the total charge and that the relative size of the professional fees among providers may not correspond to the relative total price for the procedure. Personal communication with David McCullough, M.D., Chairman of the Division of Urology at Bowman Gray School of Medicine of Wake Forest University.

<sup>48</sup>David McCullough, Chairman of the American Urologic Association Ad Hoc Committee on ESWL and Chairman of the Division of Urology at Bowman Gray School of Medicine, explained that the larger fee was also justified by the high cost of training urologists to perform lithotripsy. Personal communication with David McCullough, M.D. (Jan. 1987). For example, he estimated that the cost of training five Bowman Gray urologists to perform lithotripsy, including forgone earnings, was \$100,000.

<sup>49</sup>AMERICAN UROLOGIC ASSOCIATION, SUMMARY AND RECOMMENDATIONS OF THE MEETING OF THE AD HOC COMMITTEE TO STUDY THE SAFETY AND CLINICAL EFFECTIVENESS OF THE CURRENT TECHNOLOGY OF 1) PERCUTANEOUS LITHOTRIPSY, AND 2) NON-INVASIVE LITHOTRIPSY 5 (May 9, 1984) [hereinafter AUA SUMMARY AND RECOMMENDATIONS]. The Ad Hoc Committee is currently chaired by North Carolinian David McCullough, M.D., who is also Chairman of the Division of Urology at Bowman Gray.

<sup>50</sup>Paulson stated that colleagues told him of the anger many urologists, particularly those in North Carolina, had toward Paulson for his stand on this issue. Personal communication with David Paulson (Nov. 1986). Paulson believes that some urologists may have retaliated, but believes they were too "shrewd" to make such retaliatory actions obvious. *Id.*

<sup>51</sup>See AUA SUMMARY AND RECOMMENDATIONS *supra* note 49 at 5; AMERICAN UROLOGIC ASS'N, AD HOC COMMITTEE TO STUDY THE SAFETY AND CLINICAL EFFICACY OF THE CURRENT TECHNOLOGY OF PERCUTANEOUS LITHOTRIPSY AND NONINVASIVE LITHOTRIPSY 14, 16-17 (May 16, 1985).

<sup>52</sup>Personal communication with William De Maria, M.D., Medical Director, NCBCBS (Jan. 1987).

declared its intention to bill NCBCBS-insured patients for the balance of the full fee.<sup>53</sup>

Sadly, NCBCBS could not hope to carry the day for several reasons. First, like most other Blue Shield plans, NCBCBS was committed in its contracts with subscribers to pay up to the UCR limit. To NCBCBS, this meant that, once the procedure had been billed for in a sufficient number of cases, it would have to step up its allowance to whatever had become "usual" for the particular provider and "customary" in the community. Although the plan might still challenge a fee as being unreasonable, a plan official at one point gave the impression that the plan did not regard "reasonableness" as an independent check on usual and customary charges.<sup>54</sup> At another point, this official expressed doubt that the unreasonableness of the allowance demanded by the urologists could be established, because other insurers around the nation were paying it.<sup>55</sup> In making this excuse, however, plan officials still seemed to assume that reasonableness is to be judged by what others do, not by objective economic criteria.

A second reason why the NCBCBS effort was unlikely to succeed was the unlikelihood that price competition by providers during the short period when the low limit on NCBCBS coverage was in effect would yield price reductions or reliable yardsticks for future payments. Even if patients, faced with paying the excess over NCBCBS's allowance, had known enough to seek out a lower-cost provider, no service area had more than one provider during the crucial period. In addition, providers would have known that the UCR level would jump dramatically if they could resist for only a short time the temptation to compete.

Finally, NCBCBS officials were unwilling to force a showdown over ESWL fees because they feared that such a challenge would induce urologists across the state to refuse to join NCBCBS's participating-physician program.<sup>56</sup> Ironically, NCBCBS's concern over attracting physicians to this program undercut the program's ostensible cost-containment objective, which was to be achieved by inducing physicians not to balance-bill subscribers. In this instance, plan officials' desire to make the program a success in terms of participation effectively prevented them from vigorously negotiating with physicians over an important cost item. Of course, the plan may have sensed accurately that no urologists (other than perhaps those at Duke, which may have higher costs in

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<sup>53</sup>Personal communication with William Jordan, M.D. (July 1985). This meant that the physicians associated with Carolina Lithotripsy would not "participate" in NCBCBS and that their patients would therefore not be protected from "balance billing." See *supra* note 45.

<sup>54</sup>Personal communication with Clifford Balin, Director of Professional Benefits, NCBCBS (Nov. 1986).

<sup>55</sup>Personal communication with Clifford Balin, Director of Professional Benefits, NCBCBS (Jan. 1987).

<sup>56</sup>*Id.*

other respects) would agree to participate at the lower rate and that balance billing would not trigger price shopping and effective price competition in the highly concentrated ESWL market.

Because the NCBCBS effort was doomed from the outset, the gesture that it made—difficult as it was for the plan officials concerned<sup>57</sup>—must strike an outsider as a pathetic demonstration of how ineffectual Blue Cross and Blue Shield plans generally are in challenging providers on economic issues.

The NCBCBS experience with lithotripsy fees also reveals the basic fallacies of the UCR method of setting reimbursement limits.<sup>58</sup> Essentially, the idea behind UCR is not, despite appearances, that market-determined prices can serve as a yardstick of what a proper allowance might be; there is in fact no pretense that only market-determined (as opposed to insurer-reimbursed) fees are considered in setting UCR limits. Instead, the premise underlying a UCR fee ceiling is simply that the great majority of physicians, as ethical practitioners exercising professional discretion, do not charge unreasonable or unconscionable prices and that it is therefore necessary only to compare a physician's fee with those of his peers to discover its reasonableness. Only a minute's reflection reveals how completely this conception of how professional services should be priced embodies the ideology of organized medicine, with its strong opposition to any arrangement inviting price competition among physicians. It is apparent then how NCBCBS, like other Blue Cross and Blue Shield plans that have followed similar policies, serves the interests of a medical cartel.<sup>59</sup> Only an insurer that had been bred specifically—as Blue Shield plans were<sup>60</sup>—for the purpose of advancing physicians'

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<sup>57</sup>Plan personnel viewed themselves—with some justification—as being courageous in taking on the urologists and indicated that they would probably not have been able to do as much as they did had Dr. Paulson, a respected physician, not come forward as an ally. Personal communication with William DeMaria, M.D., Medical Director, NCBCBS (July 1985). One plan official stated that the allowance for ESWL was finally set at an amount equal to NCBCBS's average for an open surgical procedure. Personal communication with Clifford Balin, Director of Professional Benefits, NCBCBS (Jan. 1987). This allowance was viewed as an accomplishment because it is 10% to 25% less than urologists' actual stated charges for lithotripsy. *Id.* However, this allowance is obviously far in excess of that which NCBCBS sought.

<sup>58</sup>See Crump & Maxwell, *Health Care, Cost Containment, and the Antitrust Laws: A Legal and Economic Analysis of the Pireno Case* 56 S. CAL. L. REV. 913, 915-18 (1983) (description and defense of the UCR method of payment); Roe, *The UCR Boondoggle: A Death Knell for Private Practice?*, 303 NEW ENG. J. MED. 41 (1981) (stating that the UCR concept has failed to control escalation of medical costs because it contains none of the limits applied to other services covered by insurance).

<sup>59</sup>See *infra* text accompanying notes 100-21.

<sup>60</sup>See, e.g., ANDERSON, *HEALTH SERVICES IN THE UNITED STATES* 121-32 (1985) (explaining that Blue Shield plans were sponsored by state and county medical societies); BUREAU OF COMPETITION, FTC, *MEDICAL PARTICIPATION IN CONTROL OF BLUE SHIELD AND CERTAIN OTHER OPEN-PANEL MEDICAL PREPAYMENT PLANS* (Staff Report and Proposed

economic interests could maintain that the UCR system is a responsible way to disburse the public's money to physicians.

The long survival of the UCR method for "controlling" physician fees might suggest that consumers approved the ideology supporting the practice of using nonmarket rather than market mechanisms for procuring medical services. A closer look, however, reveals that because of ethical and legal restraints imposed on contract and corporate practice<sup>61</sup> and the resistance of provider cartels to those payers who sought to buy provider services on competitive terms,<sup>62</sup> consumers were rarely offered any alternative. Although recent years have seen the growth of such alternatives as health maintenance organizations (HMO's) and so-called preferred-provider organizations (PPO's), traditional payment mechanisms remain dominant in North Carolina.<sup>63</sup> The recent experience with lithotripsy fees provides an example of the high cost that consumers bear as a consequence. As discussed below, this experience, which is far from an isolated instance, demonstrates the burdens that providers and Blue Cross or Blue Shield plans, acting together, impose on consumers.

