Medicalization, Markets and Consumers*

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This paper examines the impact of changes in the medical marketplace on medicalization in U. S. society. Using four cases (Viagra, Paxil, human growth hormone and in vitro fertilization), we focus on two aspects of the changing medical marketplace: the role of direct-to-consumer advertising of prescription drugs and the emergence of private medical markets. We demonstrate how consumers and pharmaceutical corporations contribute to medicalization, with physicians, insurance coverage, and changes in regulatory practices playing facilitating roles. In some cases, insurers attempt to counteract medicalization by restricting access. We distinguish mediated and private medical markets, each characterized by differing relationships with corporations, insurers, consumers, and physicians. In the changing medical environment, with medical markets as intervening factors, corporations and insurers are becoming more significant determinants in the medicalization process.

Over the past three decades there has been a marked increase in the medicalization of society (Zola 1972; Conrad and Schneider 1992; Barsky and Boros 1995; Riska 2003). Medicalization occurs when previously nonmedical problems are defined and treated as medical problems, usually in terms of illnesses or disorders. While medicalization can be bidirectional, there is strong evidence for increases in medicalization. This growth of medical jurisdiction is "one of the most potent transformations of the last half of the twentieth century in the West" (Clarke et al. 2003:161). In this same period, the institution of medicine has undergone major changes in its social organization, with the advent of managed care, the declining power of the medical profession, and a rise in consumer advocacy and accountability (Starr 1982; McKinlay and Marceau 2001). As medicine has changed, has the process of medicalization been transformed as well? In an ambitious paper, Clarke and her colleagues (2003) argue that the technoscientific changes in medicine have expanded medicine's boundaries even further into biomedicalization, a wide ranging process that includes complex and multi-sited transformations in medical knowledge, technology, surveillance, and bodies. Our task here is narrower and more focused. We ask, how have changes in the institution of medicine affected the process of medicalization? Have the shifting power dynamics in medicine altered medicalization? What are current engines driving increased medicalization? What factors constrain its growth?

Most previous analyses of medicalization focused on the influence of physicians, lay reformers, or medical and scientific discoveries. This paper departs from that tack, focusing instead on the creation of markets and the impact of these markets on medicalization. Although the players are similar, the emphasis is different. Given the changing medical scene, important arenas of medicalization are moving from professional to market domains.

In this paper we examine the impact of

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changes in the medical marketplace on the increasing medicalization of society. We first review the extant general explanations for the increased medicalization, setting these in the context of recent changes in the medical system and expanding medical knowledge. The core of the paper focuses on two aspects of the changing medical market place: Direct-to-consumer advertising of prescription drugs in insurance mediated medical markets and the emergence of new private medical markets. The final section links these two aspects of the changing medical marketplace to medicalization and to consumers' access to health care.

AGENTS OF MEDICALIZATION

There are numerous broad social factors that have encouraged or abetted medicalization, including the diminution of religion; an abiding faith in science, rationality, and progress; an increased reliance on experts; and a general humanitarian trend in Western societies (Conrad 1992:213). These factors, rather than being explanatory, set the context in which medicalization occurs.

Sociologists and other analysts have identified direct factors that facilitate medicalization. Foremost among these, on the "supply" side is the prestige and power of the medical profession. It is well known that the medical profession gained great influence and authority in the first three quarters of the twentieth century, attaining both a professional dominance (Freidson 1970) and cultural authority (Starr 1982). Professional dominance and medical monopolization gave medicine jurisdiction over virtually anything to which the label "health" or "illness" could be attached (Freidson 1970). Studies of problems ranging from childbirth (Wertz and Wertz 1989) to child abuse (Pfohl 1977) to the rise of behavioral pediatrics (Halpern 1990) all purport some kind of intra-professional explanation for an increase in medicalization. It should be noted, however, that sometimes problems have been thrust onto the medical profession, which may be resisted (e.g., Kurz 1987).

On the "demand" side of medicalization, there has been growth in consumer demand for medical solutions. Barsky and Borus (1995) suggest that the public's tolerance for mild symptoms and benign problems has decreased, spurring a "progressive medicalization of physical distress in which uncomfortable body states and isolated symptoms are reclassified as diseases . . ." (p. 1931). Conrad and Potter (2000) note that the expansion of attention deficit hyperactivity disorder (ADHD) from a childhood to an adult disorder typically involves patients asking doctors for a diagnosis and medication. Patients have become more knowledgeable, demanding, and critical of medical care (Williams and Calnan 1996). The Internet has facilitated consumer involvement by offering easily accessible health-related information and providing a method for communication among like-minded individuals (Hardey 2001). Organized lay interests and advocates frequently play a significant role in medicalization, such as in the creation and institutionalization (in DSM-III) of the diagnosis post-traumatic stress disorder (Scott 1990). However, advocates for sexual addiction (Levine and Troiden 1988) and multiple chemical sensitivity disorder (Kroll-Smith and Floyd 1997) have not had such success.

New medical knowledge can also contribute to medicalization, especially in terms of etiology and treatment. The Human Genome Project and the attendant rise of genetics is one major potential source of increased medicalization. If a problem can be shown to have a genetic component it becomes a good candidate for (new or renewed) medical definitions (Conrad 2000). Similarly, the development of new medical treatments with pharmaceutical drugs can be an important factor in the medicalization of particular problems, such as the impact of Ritalin on ADHD or estrogen replacement therapy on menopause. However, it is important to emphasize that new biomedical knowledge or interventions alone cannot engender medicalization. Etiology or treatment may be a central component of a claim to medicalization, but those claims must be championed by supporters or promoters of a diagnosis, be they physicians, patients, lay advocates, or commercial entities such as drug companies.

Many of the key medicalization studies were completed over a decade ago. Important changes have occurred in health care since then, especially the increased corporatization of health care (Light 2000). Light (1993) has proposed the concept "countervailing powers" to describe the changing balance of power among the medical profession and related social institutions. In American society, profes-

sional medicine historically dominated health care, but we now see "buyers" (e.g., corporations that pay for employees' health insurance); "providers" (e.g., physicians, hospitals, HMOs); "payers" (e.g., insurance companies, governments); and "consumers" (e.g., patients, advocacy groups) all vying for power and influence over medical care. The growing influence of the biotechnology industry (especially the pharmaceutical and genomics industries), has increased the complexity of the "the medical-industrial complex" (Relman 1980; Clarke et al. 2003).

In this paper we explore how the development and promotion of new technologies, consumer demand, and the emergence of new medical markets have facilitated new areas of medicalization. Using the cases of Viagra, Paxil, human growth hormone, and in vitro fertilization (IVF) as illustrations, we contend that, in the climate of increased corporatization of health care and decreased public regulation, the creation or expansion of new medical markets are a significant force toward medicalization.

