



ELIE OFEK

Product Team Cialis: Getting Ready to Market (Abridged)

It was early 2002, and Mark Barbato, the executive director and global product team leader for Cialis, knew he faced a daunting task: launching a medicine for the treatment of male impotence in a market with an established leader—Viagra.¹ Not only had Viagra been generating over \$1 billion in sales annually for its parent company Pfizer for three consecutive years, but it also enjoyed the highest brand recognition of any other pharmaceutical drug in the world.

Despite the huge success of Viagra, Barbato and his team were very optimistic about the future prospects for Cialis (active ingredient *tadalafil*). The innovative new drug, developed through a joint venture (Lilly ICOS LLC) between Eli Lilly, the pharmaceutical giant, and ICOS, a young biotech upstart, showed promising clinical results. At an upcoming prestigious urology conference, to be held in the spring of 2002, medical investigators would present data showing that a 20mg oral dose of Cialis improved the ability of up to 81% of men suffering from male impotence to respond to sexual stimulation over an extended period of time, even 36 hours after taking the drug. Since Viagra's effect lasts approximately four hours after dosing, the new treatment offered such men a significantly greater window of opportunity to choose the right moment of intimacy. Furthermore, the body's ability to absorb Viagra was diminished when the drug was taken during or after a high-fat meal, potentially leading to slower onset time.² In contrast, the absorption of Cialis was not affected by food intake. Cialis demonstrated a generally favorable safety profile, similar to that seen with Viagra. Both drugs were not to be taken in conjunction with nitrates, which may be given to treat select heart problems. The incidence of visual irregularities, a side effect of Viagra, was notably rare for Cialis.³

Following Cialis's successful phase III clinical trials, a new-drug application (NDA) was submitted to the U.S. Food and Drug Administration (FDA) on June 28, 2001, and a similar application was filed in July with the European Agency for the Evaluation of Medicinal Products. With the approval process taking an average 12–18 months in both jurisdictions, the Lilly ICOS LLC board members were hoping for a launch in 2002. In preparation for the launch, a brand council was scheduled for January 18. The

¹ Cialis is a trademark of Lilly ICOS LLC. Viagra is a trademark of Pfizer, Inc.

² Lower peak blood levels can also result. The regulatory guidelines used to determine the presence or absence of a food interaction (for package inserts/labels) are based on a very specifically defined high-fat meal.

³ "Giving Viagra a Run For Its Money," *BusinessWeek*, October 23, 2000.

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brand council would bring together top Lilly marketing representatives from around the world, all eager to learn how Cialis would be differentiated from the competition and how they should promote the new drug once it was approved. With the meeting less than two weeks away, the global marketing director for the Cialis product team, Rob Brown (from Lilly), and Leonard Blum, vice president of sales and marketing at ICOS, had their work cut out for them. They had to come up with a strategy that would guide all future marketing activity. In particular, they had to clearly identify a target market for the drug and a way to position it against the competition. Brown and Blum were contemplating three possible approaches: Cialis could either follow a “niche” strategy, whereby a specific and relatively narrow segment would be identified and targeted; it could follow a direct “compete” strategy and go head-to-head with Viagra’s positioning; or it could follow a “beat” strategy and try to come up with a differentiated positioning that would allow it to pursue a broad market.

ED – A Treatable Medical Condition

When Pfizer created a little blue pill called Viagra, it produced a widely used oral treatment for a medical condition rarely discussed in public – male impotence, or erectile dysfunction (ED). For men who suffer from ED, the process by which increased blood can flow to tissue necessary for attaining an erection is impaired. Most cases of ED are associated with another medical disease, certain medications, or lifestyle factors such as smoking or excessive alcohol consumption. (Primary morbidities linked to ED are shown in **Exhibit 1**.) The nature and incidence of these diseases tend to produce a strong age correlate with the ED condition. As for psychological factors, such as stress and depression, experts believe they account for roughly 20% of ED cases. An estimated 30 million men in the United States and 150 million worldwide experience chronic ED. Furthermore, the National Institutes of Health estimates that as many as 50% of all men between the ages of 40 and 70 experience some form of ED.⁴

Viagra (active ingredient *sildenafil citrate*) temporarily inhibits the phosphodiesterase type 5 (PDE5) enzyme that normally interferes with the increased blood-flow process necessary for attaining an erection. Viagra is a prescription medication that can be taken up to once daily. It has a 30-minute to one-hour onset time (time from taking the pill until it becomes effective) and requires sexual stimulation for it to produce an erection. Viagra’s half-life was three to five hours.⁵ Pfizer studies indicated that Viagra improves erection in approximately 80% of men who suffer from ED. Viagra is not safe to take with nitrates used to treat certain heart conditions and has a list of common side effects. These include facial flushing, headaches, indigestion, and blue-tinted vision. In the United States, Viagra costs around \$10 per pill at retail (when no coverage from health insurance is provided).⁶

Viagra’s Launch

Viagra had a notably successful launch. A total of 600,000 prescriptions were filled in the first month (April 1998), and its brand name immediately became the common noun for the symptom it said it would treat – erectile dysfunction.⁷ Its recognition far transcended the circles of ED patients. It quickly

⁴ “Urology Channel,” *Business Wire*, May 21, 2001.

⁵ A drug’s half-life measures the time it takes for the drug’s concentration in the blood stream to reach exactly one-half of its initial concentration and is a common metric for the duration of effectiveness. Package inserts contained information on a drug’s half-life.

⁶ “The New Era of Lifestyle Drugs,” *BusinessWeek*, May 11, 1998.

⁷ BrandEra.com, from “How Viagra Revived After a Cold Shower,” *BusinessWeek*, August 20, 2000, <http://www.brandera.com/digests/00/08/23>.

mushroomed into a cultural phenomenon, becoming the subject of dinner-table conversations and late-night television comedy (see **Exhibit 2** for examples of how Viagra was portrayed in popular magazines). When Pfizer introduced Viagra, it used Bob Dole, a 75-year-old, well-known former politician, to support Viagra on TV. The Bob Dole ads urged men with ED to have checkups. For many older people, Dole emerged as a hero who displayed a rare combination of determination, courage, and humor. In a 1998 interview on CNN's "Larry King Live," Dole revealed he had taken part in clinical trials for Viagra to treat the impotency resulting from the removal of his cancerous prostate in 1991.⁸

Six months after Viagra went on the market, however, things turned sour. The FDA received reports of 130 deaths of patients taking Viagra; over half of the incidents were cardiovascular related. Prescriptions plummeted immediately. Pfizer understood there had to be an orderly process to combat the legitimate safety fears. The first step was to retest the drug to assure policymakers and the public that Viagra would not place the user at risk. A follow-up study on Viagra's safety was conducted in Sweden immediately after the controversy erupted. Patients with both cardiovascular disease and erectile dysfunction took the drug in a carefully controlled test. Viagra was effective, while the heart attack rate was no greater for its users or the control group that was given a placebo. Pfizer made a concerted effort to communicate these findings to key decision makers and experts in the medical community.⁹ Pfizer then rolled out a \$53 million advertising blitz, and its sales force made close to 700,000 doctor visits to push the medication throughout 1999. The aggressive marketing turned around the downward spiral as sales that year topped \$1 billion.