### B. *The Doctors Split Their Winnings*

In another expression of its concern about cost containment, NCBCBS at one point declared its opposition to payments by lithotripsy centers to physicians merely for referring patients for treatment.<sup>64</sup> Although these payments were represented as being fees for follow-up services, NCBCBS personnel feared that the fees paid to the referring physicians were in fact unethical fee splitting—that is, rebates or kickbacks paid for procur-

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Trade Regulation Rule, April 1979) (describing historical origins of Blue Shield plans as creatures of state and local medical societies).

<sup>61</sup>In *American Medical Ass'n v. FTC*, 638 F.2d 443 (2d Cir. 1980), *aff'd by an equally divided Court*, 455 U.S. 676 (1982), the court enforced an FTC decision condemning professional societies' ethical prohibitions on "contract practice"—that is, physicians contracting with lay-controlled intermediaries that might be viewed as retailing professional services to the public. Common-law and statutory restrictions on corporate intermediation in the doctor/patient relationship have also interfered with the ability of consumers to employ a sophisticated agent to select health care providers and bargain with them on consumers' behalf. See, e.g., Att'y Gen. Op. No. 81-1004 (Calif., April 7, 1982); Rosoff, *The "Corporate Practice of Medicine" Doctrine: Has Its Time Passed?*, HEALTH LAW DIGEST, Dec. 1984, at 1 (Supp.).

<sup>62</sup>See, e.g., Havighurst, *Professional Restraints on Innovation in Health Care Financing*, 1978 DUKE L.J. 303, 306-19.

<sup>63</sup>See *infra* notes 119-20; see also Conn, *Health Maintenance Organizations Arrive in North Carolina*, N. C. INSIGHT, Feb. 1985, at 58, 62 (noting that there were 36,600 enrollees in North Carolina HMO's in January 1985).

<sup>64</sup>Personal communication with William DeMaria, M.D., Medical Director, NCBCBS (July 1986).

ing the patient's business for the center.<sup>65</sup> NCBCBS later accepted urologists' assurances that appreciable services were indeed being provided following treatment with ESWL.<sup>66</sup> At least one physician receiving such a fee viewed it as a payment for the referral, however.<sup>67</sup> In any event, the practice has not been discontinued.<sup>68</sup>

The medical profession has long regarded fee splitting as an unethical practice, and it has been the object of attention by licensing authorities and professional associations concerned with professional conduct.<sup>69</sup> A primary concern has been that rebates will distort a physician's professional judgment in referring a patient to a specialist, causing either referrals for unnecessary care or the selection of a specialist on a basis other than exclusive concern for the patient's welfare. The issue is more complex, however, than it first appears, and indeed it is possible that a referral fee may actually improve the chances that a patient will get optimal treatment. Without such an inducement to refer the patient, a primary physician may be tempted to provide a service himself rather than allow another more qualified or better equipped physician to earn the fee.<sup>70</sup> In the case of a patient with a kidney stone, for example, a physician might be induced to exaggerate his doubt about how the case should be managed and then to resolve such doubt in favor of medical management or surgery rather than referral for ESWL. As economist Mark Pauly has observed, prohibitions on fee splitting may leave the

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<sup>65</sup>Plan personnel had two concerns about payments for follow-up services to a referring physician for "post-procedure" care. First, they sought assurance that this payment was not merely a referral fee but was for care actually provided. Second, they wanted to ensure that patients had full knowledge of these fee arrangements. Personal communication with Clifford Balin, Director of Professional Benefits, NCBCBS (Jan. 1987).

<sup>66</sup>*Id.*

<sup>67</sup>Personal communication with John Weinerth, M.D., Associate Professor of Surgery, Duke University Medical Center (July 1986).

<sup>68</sup>NCBCBS, in paying the physician's charge or reimbursing a patient for a cost incurred, had no easy way of knowing whether the physician was splitting the fee with another physician. NCBCBS did, however, refuse to reimburse the portion of the lithotripsy professional fee designated for "after care" by the primary urologist unless such care was actually provided. Personal communication with William DeMaria, M.D., Medical Director, NCBCBS (Aug. 1986).

<sup>69</sup>See, e.g., AMERICAN MEDICAL ASS'N, PRINCIPLES OF MEDICAL ETHICS § 6.03 (1982); 53 Ops. Cal. Att'y Gen. 117, 118 (1970) (interpreting the California prohibition). The American College of Surgeons has adopted an interpreting statement explaining that it considers a form of fee splitting the practice of billing a patient a single fee for lithotripsy and then distributing a portion of the fee to the referring physician. *Regents Issue Statement on Fees for Lithotripsy*, AM. COLLEGE SURGEONS BULL., April 1986, at 21. The College stated that the charge for services and identity of the provider should be disclosed to the patient. *Id.*

<sup>70</sup>As the supply of physicians grows and primary physicians become less busy, they may feel greater pressure to keep patients rather than refer them to specialists. Pauly, *The Ethics and Economics of Kickbacks and Fee Splitting*, 10 BELL J. ECON. 344, 348 (1979).

patient no less dependent upon the primary physician's ethical ability to subordinate self-interest in making professional judgments.<sup>71</sup> In addition, Pauly notes that other forms of reciprocity — cross-referrals and conferral of other benefits—are practiced and are condoned or at least ignored by licensing and professional authorities. It is not clear that patients' interests would be adversely affected if fee splitting were permitted and openly practiced.<sup>72</sup>

From the perspective of NCBCBS and other, particularly governmental, third-party payers, fee splitting naturally appears as an instance of "fraud and abuse."<sup>73</sup> Assuming, however, that the treatment itself was needed and of acceptable quality, it is not clear why a payer should be concerned how the fee that it has agreed to pay is divided among providers. Although the willingness of the referral specialist to rebate a portion of his fee is a clear sign that the fee is excessive, there is no reason to expect that the fee would be reduced if fee splitting were prohibited. The irony here is that such rebates are a manifestation of price competition among specialists and proof that competition can yield substantial benefits to anyone who controls the selection of the specialist—something that traditional third-party payers have been reluctant to do. It is of course understandable why NCBCBS would be embarrassed by unjustified payments to referring urologists; such payments obviously come out of the excessive fees that NCBCBS has been unable to resist paying for the procedure. Nevertheless, efforts by NCBCBS and professional interests to suppress fee splitting would not serve to lower that fee or benefit consumers.

Indeed, it appears once again that the consumer's interest may lie in fostering, not suppressing, fee splitting. Although at first glance it may not seem to matter to consumers how physicians divide their excessive

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<sup>71</sup>*Id.* at 349; see also Schaffer & Holloman, *Consultation and Referral Between Physicians in New Medical Practice Environments*, 103 ANNALS INTERNAL MED. 600, 601 (1985).

<sup>72</sup>Tort law and possibly other legal remedies would presumably discourage the worst abuses. Also, if fee splitting were a known practice, patients would be on their guard, and some physicians might disclose their practice and share the savings with patients. Pauly, *supra* note 70, at 349.

<sup>73</sup>Indeed, section 1877(b)(1)(A) of the Social Security Act, added by the Medicare-Medicaid Anti-fraud and Abuse Amendments of 1977, expressly prohibits the receipt of "kickbacks," "bribes," and "rebates" made "directly or indirectly, overtly or covertly, in cash or in kind . . . in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under this title." 42 U.S.C. § 1395nn (1985) (Medicare). See also *id.* § 1396h(b) (Medicaid). In *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985), the court held that this statute was violated if the fee was to induce the physician to use the service, even if the fee was also intended to compensate the physician for professional services. See generally Gebhard, *Lithotripsy Referral Fees: Medicare Fraud and Abuse?*, AM. COLLEGE SURGEONS BULL., April 1986, at 16.

profits, the matter is not so simple. If a primary physician expects a rebate for referring stone patients for ESWL, he is likely to increase his competitive efforts to attract such patients, offering price and other inducements that will lower his net return and confer benefits on consumers. Again as Pauly has observed, the medical profession's historic opposition to fee splitting represents, in some measure, a desire to suppress price competition among specialists and to remove the destabilizing effects of rebates in markets for primary care.<sup>74</sup> By the same token, consumers would probably be better off if fee splitting were acknowledged as a legitimate competitive practice. Indeed, competition in fee splitting could compensate in some measure for the failure of NCBCBS and other payers to force ESWL centers to compete for the opportunity to serve their insureds.