ON MEDICAL MARKETS

Until the last decade or so, sociologists rarely examined medicine as any kind of marketplace. But it is becoming clear that, with the development of managed care, corporatized medicine, and the rise of the biotechnology industry, medical markets are increasingly important in the analysis of health care.

When medical products, services, or treatments are promoted to consumers to improve their health, appearance, or well-being, we see the development of medical markets. The idea of medical markets has been described as a "theoretical anomaly" (Light 2000:395), as medical markets often do not meet many of the elements in classical definitions of a competitive marketplace. In a free market, consumers are supposed to be informed, appreciate differences in quality, and have bargaining power and free choice about buying, but these assumptions are often violated in health care markets (Lown 2000). Asymmetry of information and "uncertainty in the definition, recognition, and diagnosis of disease states" (Montagne 1992:401) in particular distinguish medical markets from other "consumer" markets.

There are, however, some medical markets that do resemble classic consumer markets, in which goods and services are exchanged as commodities. Over the last few decades, the "medical-industrial complex" has grown, "mainly as a response to the entrepreneurial opportunities afforded by the expansion of health insurance coverage offering indemnification through Medicare and employment-based plans" (Relman 1991:856). In short, the existence of third party funding has encouraged certain types of medical markets because of available insurance, although this has been partly restrained by managed care.

The use of advertising, the development of specific medical markets, and the standardization of medical services into product lines have contributed to an increased commodification of medical goods and services. Advertising of health care has become more commonplace (Dyer 1997), and new medical markets have emerged, particularly for specialty services. Imershein and Estes (1996) argue that medical services are increasingly organized into product lines (with attached payment schemes), consistent with a market-based approach to exchange. Cosmetic surgery is the most commodified of medical specialties, offering treatments that are often not covered by insurance, such as liposuction and breast augmentation (Sullivan 2001). Cosmetic surgeons advertise to stimulate demand for their services, for which patients pay cash (or borrow from finance companies that partner with cosmetic surgeons, much like purchasing a car).

In the last five years, a loosened regulatory environment has given pharmaceutical and biotechnology companies more freedom in advertising their wares, both to physicians and consumers. The Federal Drug Administration Modernization Act of 1997 made several changes that have facilitated medicalization. Most relevant to our analysis, the act loosened the restrictions placed on the kind of information that pharmaceutical companies could share with physicians regarding "off-label" uses of their drugs, and subsequently, the information that must be included in direct-to-consumer advertisements.

The constant development of new technologies, treatments, and drugs sparks consumer interest in obtaining access to these new medical goods and services, and advertising can further increase consumer demand. Consumers may gain access to these goods and services

through one of two kinds of markets: mediated markets and private markets.

In mediated markets, there is an indirect relationship between consumers, on the demand side, and medical producers or providers, on the supply side, with third party payers occupying an intervening role. Third party payers (typically private or public insurers) intervene in the exchange relationship between consumers and providers or producers in two ways: by defining what is "medically necessary" and then paying for only those goods and services that they have deemed medically necessary. The degree of control exercised by third party payers varies, depending upon the level of "management" of care being exercised. Managed care regulations dampen consumer demand for medical goods and services, particularly regarding access to new technologies (Mechanic 2002), reducing consumers' ability to purchase medical solutions to perceived health problems.

Consumers who want medical goods or services but cannot obtain them through mediated markets may turn instead to private markets, depending upon the cost of the goods or services and consumers' financial resources. In private markets, there is a more direct economic relationship between consumers and medical producers or providers: If consumers can afford a treatment, they can most likely find a medical provider who will provide it for "cash." Again, cosmetic surgery is one example of private medical markets. In private medical markets, care is provided to consumers who can afford to pay for it, and other potential consumers are excluded.

In our analysis, we examine how four relatively recent medical developments are distributed through mediated and private markets, and how distribution through these two types of markets is related to medicalization. Specifically, we look at (1) the creation of demand for new medical products in mediated medical markets; and (2) the development of private medical markets.

CREATING AND CAPITALIZING ON MEDICAL MARKETS

In 1999, the pharmaceutical industry was the most profitable industry in the United States, with an 18.6 percent return on revenues (Angell 2000). It is among the fastest growing components of health care, rising at 15 percent a year, now constituting 8 percent of health care spending (Angell 2000). In the same year, Americans purchased 2.5 billion prescriptions, averaging nine per American, for a total of $125 billion (Cohen et al. 2001). The pharmaceutical industry has a long history of marketing prescription medication directly to doctors through "detailing," direct mail, ads in medical journals, gifts, travel subsidies, and sponsoring events (Wanzana 2000).

While some direct-to-consumer advertising existed in the United States for over two decades (Pines 1999), recently the pharmaceutical industry has substantially increased its investment in targeting consumers directly. Annual spending on direct-to-consumer advertising for prescription drugs tripled between 1996 and 2000; it is only 15 percent of all marketing, but by far the fastest rising segment. Much of this increase has been in television advertising after the Federal Drug Administration Modernization Act of 1997 made it easier to advertise drugs to the general public (Lyles 2002). This change allowed broadcast ads to name both the disorder and the drug so long as they also contain limited risk and benefit information, making television drug advertising more feasible and more attractive to the pharmaceutical industry. Spending specifically on television advertising increased six-fold between 1996 and 2000, to $1.5 billion dollars (Rosenthal et al. 2002).

The pharmaceutical companies claim that direct-to-consumer advertising has an educational function that creates better informed consumers, encouraging consumers to consult their physicians about underdiagnosed symptoms and treatment options, and enabling patients to make better choices (Bonaccorso and Sturchio 2002; Lyles 2002). Critics are concerned that such advertising leads to physicians wasting time during medical visits explaining why a treatment is not appropriate, can lead to unnecessary use of medical resources and excessive profits for drug companies, and medicalize normal conditions (Mintzes 2002; Rosenthal et al. 2002). The vast majority of direct-to-consumer advertising focuses on a limited number of drugs; in 2000, 20 drugs accounted for 60 percent of direct-to-consumer advertising. These include a wide range of drugs, including antidepressants, antihistamines, antihyperliplidemics, and anti-inflammatory agents.

One aspect of direct-to-consumer advertising that has not been discussed is its impact on expanding the medicalization of human problems. So-called "consumer education campaigns" are used to introduce products, bringing new people into a market by creating a previously unrecognized demand for the product (Applbaum 2000). The direct-to-consumer advertising may well shape the way the public conceptualizes problems and it may increase consumer demand for medical solutions. At least two of the top 20 drugs promoted with direct-to-consumer advertising (see Rosenthal et al. 2002) have significant implications for medicalization: Viagra (ranked 6) and Paxil (ranked 4).

