# STATE REGULATION OF MEDICAL NECESSITY: THE CASE OF WEIGHT-REDUCTION SURGERY

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## INTRODUCTION

As Professor Sage so ably explains,[1] medical necessity is the ground on which health care's cost/quality tradeoff battles are most visibly fought. The primary mechanism an insurer has for exercising case-by-case control over excessive medical costs is reviewing whether treatment meets the insurer's definition of medical necessity. Therefore, regulatory controls over medical necessity determinations are of immense importance for how medical spending decisions are made.

This Comment explores how state managed care regulations, and in particular, external review laws, affect health insurers' ability to define and apply medical necessity. As summarized by Professor Sage and others, external review laws, which exist in most states, allow patients to appeal to an independent physician when denials of insurance coverage are based on lack of medical necessity.[2] Most states also define what medical necessity means for purposes of health insurance coverage.[3] Some commentators have expressed concern



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1. William M. Sage, *Managed Care's Crimea: Medical Necessity, Therapeutic Benefit, and the Goals of Administrative Process in Health Insurance*, 53 DUKE L.J. 595 (2003).

2. *See, e.g.*, Aaron Kesselheim, *What's the Appeal? Trying to Control Managed Care Medical Necessity Decisionmaking through a System of External Appeals*, 149 U. PA. L. REV. 873, 877 (2001) (stating that "by 1999 thirty states and the District of Columbia had established rights to external review for private health plan enrollees").

3. STANFORD UNIV. CTR. FOR HEALTH POLICY, STATE-BY-STATE COMPENDIUM OF MEDICAL NECESSITY REGULATION 12–14 (2001), *available at* http://www.hcfo.net/pdf/stanford.pdf.

that state or federal regulation of medical necessity will substantially curtail insurers' ability to contain costs and manage care in a responsible and socially productive manner.[4]

Exploring this concern was one objective of an empirical study I conducted in 2002 to assess the impact of state managed care patient protection laws.[5] Six states were selected for in-depth case studies—Iowa, Louisiana, Michigan, New Jersey, Texas, and Virginia—to reflect a range of market, demographic, and legal characteristics. In each state, confidential interviews were conducted with twenty to thirty key informants, including health plan managers, regulators, patient advocates, and various industry observers. In addition, a focus group was conducted with nine experienced health care lawyers from across the country, and interviews were conducted at the home office of three of the largest national health plans. The total of 178 interview and focus group subjects consisted of 56 people with 28 health plans or insurance industry groups; 38 providers or patient advocates; 43 insurance agents, human resource managers, or employer representatives; and 41 regulators, industry analysts, independent lawyers, or other market participants or observers.

Interviews were semistructured, following an interview guide that allowed for substantial variation to focus on the topics of particular relevance to different interview subjects. Each interview included some discussion of external review and the definition of medical necessity, but the interviews covered a broad range of other issues relating to managed care patient protection laws.

This Comment reports on the findings from these interviews relating to states' regulation of medical necessity, using bariatric surgery as the main case in point. It begins with an overview of bariatric surgery and its prominence in external review decisions. The Comment then analyzes insurers' various strategic responses to their persistent record of reversals in these cases. The article concludes that

4. *See, e.g.*, Clark C. Havighurst, *How the Health Care Revolution Fell Short*, 65 LAW & CONTEMP. PROBS. 55, 93 (Autumn 2002) ("External review essentially denies health plans any intermediary roles in selecting treatments. . . . [S]uch regulation drastically curtail[s] opportunities for health plans to . . . achieve consistency in administering . . . benefits."); David A. Hyman, *Regulating Managed Care: What's Wrong with a Patient Bill of Rights*, 73 S. CAL. L. REV. 221, 260–61 (2000) ("Specific consumer protections have become legislative priorities simply because they appear to benefit a specific group of voters, or because they play well in the press—regardless of the practical significance of the problem, or the benefits of the reform.").

5. Frank A. Sloan & Mark A. Hall, *Market Failures and the Evolution of State Regulation of Managed Care*, 65 LAW & CONTEMP. PROBS. 169, 169 (Autumn 2002).

most insurers limit coverage of bariatric surgery in some fashion, rather than covering it with few or no questions asked. In this one area, then, insurers have not completely abandoned their role as stewards of limited medical resources, despite considerable regulatory and public pressure to relent. This area stands apart from most areas of medicine, however, in that insurers have largely abandoned direct attempts to limit coverage for most medical procedures and instead have adopted a pass-through attitude toward medical spending.

## I. BARIATRIC SURGERY

Surgery for weight reduction is the focal point for reporting these research findings because interview subjects so frequently mentioned these procedures as a controversial issue in the external review process. Surveys of external review decisions in California and Texas found that this is the single most frequently appealed medical-surgical procedure (as distinguished from behavioral health care),[6] and my interviews also confirmed this to be the case in other states. Moreover, insurers said that they always or almost always lose these appeals, in contrast with their overall track record of winning about half the time, or even more often in some states.[7]

Each decade, a new area of medicine emerges that seems to epitomize the issues of greatest salience for the resource allocation issues of the day. In the 1980s, many litigated coverage disputes

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6. *See* David M. Studdert & Carole Roan Gresenz, *Enrollee Appeals of Preservice Coverage Denials at 2 Health Maintenance Organizations*, 289 JAMA 864, 867–68 (2003) (finding that one in ten medical necessity appeals in California involved obesity treatment); Consumers Union, *Independent Review Organizations: Consumers Gain Needed Care When Unaffiliated Medical Experts Review Health Plan Denials* (May 2002) (reporting that of 263 Texas cases reviewed, surgical treatment for obesity was the only medical-surgical procedure consistently appealed).