It would be claiming too much to suggest that the problem of obtaining optimal treatment for stone patients at a competitive price would disappear if fee splitting were tolerated. Questions would still exist concerning the incentives and professional integrity of referring physicians and the ability of patients or insurers to detect and thus deter physician abuse. Moreover, the high level of concentration in ESWL markets suggests that competition may not be effective in forcing ESWL fees down to truly competitive levels.<sup>75</sup> Finally, some of the competitive strategies employed by primary physicians to attract stone patients would undoubtedly involve wasteful nonprice inducements, adopted precisely because price competition is unavailing when patients are heavily insured. Despite these reservations, however, the problems uncovered in the existing system make it highly probable that efficient allocation of resources is more likely to be approached under open competition than under the conventional arrangements sponsored by NCBCBS and favored and fostered by organized medicine.

#### IV. THE COMING SHOWDOWN—BUYING AND SELLING ESWL UNDER THE NEW RULES

North Carolina's deregulation of lithotripters prompts speculation about the outcome of the new lithotripsy game. Many bettors predict

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<sup>74</sup>Pauly, *supra* note 70, at 348. For other instances in which prohibitions of rebating served anticompetitive purposes, see Department of Ins. v. Dade County Consumer Advocate's Office, 492 So. 2d 1032 (Fla. 1986) (statute prohibiting rebates to consumers by insurance agents held unconstitutional); Owen, *Kickbacks, Specialization, Price Fixing, and Efficiency in Residential Real Estate Markets*, 29 STAN. L. REV. 931, 949-55 (1977) (title insurer's rebates to brokers).

<sup>75</sup>Given the oligopolistic character of the ESWL market, the amount of the rebate is likely to become standardized through tacit collusion. See *infra* text accompanying note 91.

that North Carolina citizens will lose, incurring substantially higher costs without enjoying commensurate benefits. Although a consumer victory can be imagined, it remains to be seen whether the players fielded by consumer interests, particularly NCBCBS, will change their strategy and improve their performance enough to produce an outcome different from that envisioned by the oddsmakers.

#### A. *Prospects for a Consumer Defeat*

If payment systems retain the forms favored by NCBCBS and providers, North Carolinians face the prospect that they will have to pay in full the costs of purchasing and maintaining an excessive number of costly lithotripters. In a normal competitive market, consumers are benefitted, not harmed, by excess producer capacity. As sellers ignore their "sunk" costs—that is, those investments that cannot be recovered by withdrawing from the market—competition causes unit prices to fall below average total cost, giving consumers a bargain until equilibrium is restored by the withdrawal of some capacity.<sup>76</sup> Competitive conditions also deter the creation of inefficient overcapacity because a would-be investor could not expect to recover his investment in new facilities unless existing facilities were either inadequate or relatively inefficient. In health care, unfortunately, because traditional reimbursement mechanisms give patients little reason to shop for low prices, it has not been possible to count on competition to drive prices below average total cost and to discourage overinvestment. If would-be investors in North Carolina lithotripters currently believe that existing financing arrangements are not likely to change before they have recovered their capital outlays,<sup>77</sup> North Carolina consumers do indeed face unjustified higher costs as a consequence of deregulation.

Higher prices to North Carolinians may also result from other causes. If payment systems do not threaten now or in the near future to put competitive or other pressure on high-cost providers, a would-be investor

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<sup>76</sup>Under competition, prices tend to equal marginal cost, the cost of the last unit produced. With overcapacity, marginal cost includes no capital costs. On the other hand, if production is at full capacity, marginal cost includes the cost of the capacity that must be added to increase production. See generally P. AREEDA, *ANTITRUST ANALYSIS* ¶ 114-16 (3d ed. 1981).

<sup>77</sup>An issue arises concerning the period over which an investor can recover his investment. In North Carolina, ESWL providers have pressed to have NCBCBS reimburse hospitals for lithotripter depreciation on the basis of a two-year useful life; NCBCBS has argued for amortization over five years. Personal communication with Clifford Balin, Director of Professional Benefits, NCBCBS (Aug. 1986). NCBCBS has resolved the dispute. *Id.* Obviously, a longer period of payback increases the risk that market conditions, including insurer practices, will change in ways detrimental to providers and will thus discourage overinvestment in lithotripters.

has no reason to await the availability of a lithotripter less costly than the Dornier device. In addition, consumers cannot expect to enjoy across-the-board cost savings when lower-cost devices do appear; they would instead, under prevalent cost-reimbursement formulas, continue to pay the full depreciation costs of obsolete equipment.<sup>78</sup> Finally, the absence of effective price competition would also allow providers who are not reimbursed strictly on the basis of costs actually incurred—physicians, in particular—to charge prices well in excess of their costs. It has already been shown how UCR allowances in North Carolina represent excessive payments for professional services. The ability of physicians to overcharge for their role in ESWL reflects the noncompetitive conditions prevalent in that market. Unfortunately, unless changes occur in payment systems, eliminating CON-protected monopolies of ESWL may not bring prices down.

A proliferation of lithotripters might also trigger higher health care costs in the form of overuse of the devices to treat stone patients who could be managed satisfactorily at much less expense without resorting either to the device or to surgery.<sup>79</sup> Traditional payment systems offer only weak defenses against such overutilization. One theory supporting CON regulation was that supply could be curtailed to an extent that

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<sup>78</sup>The Medicare program's position regarding capital costs is very much in limbo at the moment, contributing substantially to the uncertainty facing would-be investors in North Carolina lithotripters. Currently, under Medicare's prospective payment system, capital costs (depreciation, interest, and return-on-equity for for-profit institutions) are not included as part of per-case payment rates, but are reimbursed at actual cost. See E. POWER, *EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY AND THE MEDICARE PROSPECTIVE PAYMENT SYSTEM* 8, 14 (1985). Because hospitals are assured coverage of the acquisition costs, hospitals are encouraged to acquire new technologies. *Id.* at 19.

However, the Reagan Administration has proposed a plan to phase Medicare capital payments into DRG's over a four-year transition period, beginning with fiscal year 1987 cost reports. Firshein, *HHS Capital Plan Arouses Provider Anxieties*, *HOSPITALS*, June 20, 1986, at 24 [hereinafter *HHS Capital Plan*]. Payments would be based on hospital-specific and national rates, with fiscal year 1983 cost reports trended forward. Firshein, *Providers Call '87 PPS Increase 'Unacceptable'*, *HOSPITALS*, July 5, 1986, at 31.

Meanwhile, hospitals and other providers are urging Congress to intervene. *Id.* Senator David Durenberger (Rep.-Minn.) has proposed a plan to fold Medicare capital payments into DRG's over a seven year period. *HHS Capital Plan, supra*, at 24. In addition, both the House and Senate have approved a supplemental appropriations bill that includes a one-year moratorium on inclusion of capital costs. *Hospital Shouldn't Wait to Evaluate Medicare Changes for Fiscal Year 1987*, 4 *PROSPECTIVE PAYMENT SURVIVAL* 108 (1986).

<sup>79</sup>Even though efficiency considerations may dictate using ESWL in many cases if overcapacity already exists, new capital investments enabling the provision of ESWL in identical cases would not necessarily be indicated. This anomaly results because, if the capacity is not already in place, the marginal cost of additional treatments, which must be compared to the advantages of ESWL over alternative therapy, includes the cost of new capacity and is therefore significantly higher than it would be if a lithotripter were standing idle. See *supra* note 76.

would force health care providers to ration limited resources to their best uses. Political conditions, however, have usually made it impossible for CON regulators to challenge medical opinion on appropriate utilization or to do more than try to prevent the creation of unused capacity.<sup>80</sup> Although CON regulation has therefore probably done little to contain the excess demand for services induced by passive insurance plans,<sup>81</sup> the lifting of CON restrictions, by removing the occasion for regulatory determinations of need, may have created some additional risk that physicians will extend their use of ESWL technology well beyond the point at which its benefits are at least equal to its cost of roughly \$6,000 per procedure.<sup>82</sup> Lacking the ability to resist paying for all services that

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<sup>80</sup>See C. HAVIGHURST, *supra* note 13, at 36 (reporting an informal survey indicating that CON regulators see their role only as preventing duplication, not as forcing rationing).