Developing the Next ED Drug

It all began when ICOS, a small biotech start-up based in Bothell, Washington, was trying to develop therapeutically useful inhibitors of the phosphodiesterase family of enzymes. To achieve this goal, ICOS teamed up with Glaxo Wellcome, a large pharmaceutical company based in the U.K. After a few years of co-development, several potentially valuable compounds materialized. However, in the mid-1990s, the collaboration ended, leaving each party free to pursue the research and development (R&D) of PDE inhibitors independently. One specific molecule under development at ICOS, designated IC351, represented a structurally novel class of PDE5 inhibitors and in initial phase II trials showed it was effective at improving erections in men suffering from ED (provided they were sexually stimulated). Early experiments also indicated an onset time of 30 minutes and a half-life of over 17 hours, significantly greater than that of Viagra. Furthermore, IC351 was chemically narrowly targeted on the PDE5 enzyme, and it did not significantly inhibit other PDE enzymes, particularly PDE6. It was believed that inhibition of this enzyme was the reason for Viagra's blue-vision side effect. Encouraged by these results, ICOS initiated additional phase II clinical trials. ICOS management realized it was time to start thinking ahead. But while the company felt it had honed its R&D skills by this time, it had never taken any product to market. With no experience in FDA registration trials and no marketing capabilities, ICOS was once again in search of a partner.

In the fall of 1998, after talks with several major pharmaceuticals, the ideal partner was found—Eli Lilly and Company. A dedicated product team was quickly formed that had several immediate challenges. On the medical side, phase II human trials needed to be completed, and phase III human trials had to be carefully designed and carried out. These trials would give the team a better understanding of the medical effects of the drug on ED patients and more clearly define its safety profile. On the marketing side, though completion of these clinical phases was not expected anytime

⁸ Fred Brock, "A Dose of Sense from Viagra's Spokesman," *The New York Times*, June 4, 2000.

⁹ "How Viagra Revived After a Cold Shower," *BusinessWeek*, August 28, 2000.

soon, there was a sense of urgency with respect to the need for conducting market research. Given Lilly's resources, it would lead this endeavor.

In the mid to late 1990s, Lilly had essentially rethought the way marketing should be integrated into product development and introduction. Several reasons contributed to this shift. First, many of the big pharmaceutical companies were embracing a high-risk, high-return strategy, with product development efforts concentrated on finding the next big blockbuster drugs. Lilly was particularly focusing on the discovery and development of innovative drugs (i.e., "first-" or "best-in-class" vs. "me-too" alternatives). Also, CEO Taurel specifically instructed his Lilly employees not to bother with any drug unlikely to top \$500 million in annual sales.¹⁰ Second, alongside spending on finding cures for chronic and life-threatening medical conditions (such as cancer, cardiovascular diseases, and high cholesterol), industry resources were increasingly being allocated to the development of "quality-of-life" medicines. Such drugs treat chronic conditions that are not life threatening or severely debilitating (such as male baldness, male erectile dysfunction, female sex disorder, or skin rejuvenation) and are hence typically not covered by most health plans. For these drugs, marketing's role in identifying attractive market segments and convincing both doctors and patients to embrace them was of great importance and could build on Lilly's strategy of innovation. Third, the FDA revised the rules on prescription drug promotion in 1997. This facilitated direct-to-consumer (DTC) advertising and particularly affected the ability of pharmaceutical companies to use TV media to influence the demand for their offerings beyond the traditional detailing of doctors (note that regulations about marketing prescription drugs directly to consumers varied significantly across countries).¹¹ After only four years the results were quite dramatic. Studies showed that nearly a third of all adults initiated discussion with their doctors about drugs they saw advertised on TV, with 44% then receiving a prescription.¹²

As a result of the above trends, Lilly management made a conscious effort to get marketing much more involved in the product development cycle, while taking care not to run afoul of the company's ethical and regulatory obligations. To facilitate this process, the Global Marketing Sales Organization (GMSO) was set up. GMSO had three sub-functions – Global Marketing Planning (GMP), Global Market Research (GMR), and Global Marketing Sales Training. Its role was to funnel ideas for research projects based on ongoing input from sales reps visiting physicians and market needs identified by GMR, forecast market potential to see whether projects should be terminated or moved forward, and translate the medical implications of drugs into future commercial success. GMSO would also conduct brainstorming sessions for the product team, called "deep dives." Mark Kershisnik, executive director of GMP, elaborated:

The pharmaceutical industry is in many ways about the marketing of negatives. By taking a drug, a person is reminded she or he has a problem, that something is wrong with them. It is important when thinking about how to take a drug to market to be cognizant of possible scenarios that involve physician, patient, public, or competitor reactions. Through the ongoing experience gained in the GMSO, we can help the product team effectively prepare for these scenarios and in many cases preempt them.

¹⁰ "Eli Lilly: Life After Prozac," *BusinessWeek*, July 23, 2001.

¹¹ Detailing sessions are visits to doctors' offices by sales reps to give physicians information about the appropriate use, efficacy, dosage, side effects, contraindications, and studies regarding new and existing prescription drugs.

¹² "Pushing Prescription Drugs," *CBS News Healthwatch*, November 30, 2001.

Understanding the ED Market

It was evident to the product team that a prerequisite for a successful launch was solid up-front market research, even if such a launch was three or four years down the road. One of the first challenges the product team faced was coming up with a name for the new drug. Brown, the global marketing director, advocated a neutral name that did not convey any strong connotations, so that a brand meaning could later be molded into the product once the team understood the market better. After testing numerous alternatives, checking for potential negative associations in many languages and ensuring no trademark conflicts, the name “Cialis” was chosen.¹³

Physicians

It seemed natural to begin with a preliminary understanding of how physicians viewed ED treatment. In early 1999, a preliminary conjoint study was performed with 350 doctors, with a roughly even split between urologists and primary-care physicians (PCPs).¹⁴ Across both sets of doctors, the study revealed that *efficacy* (the fraction of patients for whom the drug would be effective) was the most important attribute, followed by *safety*. These two attributes accounted for a relative importance of roughly 70%. The *duration* attribute (indicating how long one dosage of the drug can improve ability to achieve an erection) was noted by the respondents to have a relative importance of less than 10%.¹⁵

To get a sense of attitudes toward ED treatment, interviews were conducted with physicians at medical conferences. The interviews revealed that knowledge about ED varied between urologists and PCPs. As expected, urologists were quite familiar with the medical causes and incidence of ED and were comfortable talking about it with patients. PCPs, however, were a different story. The interviews revealed that the majority of PCPs would not feel comfortable discussing sexual problems with their patients during yearly checkups. This was true even if the individual suffered from one of the diseases associated with ED (see **Exhibit 1**) and hence was at higher risk of incurring erectile disorders. Many expressed apprehensions about prescribing a drug like Viagra to patients who had entrusted them with their health, citing the recent deaths associated with the use of Viagra. The inability to perform sexually was secondary in their opinion to the potential risks arising from the drug. Of those that did prescribe medication for ED, close to 90% said the patient had initiated the request for the drug. These doctors also confessed they would typically not proactively follow up on the drug's success.

Patients

Though Cialis would be a prescription drug, Brown pushed for a better understanding of the ED patient perspective. As a result, in June of 1999, GMR undertook a six-month study to explore how consumers in the United States and Europe (France, Germany, Italy, Spain, and the United Kingdom) viewed ED and its treatment. To do so, a screening survey was administered to 32,644 patients visiting their PCPs (across all countries). Of the original sample, 28,022 replied they did not suffer from ED,

¹³ Interestingly, most pharmaceuticals use the generic drug name prior to FDA approval (for example, Viagra was publicly referred to as *sildenafil citrate* prior to FDA approval). But “Cialis” would be used by Lilly and ICOS to refer to their product throughout the later stages of the clinical trials and approval process (and not referred to by its generic name of *tadalafil*).

