The Economics Of Viagra

A new blockbuster drug raises important questions about what is viewed as "medical necessity" by insurers.

BY ALISON KEITH

VIAGRA HAS BEEN ON THE MARKET for nearly two years. Everyone knows its name. It had the fastest initial sales growth of any pharmaceutical product following its April 1998 launch in the United States (although its record has since been surpassed). As the first approved effective oral treatment for erectile dysfunction (ED), Viagra has had a powerful and freeing impact on public discussion of sexuality and has spawned a near-infinite number of jokes.

The magnitude of Viagra's sales has, perhaps, driven third-party payers to look for new rationales to avoid paying for it. Viagra is described by some as a "lifestyle" drug, supposedly distinguishable from serious, important medical therapies. In contrast, not only those suffering from ED but also medical authorities recognize that it is indeed a serious medical condition, often caused by other serious medical conditions. Viagra and its experience in the health care market raise questions as to where a line might be drawn between serious medical conditions and health-related quality of life, and whether such a borderline is even meaningful.

■ **Background.** An estimated thirty million men in the United States and 100 million men worldwide are affected by ED, the failure to achieve and maintain an erection sufficient for satisfactory sexual experience. In a large U.S. survey it was found that 52 percent of men ages forty to seventy reported some degree of ED.[1] Although the rate and severity of ED increase with age, age itself does not appear to be the primary cause. Nearly 80 percent of ED is associated with organic causes.[2] Age-related illnesses such as vascular disease and diabetes, the medicines taken to treat those illnesses, and the long-term effects of smoking and alcohol abuse all contribute to increasing prevalence. Additional risk factors for ED include atherosclerosis, diabetes, severe depression, and injuries and surgery, including radical prostatectomy and spinal cord injury.[3]

■ **How Viagra works.** Viagra (sildenafil citrate) works, in response to sexual stimulation, by increasing the blood flow to the

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penis. In clinical trials 74 percent of patients on Viagra reported improved erections, compared with 16 percent of those on placebo.[4]

Extensive experience, both in clinical trials and in use after approval, has shown Viagra to be well tolerated. In clinical trials Viagra did not result in increased rates of myocardial infarction or other serious cardiovascular events during either short- or long-term treatment.[5] Further, there is no epidemiologic evidence that Viagra adds to the cardiovascular risk inherent in sexual activity. There is a broad base of experience from which to draw this epidemiologic conclusion: In the first year and a half of marketing in the United States, more than 15.6 million prescriptions of Viagra had been filled. As evidence of satisfactory use, refills accounted for nearly half of these.[6]

The use of Viagra in combination with organic nitrates is contraindicated because of a potentially serious decline in blood pressure. This contraindication, which is particularly relevant for patients taking cardiovascular medications (some of which contain nitrates), has been clearly communicated to physicians and the public. Among the most common side effects revealed in clinical trials were headache (16 percent), facial flushing (10 percent), and indigestion (7 percent). In addition, some mild and transient visual effects were reported (3 percent).[7]

■ **Viagra's competitors.** Prior to the introduction of Viagra, the alternative prescription treatments were mostly non-oral medications. In the United States, for example, the primary alternatives were penile prostheses; vacuum constriction devices; penile injection therapy; transurethral suppositories; and professional counseling. In many countries traditional remedies such as yohimbine are also used.

■ **Viagra sales.** Viagra was first launched in April 1998 in the United States, shortly after the Food and Drug Administration (FDA) granted approval, and is now being sold in more than fifty countries.[8] More than $400 million worth of Viagra was sold in its first quarter on the U.S. market; in the week of 8 May 1998—one month after launch—more than 300,000 total prescriptions were written for Viagra.[9] Since then Pfizer has maintained a list price of $7 per tablet. Viagra is substantially less expensive than its pharmaceutical competitors: Muse, the transurethral suppository, and Caverject, the penile injection. Viagra has an average wholesale price of $8.75 per pill, while, on the same basis, Caverject and Muse are priced at $20–$30 per treatment.[10]

Prescriptions peaked and leveled off in the quarters following Viagra's launch. One reason was the information men gained by trying the drug. Some discovered that Viagra was not effective for