7. Consumers Union found that insurers lose these cases 70 percent of the time in Texas, compared with their overall loss rate of about 50 percent. Consumers Union, *supra* note 6, at 8. One lawyer who specializes in challenging coverage denials for obesity treatment claims to have a 90 percent success rate when these denials are based on lack of medical necessity. *See* Obesity Law & Advocacy Ctr., Frequently Asked Questions (FAQ's), *at* http://www.obesitylaw.com/faqs.htm (last visited Nov. 2, 2003). Another confirmation comes from casual perusal of patients' descriptions of dealings with their insurance companies, posted on the following website: http://www.obesityhelp.com/morbid obesity/insurers.phtml (last visited Nov. 1, 2003). The vast majority of these patients say they were successful in obtaining coverage, either at an initial stage of consideration, or on appeal. *Id*. However, Studdert & Gresenz report that two insurers studied in California win these cases more often than other appeals. Studdert & Gresenz, *supra* note 6, at 867.

addressed various unorthodox treatments for cancer.[8] In the 1990s, the focus shifted to technologically advanced experimental treatments for cancer.[9] During the same period, skirmishes erupted over treatment for infertility and sexual dysfunction.[10] The case *du jour* is

8. *See* Jones v. Laborers Health & Welfare Trust Fund, 906 F.2d 480, 481 (9th Cir. 1990) (holding that hyperthermia for breast cancer was not covered because it was deemed not medically necessary and experimental); Dallis v. Aetna Life Ins. Co., 768 F.2d 1303, 1307 (11th Cir. 1985) (stating that an insurer must pay for "immuno-augmentative therapy" provided in Bahamian clinic by a nonphysician, even though the therapy was not approved by FDA for use in the U.S.); McLaughlin v. Conn. Gen. Life Ins. Co., 565 F. Supp. 434, 454 (N.D. Cal. 1983) (same); Free v. Travelers Ins. Co., 551 F. Supp. 554, 560 (D. Md. 1982) (denying coverage for laetrile (a chemical found in apricot pits)); Bruno v. Sec. Gen. Life Ins. Co., 522 So. 2d 1242, 1243 (La. Ct. App. 1988) (denying coverage for nutritional supplements prescribed by a physician because they were not "medically necessary"); Shumake v. Travelers Ins. Co., 383 N.W.2d 259, 266 (Mich. Ct. App. 1985) (holding that an insurer must pay for laetrile therapy and nutritional therapy for lung cancer); Tudor v. Metro. Life Ins. Co., 539 N.Y.S.2d 690, 691 (N.Y. Sup. Ct. 1989) (holding that an insurer must cover mercury vapor testing by a physician who "treats the whole person, with biochemical methods and emphasis on elemental deficiencies and food allergies"); Taulbee v. The Travelers Cos., 537 N.E.2d 670, 676 (Ohio Ct. App. 1987) (holding that an insurer must pay for immuno-augmentative therapy); Wilson v. Travelers Ins. Co., 605 P.2d 1327, 1330 (Okla. 1980) (holding that an insurer must pay for laetrile even though it was made illegal subsequent to the treatment); Jacob v. Blue Cross & Blue Shield of Or., 758 P.2d 382, 383 (Or. Ct. App. 1988) (finding that immuno-augmentative therapy fell within an exclusionary provision of insurance contract).

9. *See* Mark A. Hall & Gerard F. Anderson, *Health Insurers' Assessment of Medical Necessity*, 140 U. PA. L. REV. 1637, 1637–42 (1992) (investigating whether or not courts or insurers should make judgments of medical appropriateness, especially in regards to new, very expensive, undertested cancer treatments); Michelle M. Mello & Troyen A. Brennan, *The Controversy over High-Dose Chemotherapy with Autologous Bone Marrow Transplant for Breast Cancer*, HEALTH AFF., Sept./Oct. 2001, at 101, 103–06; Richard S. Saver, *Reimbursing New Technologies: Why Are the Courts Judging Experimental Medicine?*, 44 STAN. L. REV. 1095, 1111–20 (1992) (using Autologous Bone Marrow Transplant (ABMT) as a case study to demonstrate the inherent problems in relying on judicial assessments of what is or is not "experimental").

10. *See* Reilly v. Blue Cross & Blue Shield United of Wis., 846 F.2d 416, 426–27 (7th Cir. 1988) (Posner, J., concurring and dissenting) (finding no evidence that the insurer acted arbitrarily or capriciously in denying coverage as "experimental in nature"); Facchina v. NECA-IBEW Local 176 Health & Welfare Fund, 702 F. Supp. 641, 647 (N.D. Ill. 1988) (holding it was arbitrary and capricious to decide that impotence is not an illness; insurer must pay $9,515 for a prosthetic penile implant, plus attorney fees); Davidson v. Aetna Life & Cas. Ins. Co., 420 N.Y.S.2d 450, 453 (Sup. Ct. 1979) (holding that a sex-change operation was medically necessary for psychological reasons); Kinzie v. Physician's Liab. Ins. Co., 750 P.2d 1140, 1143 (Okla. Ct. App. 1987) (upholding the trial court's ruling that as matter of law in vitro fertilization is not medically necessary to treat an illness; child birth is elective). *See generally* Hazel Glenn Beh, *Sex, Sexual Pleasure, and Reproduction: Health Insurers Don't Want You to Do Those Nasty Things*, 13 WIS. WOMEN'S L.J. 119 (1998) (examining "health insurer attitudes toward sexual health, satisfaction, and reproduction by focusing on insurance coverage for treatment of erectile dysfunction (impotency), gender dysphoria (transsexuality), pregnancy, infertility, contraception, and abortion").

weight reduction surgery for obesity.[11] Grouped under the generic term bariatric surgery, there are a number of surgical procedures whose common end is to reduce greatly the stomach's volume. "Stomach stapling" is the lay term for the most common of these procedures, but "lap banding" is also quickly gaining popularity.[12]

A lot could be said about the light that each of these examples sheds on social concerns at different points in time, but space does not permit this digression, except for the last example. Like a minimalist work of abstract art, the bariatric surgery example is revealing both in what it contains and in what is not there. The fact that disputes over bariatric surgery are so common in external review, but have not appeared in any significant number in court,[13] indicates that external review has been successful in meeting its objective of resolving these disputes more efficiently. On the other hand, the fact

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11. Coverage disputes over obesity have also appeared in earlier decades, but not as consistently. In fact, obesity was the subject of one of the earliest reported medical necessity cases, *Mount Sinai Hospital v. Zorek*, 271 N.Y.S.2d 1012 (N.Y. Civ. Ct. 1966), which upheld coverage of ten days of hospitalization for an obese patient undergoing a "starvation diet." The court ruled that the medical risks of this aggressive approach warranted hospitalization, and the decision to take this approach is one that only the patient and the treating physician, not the insurer, is entitled to make. *Id.* at 1018–19.