¹⁴ Primary-care physicians care for the general health needs of their patients. They coordinate referrals to specialists and arrange for applicable testing and hospitalization when necessary. Primary-care physicians are trained in internal medicine (diagnosis and treatment of the adult population), pediatric medicine (diagnosis and treatment of children and adolescents), or family practice medicine (diagnosis and treatment of both adults and children).

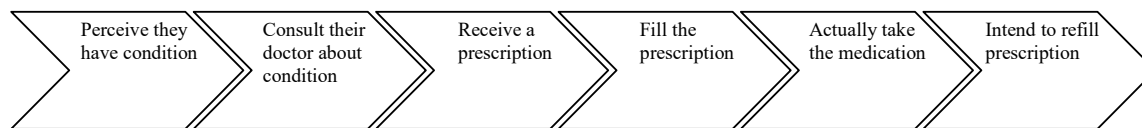
¹⁵ Results from the conjoint study were transformed so that the importance of each attribute was given as a percentage. The other attributes in the study related to *onset time* and *side effects*.

2,450 reported suffering ED but had not sought treatment, while the remaining 2,172 sought treatment for their condition. The screening phase revealed some interesting statistics on ED prevalence by age and country and other demographic information (see **Exhibits 3 and 4**). As expected, the prevalence of ED increases with age. In all countries the average ED patient was in his 50s, with over 80% having a sexual partner. The U.S. ED patients seemed to be more highly educated than in other countries.

To gain a deeper understanding of consumer behavior drivers, a follow-up questionnaire was then administered to those screened to have ED. The first set of questions aimed to establish how individuals who perceived they had ED progressed through the six stages of dealing with their condition, through what Lilly marketers termed the “Health Care Transaction Model” (HCTM) (see **Figure A**). Each stage represents the fraction of patients from the stage before to have continued to the current stage.

Figure A Health Care Transaction Model

Perception Consultation Treatment Delivery Compliance Evaluation



Source: Lilly ICOS.

The results revealed that fewer than half of those who perceived they had ED consulted a physician and that the type of physician consulted varied by country (**Exhibit 5a**). A variety of factors were found to influence patients to seek treatment (**Exhibit 5b**), with spouse or sex partner the most highly cited. Probing on the barriers to seeking treatment revealed that different reasons figured prominently depending on age (see **Exhibit 6**). In particular, younger men expressed higher levels of embarrassment in talking about the condition and were waiting for it to go away, while for older men the belief that this was a normal phenomenon of aging created a reluctance to seek treatment. According to the study, for those who did seek treatment, Viagra was the most commonly suggested medication. Most patients filled the first prescription they received (see **Exhibit 7** for information on the location and payment for the prescription).

The level of satisfaction with Viagra, among all those who had tried it, was measured. The results, presented in the table below, revealed that a substantial percentage of males were not entirely satisfied.

Table A Satisfaction with Viagra

Satisfaction Level	U.S. (%)	France (%)	Germany (%)	Italy (%)	Spain (%)	U.K. (%)
Very satisfied	24	23	27	28	29	23
Somewhat satisfied	34	49	57	51	37	36
A little satisfied	19	20	14	16	14	11
Not at all satisfied	23	8	3	5	19	30

Source: Lilly ICOS.

Future intent to use Viagra was broken down into three groups based on past usage behavior: *Viagra current users*, *Viagra dropouts* (used Viagra at least once in the past but discontinued usage), and those

who had *never used Viagra*. In the United States, 91% of current Viagra users expressed high/very high intent to continue taking the drug in the future, 46% of Viagra dropouts reported high/very high intent to use the drug in the future, and only 39% of those who never tried Viagra reported intent to ask for it in the future. The trend was similar in other countries.

The second set of issues in the survey explored more directly how the end patient would value Cialis. Respondents first gave their relative importance for four different attributes associated with an ED drug. The results were broken down by Viagra usage (see **Exhibit 8**). In addition, subjects were asked for their interest in trying Cialis in the future (based on the drug's written profile). The relatively high willingness to try Cialis across countries (see **Table B**) was encouraging.

Table B Interest in Trying Cialis (%)^a

	U.S.	France	Germany	Italy	Spain	U.K.
Viagra current users	90%	97%	97%	58%	70%	100%
Viagra dropouts	84	68	89	52	70	100

Source: Lilly ICOS.

^a Percentages represent respondents who agreed or strongly agreed with the statement: "I am willing to try this new drug." Written profile described Cialis as having a 30-minute onset time, allowing a 24-hour window of opportunity, and that it could not be taken with nitrate.

The extensive survey was also complemented by more qualitative input. Mark Blakely, who was managing GMR's involvement with Cialis, helped the product team conduct a series of 45-minute in-depth interviews with ED patients. Even though half of those interviewed were current Viagra users and half non-Viagra users (with a mix of Viagra dropouts and those who never tried the drug), Blakely was struck by the common "downward spiral" dynamic characterizing the ED condition:

The interviews revealed that in most ED cases, when a man first experiences inconsistent ability to perform sexually, there is feeling of personal embarrassment. If the condition persists, the individual often begins questioning his role in the relationship, accompanied by a sense of unfairness to [the] partner; the relationship may become strained. Over time, not only does the ED patient feel insecure and detached from his partner, but his self-identity suffers. This causes him to question his role in other contexts of his life, including his interactions with friends or even colleagues at work. Thus, what started as a relatively noncritical physical condition spirals into a psychological anxiety problem considerably affecting the individual's identity and even his sense of place in the world. Clearly, there appeared to be more associated with ED than a sufferer's inability to get an erection.

Partners

Given that the vast majority of men with ED reported they were in a relationship (see **Exhibit 4**), market research was also conducted on ED partners. First, a set of 104 in-depth interviews was carried out with spouses of ED sufferers between the ages of 35 and 65. Care was taken to select a roughly even split between those with a partner who had used Viagra and those who had not yet consulted a doctor about the condition. A common aspect of partners' responses across countries was the lack of information on ED prevalence and the potential reasons for its occurrence. Some partners believed that ED was caused by stress, particularly work-related stress. Others recognized medical conditions

(predominantly diabetes) as the cause. Several interviewees felt that they were the main cause for their husband's ED, because they felt they were no longer attractive. As for the outcome of their male partner suffering from ED, most partners reported less physical intimacy of any kind. This included less hugging and less kissing. Their relationship was described as more tense since the time their partner had begun showing signs of ED. For most couples, joint discussions of ED were uncomfortable and "off limits." Partner knowledge of Viagra was largely passive, with the two most common sources of information being media reports and word of mouth. (The type of information partners received in each medium is summarized in **Table C**.)

Table C Partner Knowledge of Viagra by Source

Media Reports	Word of Mouth
Focus on "scares," such as reports of men dying of heart attacks after taking Viagra	Jokes
Viagra associated with use by older men	Sensationalistic stories (such as men being sexually stimulated for three hours)
	Image of Viagra as a "playboy" drug

Source: Lilly ICOS.

The study also revealed that partners' satisfaction with Viagra was mixed. Virtually all participants acknowledged inconveniences with the drug, as reflected in the following statements:

- "My partner must awkwardly ask me if he should take the pill."
- "Because my partner must ultimately take the tablet, I usually don't initiate sex."