Viagra and Erectile Dysfunction

Male impotence has been a medical problem for many years. There is some evidence of medicalization in the Victorian era (Mumford 1992), although its dominant framing throughout much of the 20th century appears to have been as a psychogenic problem. In the 1990s, the problem became redefined as sexual dysfunction and its treatment was promoted by urologists, the medical technology industry, mass media, and entrepreneurs (Teifer 1994). A consensus conference in 1992 officially renamed the problem "erectile dysfunction" (National Institutes on Health Consensus Development Panel on Impotence 1993), highlighting its nature as a biogenic rather than psychogenic problem. Available treatments such a penile surgery, implants, and injections were medical, although their results were mixed (Teifer 1994).

In March 1998, the Federal Drug Administration (FDA) approved Viagra (sildenafil citrate) as a treatment for erectile dysfunction. Intended primarily for the use of older men with erectile problems and for erectile dysfunction associated with prostate cancer, diabetes, or other medical problems (Loe 2001), Viagra was the first non-invasive medical treatment for male sexual dysfunction. The medication operates by increasing the blood flow to the penis, allowing a man to achieve and sustain an erection when sexually aroused. Ingested orally, it takes effect in 30 to 60 minutes and can last from 4 to 6 hours.

A demand for a drug for erectile problems surely existed before Pfizer began advertising Viagra. Estimates of the prevalence of erectile dysfunction range from 10 to 20 million men (Fabbri et al. 1997) to suggestions that up to half all American men are "sexually dysfunctional" (Laumann et al. 1999*)*. Erectile difficulties affected not only men but their partners as well, and they were linked to powerful issues surrounding masculinity and sexual performance, making "erectile dysfunction central to masculine self esteem" (Teifer 1994:370). Pfizer Pharmaceuticals, the manufacturer of Viagra, tapped into this vast potential market and shaped it by promoting sexual difficulties as a medical problem and Viagra as the solution.

With an aging population, a high prevalence of sexual dysfunction, and an even larger concern with sexual performance insecurity, the potential American market was huge, with an even more extensive worldwide market. The initial advertising for Viagra was minimal (Carpiano 2001), but Pfizer soon marketed Viagra aggressively both to physicians and the general public. The direct-to-consumer ads included spokesmen as mainstream as former Senator and Presidential candidate Bob Dole, well recognized athletes, and ordinary people, all testifying to the wonders of Viagra and how it has changed an important part of their lives. One typical ad showed baseball star Rafael Palmiero with the words "I take batting practice," indicating both that vigorous athletes can take Viagra and that even stars might need some help in performance. Viagra became an official sponsor of major league baseball, as well as sponsoring both the Viagra car in the NASCAR circuit and Spanish language soccer broadcasts. Thus advertising expanded the market to include virtually any man who might consider himself as having some type of erectile or sexual problems.

Viagra sales were phenomenal. Physicians wrote 2.9 million prescriptions in the first three months of its availability; in the first year alone, over three million men were treated with Viagra, translating into $1.5 billion in sales (Carpiano 2001). Perhaps 200,000 prescriptions for Viagra are written weekly (Tuller 2002), with untold more Viagra sold through the Internet and other outlets. In 2000, Viagra was ranked 6th in terms of both direct-to-consumer spending and sales, with a total of $89.5 million spent and $809 million in sales, and a 17 percent increase in utilization from 1999 to 2000 (NIHCM 2001).

Viagra was a factor in the diagnostic expansion of sexual dysfunction and the increased medicalization of sexual performance (cf. Conrad and Potter 2000). Prior to Viagra, medical treatment was largely limited to major dysfunctions (e.g., as from prostate surgery). Now it included mild dysfunctions (e.g., occasional erectile problems) and could be used as an enhancement (Conrad and Potter 2004), offering a "jump start" or extra strength for sexual encounters (Loe 2001).

Viagra is not an inexpensive medication: It costs about $10 per pill. Within months of the FDA's approval of the drug, many large insurers (e.g., Kaiser Permanente and Aetna U.S. Healthcare) decided that they would not cover the drug, except at an extra cost to employers or individuals, while others did cover the drug (e.g., Blue Cross/Blue Shield plans in Indiana and California, Harvard Pilgrim Health Care, and the Defense Department's health plan). However, many insurers who currently cover the drug limit the number of pills per month. For example, Tufts Health Plan (2002) covers four tablets every 30 days, and Blue Cross and Blue Shield of Texas (2003) covers eight tablets every 30 days. In Britain, however, the National Health Service covers Viagra only for sexual dysfunction related to conditions such as diabetes, prostate cancer, and renal failure (Michael Bury, University of London-Royal Holloway, personal communication).

The health insurance industry was involved in the debate over whether "sexual dysfunction" was a medical necessity and whether Viagra should be covered by health insurance, resulting in mixed insurance coverage for Viagra. In this case, the insurance industry attempted to counteract increased medicalization of male sexual dysfunction by restricting access to Viagra. However, individuals with a physician's prescription could of course purchase the drug on their own or through a range of Internet sites.

One important social benefit from the popularity and widespread use of Viagra is a reduction of the stigma of sexual dysfunction. Seeing ads for Viagra in so many mainstream locations and making Viagra part of everyday discussions has made sexual dysfunction and its treatment appear conventional and commonplace. This has most likely also increased the market for Viagra, since it would be less stigmatizing to inquire about and use it.

The success of Viagra and the subsequent expansion of the concept of male sexual dysfunction has prompted other companies to enter and expand this market, including pharmaceutical companies either developing new drugs to compete with Viagra (Tuller 2002) or seeking a "female Viagra" (Moynihan 2003; Hartley 2003). Given the aging baby boomers and the entrepreneurial pharmaceutical industry's increased promotion of "lifestyle" drugs marketed directly to consumers (Mamo and Fishman 2001), the medicalization of sexual dysfunction is likely to continue to expand, at least for the foreseeable future.

Paxil and Social Anxiety Disorders

When the FDA approved Paxil (paroxetine hydrochloride) for the treatment of depression in 1996, Paxil followed Prozac and several other selective serotonin reuptake inhibitors (SSRIs) into an already saturated market for the treatment of depression. The manufacturer of Paxil (now called GlaxoSmithKline) responded to the saturated "depression market" by requesting FDA approval for additional applications of Paxil, specializing instead in the "anxiety market," including panic disorder and obsessive compulsive disorder at first, and then social anxiety disorder (SAD) and generalized anxiety disorder (GAD). Paxil's application to SAD and GAD has contributed to the medicalization of emotions, expanding medical jurisdiction over emotions such as worry and shyness.