<sup>81</sup>See references cited note 40 *supra*. See also C. HAVIGHURST, *supra* note 13, at 58-63 (demonstrating graphically how "inflationary pressures [attributable to passive insurance plans] may, like a balloon, bulge out at another place even if growth in one direction is effectively prevented").

<sup>82</sup>Indeed, North Carolina urologists have already begun to suggest that the device is appropriately employed to treat stones that are small enough to pass (with some discomfort, to be sure) through the urinary tract. *E.g.*, Personal communication with John Weinerth, M.D., Chief of Urolithiasis Service and Associate Professor of Surgery, Duke University School of Medicine (July 1986). Elsewhere urologists are finding other possible uses for lithotripsy, including its use against gallstones. See Sauerbruch, *Fragmentation of Gallstones by Extracorporeal Shock Waves*, 314 *NEW ENG. J. MED.* 818 (1986). The procedure may also be useful against bladder and kidney tumors. See Russo, *High Energy Shock Waves Suppress Tumor Growth in Vitro and in Vivo*, 135 *J. UROLOGY* 626 (1986); *Shock Waves Being Used to Bombard Cancer*, *Durham Morning Herald*, Nov. 17, 1986, at 1B, col. 1.

The "need" for lithotripsy and indeed for most medical services is difficult to determine for several reasons. Most observers are much more comfortable in asking simply whether the service is at all beneficial than in judging whether beneficial treatment is appropriate by comparing benefits with marginal cost. Moreover, the variability of marginal cost noted *supra* notes 76 and 79 reveals that appropriateness may depend on the availability of unused equipment and not exclusively on medical circumstances. The resolution of the need question is also complicated by partisanship. In utilization review, providers tend to be liberal in defining the need for their own services. See generally Havighurst & Blumstein, *Coping with Quality/Cost Tradeoffs in Medical Care: The Role of PSROs*, 70 *Nw. U.L. REV.* 6 (1975). In CON review, the "haves" tend to minimize need and the "have-nots" to exaggerate it.

One Duke physician has stated that the studies used by the North Carolina CON agency greatly underestimated the need for lithotripsy. Personal communication with John Weinerth, M.D., Chief of Urolithiasis Service and Associate Professor of Surgery, Duke University School of Medicine (Aug. 1986). The North Carolina Work Group Report, prepared by physicians and administrators, estimated that approximately 20% of renal stone patients would be lithotripsy candidates. See North Carolina Lithotripter Work Group Report (June 14, 1985). Weinerth argued, however, that recent unpublished reports from lithotripsy centers throughout the United States indicate that 85% of all renal stone patients would benefit from lithotripsy. Weinerth explained that certain types of patients that were previously thought ineligible for lithotripsy, such as pediatric patients, patients with bilateral stones, and patients with staghorn calculi, may be lithotripsy candidates. However, a study

physicians prescribe in good faith, traditional health insurers expose North Carolina consumers to yet another source of unjustified higher costs.

### B. Available Defenses

If unjustified cost increases of the foregoing kinds are to be averted in North Carolina, insurers of ESWL must find ways of limiting the fees and charges they will pay and of ensuring that only justified services are provided. The defensive strategies available include writing insurance policies that restrict coverage of the procedure, limit the amount payable for it, or deny or limit coverage of the ESWL services of particular providers.<sup>83</sup> Vigorous implementation of these approaches would be inconsistent with the practices of traditional insurers, however, being more like the choice-limiting methods of HMO's, PPO's, and other alternative financing and delivery mechanisms. Because financing plans of the latter types enroll only a small fraction of insured North Carolinians,<sup>84</sup> cost escalation is highly likely unless fundamental changes occur in the coverage enjoyed by the great majority of citizens. The small increases in the overall cost of traditional health insurance that are attributable to the deregulation of lithotripters are unlikely in themselves to induce a significant shift to alternative health plans.

Perhaps the easiest cost-containment strategy for controlling overutilization of ESWL is a contractual limitation of the plan's obligation to pay for the service in the absence of specified medical indications. As a practical matter, however, such a contractual condition of coverage is difficult to administer. For example, enforcement of a provision denying coverage for the shattering of small stones below two millimeters<sup>85</sup>

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at Shands Hospital of the University of Florida estimated that even fewer renal stone patients would be lithotripsy candidates. See Memorandum from Shands Hospital to All State Health Planning Agencies (April 17, 1985). Shands Hospital was involved in the clinical testing of the lithotripter and thus was among the first to receive the machine. Weinerth explained that the Shands group may have been overly conservative in their estimate of the need for lithotripsy because they had no interest in having a large number of lithotripsy centers enter the market.

<sup>83</sup>For a general discussion of cost-control strategies available to private financing programs, see Havighurst & Hackbarth, *Private Cost Containment*, 300 N. ENG. J. MED. 1298 (1979).

<sup>84</sup>See *infra* note 120.

<sup>85</sup>See Drach, *Urinary Lithiasis*, in CAMPBELL'S UROLOGY 1123 (5th ed. 1986) (stating most urinary stones less than 5 mm will pass spontaneously and patients with small stones may be treated with pain relief and instructions about recovery of stone). See also Preminger, *The Current Role of Medical Treatment of Nephrolithiasis: The Impact of Improved Techniques of Stone Removal*, 134 J. UROLOGY 6, 6, 9 (1985) (stating that in a study of 103 consecutive stone clinic patients, only 2% of the patients on medical therapy required an operation for newly formed stones, whereas 58% to 69% required an operation for new stones before beginning medical treatment; noting that the cost of management is less than \$1,000 per year).

would require either that the plan accept the physician's representation of the stone's size or that x-ray evidence be obtained before the procedure. Enforcement of an evidentiary requirement by denial of coverage would be unreasonable, however, unless the patient or the physician knew of it in advance. Not only are patients unlikely to be aware of such administrative details, but physicians may also be unaware or may refuse to cooperate, insisting that the insurer should accept either their representations of the facts or their clinical judgments concerning patients' needs. In a similar situation, Indiana dentists organized a concerted refusal to provide x-rays to dental insurers for cost-containment purposes. Although that conspiracy was held to be an antitrust violation,<sup>86</sup> individual refusals to cooperate with insurers are to be anticipated.<sup>87</sup> Urologists might well claim that individual cases differ so that medical necessity cannot be determined without a fuller medical inquiry. Consequently, given the burdens associated with coverage restrictions and their unpopularity with patients and providers alike, it appears improbable that the possibility of saving a few dollars on claims for ESWL will alone trigger adoption of these strategies by North Carolina insurers.

North Carolina insurers might bring unit prices and utilization under some control by increasing cost sharing by patients, by tightening limits on reimbursable fees, or by shifting to fixed-indemnity coverage. Each of these approaches would be aimed at reducing the insurer's exposure and increasing the consumer's financial stake in each transaction in the expectation that he will shop for care with cost considerations more prominently in mind. Consumers may not be happy, however, to accept these new responsibilities and increased financial burdens. Moreover, there is little reason to believe that consumers would be especially effective shoppers or that conditions conducive to price competition prevail in the market for ESWL. Although a fixed indemnity payment for ESWL would seem to be a sensible policy and one that a particular insurer could rather easily adopt, strategies of this kind have been freely available to all insurers for a long time but have rarely been employed. It is

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<sup>86</sup>FTC v. Indiana Fed'n of Dentists, 106 S. Ct. 2009 (1986).

<sup>87</sup>A legal issue would arise if a physician billed for a service he had rendered knowingly without complying with the preconditions of the patient's insurance. Although precedent is scanty, cf. Eisenberg & Rosoff, *Physician Responsibility for the Cost of Unnecessary Medical Services*, 299 N. ENG. J. MED. 76 (1978), such a negligent failure to meet the patient's needs would seem to open the physician to professional liability for damages equal to the amount of insurance reimbursement lost. However, even though a patient might thus successfully resist a suit to collect the physician's bill, an insurer would undoubtedly find it both awkward to deny the patient's claim and difficult to ensure that physicians were aware of its requirements and their applicability to particular patients. Nevertheless, some insurers have required patients to obtain either second opinions on the need for treatment or the insurer's prior authorization of coverage for such elective procedures.

unlikely that the deregulation of ESWL poses enough of a threat of cost escalation to prompt significant redesign of coverage along these lines.