Despite these grievances, most preferred their partner take Viagra than nothing at all. In terms of its role in the HCTM (see **Figure A**), partner impact was discovered to be high in the perception phase (helping men recognize they suffer from ED), moderate in prompting one's partner to consult a doctor and seek treatment, and very low in the delivery and compliance stages of the model. Impact started rising again in the evaluation stage, with partners encouraging men to persist with treatment.

Dan Lockhart, a GMR senior researcher, complemented the partner study by conducting an extensive survey of academic literature on the sexual habits of couples. He discovered that the frequency of sexual activity was higher on weekends and typically occurred at night. Furthermore, it was well established that conjugal functioning was an important aspect of people's lives during retirement.

Recent Competitive Developments

As the Cialis team was moving forward quickly in terms of clinical trials, the FDA submission, and marketing research in preparation for the launch, its competitors were not sitting by idly. Pfizer kept aggressively promoting Viagra, and a new competitor, Bayer, was on the horizon (see **Exhibit 9** for selected financials for these companies). The Cialis product team closely monitored these competitors.

Pfizer – Pumping Up the Marketing Machine

With drugs like Viagra and cholesterol-fighter Lipitor, Pfizer set an industry record in 2000 as eight of its products generated sales of more than \$1 billion each (see **Exhibit 10**). Even so, Pfizer had been steadily expending more R&D resources. In 2002, the company announced plans to invest \$5.3 billion in R&D, up from the \$4.8 billion spent in 2001.¹⁶ But Pfizer was also known for its marketing prowess, in particular, its fierce and sustained marketing campaigns post launch. Pfizer employed the largest sales force in the industry, boasting 30,000 salespeople worldwide visiting doctors and transferring information about its products.¹⁷ With a philosophy that convincing doctors of the safety and efficacy of drugs often comes down to poise and aggressiveness, Pfizer often hired ex-soldiers, former Army officers and West Point graduates, to its sales force.¹⁸ In addition to the detailing of physicians by salespeople, direct-to-consumer advertising was an important part of Pfizer's communication mix. On Viagra alone, Pfizer was reported to have spent \$108 million in 2000 on advertising.¹⁹ While early ads featured Bob Dole as a well-known and respected figure advocating the drug, recent ads took a far more vigorous tone. In the fall of 2001, Viagra TV ads featured Mark Martin, a well-known NASCAR race driver now in his 40s. The ads showed Martin's #6 Viagra-sponsored Taurus zooming on the track and urged men to visit their doctor and see if a "six-pack" free sample of Viagra was right for them. Pfizer had also begun running print ads in national news magazines featuring couples. One such ad, with a close-up of a couple in their 30s or 40s, suggested that if there has been a decline in sexual activity, it may be the result of underlying health conditions. The ad prompts the partner to have their male partner see their doctor. The ad reminded the reader that Viagra is a proven treatment by emphasizing in bold letters that 9 million men have used the drug. It also gave a toll-free number and Viagra's website address for obtaining more information.²⁰

Viagra sales reached nearly \$1.5 billion in 2001, with gross margins of 90%. For every million patients who asked for Viagra, approximately 30,000 had untreated diabetes, 140,000 had untreated high blood pressure, and 50,000 had untreated heart disease.²¹ Beyond the data on overall Viagra sales (see **Exhibit 11** for quarterly sales by country), GMR also tracked the makeup of these sales over the three-year period since Viagra's launch by analyzing data from a sample of pharmacies. It was discovered that the average prescription size in 2001 was 6.5 tablets and that prescriptions were refilled on average every 55 days. That said, one year after initiating treatment, only about 25% of patients were still using Viagra.

Levitra from Bayer

In November 2000, the German pharmaceutical giant Bayer released results of phase II clinical trials for its own ED drug, Levitra.²² The drug proved to be very effective at lower dosages than Viagra (as low as 5 mg). Bayer also designed trials to focus on showing good results in diabetic men, considered

¹⁶ Pfizer fourth-quarter earnings release, January 23, 2002.

¹⁷ Pfizer 2000 annual report.

¹⁸ "Science and Savvy," *Forbes Magazine*, January 11, 1999.

¹⁹ Justin Gillis, "2 New Drugs to Compete with Viagra; Companies See Untapped Market," *The Washington Post*, August 12, 2001.

²⁰ *Time Magazine*, February 2001.

²¹ Fred Brock, "A Dose of Sense from Viagra's Spokesman," *The New York Times*, June 4, 2000.

²² In the fall of 2002 Bayer and GlaxoSmithKline announced the selection of Levitra (active ingredient is *varденафил гидрохлорид* [HCl]) as the global trade name for *varденафил* (*Reuters News*, September 23, 2002).

a hard-to-treat segment. The duration of Levitra's effect, however, was roughly the same as that of Viagra's (with a half-life of four to six hours).²³ In addition, Bayer conducted market research and reported that 76% of ED patients surveyed claimed they would be interested in a new treatment (other than Viagra) that works reliably.²⁴ Encouraged by these results, Bayer began thinking about commercialization. While in Europe Bayer had very good marketing coverage, its U.S. presence was relatively weak; the U.S. sales force had only 1,250 representatives.²⁵ Given the importance of the U.S. market to Levitra's success, a marketing partnership was explored. In November 2001, Bayer signed a co-promotion agreement with GlaxoSmithKline (the Anglo-American pharmaceutical giant).²⁶ As 2001 had been a disappointing year for Bayer, with a 2% decrease in total sales and a first-ever net quarterly loss,²⁷ the company was hoping that Levitra would boost its bottom line.

Getting Ready for the Launch

The success of Cialis was important for both parent companies. For Lilly, the expiration of the Prozac® (fluoxetine HCl) patent in August of 2001 (three years ahead of plan) was straining earnings, and for ICOS this would be the first drug to be launched after more than ten years in existence. Lilly brought its experience and resources to the table, while ICOS brought the nimbleness and sense of urgency of a start-up. The collaboration also functioned exceptionally well in terms of working closely with the scientific community during the prelaunch period. ICOS and Lilly identified worldwide opinion leaders among urologists, psychologists, and other physicians with a focus on men's health-care issues. These physicians were convened as advisory boards. Their advice was sought on clinical development plans for the drug as well as how to position the drug in the marketplace. Medical experts, as well as investigators themselves, also presented research findings at several key conferences.

The Challenges Ahead

As a big part of the medical activity associated with Cialis culminated in the application to the FDA in June of 2001, attention was now focused on the marketing challenges that lay ahead. In preparation for the upcoming brand council, Brown and Blum reviewed the results of the extensive market research conducted over the past two and a half years. Several issues needed to be resolved for the product team to be able to present a coherent strategy to the affiliates. First, it was important to agree on the patient target market. On the one hand, it seemed logical to consider Viagra usage status in any segmentation scheme. After all, someone who discontinued using that drug was probably dissatisfied with it for some reason or another. Given that by the end of 2001 there were an estimated 6 million to 7 million Viagra dropouts in the U.S. (compared to 3 million Viagra current users), this seemed fertile ground. On the other hand, age and comorbidities seemed potentially relevant as well. Furthermore, it was important to understand which product benefits to emphasize and how. Would the longer duration of Cialis be equally valued by all ED patients? Was the lack of interaction with high-fat meals important? Should the answer to these questions differ for Europe vs. the U.S.?

²³ Bayer press release, June 1, 2001, and pharmaceutical report, February 15, 2002 (School of Pharmacy, University of Washington).

²⁴ Bayer press release, June 1, 2001.