SAD and GAD were fairly obscure diagnoses when they were added to the American Psychiatric Association's Diagnostic and Statistical Manual (DSM) in 1980. According to the DSM-IV, SAD (or "social phobia") is a persistent and extreme "fear of social and performance situations in which embarrassment may occur" (American Psychiatric Association 1994:411) and GAD involves chronic, excessive anxiety and worry (lasting at least six months), involving multiple symptoms (American Psychiatric Association 1994: 435–36). Both conditions are defined as being associated with significant distress and impairment in functioning. Horwitz (2002) notes how small changes in wording of criteria for SAD resulted in a tremendous growth in its estimated prevalence (and potential market).

Marketing diseases and then selling drugs to treat those diseases is now common in the

"post-Prozac" era. Since the FDA approved the use of Paxil for SAD in 1999 and for GAD in 2001, GlaxoSmithKline has spent millions of dollars to raise the public visibility of SAD and GAD, by sponsoring well-choreographed disease awareness campaigns. The pharmaceutical company's savvy approach to marketing SAD and GAD, which relied upon a mixture of "expert" and patient voices, simultaneously gave the conditions diagnostic validity and created the perception that it could happen to anyone (Koerner 2002). Soon after the FDA approved the use of Paxil for SAD, Cohn and Wolfe (a public relations firm that was working for what was then SmithKline) began putting up posters at bus stops with the slogan, "Imagine Being Allergic to People." Later in 1999, a series of ads featured "Paxil's efficacy in helping SAD sufferers brave dinner parties and public speaking" (Koerner 2002:61). Barry Brand, Paxil's product director, said, "Every marketer's dream is to find an unidentified or unknown market and develop it. That's what we were able to do with social anxiety disorder" (Vedantam 2001).

Through media campaigns, GlaxoSmithKline redefined SAD and GAD, paradoxically, as both common (reducing the stigma associated with having a "mental illness") and abnormal (subject to medical intervention, in the form of Paxil). Prevalence estimates of both SAD and GAD range widely. For example, estimates of the prevalence of SAD range from 3 percent to 13 percent (American Psychiatric Association 1994:414), with the National Institute of Mental Health estimating that 3.7 percent of the U.S. population has SAD (Vedantam 2001). Higher prevalence rates are associated with less stringent application of the DSM-specified criteria for these conditions.[1] Horwitz (2002) argues that, "Because community studies consider *all* symptoms, whether internal or not, expectable or not, deviant or not, as signs of disorder, they inevitably overestimate the prevalence of mental disorder in the community" (p.105). Likewise, the disease awareness campaign focused on individuals' feelings in social situations likely to evoke fear in many people, especially public speaking, and offered consumers symptom-based "self tests" to assess the likelihood that they had SAD and GAD (www.paxil.com). This kind of clinical ambiguity is fertile ground for creating an expansive medical market.

Some question the validity of SAD, due to its loosely defined boundaries and the aggressive marketing of it as a disease: "[T]he impression often conveyed by commercials for the drugs is clear: almost anyone could benefit from them" (Goode 2002). Murray Stein, a psychiatry professor at the University of California at San Diego, has called the use of prescription medicines such as Paxil, which are costly and may have significant side effects, "cosmetic psychopharmacology" (Vedantam 2001:1). Paxil's web page (www.paxil.com) stresses the elimination of symptoms (e.g., improved sleep) and improved performance (e.g., "improved ability to concentrate and make decisions") as benefits.

Efforts to define SAD and GAD as conditions, and market Paxil as treatment for them, have been extremely successful. Paxil is one of the three most widely recognized prescription drugs, after Viagra and Claritin (Marino 2002), and it is currently ranked sixth in terms of prescriptions (Nittan 2001), with U.S. sales of approximately $2.1 billion and global sales of $2.7 billion. It is of course not possible to distinguish how much of this was for SAD or GAD and how much of it was prescribed for other problems including depression, obsessive compulsive disorder, or post traumatic stress disorder.

But there has been some recent backlash against the drug. In 2002, a federal judge ordered a temporary halt to Paxil ads over the claim that Paxil is not habit forming (White 2002). Apparently, patients and health care providers have submitted thousands of reports to the FDA describing withdrawal symptoms (Peterson 2002). Multiple lawsuits have been filed, asserting that physicians and consumers were misled by advertisements regarding the severity of withdrawal (Barry 2002). Like similarly marketed consumer goods, such as music and clothing, it is possible that Paxil's popularity may be waning. However, along the way, the GalaxoSmithKline campaign for Paxil has increased the medicalization of anxiety, inferring directly and indirectly that shyness and worrying may be medical problems and that Paxil is the way to treat them.

DEVELOPMENT OF PRIVATE MEDICAL MARKETS

When treatments or services are not covered by health insurance, but the demand for the

medical service or treatment remains, a private medical market may evolve. Private medical markets emerge when an available medical intervention—frequently medical technology or an "off-label" use of an approved drug—meets consumers willing to pay out of their pockets to receive treatment. Such markets are sustained by consumer demand, and they can be expanded by increasing the availability of the intervention, reducing the cost of the treatment, or expanding the range of uses or target populations. Some of these interventions can be seen as medical enhancements rather than treatments for a disease, but this is a slippery slope. This commercialization of medicine has been well-developed in cosmetic surgery (Sullivan 2001), but it exists in other areas as well. The relation of increasing medicalization and private markets for biomedical enhancements and technology are illustrated through two cases: the use of human growth hormone for idiopathic shortness and in vitro fertilization for infertility.

Human Growth Hormone and Idiopathic Short Stature

Medications are frequently prescribed for "off-label" uses, as treatments of conditions beyond those approved by the Federal Drug Administration. While physicians, in practice,[2] have autonomy and authority to prescribe for off-label uses of a drug, manufacturers cannot legally market for off-label uses.

Prior to 1985, human growth hormone extracted from cadavers was used to treat individuals who had a growth hormone deficiency. The growth hormone was in low supply and thus very expensive and carried severe risks of Creutzfeldt-Jacobs disease, a potentially fatal brain disease. In 1985 the FDA removed it from the market. With fortuitous timing, Genentech introduced an FDA approved synthetic human growth hormone within six months of the removal of cadaver-extracted growth hormone. The recombinant hormone, marketed as Protropin, could be produced in "potentially unlimited quantities" (Lantos et al. 1989:1020) to such an extent that physicians credited the new technology with ending the market shortage of the hormone (Glasbrenner 1986). Genentech soon claimed 75 percent of the existing $200 million U.S. market (Werth 1991). The hormone had been approved by the FDA only for treating hypopituitary dwarfism (or growth hormone deficiency) and chronic renal failure. While individual cases might be disputed, the medical profession established strict guidelines (Bercu 1996) to distinguish between growth hormone deficiency disorder and what has been called idiopathic short stature or ISS (children with normal growth hormone who are short).[3]

As time went on, physicians, patients, and drug companies all sought other medical uses for human growth hormone. By 1990, researchers and leading drug companies were investigating the possibility of administering human growth hormone to children with "idiopathic short stature," that is "normal" children who were of short stature but had no deficiency of the hormone. Short stature is defined as the lower 3 percentiles for age and sex, which is roughly two standard deviations below the sex-age means. For adult males it is 64.5 inches or less; for adult females it is 59.5 inches (NHANES 2000). It is estimated that 1.8 million children in the United States and a similar number in Europe can be characterized with significant short stature. Only 20 percent of these are referred to pediatric endocrinologists and only 5 percent of these are growth hormone deficient (Hintz 1996). The vast majority of short children therefore can be considered idiopathic short stature, defined as "a heterogeneous state that encompasses individuals with short stature, including those with FSS (familial short stature), for which there is no recognized cause" (Kelnar et al. 1999:151). The causes of short stature may well be familial (short parents), genetic, or nutritional, but it can be seen as "normal shortness" as opposed to more specific "deficiency shortness."