12. Stomach stapling is the lay term for several different versions of "gastric bypass," each of which involves surgically reducing the size of the stomach and shortening the length of the intestinal tract. For a lay description, see Atul Gawande, *The Man Who Couldn't Stop Eating*, NEW YORKER, July 9, 2001, 66, 71. The newer, less invasive procedure uses a laparoscope through small incisions to encircle the stomach with a plastic band that can be adjusted following surgery. *See* Robert E. Brolin, *Bariatric Surgery and Long-Term Control of Morbid Obesity*, 288 JAMA 2793, 2793 (2002).

13. I have been able to find only six decisions regarding the medical necessity of weight reduction surgery, three federal and three state. *See* Thrasher v. Corporate Sys., Inc., No. 2:01-CV-295-C, 2002 WL 31572682, at *2 (N.D. Tex. Feb 7, 2002) (holding that gastric bypass benefits were properly denied where insurance policy expressly excluded such benefits); Livingston v. Cent. States, S.E. & S.W. Areas Health & Welfare Fund, 900 F. Supp. 108, 118 (E.D. Mich. 1995) (deciding that an insurer's decision to deny benefits for gastric bypass because it was cosmetic surgery was not arbitrary and capricious); Exbom v. Cent. States, S.E. & S.W. Areas Health & Welfare Fund, No. 88 C 5058, 1989 WL 27453, at *3–4 (N.D. Ill. Mar. 21, 1989) (concluding that insurer's determination that gastric bypass was "experimental" was not arbitrary and capricious); Hopp v. Grist Mill, 499 N.W.2d 812, 814–15 (Minn. 1993) (holding gastric bypass necessary to relieve thrombosis of leg); Gilbert v. Durham Life Ins. Co., No. 741, 1986 WL 9703, at *1 (Tenn. Ct. App. Sept. 5, 1986) (deciding that gastric was bypass benefits properly denied where insurance policy expressly excluded such benefits); Evans v. W.E.A. Ins. Trust, 361 N.W.2d 630, 639–40 (Wis. 1985) (holding that school district's denial of benefits for gastric bypass to treat obesity was arbitrary and capricious). One case involved workers compensation insurance (*Hopp v. Grist Mill*); the rest were about conventional health insurance. Half were in the 1980s, and half were in the 1990s or later. Two ruled for the patient (*Hopp v. Grist Mill* and *Evans v. W.E.A. Insurance Trust*), and the other four ruled for the insurer.

that virtually no other medical-surgical procedure results in external review with any frequency[14] indicates that health insurers may have given up trying to impose their own concept of medical necessity in most areas of medicine.

The latter point was confirmed in interviews with insurers, who said they have greatly reduced the number of treatments that must be submitted for prior authorization. Also, many insurers said that when their denials are challenged through internal review, they often agree to reverse the initial decision rather than incur the costs of a review and risk the negative publicity, or possible liability, entailed in being reversed. In short, most major insurers appear to be reverting to their inflationary ways prior to the 1980s, when provider-friendly insurers such as Blue Cross and Blue Shield paid for virtually any recognized treatment that a physician might order, with few or no questions asked.[15] Indeed, one prominent insurer claims to have largely abandoned medical necessity review by writing its insurance policies in terms of broad categories of "covered services," followed by more specific exclusions, rather than limiting covered services to those that are medically necessary.[16]

Medical necessity review is now taking place mainly at the margins, focusing on treatments that might be considered cosmetic, custodial, or lifestyle enhancing rather than medically indicated. Bariatric surgery is one such procedure, but it is also one that can have compelling medical justification. Obesity is now recognized as a major public health problem, on par with tobacco and other types of substance abuse.[17] Two-thirds of adults are overweight or obese, up from one-quarter thirty years ago, and the rate of increase among the

14. *See* Studdert & Gresenz, *supra* note 6, at 867–68 (listing only two other surgical procedures—breast alteration and varicose vein removal—that are regularly appealed).

15. For more documentation of this era, see Hall & Anderson, *supra* note 9.

16. In confidential interviews, this company said that it defines covered services in part as those "provided for the purpose of preventing, diagnosing or treating a sickness, injury, mental illness, substance abuse or their symptoms."

17. *See* JoAnn E. Manson & Shari S. Bassuk, *Obesity in the United States: A Fresh Look at Its High Toll*, 289 JAMA 229, 229 (2003) ("Obesity has become pandemic in the United States."); Note, *The Elephant in the Room: Evolution, Behavioralism, and Counteradvertising in the Coming War Against Obesity*, 116 HARV. L. REV. 1161, 1161 (2003) ("The collective weight problem has reached epidemic proportions."); U.S. Dep't of Health & Human Servs., *The Surgeon General's Call to Action to Prevent and Decrease Overweight and Obesity* (2001), *at* http://www.surgeongeneral.gov/topics/obesity/calltoaction/CalltoAction.pdf (last visited Feb. 4, 2004) ("Overweight and obesity have reached nationwide epidemic proportions.").

"morbidly obese"[18] has skyrocketed in recent years, almost tripling during the 1990s.[19] Medical experts estimate that "[o]besity accounts for more than 280,000 deaths annually in the United States and will soon overtake smoking as the primary preventable cause of death if current trends continue."[20] In addition to mortality, obesity is associated with more health problems and medical costs than smoking or drinking.[21]

Recognizing the professional and economic opportunities, a large number of general surgeons and mid-sized hospitals have begun to specialize in bariatric surgery, and these procedures are being aggressively marketed directly to the public, through television and the Internet.[22] A professional society now exists for bariatric surgeons, with membership exceeding 700.[23] In 2003, over 100,000 of these procedures were expected to be performed, roughly double the number two years earlier, and sixfold over the number performed ten years ago.[24] According to some estimates, as many as 15 to 30 million Americans could be candidates for these procedures.[25] Public interest has been fueled by the fact that several minor celebrities have

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18. These categories are defined by the Body Mass Index (BMI), which is calculated by dividing weight by the square of height, expressed in metric terms. For adults, the standard definition of obesity is a BMI greater than 30, overweight is a BMI of 25–29, and morbid obesity is a BMI greater than 40. For a person 5 feet 2 inches tall, 164 pounds is obese and 219 pounds is morbidly obese. For a person 6 feet tall, these levels are reached at 221 pounds and 295 pounds respectively. Ctrs. for Disease Control & Prevention, BMI: Body Mass Index, *at* http://www.cdc.gov/nccdphp/dnpa/bmi/ (last visited Nov. 2, 2003) (on file with *Duke Law Journal*).