²⁵ "Why Bayer Turned to a Giant: As A Marketing Partner, GlaxoSmithKline will Ensure that Vardenafil Succeeds," *Med Ad News*, February 1, 2002.

²⁶ GlaxoSmithKline press release, January 2002.

²⁷ "Bayer Reflects on 'Sobering' 2001, but Strongly Hopeful for 2002," *Marketletter*, March 18, 2002.

Second, given that the marketing budget was not unlimited, there was a need to understand the relative emphasis to be placed on physicians vs. patients. Without doctors signing for Cialis, no patient would realistically be able to get hold of it. Yet, given that Cialis was considered a “quality-of-life” drug, it was becoming clear that doctors alone might not hold the key to success. Even if the correct balance between these two parties was found, should the same benefits highlighted to doctors also be highlighted to men suffering from ED? Kershnik (executive director, GMP) also prompted consideration of the role, if any, partners should play in the marketing of Cialis. Some saw a potential risk in alienating men if too many messages were directed to partners.

Third, there were competitive pressures to take into account. While clinically, both drugs were well tolerated by patients (despite the much longer half-life of Cialis), Brown estimated that Viagra would take full advantage of its nearly five years of being tried and tested. With Viagra years past its initial “death-scare” episode, it was not clear how easy it would be to convince doctors to switch. Recent discussions with many primary-care physicians revealed a certain degree of contentment with Viagra. The drug enabled many men to have sex, did not linger in their body, and hence could be considered a reasonable solution to the medical problem.

Given the similarity of the product profile of Levitra to that of Viagra, some industry observers predicted Bayer would go for a niche strategy by targeting diabetic patients with ED.²⁸ The Cialis team was well aware of analyst predictions for a fierce marketing war among all three companies that would make ED drugs, in the United States at least, the most heavily advertised category of pharmaceuticals.²⁹

In addition to addressing the above issues, there were several other decisions to be made. There was a debate on whether Cialis should be priced higher than Viagra’s \$10 per pill to reflect its longer duration, or lower, due to the fact that for the vast majority of ED patients the drug would not be fully covered by their health insurance plan (see **Exhibit 7a**). With respect to direct-to-consumer advertising, the central theme of TV ads that would be produced over the summer had yet to be decided. Should Cialis ads also have a sports-related theme? Should they feature celebrities? If so, which ones?

As the Cialis team members were getting ready to make their final recommendations to Barbatto—and then to the Lilly ICOS LLC board—they likened their decision on how to position the Cialis brand to that of a baseball player stepping up to the plate: “We feel like we have just been handed the baseball bat, and, as the ball is getting closer, we have to decide whether to take the risk and try to swing for a home run or, at the other extreme, be more conservative and merely try to reach first base.”

²⁸ Based on a quote from Helge Wehmeir, president and CEO of Bayer Corp., in *Drug Store News*, February 13, 2002.

²⁹ Justin Gillis, “2 New Drugs to Compete with Viagra; Companies See Untapped Market,” *The Washington Post*, August 12, 2001.

Exhibit 1 Comorbidities Associated with ED

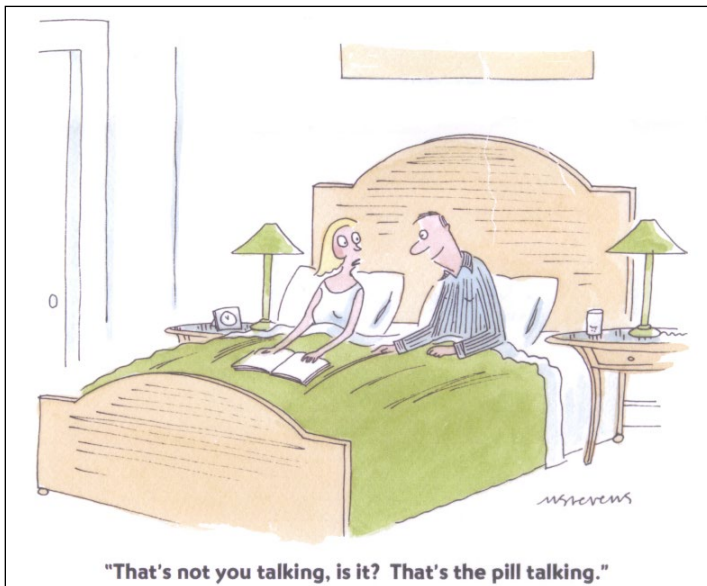
Condition	U.S. (%)	France (%)	Germany (%)	Italy (%)	Spain (%)	U.K. (%)
High blood pressure	43	20	29	42	21	33
High cholesterol	43	19	35	31	20	20
Enlarged prostate (not cancer)	20	6	25	32	18	7
Heart trouble (including angina)	18	8	14	8	5	18
Ongoing feelings of anxiety	17	20	7	30	14	28
Diabetes	17	6	11	20	6	15
Ongoing feelings of depression	17	6	9	12	6	18
Heart attack or heart surgery	17	7	8	6	4	16
Hardening of the arteries	7	6	11	13	6	5
Spinal cord injury	3	10	1	2	9	5
Prostate cancer	2	2	1	3	1	1

Source: Internal Lilly ICOS document.