A national survey of 534 pediatric endocrinologists documented that 94 percent of them had prescribed human growth hormone within the previous 5 years for children who were not hormone deficient (Cutler et al. 1996:532). Genentech and, to some extent, Eli Lilly (who marketed a similar hormone) worked closely with the Human Growth Foundation, a nonprofit advocacy group that supported "short children" (Werth 1991), a more general term including both hypopituitary dwarfism and idiopathic short stature. Genentech also supported research by pediatric endocrinologists and began its own longitudinal research on "healthy" children who were not hormone deficient. These activities further blurred the

boundaries demarcating "legitimate" and "off-label" use of human growth hormone.[4] In 2003, the FDA approved Eli Lilly's Humatrope to treat idiopathic short stature children in the shortest 1.2 percent of the population, which will likely accelerate its use in potentially short children (Kaufman 2003).

There is some evidence that shortness (and especially extreme shortness) often is a devalued status and can have social consequences, especially for males. Some researchers have found social disadvantages of shortness, including discrimination in hiring and salaries, assumptions regarding maturity and competence, issues around self-esteem and perceived attractiveness, and practical problems such as buying well-fitting clothes (see Conrad and Potter 2004). Whatever the real or imagined disadvantages of shortness, some parents have anxieties about their children's height. With the availability of synthetic human growth hormone, parents could consider interventions that would influence the height of their children.

At least 13,000 children in the United States with idiopathic short stature were treated with human growth hormone in 1994.[5] Research on growth hormone treatment with idiopathic short children has been equivocal. It is debatable how much treatment can increase growth from predicted height (cf. Hintz 1996). One major multi-center study, sponsored by Genentech, reported that of the 80 individuals in the study who reached final height, the mean gain from predicted height was 5.9 centimeters in girls and 5.0 centimeters in boys (Hintz et al. 2000). The height gains are modest; human growth hormone will not transform a short person into a tall one, but only into a less short one. Human growth hormone treatment costs about $20,000 a year and must be continued for three to six years. Parents of idiopathic short stature children must pay this out of their own funds, since health insurance will only cover treatment for hormone deficiency. If the average height gain is two inches, and the average cost is $100,000, the cost of height enhancement is roughly $50,000 an inch.

The relative ease with which manufacturers may promote and physicians may prescribe human growth hormone for off-label treatment has increased the range of possible uses (Conrad and Potter 2004). The Federal Drug Administration Modernization Act of 1997 eased limitations upon manufacturers, broadening the information that they may provide to physicians about off-label use of their products (Stapleton 1999). In terms of shortness, the potential market is considerable, with nearly four million children in the United States and Europe who could be defined as having idiopathic short stature. This could further increase the medicalization of short stature.

In Vitro Fertilization and the Medical Treatment for Infertility

The development of reproductive technologies has resulted in the medicalization of infertility. In vitro fertilization (or IVF), in which eggs are abstracted and fertilized and then implanted inside a woman's uterus, is one such case. When it was first practiced successfully, resulting in the conception of the first "test tube baby" in 1978, in vitro fertilization held out hope of a technological "fix" to an estimated 7 percent of couples who experience infertility (Centers for Disease Control 2001). "Persons now perceive that not only can the source of infertility be diagnosed, but it can be treated" (Scritchfield 1995:139), and assisted reproductive technology "has transformed infertility into a clinical need" (Bates and Bates 1996:301).

Yet the medical market for in vitro fertilization has remained fairly constrained because many consumers do not have insurance coverage for in vitro fertilization (Neumann 1997). One study found that a minority of plans (14 to 17 percent, depending upon the type of plan) cover in vitro fertilization (Alan Guttmacher Institute 1993), and another study found that 30 to 40 percent of in vitro fertilization services are covered partially and that insurance reimburses for about half of the costs when in vitro fertilization is covered (Collins et al. 1995). At first, health insurers justified their exclusion of IVF from coverage on two grounds: efficacy and cost. Initially, success rates were estimated to be 15–20 percent per attempt (Kolata 1983), and recent estimates of success rates range from 32.2 percent for women under 35 years to 9.7 percent for women ages 40–41 (Centers for Disease Control 2001). Insurance companies have often labeled in vitro fertilization as "experimental," as a result of these relatively low success rates. In vitro fertilization is also a fairly

expensive treatment, costing about $10,000 on average for one cycle (Wilcox and Rossi 2002), and it often requires multiple cycles to produce a successful pregnancy, if a successful outcome is attained at all. Some insurance carriers provided coverage for assisted reproductive technology when it first became available but dropped that benefit (Lang 1998) or decided to charge extra for in vitro fertilization coverage (*The New York Times* 1998).

In response to insurers' overall refusal to cover in vitro fertilization, many middle and upper-middle class couples pay the cost out-of-pocket, using their savings and going into substantial debt. Pamela Madsen, the executive director of the New York chapter of Resolve, an infertility support and advocacy group, had two babies using in vitro fertilization. She described her difficulty to a reporter:

> I'm tapped out, mortgaged out, credit-carded out. And we were lucky. We got our babies. We still live in a one-bedroom apartment. We had a nest egg when we got married; we had health insurance, and the system wasn't there for us (Lang 1998:12).

Facing looming personal debt from infertility treatment and substantial resistance from health insurers, middle and upper-middle class consumers have turned to litigation and legislation as means of gaining rights to reimbursement for in vitro fertilization. These couples have made "a claim upon society to guarantee, through whatever means possible, the capacity to reproduce" (Blank 1997:281). Thus far, nine states have passed legislation regulating health insurance coverage of in vitro fertilization in response to advocacy efforts by groups such as Resolve (the largest fertility support group in the United States). Recently, there have also been some calls for federal legislation to "protect the insurance rights of infertile couples" (McKee 2001).