The most practical and effective approach to cost containment in private health insurance would concentrate not on writing selective coverage of ESWL or shifting costs from the insurer to its insureds, but on excluding certain providers altogether from eligibility to provide covered services. This approach, however, would violate the principle of free choice of provider that is embedded in the standard coverage offered by NCBCBS and strongly favored by health care providers. Such exclusion would also violate North Carolina law, which permits insurers to cover the services of designated "preferred providers" on more favorable terms but prohibits an insurer from excluding providers completely from treating insured patients at the insurer's expense.<sup>88</sup> Thus, although the ability to exclude a high-cost or uncooperative provider altogether from plan coverage might allow an insurer to obtain even more favorable results, North Carolina insurers wishing to procure ESWL services for their insureds on favorable terms must employ the PPO mechanism.<sup>89</sup>

The potential value to consumers of letting the insurer act as a middleman in procuring hospital and physician services is powerfully demonstrated by the ESWL situation in North Carolina. If an insurer could deliver paying patients to a provider by designating it as either the exclusive or a preferred provider of insured services, the insurer could bargain for a fair price both from the hospital for use of the lithotripter and from the physician presiding over the procedure.<sup>90</sup> In addition, the insurer could seek providers' cooperation with its efforts to control overutilization. Conversely, an insurer, such as NCBCBS, that feels constrained to cover care at all centers on equal terms lacks the ability to steer patients away from a high-cost provider and therefore has no bargaining power.

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<sup>88</sup>N.C. GEN STAT. §§ 57-16.1, 58-260.5 -.6 (1985).

<sup>89</sup>On the PPO concept, see generally P. LINDSEY, STATE LAWS AND REGULATIONS GOVERNING PREFERRED PROVIDER ORGANIZATIONS: ANNOTATED BIBLIOGRAPHY ON PREFERRED PROVIDER ORGANIZATIONS (1986); E. ROLPH, STATE LAWS AND REGULATIONS GOVERNING PREFERRED PROVIDER ORGANIZATIONS (1986); E. ROLPH, STATE LAWS AND REGULATIONS GOVERNING PREFERRED PROVIDER ORGANIZATIONS: EXECUTIVE SUMMARY (1986).

<sup>90</sup>The practice of fee splitting, *see supra* text accompanying notes 73-75 suggests that price competition is indeed feasible if a payer is willing to influence insured patients to select the low-cost provider. NCBCBS claims that it has been able to negotiate with providers on the machine use fee. Under the plan's provider contracts, the professional fee is reimbursed at a UCR rate, but the facility fee is negotiated, taking into account the provider's costs. Personal communication with William DeMaria, M.D., Medical Director, NCBCBS (Aug. 1986). *See supra* note 77. Because NCBCBS does nothing to steer its insureds to lower-priced centers, however, its bargaining power is minimal.

Despite the theoretical potential for obtaining competitive terms from providers through hard bargaining, the small number of providers of ESWL makes the real-world prospects for effective bargaining problematic. In any oligopolistic industry, the danger exists that each of the few competitors will realize that any aggressive competitive move that it might make in search of a short-run advantage would simply cause its competitors quickly to follow suit, making all of them worse off in the long run. With this perception of their "interdependence," the oligopolists are each likely to refrain from competitive moves, producing essentially the same result as if they had agreed explicitly not to compete.<sup>91</sup> In addition to creating conditions conducive to tacit collusion, the small number of competitors in the market also facilitates explicit agreements in restraint of trade. Even if ESWL providers did not actually fix prices, they might well agree, tacitly or overtly, to eschew competitive contracting with insurers. It is highly probable that an insurer seeking a beneficial contract for ESWL services in a market with few sellers would encounter substantial resistance to its proposals.

In keeping with the prediction that a concentrated provider market is unlikely to be competitive, North Carolina HMO's reported before deregulation that they anticipated no success in obtaining lithotripsy on special terms for their patients. Deregulation of lithotripsy may have significantly improved the prospects for competitive bidding, however.<sup>92</sup> With deregulation, a payer may now shop not only among the five providers originally in the market, but also among providers who were previously barred from entry. Indeed, Duke, which already has a lithotripter and has signified a willingness to accept a small professional fee, may be a lower-priced source of treatment. Even if Duke turns out to be no cheaper overall or inadequately cooperative with insurers' utilization-control efforts, the possibility remains that an insurer, acting

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<sup>91</sup>On oligopolists' interdependence, see generally 6 P. AREEDA, *ANTITRUST LAW* ¶ 1428-36 (1986).

<sup>92</sup>The CON program previously hindered the efforts of payers to obtain lithotripsy at competitive prices. Dr. Lawrence Oakes, Medical Director for the Kaiser-Permanente plan in North Carolina, explained that if there are a number of providers of a medical service in a given area, Kaiser can award an exclusive contract to the lowest-cost provider. Personal communication with Lawrence Oakes, M.D. (June 1985). This type of bargaining, however, is impossible in a monopolistic situation. Dr. Samuel Warburton, Vice President of the Health America plan in North Carolina, reported that prior to deregulation, he was unable to negotiate a urologist's fee for lithotripsy that was close to what he believed to be a competitive price. Personal communication with Samuel Warburton, M.D. (June 1985). Since deregulation, the plan has obtained a more satisfactory price. Warburton explained that, with prices for ESWL as high as \$12,000 per procedure, Health America has been able to obtain a \$4,300 total fee for an uncomplicated renal stone procedure. Personal communication with Samuel Warburton, M.D. (Oct. 1986). Warburton said he anticipates that he may be able to bargain for a total fee of \$2,500 in 1987. *Id.*

independently or in concert with others, could stimulate the entry of yet another, lower-cost provider by offering it a long-term contract as the exclusive or preferred provider of ESWL services to its subscribers. Armed with the threat to pursue this newly available strategy, an insurer should find existing providers more willing to bargain for its business. It is paradoxical but crucial that repeal of CON requirements can generate pressure for lower prices even if no new entrant actually materializes.<sup>93</sup> Potential competition is frequently more effective than actual competition in keeping prices down in concentrated markets.

Despite the foregoing theoretical possibilities for effective cost containment, NCBCBS has so far made no move to change its methods of purchasing ESWL,<sup>94</sup> and other insurers, with a smaller overall stake, are even less likely to take specific steps to control the costs of ESWL in a deregulated environment. The financing system thus remains, as it was before deregulation, an invitation to overinvestment in lithotripters. Because North Carolina payers lack the ability or the will to control overutilization of ESWL and to buy cheaply in an overstocked market, North Carolina consumers face the prospect of a costly defeat in the new phase of the lithotripsy game.

#### V. MAKING THE GAME COMPETITIVE

An informal survey following the 1986 deregulation of ESWL by the North Carolina legislature revealed no provider with plans to install a lithotripter in the state other than the seven original aspirants, each of which was finally successful in negotiating the regulatory/political path to market entry—four by obtaining CON's, one (Piedmont) by exploiting a statutory loophole for nonhospital-based equipment, and two (Duke and St. Joseph's) by getting legislative assistance.<sup>95</sup> It is a mistake to conclude, however, because deregulation failed to trigger a burst of new investment, that market forces are satisfactorily controlling ESWL costs in North Carolina. Instead, because seven lithotripters appear themselves to be too many to service the state efficiently, it can be observed that regulation itself failed to prevent the creation of excess capacity.<sup>96</sup> More generally, it can be suggested that CON regulation,

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<sup>93</sup>*Cf.* C. HAVIGHURST, *supra* note 13, at 234-36 (discussing how allowing HMO's to build new hospital facilities without a CON stimulates not new hospitals, but greater willingness of existing institutions to bargain with HMO's).

<sup>94</sup>Personal communication with William DeMaria, M.D., Medical Director, NCBCBS (Nov. 1986) (stating that NCBCBS was contractually bound in its subscriber contracts to pay the UCR reimbursement to providers).

<sup>95</sup>*See supra* notes 16-36 and accompanying text.