Exhibit 2 Reactions to Viagra in the Popular Media

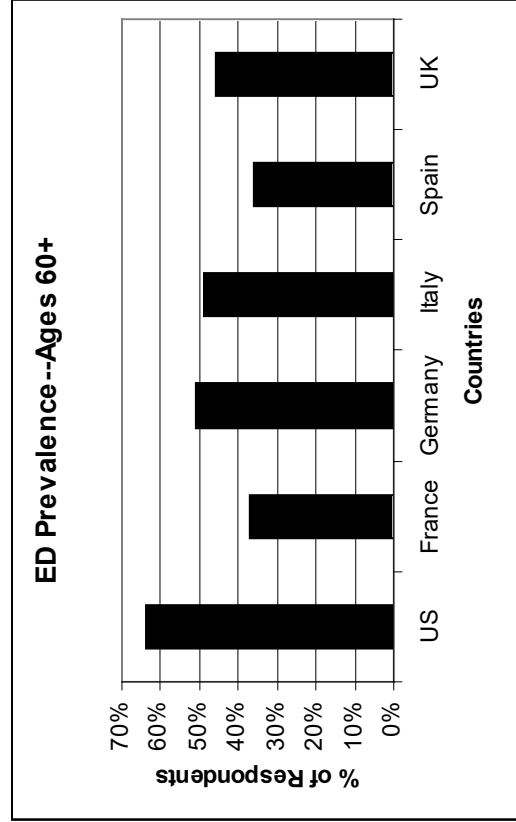
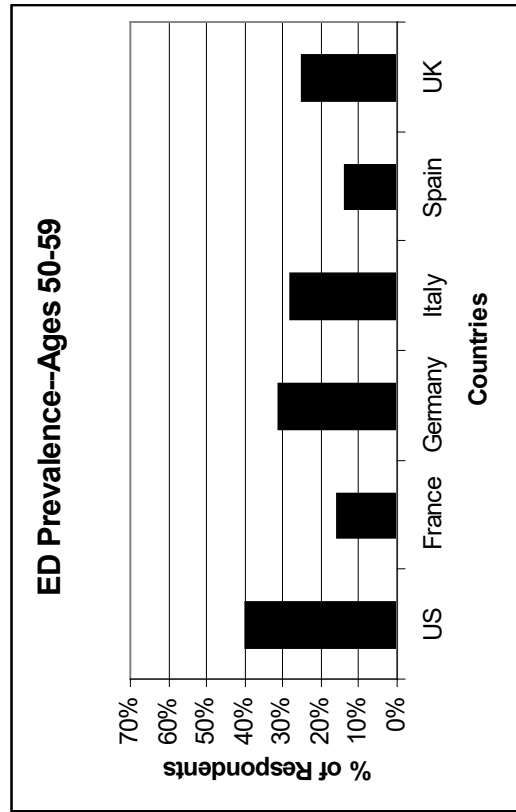
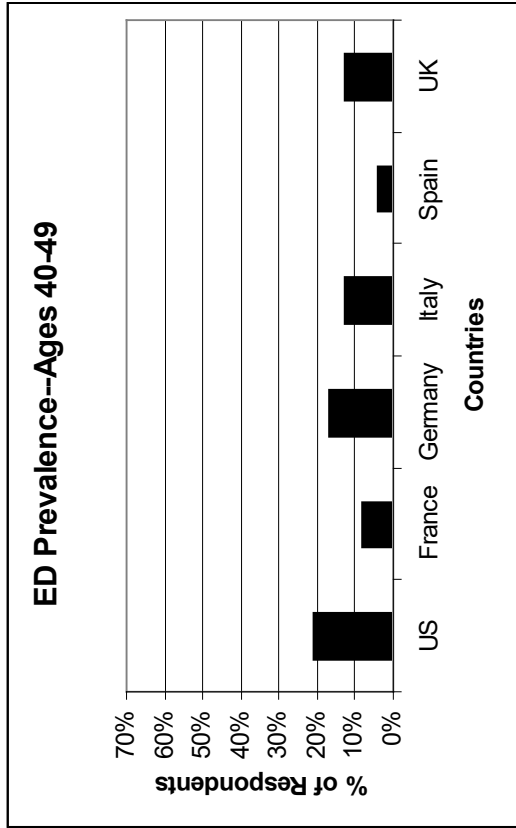
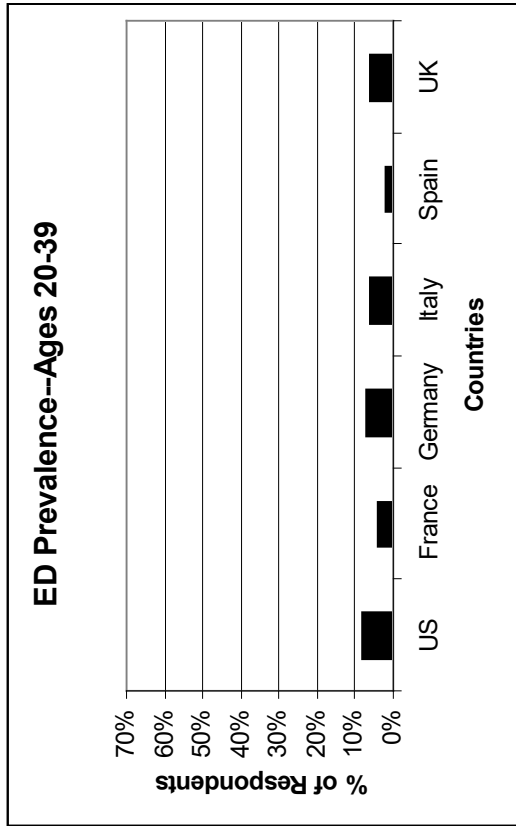


Source: Image: Christian Kargle, Getty Images.



Source: Copyright 2002 Mick Stevens from cartoonbank.com. All rights reserved.

Exhibit 3 ED Prevalence for Different Age Groups



Source: Lilly ICOS.

Exhibit 4 Demographic Indicators of ED Patients

Demographic Indicators	U.S.	France	Germany	Italy	Spain	U.K.
Age						
Mean	58.4	50.7	53.5	55.4	50.7	56.9
	%	%	%	%	%	%
Employment						
Employed full time	50	61	54	54	68	40
Employed part time	4	5	3	6	10	4
Student	<1	<1	1	2	1	2
Retired	44	26	35	35	<1	44
Not currently employed	2	8	7	3	22	10
Marital Status						
Single, never married	7	12	10	12	15	7
Married or living together	80	77	73	74	75	80
Widower	2	2	3	6	3	2
Divorced or separated	12	10	14	8	7	11
Sexual Partner¹						
Yes	86	92	85	91	86	87
No	15	8	15	9	14	13
Attendance at religious services						
Every week (or almost)	33	Not Asked	Not Asked	20	14	13
Once or twice a month	11	Not Asked	Not Asked	20	7	4
Few times a year or less	34	Not Asked	Not Asked	39	34	35
Never	21	Not Asked	Not Asked	20	45	49
Education						
Primary	9	54	55	36	29	59
Secondary	24	29	11	42	39	17
Post Secondary	67	17	34	21	31	17
Yearly Income						
Low (<~\$25K)	21	73	58	80	76	53
Mid	44	23	37	16	20	34
High (>~\$60K)	35	4	5	5	4	13

Source: Lilly ICOS.

Note: Sexual partner referred to both heterosexual and non-heterosexual partners.

Exhibit 5a Physician Consulted

Physician Consulted	U.S. (%)	France (%)	Germany (%)	Italy (%)	Spain (%)	U.K. (%)
Family doctor	74	79	37	45	40	95
Urologist or men's specialist	40	36	81	72	74	23
Cardiologist	4	11	4	3	--	5
Psychiatrist	2	16	6	4	5	2
Internet doctor	1	2	--	--	1	--

Exhibit 5b Key Drivers Influencing Treatment Seeking

Key Drivers of Seeking Treatment	U.S. (%)	France (%)	Germany (%)	Italy (%)	Spain (%)	U.K. (%)
My spouse or sex partner	43	50	36	29	51	49
Newspaper or magazine article	19	23	22	27	28	18
TV, radio or movie commercial	15	1	7	1	11	2
A TV or radio show	9	22	12	18	10	6
A newspaper or magazine ad	9	4	4	5	14	7
A friend or relative	8	10	7	14	13	7
Something that was mailed to me	8	2	--	1	1	3
A sex counselor or psychologist	2	8	1	3	11	2
Pharmacist	2	1	<1	4	9	4
Telephone/information help line	<1	4	--	--	5	2
The Internet	1	<1	3	2	6	2
Sought treatment entirely on their own	30	30	43	39	23	34

Source: Internal Lilly ICOS document.