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them. Others, who did not actually suffer from ED but who (with a doctor's authorization) had tried it anyway, confirmed that Viagra would not confer exaggerated sexual prowess. In addition, use may have been limited by increased public awareness focused on the cardiovascular safety issues in men taking Viagra, particularly on the deaths and serious adverse events that were reported to the FDA. However, no causal link has been established between Viagra and the reports of death, and the FDA "continues to believe Viagra is safe and effective if used according to the updated labeling."[11]

European registration was granted by the European Medicines Evaluation Agency (EMEA) in September 1998, and sales began in most European countries shortly thereafter. Only in Sweden, the Republic of Ireland, and, for limited uses, the United Kingdom does the government health system cover purchases of Viagra. In most countries sales have shown some leveling off after an initial peak, as was the U.S. experience.[12]

Approvals and launches in Latin America followed shortly after the drug's approval and launch in the United States, and Viagra is now available in a number of Asian countries, Australia, New Zealand, and Canada. Japan's approval, in January 1999, was unprecedented in two respects. First, the six-month approval was the most rapid Japanese approval ever. Second, for the first time Japan accepted data from clinical trials conducted elsewhere.[13]

Evidence Of Value For Consumers

The single most revealing measure of an innovation's economic value is the market's response to it. On this measure, Viagra offers a striking example: Sales of the drug grew very rapidly after launch, and those of its competitors fell dramatically. The introduction of Viagra essentially quadrupled the market for treatment of ED (in dollar sales) in the United States in eight months.[14] At the same time, Viagra cut sharply into the sales of other ED treatments, whose prescriptions fell by about half.[15] Viagra now accounts for 92 percent of new prescriptions to treat ED.[16]

The evidence is bolstered by the fact that many Viagra purchasers pay the full price out of their own pockets, since insurance coverage for Viagra is far from universal in the United States. Fifty-eight percent of U.S. Viagra prescriptions are paid for out of pocket—much higher than the average for all drugs, 22 percent.[17] By contrast,

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70 percent of prescriptions for Muse are covered by some kind of insurance.[18]

This is true not only in the United States but also in most other countries, where most government-run health plans do not cover Viagra purchases. Indeed, in many countries a high-price black market for Viagra existed before the product was legally available, indicating that consumers were willing to pay more than the market price. News stories reported black-market prices of $20–$30 per pill in some countries (for example, Malaysia, Hong Kong, and Thailand) and even in the $50 range in China.[19] One reason for the speedy Japanese approval of Viagra was for the government to establish control over the market for the drug, since a black market was thriving in Japan, including purchases over the Internet.[20]

Why Incomplete Insurance Coverage?

In view of the evidence that Viagra makes consumers better off, why do so many third-party payers resist covering it? In principle, one might argue that a health insurer should be willing to cover any treatment that its members would choose to pay for, especially if members would be willing to pay a premium to cover the cost. Why, then, the exclusions and limitations on coverage? To set the context for discussion of this issue, it is instructive to review several insurers' coverage decisions for Viagra.

■ **The United States.** Outpatient prescription drugs are sometimes, but not always, covered by insurance in the United States. Overall, 40 percent of Viagra prescriptions are covered by third-party payers, and 2 percent are covered by Medicaid.[21] Only about half of all U.S. health plans reimburse members for at least some Viagra pills.[22]

After Viagra's introduction, for example, Aetna/U.S. HealthCare and Prudential quickly decided to refuse coverage.[23] Kaiser Permanente, the nation's largest not-for-profit health maintenance organization (HMO), initially decided not to cover Viagra, citing cost. California's Department of Corporations, which regulates health plans in the state, contested Kaiser's decision. In late December 1998 Kaiser agreed to cover Viagra and resolve grievances with plan members who were denied prescriptions for Viagra during the six months that it was not on Kaiser's formulary. Kaiser also agreed to pay the state $250,000 to help pay for investigation costs.[24] The state rejected Kaiser's broader request to drop coverage for all ED treatments, but it agreed that Kaiser could (continue to) charge a 50 percent copayment for Viagra—higher than copayments for other drugs.[25] It also determined to separately consider whether Kaiser could raise its premiums by $1, allegedly to cover the added cost of

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Viagra, or instead to offer employers the option of paying extra for employees' Viagra coverage.

Even though the law appears to be clear that states must cover Viagra for Medicaid patients, actual implementation has not followed suit. Eleven states have still not approved Viagra reimbursement for Medicaid patients, even though Viagra is an FDA-approved drug and the Omnibus Budget Reconciliation Act (OBRA) of 1990 requires states to cover all such medications.