Consumers have also sought health insurance coverage for in vitro fertilization through the courts, claiming that infertility is an illness or a disability, but such attempts have had only limited success. In this arena, consumers and insurers have wrestled over the medicalization of infertility and over in vitro fertilization as a treatment for infertility. The position that infertility is a disease is supported by the American Society for Reproductive Medicine, which states that, "infertility is a disease of the reproductive system that impairs one of the body's most basic functions: the conception of children" (American Society for Reproductive Medicine 2002). Earlier cases in which consumers claimed that infertility is an illness were sometimes successful (e.g., Witcraft v. Sundstrand Health and Disability Group Benefit Plan and Egert v. Connecticut General Life Insurance Co.). More recent consumer claims that infertility is a disability, and that insurers' lack of coverage of in vitro fertilization constitutes discrimination under the Americans with Disabilities Act of 1990 have had less success in the courts (e.g. Zantanian v. WDSU-Television Inc. and Krauel v. Iowa Methodist Medical Center).

Insurers have fought hard against claims of infertility as an illness or a disability, making three main defenses: "(1) infertility is not an illness; (2) artificial reproductive technology (ART) is not medically necessary; and (3) ARTs are experimental" (Gilbert 1996:44). Regarding infertility as an illness, "some argue that infertility is sought by some couples and suffered by others. Therefore, it is a socially constructed need—not a medical need" (Bates and Bates 1996:301). Nonpregnancy is not an illness. Some insurers have argued that infertility treatment is elective and does not cure any sickness or disease (Tischler 1994). The medical necessity argument has been used to exclude in vitro fertilization from coverage by drawing attention to the social aspects of infertility and uses of IVF. Some contend that this argument is used to control in vitro fertilization's fiscal impact on insurers (Hughes and Giacomini 2001), restricting the use of in vitro fertilization to a small number of cases in which the source of infertility problems can be specifically pinpointed and addressed. For example, the use of in vitro fertilization to bypass blocked or damaged fallopian tubes is a very specific, medical use of the technology. The use of in vitro fertilization to address infertility associated with age or to help single or lesbian women have biological children is more social. This medical necessity argument has had some success in the courts (e.g., Kinzie v. Physicians Liability Insurance Company 1987).

Even with a few successful court cases, insurers in general have not accepted consumers' claims that infertility is a disease or disability and have not increased coverage. As a result, many consumers must still pay out-of-pocket for in vitro fertilization services, and some fertility clinics have turned to creative

financial arrangements to increase the private market for their services. These arrangements offer money-back guarantees or substantial refunds if patients do not get pregnant or if they miscarry early in the pregnancy (Hamilton 1996; Wilcox and Rossi 2002; Wozencraft 1996).

The private market for in vitro fertilization appears to be here to stay. Physicians are drawn to reproductive medicine because of the "cutting edge" nature of the work, as well as the potential for commercial profit (Brody 1987). In vitro fertilization clinics advertise using Internet websites with links to finance companies to help pay for the procedure. Consumers who wish to have biological children are drawn to technological solutions to infertility. Yet the consumer demand for in vitro fertilization and other reproductive technologies is constrained by insurers' refusals to pay for such services, except under specific "medical" circumstances. This has resulted in the creation of a private medical market for consumers who can afford to pay for in vitro fertilization or who are willing to take on significant debt to do so.

DISCUSSION

We have described four cases where the development of medical markets facilitated medicalization, and we have identified two forms of medical markets: mediated and private markets. We outline the main attributes of these markets in Table 1. In mediated markets, corporate medical producers attempt to increase demand for their products by promoting directly to consumers and providers, with the market mediated by health insurers and managed care organizations. Consumers become the target for market expansion, with physicians largely remaining as gatekeepers prescribing treatment.[6] In private medical markets, due to limits in types of promotion permitted (e.g., for off-label uses), corporations promote indirectly to providers or consumers (e.g., on the Internet). Consumers are the prime driver for demand, generally without insurance support, and must pay directly for medical products or services. Physicians are necessary facilitators for treatment but are sometimes promoters (i.e., entrepreneurs) for the product as well (e.g., cosmetic surgery).

There may be a tension between restricted access to health care and the expansion of mediated and private markets. Private markets tend to emerge when insurers define a problem or treatment as not medically necessary and therefore not subject to third party reimbursement. Thus insurers here attempt to constrain access to medicalized solutions by refusing to cover particular treatments or services. These markets are not fixed; given changes in promotion, insurance coverage, or consumer role, private markets could become mediated markets and vice versa. In operation, such markets are more on a continuum than mutually exclusive in their attributes.

A key to all markets is the existence of a medical product and consumer demand. In some cases, the pharmaceutical companies develop strategies to expand their markets (e.g., Viagra and Paxil), while in others the markets are more consumer-driven. Table 2 outlines the different modes of promotion and their relation to medicalization.

In two cases the development of medical markets is primarily corporate driven. Viagra and Paxil are promoted by pharmaceutical companies through direct-to-consumer advertising, but the goals and means differ. With Viagra, the goal is to increase the appeal of the product to a wider population. When first introduced, Viagra was aimed at older men or others with established erectile dysfunction. However, in recent years much of the advertising has been aimed at a younger and broader population, with the implicit message that

TABLE 1. Comparison of Mediated and Private Markets

Relation to	Mediated Markets	Private Markets
Corporate	Direct promotion to providers and consumers (direct-to-consumer advertising)	Indirect promotion to providers via off-label use or consumers on the Internet
Insurers	Problem is generally covered by insurance with relatively flexible criteria	Problem is not covered by insurance or only covered under strict medical criteria
Consumers	Targeted for market expansion	Promoter of market expansion
Physicians	Gatekeeper, with authority to define problem and prescribe treatment	Facilitator, with authority to define problem and prescribe treatment

TABLE 2. Promotion of Medical Markets and Medicalization

Product	Promoter	Goal	Means	Medicalization
Viagra	Corporate Driven	Create new populations for product	Direct-to-consumer advertising to younger and "virile" types	Expands diagnosis of erectile dysfunction
Paxil	Corporate Driven	Create new problems for approved product	Direct-to-consumer "disease awareness campaign"	Promotes disorders of SAD and GAD
Human Growth Hormone	Consumer and Corporate Driven	Expand product to non-FDA approved uses	Secure "off-label" use of product	Makes short stature into a medical problem
In Vitro Fertilization	Consumer Driven	Redefine infertility into a health problem so technology is covered by health insurance	Seek right to treatment through legislation and litigation	Further medicalizes infertility

Viagra can help them too with whatever sexual/performance problems they may have. This market expansion means offering a medical solution to a wider range of mild or transitory erectile problems. The promoters of Paxil, on the other hand, want to differentiate their drug from others on the market. After getting FDA approval for new uses, GlaxoSmithKline developed a direct-to-consumer "disease awareness campaign" to "alert" consumers that they might have a diagnosable problem (e.g., SAD) and that Paxil could be the right choice for them. This encourages people to redefine their life difficulties in medical terms and creates a further demand for the product. In both cases the advertising aims to increase the consumer demand for the medical treatment product. Increased medicalization is a by-product.