<sup>96</sup>It seems appropriate to count the Duke and St. Joseph's lithotripters as entering the market under regulation, not deregulation. *See supra* notes 25-36 and accompanying text.

almost inevitably politicized, provides unreliable protection for consumer interests whenever the financing system creates a lucrative market opportunity for providers. But whatever the final conclusion concerning regulation's value,<sup>97</sup> North Carolina's ESWL experience underscores that the fundamental source of the problem of overspending on health care is the dominant system of financing services. Under regulation, that system created powerful incentives for North Carolina providers to overexpand ESWL and gave rise to pressures that were impossible for the regulators and the political system to contain or to resist. Following deregulation, the financing system's chronic inability to take advantage of what should be a buyer's market for ESWL leaves North Carolina providers free to create unneeded, inefficient capacity and to operate it profitably at the public's expense.

Health care financing in North Carolina is typical of that found in most other markets for health services. Although there are increasing reports of major outbreaks of competitive buying and selling of provider services in many places throughout the nation, traditional financing as found in North Carolina remains the norm, and truly independent and competitive systems remain exceptional.<sup>98</sup> Despite the hopeful signs of effective competition in some markets, the ineffectiveness of the dominant health insurance mechanisms in controlling the price and cost of all health services, not just ESWL, has been notable for so long that one must wonder whether the game being played was or is a fair one<sup>99</sup> and whether a fundamental change in its rules may be necessary.

#### A. *Is the Game Rigged?—"Say It Ain't So, Joe!"*

The historical failure of conventional health care financing systems to defend consumer interests invites attention to the possibility that some of the players whom the fans have been supporting against providers

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<sup>97</sup>Deregulation might be safer if prepared for in advance. Recent deregulation in Arizona and Utah is alleged to have triggered a burst of capital spending. *See Arizona Deregulation Spurs Growth in Medical Facilities*, AM. MED. NEWS, September 19, 1986, at 7 (Arizona is experiencing an "unprecedented growth" in health care facilities as a result of repeal of CON regulations for hospitals and nursing homes). Although no objective evaluations of these experiences (by persons other than the displaced planners and regulators themselves) have been done, there may be some reason for concern. For a full statement of the case for deregulation and strategies for achieving it, see generally C. HAVIGHURST, *supra* note 13.

<sup>98</sup>*See infra* notes 119-20.

<sup>99</sup>A major source of unfairness to consumers has been providers' success in establishing the rules of competition in the health care sector. *See, e.g.*, Havighurst, *supra* note 62 (discussing restrictions imposed by providers on insurers' freedom to control costs and the potential value of antitrust law in eliminating such restrictions). Blue Cross and Blue Shield plans are also implicated in providers' efforts to make and enforce the rules of the game. *See infra* text accompanying notes 104-09.

may not have been playing to win. Unthinkable as this hypothesis may seem, the failure of NCBCBS to defend effectively against providers of ESWL is not just an isolated collapse attributable to one plan's poor management and lack of skilled players. Other teams in Blue uniforms have also consistently failed to strive for a consumer victory, appearing instead to have joined with providers to rig the outcome. Not only did the Blues themselves perform badly in the cost-containment field, but, as the following discussion briefly explains, their policies were instrumental in handicapping HMO's and commercial health insurers—other teams on which consumers might have placed their bets.<sup>100</sup>

The reason why many Blue Cross and Blue Shield plans did not battle providers successfully for lower costs and prices is, quite simply, that favoring consumers over providers was usually not in their corporate interest. Even after Blue plans were no longer controlled by the dominant hospital and physician organizations that created them, they generally adhered to a business policy of respecting and even furthering the economic interests of their original sponsors.<sup>101</sup> Indeed, many Blue plans appeared to prosper in the ensuing years, not because they offered consumers good value in insurance products, but because of the close relationships they maintained with organized providers.<sup>102</sup> Together with

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<sup>100</sup>See generally Havighurst, *Explaining the Questionable Cost-Containment Record of Commercial Health Insurers*, in *THE POLITICAL ECONOMY OF HEALTH CARE* (H.E. Frech ed., to be published). The machinations of providers and Blue Cross and Blue Shield plans somewhat excuse the poor cost-containment record of commercial health insurers. Although numerous factors affect the supply of and demand for insurers' cost-containment services and although the issue is complex, Blue/provider alliances, many of them informal, explain why consumer cost concerns have not been effectively transmitted to providers in the marketplace. *Id.* For a recent and more positive (and conventional) view of the Blues, see Greenberg, *The Evaluation of Blue Cross in a Competitive Marketplace*, *BUSINESS & HEALTH*, Nov. 1986, at 44.

<sup>101</sup>Although the FTC's efforts largely ended direct physician control over Blue Shield plans, see *BUREAU OF COMPETITION*, *supra* note 60; FTC, Statement of Enforcement Policy, 46 Fed. Reg. 48,982 (1981), that control was already attenuated by the time the FTC acted. Blue Cross plans had gradually withdrawn from direct affiliation with state hospital associations somewhat earlier. It is most unlikely that providers would have released the Blue plans from their direct control without more compulsion if they had not anticipated that once independent, the plans, as nonprofit corporations, would continue to pursue pro-provider policies in their own self-interest. See *infra* note 102.

<sup>102</sup>Because the Blues, as nonprofit corporations, were more interested in maximizing their gross revenues and market shares than in maximizing short-run corporate profits, there was a solid basis for an enduring and mutually advantageous relationship with providers. Nonprofit firms have somewhat different incentives than for-profit firms. Managers are more interested in increasing their market shares than increasing profits because the manager's salary and prestige is more closely associated with firm size than with profitability. Frech & Ginsburg, *Competition Among Health Insurers*, in *COMPETITION IN THE HEALTH CARE SECTOR: PAST, PRESENT AND FUTURE* 175 (W. Greenberg ed. 1974). In non-profit firms, such as Blue Cross and Blue Shield, the desire for growth is even stronger because there are no profits to distribute or shareholders to object. *Id.* at 175, 184.

government-conferred tax and other benefits,<sup>103</sup> these relationships gave the Blues a substantial competitive advantage over actual and potential competitors.

The pattern of Blue/provider relationships over many years and in many markets was one in which the Blue plan and the dominant organization of hospitals or physicians each used its own market position in such a way as to preserve and strengthen the market position of the other. Mutual accommodation was assured through liaison and committee structures. Most importantly, the most successful Blue Cross plans generally enjoyed large discounts from the hospitals,<sup>104</sup> and Blue Shield plans almost universally received comparable concessions from "participating" physicians.<sup>105</sup> Because these concessions were granted by providers acting in concert rather than extracted by the Blues in competitive bidding,<sup>106</sup> they left providers in a position to function as a cartel vis-

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<sup>103</sup>For tax purposes, the IRS long exempted Blue Cross and Blue Shield plans as social welfare organizations. See I.R.C. § 501(c)(4) (1982). In the Tax Reform Act of 1986, however, Congress eliminated the tax exemption granted to Blue Cross and Blue Shield plans. See H.R. 3838, 99th Cong., 1st Sess. §1012 (1985). Commercial health insurers and other proponents of this reform contended that special tax treatment of Blue Cross and Blue Shield plans is inappropriate because the plans employ business practices of commercial insurers and are engaged in an inherently commercial activity. GENERAL ACCOUNTING OFFICE, HEALTH INSURANCE: COMPARING BLUE CROSS AND BLUE SHIELD PLANS WITH COMMERCIAL INSURERS 8-10 (1986). The Blue Cross and Blue Shield Association contended that the exemption is warranted because the exemption permits Blue Cross and Blue Shield plans to cross-subsidize coverage to high-risk individuals and small groups. *Id.* at 9.

State law also often confers valuable advantages on Blue plans in the form of exemptions from premium taxes and special privileges with regard to direct contracting with providers.

<sup>104</sup>Adamache & Sloan, *Competition Between Non-Profit and For-Profit Health Insurers*, 2 J. HEALTH ECONOMICS 225, 227-29, 240-41 (1983). The mean relative Blue Cross discount is four percent and ranges as high as 27 percent. *Id.* at 229. Large discounts frequently correspond to large market shares.

A commercial insurer unsuccessfully challenged a typical Blue Cross discount in *Travelers Ins. Co. v. Blue Cross*, 481 F.2d 80 (3d Cir. 1973). For an analysis of this case pointing out its relevance to this discussion, see Havighurst, *supra* note 100.

<sup>105</sup>The concessions usually take the form of acceptance of payments under the UCR formula as payment in full. See *supra* note 45. See generally Bureau of Competition, *supra* note 60 (describing Blue Shield payment arrangements and characterizing them as price fixing when the plan is under physician control). For a case in which physician organizations offered similar collective concessions to any payer that obtained the organizations' approval (presumably by refraining from unfriendly acts), see *Arizona v. Maricopa County Medical Soc'y*, 457 U.S. 332, 356-57 (1982) (doctors' agreement on maximum fees held unlawful price fixing under the antitrust laws).