Exhibit 6 Barriers to Seeking Treatment

Barriers to Seeking Treatment—Ages 20–39	U.S. (%)	France (%)	Germany (%)	Italy (%)	Spain (%)	U.K. (%)
Waiting to see if the condition will go away	51	63	39	--	65	61
Doesn't happen all that often	46	59	47	50	31	39
Embarrassed to talk about it	43	35	15	50	16	60
Don't want to take drugs for this condition	16	31	35	50	48	14
Afraid that underlying problem might be serious	13	9	19	--	13	10
Couldn't easily afford it	13	9	6	--	10	9
Condition is not that important to me	11	18	18	50	9	9
Don't believe that anything can be done about it	3	23	2	--	--	6
Believe that the condition is a normal part of aging	10	4	14	50	1	19

Barriers to Seeking Treatment—Ages 40–49	U.S. (%)	France (%)	Germany (%)	Italy (%)	Spain (%)	U.K. (%)
Waiting to see if the condition will go away	35	65	44	--	42	51
Doesn't happen all that often	49	53	43	63	29	40
Embarrassed to talk about it	27	47	32	80	21	50
Don't want to take drugs for this condition	12	47	12	32	28	5
Afraid that underlying problem might be serious	7	16	22	--	2	13
Couldn't easily afford it	14	8	4	27	24	--
Condition is not that important to me	11	14	15	--	2	22
Don't believe that anything can be done about it	9	6	13	--	2	17
Believe that the condition is a normal part of aging	25	21	42	32	24	42

Exhibit 6 (continued)

Barriers to Seeking Treatment – Ages 50–59	U.S. (%)	France (%)	Germany (%)	Italy (%)	Spain (%)	U.K. (%)
Waiting to see if the condition will go away	43	64	46	31	39	53
Doesn't happen all that often	41	46	19	67	28	37
Embarrassed to talk about it	36	35	35	18	15	41
Don't want to take drugs for this condition	10	44	25	31	17	9
Afraid that underlying problem might be serious	9	10	20	1	11	13
Couldn't easily afford it	3	1	3	1	1	9
Condition is not that important to me	19	16	9	15	16	25
Don't believe that anything can be done about it	8	10	7	2	14	26
Believe that the condition is a normal part of aging	48	41	52	42	21	62

Barriers to Seeking Treatment – Ages 60+	U.S. (%)	France (%)	Germany (%)	Italy (%)	Spain (%)	U.K. (%)
Waiting to see if the condition will go away	27	25	33	8	20	23
Doesn't happen all that often	19	17	16	18	13	14
Embarrassed to talk about it	19	15	17	36	16	26
Don't want to take drugs for this condition	13	50	28	23	38	17
Afraid that underlying problem might be serious	12	7	17	--	4	4
Couldn't easily afford it	8	1	7	--	6	12
Condition is not that important to me	16	40	23	18	22	27
Don't believe that anything can be done about it	19	21	12	13	7	21
Believe that the condition is a normal part of aging	47	78	69	87	43	68

Source: Lilly IC05.

Exhibit 7a Payment for Viagra

Payment for Viagra	U.S. (%)	France (%)	Germany (%)	Italy (%)	Spain (%)	U.K. (%)
Individual paid full cost	46	81	90	90	90	40
Costs were shared	33	--	--	3	1	15
Individual got it free	18	19	10	6	10	--
National or private insurance paid full cost	4	--	--	--	--	45

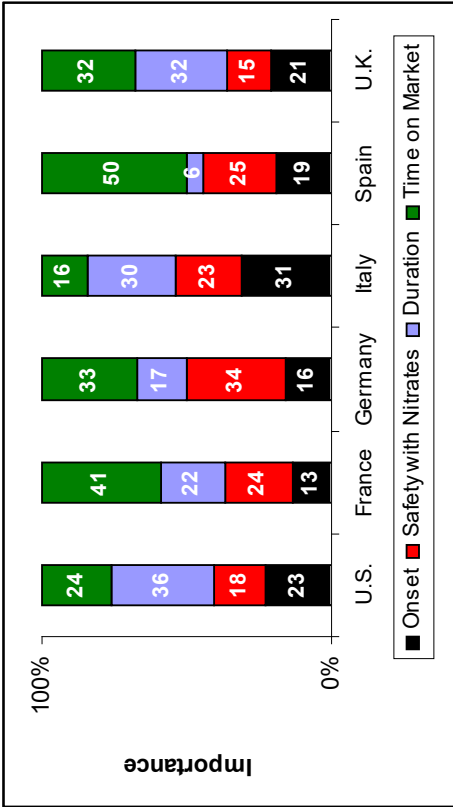
Exhibit 7b Where Respondents Got Viagra

Where Respondents Got Viagra	U.S. (%)	France (%)	Germany (%)	Italy (%)	Spain (%)	U.K. (%)
From a local drugstore	67	41	68	38	58	74
Directly from a doctor	19	20	11	5	11	8
From a mail-order drugstore	6	--	--	--	--	--
From a drugstore that I don't usually use	4	36	14	49	19	15
Somebody got it for me	2	--	2	7	2	--
In another country	--	4	3	1	9	--

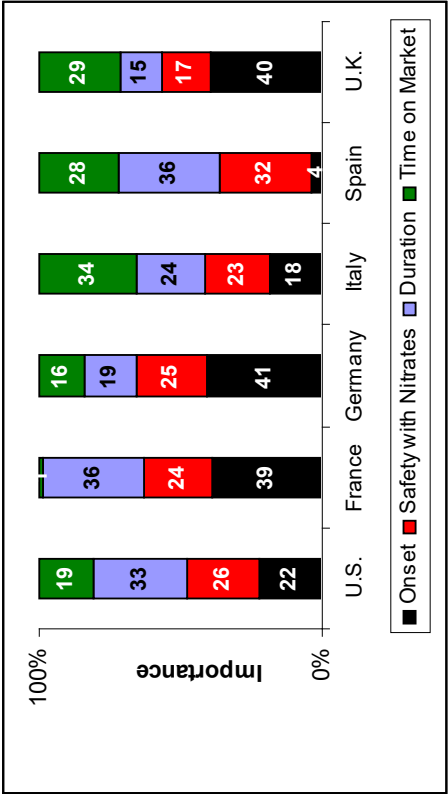
Source: Lilly ICOS.

Exhibit 8 Patient Conjoint Attribute Importance (by Viagra usage)

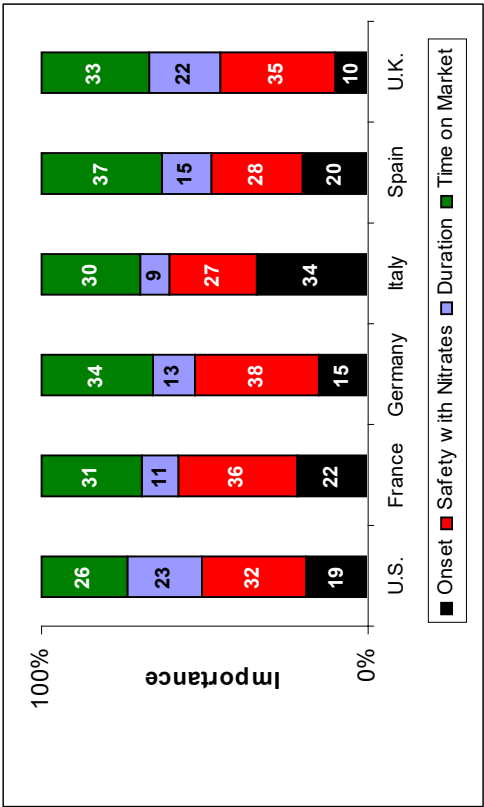
Current Viagra Users



Viagra Dropouts



Have Never Used Viagra



Source: Internal Lilly ICOS document.

Exhibit 9 Selected Financials – Eli Lilly, Pfizer, Bayer – 1996–2000 (\$ millions)

Company	Date	Net Sales	SGA ^a	R&D	Net Income	Net Income as % Sales
Eli Lilly	1996	7,346.6	3,181.4	1,189.5	1,523.5	21%
	1997	8,517.6	3,696.4	1,382.0	(385.1) ^b	--
	1998	9,236.8	4,397.2	1,738.9	2,097.9	23%
	1999	9,912.9	4,541.2	1,783.6	2,721.0	27%
	2000	10,862.2	5,246.8	2,018.5	3,057.8	28%
Pfizer	1996	11,306.0	6,050.0	1,684.0	1,929.0	17%
	1997	12,504.0	6,884.0	1,928.0	2,213.0	18%
	1998	13,544.0	7,829.0	2,279.0	3,351.0	25%
	1999	16,204.0	9,127.0	2,776.0	3,179.0	20%
	2000	29,574.0	15,877.0	4,435.0	3,726.0	13%
Bayer	1996	31,590.3	10,251.5	2,344.8	1,771.0	6%
	1997	30,571.8	9,893.8	2,203.2	1,634.6	5%
	1998	32,923.8	10,938.2	2,351.3	1,893.8	6%
	1999	25,370.4	8,653.1	2,156.0	2,016.0	8%
	2000	27,915.2	10,414.1	2,236.2	1,704.9	6%

Source: Standard & Poor's Compustat® data.