Human growth hormone can be seen as jointly corporate and consumer driven. While there was no direct corporate product advertising to consumers, Genentech had to pay a $50 million settlement for "overpromoting" human growth hormone to medical practitioners for treating unapproved conditions (including idiopathic short stature) (Nordenberg 1999). It is unclear how much the promotion to doctors and hospitals stimulated the development of the medical market for growth hormone, but is safe to assume it had some effect. Genentech and other pharmaceutical companies support consumer groups that promote hormone interventions for idiopathic short stature, but consumer groups are the primary advocates for human growth hormone treatment (Conrad and Potter 2004). For in vitro fertilization, consumers are the main proponents pressuring for insurance coverage. Through organizations, litigation, and legislation, consumers are striving to achieve medical legitimacy for all kinds of infertility so that third parties will pay for treatment. When human growth hormone for idiopathic short stature and in vitro fertilization for infertility are not covered by health insurers, consumers must pay for these services out-of-pocket, creating a private medical market. This type of market has all the characteristics of any private market: Those who can afford to pay can acquire the services.

Medical markets can change, based upon whether insurers deem the product to be a medical necessity and cover a service or drug. The in vitro fertilization debate clearly turns on whether infertility treatment is medically necessary; consumers say it is and should be covered by insurance while insurers claim having children is a social choice, not a medical one. We see medical necessity reflected in the human growth hormone and Viagra cases as well, even if the term is not typically applied. Consumer advocates claim that human growth hormone is a medical necessity since medical treatment could mitigate the suffering, stigma, and discrimination due to the biological limitation of extreme shortness. Is the treatment of erectile dysfunction a medical necessity? In terms of insurers, the answer is, "sort of." When insurers cover the cost of Viagra, they often limit it to four to eight pills a month. Does this mean sexual intercourse is a medical necessity four to eight times a month?

It is also possible to see some uses of human growth hormone, Viagra, Paxil and in vitro fertilization as biomedical enhancements rather than treatments. While there are certainly medically legitimated uses for each of these drugs and procedures, some uses may constitute enhancement rather than treatment. Biomedical enhancements are medical inter-

ventions used to improve physical or mental characteristics or performance in those with no identifiable pathology. Adding a few inches of height to one's child, insuring strong erections, increasing one's social abilities, or having a biological child might all be improvements that could be sought by many individuals. One need not have a disorder to benefit from these medical interventions. Peter Kramer (1993) claimed that Prozac can make people "better than well." There has been some debate in the bioethics literature about a distinction between therapy and enhancement, but medicalizing human problems creates a slippery slope between enhancement and legitimated medical treatment (Conrad and Potter 2004).

While erectile dysfunction, anxiety, short stature, and infertility surely can impact people's lives to varying degrees, they are not life-threatening conditions nor even major health risks. Anti-hypertensive or cholesterol reducing drugs associated with cardiovascular disease are also widely promoted, but for a well established medical problem. While prevention of disease is a major market for drugs and interventions, the relatively common problems of life, on the margins of medicine, hold the greatest potential for market expansion and medicalization.

The role of physicians as "providers" is changing in the current medical marketplace, with some areas shifting more than others. With off-label uses of drugs like human growth hormone for idiopathic short stature, physicians play a facilitating role in the market. It is a physician's prerogative to prescribe medications for uses beyond those approved by the FDA. Doctors commonly prescribe drugs for unapproved uses if, in their judgment, the drug would be an effective treatment for a patient's problem. Similarly, technical interventions such as in vitro fertilization would be totally unavailable without physician involvement. Thus physicians still have an important central role in facilitating medical markets, especially in private markets.

But the physician's role is challenged on other fronts, particularly with direct-to-consumer advertising undermining physicians' authority regarding which drugs to prescribe. Physicians have always been the major conduit between the pharmaceutical industry and patients (which is why the pharmaceutical industry spends billions of dollars advertising and promoting their wares to physicians). Physicians in the past have provided prescriptions in response to patients' direct requests, even when the scientific knowledge suggested that it was not appropriate, because they worried about economics and their professional image and because they wanted to respond to patients' requests for help (Schwartz, Soumerai and Avorn 1989). But direct-to-consumer advertising has increased consumers' role in the prescribing equation. While physicians remain the gatekeeper to these drugs, reflected in most direct-to-consumer ads ending with a statement like, "ask your doctor if Paxil [or Viagra] is right for you," there is increased pressure to respond to consumers' independent requests for medications. In the context of current debates regarding challenges to physicians' professional knowledge (Timmermans and Kolker 2004), it appears that pharmaceutical manufacturers are circumventing physicians' control over knowledge regarding available drugs.

Insurers as "payers" exert a strong influence on medical markets. In the context of the examples presented here, insurers including HMOs set the limits on some medical markets, thus acting as a constraint on access to medicalized solutions to human problems. This is particularly clear with in vitro fertilization, where insurers' definition of the treatment as "experimental" and their refusal to cover it except in very specific diagnostic situations has limited in vitro fertilization to those who could afford to pay for it. Insurers will only pay for human growth hormone for children with a diagnosed growth hormone deficiency; idiopathic short stature children only receive treatment if their families can pay for it. Few can afford the tariff. Even with Viagra, some insurance plans don't cover this treatment for erectile dysfunction, while others limit the use. It has long been an axiom in medicalization studies that the only way to get human services paid for is to turn life difficulties into medical problems. Yet under managed care insurers are responding to this medicalization by restricting payment for these services. Insurance constraints do not necessarily affect the conceptual level of medicalization but they constrain access to medicalized solutions at the patient level (Conrad and Schneider 1980)[7]. By restricting access to medical solutions in the name of "medical necessity," insurers attempt to limit individuals' claims that they are suffer-

ing from illnesses rather than everyday life (Sabin and Daniels 1994).

Consumers have a dual role related to medical markets. In some instances the market for a problem exists long before any medical promotion. Individuals have been seeking nostrums to improve sexual performance or votive objects to insure fertility for centuries, while short people have often tried to appear taller (think elevator shoes and high heels). In a sense, there is a ready-made market demand for a product. Consumers and medical interests are already allied, and consumers may become the dynamic force for market creation. In other cases, the public constitutes potential consumers who must be shaped into a market. This involves persuading consumers of the necessity or utility of a product offered or creating consumer demand. Direct-to-consumer advertising for Paxil exemplifies this, although it is partly true for Viagra as well. Such promotion can induce people to self-label their problems as medical entities and seek more medical services. This medical commodification shifts both definition and solution into the medical sphere.