<sup>106</sup>See, e.g., *Travelers Ins. Co. v. Blue Cross*, 481 F.2d 80, 84 (3d Cir. 1973) (discounts "negotiated jointly" by hospital association). Restrictions placed by physician organizations on individual physicians directly contracting with unapproved insurers were condemned in *American Medical Ass'n v. FTC*, 638 F.2d 443 (2d Cir. 1980), *aff'd by equally divided Court*, 455 U.S. 676 (1982); see also Havighurst, *supra* note 62, at 336-42.

a-vis the Blues' competitors. Although most Blue plans could have obtained larger price concessions by using their buying power to destroy the provider cartel, doing business with it usually proved more advantageous, yielding the Blues a net cost advantage over their competitors that was both larger and more permanent than they could have enjoyed under competition; as long as the cartel was effective, HMO's and commercial insurers could get no concessions from providers at all.<sup>107</sup> Consumers were thus unable to obtain coverage from plans that purchased provider services on truly competitive terms.<sup>108</sup> The Blues' greatest commercial successes were therefore gained, not by efficient operation in a competitive market, but by cultivating provider cartels that inflated the costs of their competitors.<sup>109</sup>

Organized providers, for their part, were generally glad to cooperate with and even to subsidize their biggest customer as long as it adhered to cartel-protective policies and provided insurance coverage in forms that obviated provider price competition<sup>110</sup> and kept demand for hospital and physician services artificially high.<sup>111</sup> Although providers complained

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<sup>107</sup>Until very recently, non-Blue payers were unable to bargain with providers for price discounts or concessions of any kind. For a full discussion of provider-imposed restraints, including boycotts of plans that offended providers, see Havighurst, *supra* note 62, at 336-42. Many commentators are noting the changing character of today's health care market. See, e.g., *Managed Care: Will It Push Providers Against the Wall?*, HOSPITALS, Oct. 5, 1986, at 66. The new pressures on providers to grant competitive discounts and to accept undesired cost controls result from a combination of circumstances, including antitrust enforcement against provider cartel behavior; state PPO legislation and PPO development; the increased cost-consciousness and aggressiveness of larger purchasers; increased competitiveness on the supply side of the market because of surpluses of both physicians and hospital facilities; government's example as a prudent purchaser of services; and realization in the private sector that government is not likely, as it threatened to do throughout the 1970's, to regulate private health care costs. Despite widespread observations of intensified competition, however, competition's potential has not yet been realized in every market, and indeed has probably not been fully realized anywhere.

<sup>108</sup>The perception that consumers freely chose Blue-style coverage, with free choice of provider, etc., in preference to other kinds of coverage is mistaken because alternative types of coverage were seldom offered with price tags reflecting the full cost advantage obtainable though limitations on choice and competitive purchasing. See *infra* note 111.

<sup>109</sup>For recent scholarship focusing specifically on exclusion of rivals by raising their costs, see Krattenmaker & Salop, *Anticompetitive Exclusion: Raising Rivals' Costs to Achieve Power over Price*, 96 YALE L.J. 209 (1986).

<sup>110</sup>Hospital cost reimbursement, payment of physicians under UCR and similar formulas, limited use of cost sharing, and guaranteed free choice of providers make consumers largely indifferent to price considerations, thus freeing providers to compete in other, cost-increasing ways.

<sup>111</sup>The Blues have systematically offered broader coverage than other insurers. This coverage benefits providers by giving broad scope to "moral hazard"—that is, insurance-induced demand and insensitivity to price. It has been hypothesized that the Blues squander much of their cost advantage over other carriers by writing coverage in forms most advantageous to providers. Frech & Ginsburg, *Competition Among Health Insurers*, in

from time to time about a Blue plan's practices, such complaints were usually not inconsistent with the existence of powerful Blue/provider alliances.<sup>112</sup> Even when a major confrontation occurred between a dominant provider organization and a Blue plan, the triggering event was usually a minor matter, hardly a sign that the plan had gone over entirely to the consumer's side.<sup>113</sup> Indeed, the Blue plan's disputed policy was usually inspired, not by the plan's own corporate initiative, but by the irresistible demand of a state insurance commissioner<sup>114</sup> or major customer.<sup>115</sup> For many years, virtually all cost-containment initiatives by Blue Cross and Blue Shield plans that were not exogenously compelled were carefully negotiated with the affected provider interests before being announced as a Blue victory on the consumer's behalf.

The action of NCBCBS in tying its own hands in the fight to get ESWL services for North Carolina consumers at competitive prices was therefore not atypical. Most Blue Cross or Blue Shield plans have similarly maintained payment systems that weaken consumers' incentive to economize while simultaneously eschewing the role of an aggressive purchasing agent procuring providers' services for consumers at competitive prices.

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COMPETITION IN THE HEALTH CARE SECTOR: PAST, PRESENT, AND FUTURE 210, 216-19 (1978). This insurance is overbroad (inefficient) in the sense that few consumers would buy it if its added costs, instead of being subsidized by providers, were reflected in its price relative to alternative coverage. The result of inefficient insurance is an overallocation of societal resources to health care.

<sup>112</sup>One should not attach undue significance to complaints about NCBCBS practices that emanate from provider camps; within any conspiracy in restraint of trade, there are always differences of opinion, sometimes serious ones, over the best collective strategy. Thus, complaints and even lawsuits challenging plan practices by individual providers are to be expected even if the Blue plan is faithfully serving cartel interests. Conceivably, even such striking cases as *Kartell v. Blue Shield*, 749 F.2d 922 (1st Cir. 1984) (unsuccessful challenge to a plan's alleged monopsonistic exploitation of physicians), *cert. denied*, 105 S. Ct. 2040 (1985), and *Ball Memorial Hosp. v. Mutual Hosp. Ins., Inc.*, 784 F.2d 1325 (7th Cir. 1986) (unsuccessful challenge to a Blue Cross-sponsored PPO as an exercise of monopsony power against hospitals), may involve only a difference of opinion concerning the best strategy for pricing provider services under emerging market conditions rather than the Blue plan's permanent defection from the old alliance. *But see* sources cited in note 117 *infra*.

<sup>113</sup>In *In re Michigan State Medical Soc'y*, 101 F.T.C. 191 (1983), a state medical society threatened a Blue plan with a statewide physician boycott because the plan attempted to control the cost of vision and hearing care. The medical society's vigorous and seemingly disproportionate reaction was prompted, not by the particular initiative itself, but by the Blue plan's unprecedented departure from the principle of free choice of physician. *Id.* at 216-21.

<sup>114</sup>In *Kartell v. Blue Shield*, 749 F.2d 922 (1st Cir. 1984), *cert. denied*, 105 S. Ct. 2040 (1985), the plan's refusal to allow balance billing was in part a function of state legislation and regulation.

<sup>115</sup>In *Michigan State Medical Society*, the initiative of Michigan Blue Cross and Blue Shield that was so offensive to physicians was dictated by the auto companies and the United Auto Workers. 101 F.T.C. at 216-21.

Although there have recently been some impressive departures by Blue plans from such pro-provider practices,<sup>116</sup> these defections have almost always occurred only because other prepayment mechanisms, primarily HMO's and PPO's, had already breached the defenses of the hospital and doctor cartels in the particular market. Facing price competition from efficient purchasers for the first time, the Blues had little choice but to abandon their old strategy and turn on their old allies.<sup>117</sup> Despite these notable breakdowns of Blue/provider collaboration, it is far from clear that competition is yet so intense and uninhibited in many health care markets that Blue/provider alliances are no longer effective or worth worrying about. Although the coming of competition has generated a great deal of discussion and consternation, its effects are still hard to detect in anything but anecdotes.<sup>118</sup> Most Blue Cross and Blue Shield plans have not yet definitively changed sides in the contest between consumers and providers.

There are few signs that competition has yet made enough headway in North Carolina markets to force NCBCBS to enter the fray on the consumer's side. Most NCBCBS contracts still embody free choice of provider, cost reimbursement for hospitals, UCR fee limits for physician services, and limited cost sharing, indicating that the plan has yet to break significantly with its tradition of catering to providers' essential interests. Although NCBCBS has introduced such innovations as HMO and PPO arrangements of its own,<sup>119</sup> these mechanisms do not yet face enough competition from independent health plans to induce them to bargain with providers as adversaries rather than as allies.<sup>120</sup> Indeed,

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<sup>116</sup>See, e.g., Greenberg, *supra* note 100.