^a Sales General & Administrative.

^b Reflects \$2.4 billion noncash charge to adjust the carrying value of the long-lived assets of PCS's health-care management business.

Exhibit 10 Pfizer Worldwide Human Pharmaceutical Revenue for Major Products (2000)

Therapeutic Lines	Billions of Dollars
Cardiovascular Diseases	
Lipitor	\$5.0
Norvasc	3.4
Infectious Diseases	
Zithromax	1.4
Diflucan	1.0
Central Nervous System Disorder	
Zoloft	2.1
Neurontin	1.3
Viagra	1.3
Celebrex	1.2

Source: Pfizer 2000 Annual Report.

Exhibit 11 Viagra's Worldwide Sales by Quarter (1998-2002, \$ millions)

Country	3/98	4/98	1/99	2/99	3/99	4/99	1/00	2/00	3/00	4/00	1/01	2/01	3/01	4/01	1/02	CAGR
United States	157.7	144.6	147.3	164.4	156.7	175.2	183.1	193.5	201.1	202.7	216.8	214.7	221.3	246.5	238.0	16.4%
United Kingdom	0.9	3.3	4.8	6.5	9.2	10.2	10.1	10.6	11.4	12.1	12.3	13.2	14.4	15.3	14.5	26.3
Germany	0.9	11.2	9.8	10.5	12.0	11.8	10.1	10.5	11.0	11.4	11.7	11.8	11.8	12.4	11.7	3.6
Italy	--	5.6	4.6	5.4	6.3	7.2	6.9	7.6	7.8	8.1	9.2	9.5	9.0	9.5	9.5	20.6
France	--	5.9	4.3	4.3	4.3	4.3	4.1	4.7	5.0	4.9	5.4	5.6	5.4	5.5	5.9	14.8
Spain	--	3.1	2.2	2.6	3.0	3.1	3.1	3.5	3.6	4.0	4.4	4.7	4.4	5.0	4.8	26.6
Russian Fed.	--	0.2	0.3	0.5	0.5	0.6	0.7	0.5	0.9	1.1	1.2	1.2	1.4	1.4	1.3	51.8
Finland	--	1.9	1.4	1.6	1.5	1.9	1.6	1.7	1.6	1.8	1.9	2.0	2.0	2.2	2.0	11.5
Switzerland	2.1	1.7	1.4	1.5	1.5	1.6	1.4	1.5	1.5	1.6	1.7	2.0	1.9	2.1	1.9	14.7
Netherlands	0.1	1.0	1.0	1.0	1.1	1.3	1.3	1.4	1.4	1.4	1.5	1.6	1.5	1.6	1.6	15.8
Belgium	--	1.1	1.1	1.2	1.3	1.5	1.3	1.4	1.3	1.4	1.5	1.6	1.6	1.7	1.6	10.7
Norway	--	0.4	0.9	0.8	0.9	1.1	0.9	1.0	1.0	1.1	1.1	1.2	1.2	1.4	1.3	17.4
Austria	--	1.1	0.9	0.9	1.0	1.1	0.9	1.0	1.0	1.1	1.2	1.2	1.2	1.3	1.3	13.2
Greece	--	--	0.1	0.5	0.6	0.6	0.7	0.7	0.7	0.7	0.9	1.0	1.1	1.1	1.1	33.9
Hungary	--	--	0.7	0.6	0.6	0.7	0.7	0.7	0.8	0.9	0.9	0.9	1.1	1.2	1.2	30.1
Israel	0.2	0.5	0.8	0.7	1.2	1.2	1.3	1.4	1.4	1.3	1.3	1.2	1.2	1.1	1.0	1.1
Turkey	--	--	--	0.4	0.5	1.0	1.5	2.2	2.6	3.1	2.2	2.2	2.7	1.8	1.8	58.1
Canada	--	--	1.9	5.1	4.8	6.3	6.2	7.2	7.6	8.1	7.5	8.6	9.0	9.8	9.1	27.7
Mexico	1.8	2.2	3.1	3.3	3.8	4.8	6.6	6.5	7.2	8.2	8.9	9.6	9.2	10.8	10.8	47.8
Brazil	6.0	7.2	5.1	5.6	6.5	7.2	7.9	9.5	11.4	12.1	12.1	12.5	12.2	12.8	13.6	37.1
Venezuela	0.5	0.9	1.0	1.1	1.3	1.5	1.6	2.0	2.1	2.7	2.6	3.1	3.1	3.7	3.5	56.1
Central America	0.1	0.1	0.4	0.5	0.6	0.7	0.7	0.8	0.8	0.9	1.0	1.0	1.0	1.1	1.1	29.6
Puerto Rico	0.8	1.0	1.2	1.1	1.1	1.5	1.5	1.5	1.7	2.0	1.9	1.8	2.0	2.3	0.0	24.0
Japan	--	--	11.2	10.9	10.2	10.9	9.4	11.8	12.1	13.6	10.7	12.4	12.2	14.0	11.4	9.9
Taiwan	--	--	0.7	2.8	2.3	2.3	2.6	3.0	2.9	3.2	3.3	3.8	3.1	4.2	3.9	22.5
Korea	--	--	--	--	--	1.6	1.3	2.0	2.8	3.2	3.4	3.3	3.5	4.1	4.6	16.6
Malaysia	--	--	--	1.0	1.2	1.2	1.1	1.2	1.3	1.2	1.3	1.3	1.2	1.3	1.2	6.5
Australia	2.0	2.4	2.2	2.5	2.7	3.0	2.9	2.9	3.1	3.2	2.8	3.4	3.7	4.0	3.7	15.5
Saudi Arabia	--	--	--	1.6	2.7	3.1	3.5	3.5	4.6	4.2	5.0	5.1	5.2	5.2	5.8	39.8
Poland	--	--	--	0.6	0.8	0.7	0.7	0.7	0.8	0.8	0.8	1.0	1.0	1.0	1.0	19.5
Czech Republic	--	--	0.6	0.4	0.5	0.5	0.5	0.6	0.5	0.6	0.6	0.6	0.7	0.8	0.7	21.4
New Zealand	--	0.4	0.4	0.6	0.7	0.6	0.9	0.7	0.8	1.6	0.9	0.9	0.6	0.7	0.7	1.8
Hong Kong	--	--	0.4	0.4	0.5	0.5	0.6	0.5	0.6	0.5	0.8	0.4	0.7	0.6	0.6	7.2
All Other	3.0	6.5	7.0	8.1	9.1	9.9	11.2	10.1	11.0	10.8	11.9	11.7	12.2	12.2	11.5	11.5
Total	176.1	202.3	216.8	249.0	251.0	280.7	288.9	308.4	325.4	335.6	350.7	356.1	363.8	399.7	383.8	18.6

Source: Adapted from IMS Health data.