Some plans that do provide coverage for Viagra have set limits on the quantity that will be reimbursed. Oxford Health Plans decided in summer 1998 that the limit would be six pills per month. UnitedHealthcare's coverage was, depending on the individual plan, up to eight pills per month; patient copayments were to range from $5 to $25.[26] Other health plans set the limit at four pills per month.

Individual consumers have taken health plans to court over Viagra coverage. The first class-action lawsuit was filed in May 1998 on behalf of members of Oxford Health Plans and other plans. The suit alleged that by refusing to provide full coverage for Viagra, insurance companies and their plan administrators had breached their fiduciary duty under the Employee Retirement Income Security Act (ERISA) to provide coverage for any drug that is deemed "medically necessary." The number-of-pills restriction is also being challenged in court. A federal judge planned to file a class-action suit against the federal government (his employer), challenging the limitation of four pills per month as too low. He had previously filed suit to force the plan to cover Viagra at all, after which the plan changed its policy to the four-pill standard.[27]

■ **The United Kingdom.** Following Viagra's Europewide grant of a marketing authorization by the European Commission in September 1998, the U.K. Department of Health (DOH) advised National Health Service (NHS) doctors not to begin prescribing it until prescribing guidelines were issued. This guidance was ruled unlawful by the U.K. High Court in May 1999. However, publication of guidelines was delayed. Meanwhile, physicians were frustrated because they believed that they should prescribe Viagra when it was medically appropriate. The General Practitioners Committee (GPC) of the British Medical Association (BMA) stated that "doctors had been placed in an untenable position because of the inconsistency between the interim departmental advice and their professional obligations."[28] The GPC announced that it would issue its own guidelines at a 21 January 1999 meeting if no government guidelines had appeared by then.

On 21 January itself the government issued its proposal for the funding of all ED treatments in the NHS: Viagra and other treat-

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ments would be reimbursed only for men with selected etiologies of ED (spinal cord injury, radical pelvic surgery, prostatectomy, diabetes, and multiple sclerosis but not kidney disease, liver disease, thyroid disease, depression, or circulatory conditions).[29] Cases covered by this ruling constitute only about 15 percent of all cases of ED in the United Kingdom.[30]

New government proposals came into force 1 July 1999, which limited the availability of Viagra and all other ED treatments on NHS prescriptions via Schedule 11 to the regulations setting out general practitioners' (GPs') statutory terms of service. Schedule 11 allows the DOH to dictate to a doctor the groups of patients who are able to receive a prescription for a particular type of treatment in the NHS. Two groups of patients may receive treatment for their ED through the NHS, using Schedule 11: (1) men with the following conditions—diabetes, multiple sclerosis, Parkinson's disease, and poliomyelitis; men treated for prostate cancer; men who have had a prostatectomy or radical pelvic surgery; and men treated for renal failure (transplant and dialysis), severe pelvic injury, single gene neurological disease, spinal cord injury, or spina bifida; and (2) any man who was receiving treatment for ED in the NHS as of 14 September 1998. Although this is not actually specified under Schedule 11, the DOH has said that men judged to be suffering from severe distress as a result of their ED will be able to receive NHS treatment in a hospital setting following assessment by a specialist.

■ **Japan.** Viagra was approved for use in Japan in January 1999. In March the Japanese government announced that Viagra would not be reimbursed under the national health system. The rationale is that although Viagra improves the quality of life, it does not cure an underlying condition.[31]

Reasons For Excluding Or Limiting Coverage

Among the reasons one might identify for resistance to coverage are concerns that an innovation is not effective, that it is not safe, that it is not cost-effective, or that it is simply too costly. The newest reason offered is that it is not really a "medical treatment" at all, but rather a "lifestyle enhancement" and therefore outside the realm of the health insurance contract.

■ **Efficacy, safety, and cost-effectiveness.** Compelling evidence exists of Viagra's efficacy for its intended use. Hence, efficacy has not been a concern. Furthermore, while some insurers may have raised safety as a concern, it seems implausible that this is the actual source of concern, because of the evidence that Viagra is safe when used appropriately.