19. *See* Katherine M. Flegal, et al., *Prevalence and Trends in Obesity Among US Adults, 1999–2000*, 288 JAMA 1723, 1723 (2002) (finding a 29 percent increase in extreme obesity between 1988–1994); David S. Freedman et al., *Trends and Correlates of Class 3 Obesity in the United States from 1990 Through 2000*, 288 JAMA 1758, 1758 (2002) (finding class 3 obesity increased from 1 percent to 3 percent of the population from 1988–1994).

20. Manson & Bassuk, *supra* note 17, at 229.

21. *Id.*; Roland Sturm, *The Effects of Obesity, Smoking and Drinking on Medical Problems and Costs*, HEALTH AFF., Mar./Apr. 2002, at 245, 247–48.

22. Mike Mitka, *Surgery for Obesity: Demand Soars Amid Scientific, Ethical Questions*, 289 JAMA 1761, 1761–62 (2003). For internet examples, see http://www.bariatric.com/; http://www.coribariatrics.com/; http://clos.net/; http://www.rightweigh.com/; http://liv-lite.com/ (each last visited Nov. 2, 2003).

23. Liz Kowalczyk, *Obesity Surgery Waiting Lists Increase Dramatically at Massachusetts Hospitals*, BOSTON GLOBE, Jan. 12, 2003, at A1.

24. Mitka, *supra* note 22, at 1761; Milt Freudenheim, *Hospitals Pressured by Soaring Demand for Obesity Surgery*, N.Y. TIMES, Aug. 20, 2003, at A1; Julie Piotrowski, *Obesity Surgery Brings Profits*, MODERN HEALTHCARE, Mar. 4, 2002, at 20, 20.

25. Susan Alt, *Bariatric Surgery Programs Growing Quickly Nationwide*, HEALTH CARE STRATEGIC MANAGEMENT, Sept. 2001, at 1, 9; Freudenheim, *supra* note 24.

undergone the procedure,[26] and it is has been the subject of many news stories in popular magazines and television shows, such as *People* and "Oprah."[27]

Health insurers are justifiably concerned about these trends. Bariatric surgery costs anywhere from $14,000 to $35,000—just for the surgery—assuming no significant complications.[28] In addition, these patients incur lifelong costs as high as $100,000 for monitoring the health problems that can arise from radical alterations to the digestive system.[29] More significantly, bariatric surgery carries serious medical risks, and obese patients are much greater surgical risks due to underlying cardiac, circulatory, and/or respiratory problems. Questions have also been raised about the skill of some of the physicians doing these procedures and the quality of some of the institutions where they are performed.[30] The risk of death from these procedures is quite substantial—about 1 out of 100 procedures—and major complications occur in roughly 10 percent of cases.[31]

For these reasons, bariatric surgery is not lightly recommended or undertaken. Guidelines issued by the National Institutes of Health require that a patient be either "morbidly obese," which is defined as having a body mass index (BMI) of 40 or more,[32] or that they have

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26. For instance, Al Roker, the weatherman on NBC's "The Today Show" and the singer Carnie Wilson. Allison Adato & Galina Espinoza, *Weighing the Risks*, PEOPLE, Mar. 10, 2003, at 137, 137. Comedienne Roseanne Barr, and Sharon Osbourne, Ozzy's wife on "The Osbournes" television show. PEOPLE, Sept. 1, 2003, at 102, 102. Also Michael Genadry, who is on the television show "Ed." *Dateline NBC* (NBC television broadcast, Apr. 2, 2003).

27. *See, e.g.*, Adato & Espinoza, *supra* note 26, at 137; David Kiley, *Major Loss Leaves Major Problem*, USA TODAY, May 9, 2002, at 11D; Sophfronia Scott & Ulrica Wihlborg, *Finishing Touches*, PEOPLE, June 17, 2002, at 96; Incredible Weight Loss Stories, http://www.oprah.com/tows/pastshows/tows_2000/tows_past_20001109.jhtml (last visited on Jan. 9, 2004).

28. Alt, *supra* note 25, at 9. For an estimate of costs due to complications of surgery, see Benjamin M. Craig & Daniel S. Tseng, *Cost-Effectiveness of Gastric Bypass for Severe Obesity*, 113 AM. J. MED. 491, 493 (2002) (showing, in Table 1, the average costs for a man to be $26,100, and the average cost for a woman to be $20,500).

29. Freudenheim, *supra* note 24. Patients must adhere strictly to limits on what they can eat, and they often need to take special nutritional and dietary supplements.

30. Mitka, *supra* note 22, at 1762; Gawande, *supra* note 12, at 75.

31. Alt, *supra* note 25, at 13; Craig & Tseng, *supra* note 28, at 493; Adato & Espinoza, *supra* note 26, at 137; Julia Sommerfeld, *Weight Loss Surgery Means Weighing Risks*, SEATTLE TIMES, Mar. 3, 2002, at A1. For the latest statistics, see AM. SOC'Y FOR BARIATRIC SURGERY, RATIONALE FOR THE SURGICAL TREATMENT OF MORBID OBESITY (2001), *at* http://www.asbs.org/html/ rationale/rationale.html (last visited Nov. 2, 2003) (on file with *Duke Law Journal*).

32. *See supra* note 18.

significant health problems related to obesity, such as diabetes, heart disease, hypertension or sleep apnea.[33] In addition, these guidelines state that surgery should be a last resort, only after other methods of weight reduction have failed.[34]

When these procedures are warranted, and are done without injuring the patient, they do succeed in substantially lowering weight in most patients. On average, these patients permanently lose half of their excess weight.[35] However, "there is limited evidence addressing the long-term consequences [of surgery] and its influence on the quality of life of patients,"[36] so a full assessment of the medical costs and benefits has not yet been done.[37]

When insurers deny coverage for bariatric surgery, they do so for a number of reasons, according to interviews. Sometimes, they question the skill level of the particular providers proposing to do the surgery, or they are unwilling to allow the patient to use a preferred physician or hospital who is not in the insurer's normal network. Other times, insurers may decide that a particular patient's health condition puts him or her at too great a risk for this procedure. More frequently, insurers choose to apply criteria for medical necessity that are more demanding than the treating physician's. For instance, they may require both a certain weight level and a set of associated health problems, rather than regarding obesity itself to be a health condition,[38] or they may require documentation of more aggressive

33. Am. Gastroenterological Ass'n, *Medical Position Statement on Obesity*, 123 GASTROENTEROLOGY 879, 879 (2002); Nat'l Inst. of Health, *Gastrointestinal Surgery for Severe Obesity: Consensus Development Conference Statement*, 55 AM. J. CLINICAL NUTRITION 615S, 617S (1992 Supp.).