Recent changes in FDA regulations allow for a different kind of drug marketing by loosening off-label provisions and enabling television advertising of prescription drugs, facilitating the emergence of new medical markets. Broadcast ads can now name the disorder and the drug, so long as they include limited risk and benefit information (Lyles 2002). As noted, corporate pharmaceutical spending on television advertising increased six-fold from 1996 to 2000, and ads for products such as Paxil and Viagra have become common.

Off-label uses of FDA approved drugs is one of the easiest routes to the expansion of medical markets. Once a drug has been approved for one use or population, it can be prescribed for broader purposes. Ritalin is approved for childhood ADHD, but for the past decade it has been used widely with adults (Conrad and Potter 2000). Provigil (modafinil) is approved for sleep disorders, such as narcolepsy and hypersomia, but in its direct-to-consumer advertising, Cepahlon, the manufacturer, has touted that the drug can drastically reduce the amount of sleep required without affecting performance (Wolpe 2002). While drug companies have been limited in their advertising for off-label uses, FDA regulations allow for considerably more latitude in promotion. Manufacturers will likely promote off-label applications to the extent legally permitted, perhaps expanding diagnoses (Conrad and Potter 2000) and further medicalization.[8]

Medicalization narrows the definition of health and widens the definition of sickness. The direct-to-consumer advertising focuses on "help seeking" advertisements (Lyles 2002), which try to create an "awareness" of symptoms or conditions among consumers. "Consumer education campaigns" are used to introduce new products or extended applications, essentially bringing new people into a market by creating a previously unrecognized demand for a product (Applbaum 2000). The marketing of Viagra expands the bounds of erectile dysfunction, implying that it is not "healthy" or "normal" to have variation in penile erections. Paxil ads emphasize that it may be pathological to be anxious or shy in social situations and that this can be changed by using the drug. Employing human growth hormone to treat short stature indicates a narrowing of the range of normal height as well as reinforcing the notion that shortness is deviant and undesirable, and that it should be altered. The marketing of Paxil, Viagra and, to a lesser degree, human growth hormone targets relatively healthy people. Drug companies' search for markets creates broader disease definitions for their products, indirectly reducing what is "normal."

CONCLUSION

We highlight the increasing importance of pharmaceutical companies, insurers, and consumers for medicalization as they are involved in the creation of medical markets. The medical profession has a diminished but still key role in medicalization. Given the changes in medicine and its organization, important arenas of medicalization are moving from professional to market domains.

It is not new knowledge or technology that engenders medicalization but how they are used. Corporate and medical promotion of products, treatments, and drugs underlies the emergence of new medical markets. With our corporatized medical-industrial complex, the creation or expansion of medical markets becomes an important conduit to medicalization. Consumer demand is not simply unfettered desire for medical solutions, but it is

shaped by the availability and accessibility of medical interventions. This creates a new set of relationships among corporate entities, insurers, physicians, and consumers.

In the context of the changing balance of power among the medical profession and related institutions, the engines of medicalization are found in the marketplace nexus of the biotechnology industry and rising consumerism. The brakes take the form of insurers, including private and government sponsored managed care. As corporate entities and consumers pursue the goals of promotion or reception of new medical interventions, we are likely to see the development of new medical markets along with a growing pressure to medicalize the troubles and problems of everyday life.

NOTES

1. According to the DSM, the diagnostic criteria for SAD include: a marked and persistent fear of social or performance situations in which embarrassment may occur, an immediate anxiety response, a recognition that the fear is excessive or unreasonable, avoidance of the situation or endurance with dread, interference with daily routine or marked distress about the phobia, and the fear not being due to substance effects or other conditions (American Psychiatric Association, 1994:411).
2. Professional medicine has long approved of off-label uses of drugs. In 1999, the American Medical Association approved a position statement (Resolution #528), introduced by the Society of Cardiovascular and Interventional Radiology, on off-label use of devices and medications. In summary, the AMA permits physicians to decide what to prescribe for their patients and for what medical conditions, because physicians are best able to base these decisions on "current clinical standards and not just FDA-approved indications."
3. Criteria include (1) height of less than three standard deviations below the mean for a child's age and sex, (2) abnormal growth velocity (less than 25th percentile for bone age), and (3) growth hormone provocative testing results with peak growth hormone of less than10 (g/L in a polyclonal radioimmunoassay (Bercu 1996). It is this latter criterion that has produced the most controversy (Lantos et al 1989; Bercu 1996). For example, peak growth hormone levels between 7 and 10 are considered a "gray zone," and different methods of assessing growth hormone levels produce varying results (Lantos et al. 1989).
4. In 1994, several federal agencies began a series of investigations targeting Eli Lilly and Genentech for overpromoting their growth hormone products, that is, marketing them for non-approved uses (for details, see Conrad and Potter 2002). The FDA alleged and documented that, by the end of 1985, Genentech had "begun marketing Protropin for use in the treatment of medical conditions for which it did not have FDA approval" (Nordenberg 1999:33). From 1985 to 1994, Genentech marketed Protropin to a variety of medical practitioners (doctors, hospitals, and others) for treating unapproved conditions, including idiopathic short stature (Nordenberg 1999). Genentech paid $50 million in settlement, including a $20 million penalty to reimburse Medicaid and CHAMPUS (Nordenberg 1999).
5. This is an extrapolation. In 1994, about 7,000 children were believed to suffer from short stature due to human growth hormone deficiency but 20,000 children were treated with human growth hormone (Biotechology News, 1994). Therefore at least 13,000 children were treated for idiopathic short stature that year.
6. There is increasing advertising on the Internet for Viagra, human growth hormone, and other prescription medications. While it is assumed that a doctor must evaluate the short forms consumers need to complete before ordering medications, the wide availability of medications through the Internet sources compromises the physician's gatekeeper role.
7. Some have suggested that direct-to-consumer advertising is in part a reaction to managed care. Lyles (2002) notes that, "managed care controls that limit the physician's prescription authority also reduce the potential of promotional activities targeting physicians; consequently pharmaceutical companies have responded by seeking alternative ways to influence physician prescribing" (p. 27).
8. A recent case illustrates this. Parke-Davis, a

major pharmaceutical company, developed a marketing strategy to promote their epilepsy drug, Neurontin, for four off-label uses. The company estimated it could earn $150 million by promoting the drug to doctors for social phobias, panic disorder, bipolar illness, and neuropathic pain in journals and at medical conferences rather than embarking on the clinical trials and lengthy process of seeking FDA approval. 80 percent of the prescriptions for Neurontin are for off-label uses. U.S. sales for 2002 are estimated as $2 billion. The company claims it was only distributing materials for educational purposes, but critics saw it as an unethical form of marketing (Kowalczyk 2002).

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