It is also not likely that concern over cost-effectiveness is driving

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limitations on coverage. Indeed, for men already being treated for ED, the switch to Viagra is very likely cost-saving. As mentioned above, Viagra is considerably less expensive than pharmaceutical alternatives and undoubtedly less costly than surgery.[32] Indeed, the BMA noted that in Britain Viagra is "cheaper and more acceptable for patients than alternative treatments and highly cost-effective per QALY [quality-adjusted life year] terms."[33]

■ **Cost.** The most obvious driver of refusal to cover Viagra is concern over the rise in spending that accompanies this kind of innovation. When an attractive new therapy for a condition many patients care about but were heretofore unable to treat adequately is introduced, total expenditures for treatment are certain to rise. The classical insurance-generated cost-increasing forces of moral hazard and adverse selection also may come into play.

■ **Moral hazard.** Moral hazard was one of the reasons put forward for the decision in the United Kingdom. According to the DOH Standing Medical Advisory Committee's report, "Diagnosis of erectile dysfunction depends on self-reporting, so it may be difficult to avoid additional costs for men who do not have erectile dysfunction and who wish to try to enhance normal performance."[34] This concern, however, should be defeated by the recognition that consumers quickly recognize that the product does not "enhance normal performance."

Still, moral hazard accounts for some of the increase in demand for Viagra, but probably only a minor fraction. It appears that the moral-hazard justification for limiting coverage may have been overstated. For example, Kaiser's initial estimate of the cost impact apparently assumed that every man in Viagra's target population would take thirty pills per month. Kaiser argued that covering Viagra would cost at least $100 million per year, impairing its "ability to cover other vital health care needs" and requiring premium increases that would make health insurance too expensive for many.[35] The State of California challenged the $100 million estimate, finding instead that the pill was likely to be consumed at a much lower rate than initially assumed.[36] And the estimate of thirty pills per month stands in stark contrast to actual average prescription size of eight pills, typically considered a thirty-day supply.

■ **Adverse selection.** Although adverse selection was not mentioned as an explanation for not covering Viagra, health plans might have been concerned that men coming to the doctor to get Viagra might be treated for the first time for other serious conditions as well. In the past only a small fraction (14 percent) of men with ED sought treatment for it.[37] Viagra appears to be changing this: According to IMS Health, the number of American men who sought help

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from a doctor about a penile disorder rose 75 percent, from 2.8 million in 1997 to 4.8 million in 1998.[38] If men with undiagnosed hypertension, diabetes, or other such conditions were brought into treatment earlier by Viagra, the health benefits might be substantial, but costs would rise as well, at least in the short term.

Insurers apparently feared having to divert resources from other medical conditions to treatment of ED; Kaiser stated this explicitly in the *Wall Street Journal*.[39] A British government spokesman explained publicly that its reimbursement decisions were driven by cost considerations and were designed to keep expenditure on treating impotence at roughly the current level.[40] Of course, the alleged encroachment of ED treatment on treatment for other conditions need not happen if overall budgets can be increased to cover the additional ED treatment costs. But Kaiser said that a sufficient premium increase in the future was not feasible, either, since the size of the necessary premium increase would put the cost of its plans out of reach for too many people.[41]

This does not appear to be a full explanation. Any insurance plan—whether a private managed care organization or a government—covers a mixture of treatments only some of which are relevant for any individual patient. Women will not need treatment for prostate cancer, nor men for ovarian cancer. Anyone who chooses not to have children will not use a delivery room. Therefore, the prediction that the average premium increase attributable to Viagra will be unacceptable to buyers or taxpayers rests on the argument that demand is simply so responsive to coverage that no appropriate, stable premium increase can be established. This conclusion seems clearly contradicted by the evidence from the marketplace.

■ **Medical necessity versus lifestyle.** Finally, can insurers' desire not to cover Viagra be traced to their desire to exclude it because it is merely a "lifestyle enhancement" and not a treatment for a real medical condition? To an economist, this explanation also has a hollow ring. A bit of thought reveals that the distinction between lifestyle and medical necessity is arbitrary at best.