34. Am. Gastroentreological Ass'n, *supra* note 33, at 881.

35. Mitka, *supra* note 22, at 1762.

36. Andrew Clegg et al., *The Clinical Effectiveness and Cost-Effectiveness of Surgery for People with Morbid Obesity: A Systematic Review and Economic Evaluation* vi, *available at* http://www.nice.org.uk/pdf/assessmentreport-surgeryforobesity.pdf (2001).

37. Craig and Tseng estimated that gastric bypass surgery does not reduce lifetime medical costs or increase life expectancy, but it does improve the quality of life. Craig & Tseng, *supra* note 28, at 494. However, theirs was not a controlled observational study, and it was based on assumptions about quality of life rather than direct measures. Thus, for instance, they "assumed that a person who loses weight has the same quality of life as someone who is at that [same] reduced rate." *Id.* at 493. This assumption is highly questionable considering the severe restrictions on diet and various digestive problems that accompany drastic reduction in stomach size, as documented, for instance, in Gawande, *supra* note 12, at 71–72.

38. For an example of this general approach, which the court rejected as unauthorized by the insurance policy, see *Evans v. W.E.A. Insurance Trust*, 361 N.W.2d 630, 633–34, 637–38 (Wis. 1985).

efforts at nonsurgical weight reduction than the patient has undergone or is willing to undergo.

As noted above,[39] when patients appeal these denials to external, independent physicians, insurers consistently lose much more often than they do in other external review cases—almost all of the time according to most insurers who were interviewed. So far, insurers have not been inclined to challenge these losses in court.[40] Instead, they have used a number of contractual or business strategies to respond to the persistent unwillingness of most external reviewers to honor more conservative approaches to weight reduction surgery. As the following Part discusses, the success or failure of these strategies is a revealing case study of the interplay between regulatory agencies and private initiatives, and of the particular form of economic justice embodied in health insurers' definition of medical necessity.

## II. INSURERS' RESPONSES TO EXTERNAL REVIEW DECISIONS

Insurers can respond in four different ways to their persistent inability to sustain coverage denials for weight reduction surgery.[41] They can simply give in and approve most or all such requests. They can continue to assert their own standards or criteria for medical necessity, relying on the authority given to them in the insurance contract's general definition of medical necessity. They can attempt to make the insurance contract more explicit by specifying the particular medical criteria that will govern coverage of these procedures. Or, the contract can specifically exclude all weight reduction surgeries. Interviews with insurers revealed that each approach is taken by at least some insurers; these interviews also reveal the degree to which each strategy succeeds or fails.

### *A. Giving In, and Approving Almost Everything*

Most insurers have not simply given in and approved all requests for bariatric surgery that have a plausible basis. In contrast with many

39. *See supra* note 7 and accompanying text.

40. It is not entirely clear why they have not done so. Possible reasons include avoiding adverse publicity, the poor chance of success considering the degree of binding authority given to independent physicians by external review statutes, and concern about setting a negative precedent that would preclude their flexibility to use some of the strategies discussed in Part II.

41. For a general overview, documenting examples of most of these responses, see Alt, *supra* note 25.

other areas of medical necessity review,[42] here, they continue to hold their ground. They require, for instance, that patients have significant health problems related to obesity, rather than simply being extremely obese, or they may insist that patients document repeated failures of medically supervised weight reduction programs.[43] When challenged on appeal, insurers often lose because external reviewers believe the insurer is being too demanding in how it applies these medical necessity criteria, but most insurers who were interviewed said they nevertheless continue to apply essentially the same criteria as prior to the advent of external review.

Some insurers said that the consistent string of reversals prompted them to abandon their particular medical necessity criteria in favor of those being used by external review physicians. However, this was a minority response, both for bariatric surgery and for external review more generally. Most insurers said they have made no changes to the substance of their medical management policies based on external review decisions, even after losing. They explained that these decisions are case-specific and set no binding precedent about how future cases should be decided. Therefore, even after losing on appeal, insurers consider themselves free to make essentially the same decision in future cases. Moreover, they noted that few areas of medicine produce any volume of appeals, and for those that do, reviewers' decisions are often inconsistent, so usually no clear signal is sent about whether an insurer should change the substance of its medical criteria.

Insurers also reported that they will occasionally review one of their medical management policies based on external review losses, and a few insurers cited instances where they changed coverage policy when weakly supported criteria or poorly designed internal policies were brought to light by external review. However, these instances were exceptions to the usual approach of giving review decisions no effect beyond a particular case. In general, insurers and their medical

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42. *See supra* notes 15–16 and accompanying text.

43. *See, e.g.*, AETNA, COVERAGE POLICY BULLETIN NO. 0157: OBESITY: SURGICAL TREATMENT (2003), *at* http://www.aetna.com/cpb/data/PrtCPBA0157.html (stating that the selection criteria to be considered for gastric bypass requires a patient to have participated in a physician-supervised weight loss program for at least six months). Other examples of insurers' medical necessity criteria can be found in the numerous testimonials posted on the following patient support group website: http://www.obesityhelp.com/morbidobesity/ (last visited on Nov. 2, 2003). This is a rich data source for exploring in more detail a variety of circumstances relating to bariatric surgery, including the patients' condition prior to surgery, the type of procedure done, and patients' experiences following surgery.

directors believe their medical management policies have independent integrity, so they are not inclined to make substantive changes based simply on isolated or even consistent external review losses.

The trend toward more lenient prior authorization requirements[44] is driven not by a pattern of losses during external review, but instead by the simple economics of conducting the reviews themselves. Insurers explained that they found, after study, that the costs of conducting medical necessity reviews prior to treatment exceeded the savings generated in most areas of medicine. Also, they came to realize how much physicians and patients hate subjecting themselves to the hassle and delay caused by these reviews. Thus, avoiding contentiousness and public backlash is another reason insurers frequently gave for becoming "managed care lite"—i.e., scaling back on the list of procedures that require medical necessity review prior to treatment. However, bariatric surgery remains one of the areas where most insurers said they still require prior authorization. Where insurers still conduct prior authorization, they feel entitled to apply their own legitimate criteria of medical necessity—even if they consistently lose appeals of these decisions.