<sup>117</sup>See *supra* note 111; *infra* note 126. The precise inspiration for the Blue initiatives challenged in *Kartell*, 749 F.2d 922, and *Ball Memorial*, 784 F.2d 1325, is difficult to determine, but it is probable that these were competition-inspired departures from the Blues' historic policy of cooperating with provider interests. *But see supra* notes 112 & 114. If so, they should be regarded as exceptions that prove the rule. Why, for example, did such cases not appear much earlier?

<sup>118</sup>See *supra* note 107.

<sup>119</sup>Blue Cross's Personal Care Plan of North Carolina, Inc. (PCP) is an HMO of the individual practice association variety. In addition, Blue Cross has transferred some standard HMO contracts to PCP. As of April 1986, PCP had 21,000 enrollees, and it subsequently added 73,784 state employees. N.C. DEP'T OF INSURANCE, HEALTH MAINTENANCE ORGANIZATIONS: STATUS IN NORTH CAROLINA (April 1986 & Supp. July 3, 1986). Although NCBCBS officials claim that such recent innovations as a preadmission certification program, PPO and HMO arrangements, the participating physician program, and a program to encourage ambulatory surgery are evidence of their willingness to challenge providers, the text gives reasons for disputing this claim.

<sup>120</sup>Enrollment in active alternative health plans in North Carolina totalled 134,791 in April 1986, with 78,913 state employees added subsequently, for a total of 213,704. *Id.* Of these subscribers, Blue Cross's PCP enrolled 94,784. Several of the remaining plans were sponsored by dominant physician interests. Thus, the only truly independent plans able and philosophically willing to purchase physician services on a competitive basis were Health America, Kaiser, and PruCare, which enrolled 43,116, 23,366, and 11,877 subscribers, respectively (out of a state population of 5.9 million). *Id.*

these mechanisms may serve primarily as “fighting ships,” weapons that allow NCBCBS and their provider allies to repel or discipline independent plans that seek to enter the market and to force providers into unwanted competition.<sup>121</sup> If so, the alliance’s newly forged strategic capacity to slash prices to meet a competitive threat is more an impediment to than a manifestation of the emergence of effective competition in the state. Certainly NCBCBS’s inability to control the price and cost of lithotripsy in North Carolina suggests that the old alliance is still very much intact.

*B. Revising the Rules—“On Your Mark, Get Set, Go!”*

If ESWL costs in North Carolina should rise in the aftermath of the repeal of CON requirements for lithotripters, the natural impulse will be to blame the legislature for deregulating this new technology. Nevertheless, because the true source of the problem lies in antiquated, pro-provider payment mechanisms, it can be argued that the legislature’s greater failure was in deciding to deregulate only lithotripsy. Because payments for lithotripsy are only a very small percentage of insurers’ overall payments for health care services, the threat of higher costs for this one service is unlikely to trigger the fundamental changes in financing arrangements that are needed if costs are to be brought under effective control by market forces. Across-the-board deregulation, however, would be such a dramatic change in the rules that all players on the demand side of the market, particularly NCBCBS and its customers, would have little choice but to reexamine their game plans. The sudden need of consumers and major purchasers of health insurance to find better allies in the cost-containment effort would bring about a competitive rush to find new defenses against provider overcharging, overspending, and overinvestment.

The main policy reason why most states are continuing CON regulation today, after the theoretical argument for it has been largely disproved,<sup>122</sup> is their belief that their local health care markets are not

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<sup>121</sup>A prepayment plan controlled by dominant provider interests presents the same hazard to competition that is presented by an informal Blue/provider alliance. On the antitrust and policy implications of prepayment plans controlled by dominant provider organizations, see FTC, *supra* note 101; Havighurst & Hackbarth, *Enforcing the Rules of Free Enterprise in an Imperfect Market: The Case of Individual Practice Associations*, in *A NEW APPROACH TO THE ECONOMICS OF HEALTH CARE* 377 (M. Olson ed. 198 ). For evidence of how a financing plan and a provider cartel, operating together, can exclude or discipline other payers, see Goldberg & Greenberg, *The Effect of Physician-Controlled Health Insurance: United States v. Oregon State Medical Society*, 2 J. HEALTH POL. POL’Y & L. 48 (1977). Because the same problems could also arise where the Blue/provider alliance was of the informal variety, Blue Cross’s PCP may be more anticompetitive than procompetitive.

<sup>122</sup>The theory of CON regulation was that payment systems inevitably and inefficiently distort spending. See references cited *supra* note 12. Changes in purchasing practices can

yet sufficiently competitive to entrust them with the task of allocating resources and discouraging overinvestment.<sup>123</sup> Many states, however, are moving toward deregulation in small increments by raising the capital investment thresholds of CON requirements and exempting additional categories of providers and investments.<sup>124</sup> Although these steps may seem desirable in the general sense that they get government off providers' backs, deregulation is more likely to represent a pro-consumer change in the rules of the game if it is done on a wholesale rather than a piecemeal basis.<sup>125</sup> Only then would the legislature's move constitute a clear message to players who purchase and players who sell obsolete forms of health insurance that they can expect to be losers in future competition unless they change their strategies in fundamental ways. Only if that message is sent, received, and acted upon will consumers be in a position to hold their own in struggles over the uses of medical technology, old and new. A totally deregulated market is most likely to generate the radical rethinking and restructuring that is needed to force NCBCBS and other Blue Cross and Blue Shield plans finally to break with their provider allies and to use their bargaining power on the consumer's behalf.<sup>126</sup>

Because introducing meaningful change in health care financing mechanisms seems to be a slow and difficult process requiring the reeducation of many players and the devising of intricate new strategies, the best policy option available to North Carolina and other states is probably to announce the expiration of their CON laws as of some fixed future

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offset many of these distortions, however, and those that remain should be regarded as a cost of having insurance, not as inefficiency. *See supra* text accompanying notes 83-94; P. JOSKOW, *supra* note 12, at 21-31.

<sup>123</sup>An alternative justification for CON regulation of hospitals and their competitors is the alleged necessity to preserve cross-subsidization of indigent care, education, and research. Curbing competition enables hospitals to overcharge some patients and thereby to generate revenues to fund these worthy purposes. For arguments against using regulation for this purpose, see e.g., Havighurst, *The Debate Over Health Care Cost-Containment Regulation: The Issues and the Interests*, in *INCENTIVES VERSUS CONTROLS IN HEALTH POLICY* 9 (J. Meyer ed. 1985). The case for controlling nursing home investments is unique to that industry, because of its heavy involvement with the Medicaid program, and is not considered here. *See* C. HAVIGHURST, *supra* note 13, at 353-63.

<sup>124</sup>*See* Simpson, *supra* note 37.

<sup>125</sup>*See* discussion of a "market-forcing" regulatory strategy in C. HAVIGHURST, *supra* note 13, at 321-44.

<sup>126</sup>There is a degree of irony in unleashing the market power of the Blue plans, which were created to serve providers and which served their interests so well for so long, against their original sponsors. *See Ball Memorial*, 784 F.2d 1325; *Kartell*, 749 F.2d 922, discussed *supra* notes 112 and 117. But there is a potential paradox as well. Where a Blue plan possesses market power, it might be vulnerable to attack under section 2 of the Sherman Act because of exclusionary practices of the type noted *supra* text accompanying notes 100-09. But to raise such a challenge, providers would have to claim that a Blue plan unlawfully monopolized the market by fostering the providers' own cartel.

date. The setting of such a sunset date should be done in a way that clearly warns purchasers and providers of health insurance of the need to find alternative means of cost containment, while providing them time to change their allegiances and to consider and install the defenses they prefer.<sup>127</sup> Such a legislative move, if accompanied by efforts to free the local market of legal and other restrictions on innovation, would materially improve the chances for a consumer victory not only in the lithotripsy game but also in the larger battle against wasteful health care spending.

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<sup>127</sup>The object would be to avoid problems similar to those allegedly encountered in Arizona and Utah when CON was repealed. *See supra* note 97. In particular, the federal government itself needs more time to change its current approach to reimbursing capital costs, which still invites excessive investment. *See supra* note 78.