In many forums, the coverage debate has turned squarely on the question of what treatments are or should be considered medically necessary. The State of California stated, in its opposition to Kaiser's original decision not to cover Viagra, that its insurance regulations require insurance to cover medically necessary goods and services

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and to provide health coverage to patients "unhindered by a plan's fiscal concerns."[42] In addressing this issue in a class-action case, an attorney asked, "Is sexuality a mere 'convenience' or a vital human function?" He noted that since health insurance providers had "historically provided unlimited coverage for more invasive and painful but equally expensive treatments for impotence," the decision not to cover Viagra was driven by financial considerations.[43]

One can easily argue that Viagra is a medically necessary treatment. ED is a prevalent condition that interferes with an important component of human health. The impact of ED extends beyond sexual activity itself. Anger, depression, and anxiety resulting from ED can impair the quality of life of both affected men and their sexual partners and can cause harm to personal relationships. Also, patients assess ED as a serious health condition. At a meeting sponsored by the World Bank at the World Health Organization in 1995, attendees were asked to rank the average handicap stemming from a variety of conditions.[44] ED was ranked similarly with infertility, rheumatoid arthritis, and angina.

The debate over "lifestyle" conditions and treatments is really a reflection of a larger question of the continuum from immediately life-saving treatments to those that make life more pleasant by improving health-related quality of life. The apparently easy distinction between conditions that affect real health and those that merely affect lifestyle is, in fact, arbitrary. Certain activities—in this case, sex—are viewed by some as personal options that are not inherently part of the definition of good health and therefore should not be included in health insurance. Cosmetic improvements, such as baldness remedies, weight-loss programs, and cosmetic surgery, are included in this bundle.

However, the same options apply to a wide range of medical conditions that are commonly considered legitimate health concerns. On one end of the spectrum, treatment for smoking cessation may be considered a lifestyle issue; in fact, quitting smoking is one of the most beneficial things that one can do to improve one's long-term health prospects. One could also argue that treatment for arthritis or migraines primarily affects lifestyle and not the ability to survive. In the extreme, one might argue that recent innovations in the treatment of stroke are principally lifestyle enhancements, aimed at preventing a lifestyle burdened by immobility or other lost functions. The point, of course, is that virtually all medical treatment affects patients' ability to live the lives they prefer. There is simply no bright line distinguishing lifestyle from medical necessity.

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AN ARBITRARY DISTINCTION between health and lifestyle will be increasingly out of place as chronic conditions come to the fore with increasing prevalence, as populations age, and as new technologies emerge to treat or manage these conditions. If these new technologies are to be allowed to provide the benefits they promise, insurers must do a better job of aligning coverage decisions with their members' true valuation of the benefits—that is, their willingness to pay.

Viagra is a registered trademark of Pfizer Inc. Muse is a registered trademark of Vivus Inc. Caverject is a registered trademark of Pharmacia & Upjohn Company.

NOTES

1. H.A. Feldman et al., "Impotence and Its Medical and Psychosocial Correlates: Results of the Massachusetts Male Aging Study," *Journal of Urology* 151, no. 1 (1994): 54–61.
2. Ibid.; A.E. Benet and A. Melman, "The Epidemiology of Erectile Dysfunction," *Urologic Clinics of North America* 22, no. 4 (1995): 699–709; M.M. Foreman and P.C. Doherty, "Experimental Approaches for the Development of Pharmacological Therapies for Erectile Dysfunction," in *Sexual Pharmacology*, ed. A.J. Riley, M. Peet, and C. Wilson (Oxford: Oxford University Press, 1993), 87–113; and "NIH Consensus Development Panel on Impotence," *Journal of the American Medical Association* 270, no. 1 (1993): 83–90.
3. Benet and Melman, "The Epidemiology of Erectile Dysfunction."
4. I. Goldstein et al. for the Sildenafil Study Group, "Oral Sildenafil in the Treatment of Erectile Dysfunction," *New England Journal of Medicine* 338, no. 20 (1998): 1397–1404; and H. Padma-Nathan, W.D. Steers, and P.A. Wicker, "Efficacy and Safety of Oral Sildenafil in the Treatment of Erectile Dysfunction: A Double-Blind, Placebo-Controlled Study of 329 Patients," "FBCalifornian-Italic"International Journal of Clinical Practice (September 1998): 375–379.
5. A. Morales et al., "Clinical Safety of Oral Sildenafil Citrate (VIAGRA) in the Treatment of Erectile Dysfunction," *International Journal of Impotence Research* 10, no. 2 (1998): 69–74.
6. As evidence of satisfactory use, refills now account for more than half of all prescriptions. S. Pomerantz, "Viagra Market Update, Week Ending 11/26/99" (New York: Pfizer, 13 December 1999).
7. Pfizer, Viagra Product Monograph (July 1998).
8. T. Trucia and S. Pomerantz, "Viagra World Wide Market Update, August–September 1999" (New York: Pfizer, 1999).
9. IMS Health, Retail and Provider Perspective, 1998, and National Prescription Audit, 1998.
10. *1999 Drug Topics Red Book* (Montvale, N.J.: Medical Economics Company, 1999). The *Red Book* provides average wholesale prices (AWPs), which add a distribution margin to the manufacturer's price.
11. Food and Drug Administration, "Pfizer Updates Viagra Labeling," FDA Talk Paper T98-83, available online at www.fda.gov/cder/consumerinfo/viagra/default.htm.
12. Trucia and Pomerantz, "Viagra World Wide Market Update, August–September 1999."
13. "Japanese Women's Groups Angry after Health Ministry Approves Viagra," Tokyo, Dow Jones News (26 January 1999).
14. M. Duffy and S. Pomerantz, "Viagra Market Update, Week Ending 12/18/98"