### *B. Writing Insurance Policies to Give Insurers More Discretion*

To avoid losing appeals, insurers could tighten up the wording of their insurance policies in a way that allows them to enforce more restrictive or demanding standards of medical necessity. Previously, this was done by stating that medical necessity will be determined at the insurer's sole discretion.[45] This language was primarily in response to a Supreme Court decision interpreting the Employee Retirement Income Security Act of 1974 (ERISA)[46] that required federal courts to defer to insurers' coverage denials when insurers have this discretionary authority.[47] The creation of external review laws, however, has negated this deference by mandating that the independent physician who conducts the review has full discretion

44. *See supra* note 15 and accompanying text.

45. Hall & Anderson, *supra* note 9, at 1645–48.

46. 29 U.S.C. § 1001 (2000), which regulates employee benefits, such as health insurance, and governs coverage disputes under employer-sponsored health insurance.

47. *See* Firestone Tire & Rubber Co. v. Bruch, 489 U.S. 101, 117–18 (1989).

and final authority.[48] Thus, external reviewers are not obligated to give any deference to the insurer's initial decision and are told to apply their own independent medical judgment.

Another tack, then, might be to change the substance of the general medical necessity definition in insurance contracts. Several respected health policy experts and groups have articulated relatively elaborate definitions of medical necessity that permit or require insurers to assess more rigorously the cost-effectiveness of medical technologies,[49] and some of these definitions have found their way into insurance policies and even state laws.[50] A different set of health policy experts has mounted a counter-movement, arguing for definitions of medical necessity that would more conclusively give treating physicians the final say.[51] For the most part, however, neither movement has taken hold. Interviews revealed that most insurance contracts continue to use traditional definitions of medical necessity, or they just use the term without defining it. And most state laws that define medical necessity continue to do so in a traditionally generic fashion that refers broadly to "generally accepted principles of professional medical practice."[52]

Despite this inertia, standard definitions of medical necessity are broad enough that they conceivably could allow insurers to implement medical necessity in a fashion—consistent with the "respectable minority" rule under medical malpractice law[53]—that

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48. Despite this tension with federal law, the Supreme Court has ruled that state external review laws are not preempted by ERISA, at least in the form enacted in Illinois. *See* Rush Prudential HMO v. Moran, 122 S. Ct. 2151, 2169 (2002).

49. *See, e.g.*, Linda A. Bergthold, *Medical Necessity: Do We Need It?*, HEALTH AFF., Winter 1995, at 180, 187–88 (positing that medical necessity as a term be deleted in favor of five more specific criteria; cost effectiveness is one of those criteria); David M. Eddy, *Benefit Language: Criteria that Will Improve Quality While Reducing Costs*, 275 JAMA 650, 656 (1996) (maintaining that cost-effectiveness measures may be imperfect, but are nonetheless necessary assessments in the cost/quality problem); Sara Singer & Linda Bergthold, *Prospects for Improved Decision Making About Medical Necessity*, HEALTH AFF., Jan. 2001, at 200, 202 ("Medical directors reported that clearer evidence and cost effectiveness criteria could improve the utility of contractual definitions.").

50. STANFORD UNIV. CTR. FOR HEALTH POLICY, *supra* note 3, at 15–19.

51. *See* Sara Rosenbaum et al., *Who Should Determine When Health Care Is Medically Necessary?*, 340 NEW ENG. J. MED. 229, 229 (1999) (stating that "an insurer should be able to set aside the recommendations of a treating physician only in restricted circumstances").

52. STANFORD UNIV. CTR. FOR HEALTH POLICY, *supra* note 3, at 15–16.

53. Regarding the respectable minority rule, see Note, *Admissibility of Forensic DNA Profiling Evidence: A Movement Away from* Frye v. United States *and a Step toward the Federal Rules of Evidence:* United States v. Jakobetz, 44 WASH. U. J. URB. & CONTEMP. L. 211 (1993). The only type of regulation that clearly restricts this approach is one that specifies that the

enforces the more conservative end of the spectrum of generally accepted medical practices.[54] This possibility was explored in interviews with both regulators and insurers. The consensus was that insurers are free for the most part to implement medical necessity however they want. Doing so is not illegal. However, insurers' general standards or specific internal criteria simply are not binding on external reviewers, for reasons that will now be explained.

Most state law definitions of medical necessity do not overtly constrain how insurers define the term in their contracts or how they operationalize the definition internally. In many states, the codified definition of medical necessity is not explicitly constraining in any way; the state simply declares a definition but requires no one in particular to adhere to it.[55] Some state laws do impose such a requirement, and even when they do not, regulators often do so of their own accord when they review insurance contract forms to approve them for general use.[56] However, most regulators do not see these definitions as strictly prescriptive. Instead, they allow insurers to write more elaborate or specified definitions that are broadly consistent with the general statutory definitions. Moreover, regulators do not audit or otherwise police how insurers operationalize these definitions. For instance, in most states, regulators do not systematically examine insurers' internal medical management policies and compare them with external standards of medical practice to see if they are consistent.[57]

Thus, for the most part, insurers are free to adopt whatever medical management standards or criteria they want. They just cannot enforce them when a case goes to external review (or to

standard in the patient's state or local community governs medical necessity. *See, e.g.*, MONT. CODE ANN. § 33-37-102 (2002); N.C. GEN. STAT. § 58-3-200(b) (2002). In this regard, alternative standards of care appear to function opposite of how they do in medical malpractice law, which sees local standards as being more lenient and national standards as being more demanding. *See* Jon Walz, *The Rise and Gradual Fall of the Locality Rule in Medical Malpractice Litigation*, 18 DEPAUL L. REV. 408, 408–09 (1969).

54. For an extensive discussion of how these standards of practice might be determined empirically, see Michael A. Hall & Michael D. Green, *Empirical Approaches to Establishing the Medical Standard of Care: Introduction*, 37 WAKE FOREST L. REV. 663 (2002).

55. *See* STANFORD UNIV. CTR. FOR HEALTH POLICY, *supra* note 3, at 12 (showing that only eleven states are required to adhere to the definition of medically necessary).