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(New York: Pfizer, 15 January 1999).
15. Ibid.
16. Pomerantz, "Viagra Market Update, Week Ending 11/26/99."
17. Ibid.
18. Ibid.
19. "Viagra Sold Illegally in Malaysian Nightclubs, Pharmacies," Kuala Lumpur AFP (8 March 1999); T. Sulien Duffy, "Viagra Hits Hong Kong, but Will It Replace Traditional Impotence Cures?" Hong Kong, APW (10 February 1999); S. Wannabovorn, "Thais Say Massage, Herbs, Give That Viagra Feeling," Bangkok, Reuters (11 May 1999); and "In the Absence of Viagra, Here's to Great Brother," Hong Kong, AFP, Dow Jones News (15 January 1999).
20. "Japanese Women's Groups Angry."
21. Pomerantz, "Viagra Market Update, Week Ending 11/26/99."
22. M. Grunwald, "U.S. Judge Asserts Need for More Viagra Coverage," *Washington Post*, 27 March 1999.
23. N. Jeffrey, "Prudential HealthCare and Humana, Citing Safety, Won't Pay for Viagra," *Wall Street Journal*, 6 July 1998.
24. "Kaiser Settles Grievances with Members Denied Viagra," Sacramento, Dow Jones Newswires (29 December 1998).
25. R. Rundle, "Kaiser Permanente Will Raise Rates to Cover Costs of Providing Viagra," *Wall Street Journal*, 4 January 1999.
26. N. Jeffrey, "Kaiser Permanente Decides It Won't Cover Viagra Pills," *Wall Street Journal*, 22 June 1998.
27. Grunwald, "U.S. Judge Asserts Need for More Viagra Coverage."
28. J. Chisholm, "Viagra: A Botched Test Case for Rationing," *British Medical Journal* (30 January 1999): 273–274.
29. Ibid.
30. N. Timmins, "Financial Grounds Used to Ration Viagra," *Financial Times*, 24 January 1999.
31. "Viagra Not to Be Covered by Health Insurance," Tokyo, Japan Economic Newswire (9 March 1999).
32. Data from IMS America (18 May 1999).
33. Chisholm, "Viagra."
34. Ibid.
35. Jeffrey, "Kaiser Permanente Decides It Won't Cover Viagra Pills."
36. D. Griffith, "Viagra for Now," *Sacramento Bee*, 29 December 1998; and "Kaiser Must Cover Viagra, California State Rules; HMO to Pay $250,000," *F-D-C Reports, "The Pink Sheet"* (4 January 1999).
37. Pfizer, Men's Health Survey, 1997, in Viagra Outcomes Research Support Package, 2–11.
38. See O. Middleton, "Viagra Sales Slow from Pace of 1998 Launch," *Wall Street Journal*, 29 March 1999, citing IMS Health data.
39. Jeffrey, "Kaiser Permanente Decides It Won't Cover Viagra."
40. Chisholm, "Viagra."
41. Jeffrey, "Kaiser Permanente Decides It Won't Cover Viagra."
42. State of California, Department of Corporations, Press Release (28 December 1999).
43. Middleton, "Viagra Sales Slow from Pace of 1998 Launch."
44. C. Murray and A. Lopez, eds., *The Global Burden of Disease* (Geneva: World Health Organization, 1996), 39, Table 1.3.

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