56. *See id.* at 12 ("Regulators from twenty-three states reported that general legislation in their state might impact plans' definitions of *medical necessity* even though there is no state-mandated definition.").

57. *See id.* at 31–39.

court).[58] External review laws give independent physicians final authority over medical appropriateness for purposes of insurance coverage. Reviewing physicians do not have to follow how the insurance contract defines medical appropriateness as long as the issue is framed in terms of whether the treatment is medically necessary. At most, reviewers may be given the contract language to consider, but regulators in the states selected for this case study said that reviewers do not need to refer to the contractual language in their decisions. Indeed, in one state, an insurer said that the regulator had reversed the external reviewer in a few cases where the reviewer had felt constrained by the contract from honoring the treating physician's opinion.

This means that insurers often end up applying a double standard. They continue to apply their own medical necessity definitions and criteria at the stages of initial decision and internal appeal. However, when an external review is filed, they are either forced to honor a different standard, or they do so voluntarily, realizing they are likely to lose. Because few cases are brought to external review, this strategy allows insurers to enforce their own standards in the vast majority of cases, despite the differing views of independent physicians. This result may appear unfair or irrational, but it is the logical outcome of a system in which insurers continue to take seriously their responsibility to allocate limited medical resources, and external review is used infrequently and is not designed to create constraining precedents. This consequence, whether accidental or intended, is also fully consistent with the longstanding observation that rationing decisions are more easily made out of view of public scrutiny.[59]

### *C. Contractual Specification of Particular Criteria*

One way to avoid external review is to frame a coverage decision as being based on something other than medical necessity. The external review statutes in most states apply only to medical necessity

58. Also, courts often refuse to enforce internal criteria that are not specified in the insurance contract. Hall & Anderson, *supra* note 9, at 1704–05. For a case of this sort regarding surgery for obesity, see *Evans v. W.E.A. Insurance Trust*, 361 N.W.2d 630, 638 (Wis. 1985) (concluding that the insurance company's interpretation of the word "sickness" in its guidelines was arbitrary and capricious when it denied a morbidly obese plaintiff reimbursement for gastric bypass surgery).

59. GUIDO CALABRESI & PHILIP BOBBITT, TRAGIC CHOICES 26–27(1978) ("Averting the eyes enables us to save some lives even when we will not save all.").

decisions and not to other types of coverage decisions, such as those based on more specific exclusions of covered benefits.[60] The distinction is sometimes hard to draw. For instance, interviewees did not agree on whether coverage exclusions for experimental, cosmetic, or custodial care are subject to medical necessity review. Under one view, these are limitations on the scope of covered benefits that are similar to exclusions for dental care or mental health services.[61] According to another view, these exclusions are simply the flip side of medical necessity; that is, they are ways of articulating in general terms what is not medical, what is elective rather than necessary, or what is not accepted practice.

Despite these uncertainties, interviewees thought that there are clear cases of specific exclusions that are not subject to review. Excluding some or all transplants is one example. So is excluding coverage for Viagra, or in vitro fertilization. Rather than exclude these treatments altogether, insurers sometimes include them only if certain conditions are met—for instance, they will cover prescriptions for Viagra but restrict the quantity allowed to a specified number of pills per month,[62] or they will cover certain transplants but only if specified eligibility criteria are met. The same could be done for bariatric surgery, but none of the insurers interviewed had done so. Several explanations were heard for why this is so.

First, insurers were not confident this strategy would work. Some assumed it would, and this was confirmed by some regulators. But others (both insurers and regulators) felt that the broader principle explained above would prevail, under which reviewers are not bound by contractual specification of clinical criteria for medical necessity, but instead are free to use their own medical judgment or to follow criteria proposed by others.[63] Apparently, the issue has not been put to a clear legal test.

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60. Kesselheim, *supra* note 2, at 892–900; *see, e.g.*, Rush Prudential HMO v. Moran, 122 S. Ct. 2151, 2170–71 (2002) (holding that ERISA does not preempt an Illinois HMO statute that provides external review for claims that a procedure is medically necessary).

61. This explains a possible legal advantage to taking medical necessity language out of insurance policies altogether, as Professor Havighurst advocates, *see* Havighurst, *supra* note 4, at 64–66, and as one large insurer has done, *see supra* note 16. Doing this may help to place coverage denials on a basis that is not as clearly subject to external review.

62. Alison Keith, *The Economics of Viagra*, HEALTH AFF., Mar./Apr. 2000, at 147, 151.

63. Also, one insurer noted that, in situations where coverage is mandated by state law, regulators feel more entitled to specify the particular criteria that define the scope of the covered benefit.

Second, some insurers thought that this contractually specified approach is not practical or feasible. They noted that medical criteria change frequently and are difficult to specify in great detail. In the words of one insurer, the insurance contract needs to be a "living document," that is, one that can adapt to changing circumstances. This need for a flexible document provides a compelling explanation for why the detailed specification that some health law scholars advocate[64] may not be a practical solution for most resource allocation issues.

### *D. Complete Exclusion of Coverage*

Rather than using the insurance contract to specify medical criteria for bariatric surgery, insurers have begun to exclude coverage entirely for this type of surgery, regardless of whether or when it is medically necessary.[65] Some insurers said they have done the same for a variety of other treatments that bridge the boundary between medically necessary and cosmetic or "lifestyle" enhancements, such as Viagra (which corrects medically caused impotence)[66] or breast reduction surgery (which can alleviate back strain).

The total exclusion strategy clearly is not socially optimal. It reflects a market failure induced by regulation because it results from insurers' inability to enforce their standards for defining when the need for these treatments is most compelling. Legally, however, this strategy succeeds. It keeps the issue away from external reviewers because a specific and absolute exclusion does not raise any judgmental issues regarding medical appropriateness.

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64. *See* CLARK C. HAVIGHURST, HEALTH CARE CHOICES: PRIVATE CONTRACTS AS INSTRUMENTS OF HEALTH REFORM 178–85 (1995) ("It is doubtful whether health plans can . . . fully serve the economising interests of their subscribers, in the absence of . . . better contracts."); E. Haavi Morreim, *Medicine Meets Resource Limits: Restructuring the Legal Standard of Care*, 59 U. PITT. L. REV. 1, 48–51 (1997) (noting that "a limited number of standards might enable consumers to become better informed . . . facilitating more intelligent decisions").

65. *See, e.g.*, Robarts v. Blue Cross & Blue Shield of La., 821 So. 2d 87, 90–91 (La. Ct. App. 2002) (holding that a clause giving the insurer final say in coverage created an ambiguity that had to be interpreted in favor of the insured, who then received compensation for a breast reduction surgery); Gilbert v. Durham Life Ins. Co., No. 741, 1986 WL 9703, at *1 (Tenn. Ct. App. Sept. 5, 1986) (holding that the exclusion of coverage for weight loss was within the plain meaning of the health care contract).

66. *See* Keith *supra* note 62, at 150–51 (discussing the policies of some healthcare providers to refuse to pay for Viagra, to limit the number of pills per month, or to require higher copayments).

According to interviews, regulators in a few states have insisted that, despite such an exclusion, insurers must cover bariatric surgery or other excluded treatments when they are medically necessary. In other words, regulators have not officially mandated that these treatments be part of covered benefits, but they refuse to enforce exclusions in cases where the treatment is shown to be medically necessary, citing broader authority under laws that require HMOs, for instance, to cover all "basic benefits." When challenged on this, however, regulators have usually relented, or lost in court.[67] Also, insurers reported that this regulatory opposition is not widespread.

Still, not all insurers, and perhaps not even a majority, are excluding bariatric surgery entirely. Several reasons for continuing coverage were given or suggested in interviews.[68] An obvious possibility is that the excluded service may be one that purchasers demand. Mitigating against this factor is the negative stigma regarding obesity and attitudes about personal responsibility for health and weight.[69] Cutting the other way, however, is insurers' concern that if a specific exclusion becomes widespread, the affected interest groups will seek a legislative mandate for coverage.[70] As noted above,[71] legislative action greatly reduces insurers' ability to control the criteria that shape the covered benefit. In this way, political economy interacts with and responds to market economy.

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67. For instance, Kaiser successfully challenged the California Department of Managed Care's ruling that it may not specifically exclude coverage of Viagra when it is medically necessary to treat sexual dysfunction. Kaiser Found. Health Plan v. Zingale, 121 Cal. Rptr. 2d 741, 749 (Cal. Ct. App. 2002). The court ruled that the agency lacked the statutory authority for imposing this restriction. *Id.* at 745–46. However, one lawyer who specializes in challenging coverage denials for obesity treatment claims to have a 50 percent success rate even when these denials are based on specific exclusions. *See* Obesity Law & Advocacy Ctr., *supra* note 7.

68. One insurer noted that laws guaranteeing that insurance is renewable at the option of the subscriber deter making coverage provisions too detailed because each change in a covered or excluded item technically creates a different policy form, each of which has to be renewed in perpetuity as long as any one subscriber wishes to keep it. This increases administrative costs and complexity.

69. For discussion of this point, see Rogan Kersh & James C. Morone, *The Politics of Obesity: Seven Steps to Government Action*, HEALTH AFF., Nov./Dec. 2002, at 142, 142 ("Obesity has been the subject of powerful public disapproval for more than a century.").

70. According to one report, such mandates exist in four states so far. Julie Piotrowski, *Obesity Surgery Brings Profits*, MODERN HEALTHCARE, Mar. 4, 2002, at 20.

71. *See supra* note 4 and accompanying text.

## CONCLUSION

What does the experience with bariatric surgery tell us about agencies, private initiatives, and economic justice—the topic of this Symposium? From the perspective of someone concerned about the need for more affordable health insurance, the record is not as bad as one might have feared, nor is it as good as one might have hoped. Insurers have not completely abandoned their role as stewards of limited medical resources, despite widespread public hostility, intense resistance from many physicians, and considerable regulatory barriers. Most insurers continue in some fashion to resist wholesale coverage of bariatric surgery with few or no questions asked. Because external review is not frequent, and decisions are only case-specific, insurers are able in most cases to apply the medical management criteria that their medical directors and advisors think are legitimate. Regulation of the definition of medical necessity does not drill down deep enough into insurers' internal processes to prescribe particular substantive approaches to making coverage determinations.

On the other hand, cost considerations remain covert in medical necessity determinations, rather than being exposed to public scrutiny or contractual specification. Therefore, resource allocation continues to occur in a fashion that Professor Havighurst describes as "*sub rosa*" rather than market specified.[72] Far from making rationing decisions more explicitly, insurers have greatly scaled back the areas of medicine in which they are willing to scrutinize medical necessity. For most of the terrain covered by medical necessity, insurers have adopted a pass-through attitude toward costs: If physicians and patients think the treatment is necessary, then the primary role of insurers is simply to negotiate the best price and reflect these discounts in their overall insurance premium.[73] Insurers have largely abandoned their direct attempts to limit the utilization rate for most medical procedures.

This retreat from managed care is not primarily the result of regulatory or legal policy, however. Instead, it reflects broader social and professional antipathy to medical decisions being made by

72. Clark C. Havighurst, *Vicarious Liability: Relocating Responsibility for the Quality of Medical Care*, 26 AM. J.L. & MED. 7, 12 (2000).

73. *See* James C. Robinson, *The End of Managed Care*, 285 JAMA 2622, 2623–24 (2001) (noting that insurance companies are focused mainly on cost and cost reduction).

anyone other than the affected patient and the treating physician.[74] Accordingly, the only option left is to control patients' demand for care by increasing their out-of-pocket costs, in order to make them more cost-conscious consumers at the point of treatment decisionmaking.[75] Whether this approach succeeds in containing costs and improving care, and whether the public is any happier with it than with managed care, remains to be seen.

74. M. Gregg Bloche, *One Step Ahead of the Law: Market Pressures and the Evolution of Managed Care*, *in* THE PRIVATIZATION OF HEALTH CARE REFORM 22–48 (M. Gregg Bloche ed., 2003).

75. Victor Fuchs, *What's Ahead for Health Insurance in the United States?*, 323 NEW ENG. J. MED. 1822 (2002); Jason S. Lee & Laura Tollen, *How Low Can You Go? The Impact of Reduced Benefits and Increased Cost Sharing*, HEALTH AFF., July/Aug. 2002, at 1; James C. Robinson, *Renewed Emphasis on Consumer Cost-Sharing in Health Insurance Benefit Design*, HEALTH AFF., May/June 2002, at 16, 30–31.