

[Ofek, E. HBS Jul 2010]

[pg. 1]

- Early 2002, Mark Barbato, executive director/global product leader for Cialis
- Launch medicine for treatment of male impotence in market with established leader - Viagra
- Viagra generated over \$1B in sales annually for 3 consec. Years
 - **High brand recognition of any other pharma drug in the world**
- Barbato and team were optimistic for future prospect of Cialis; "showed promising clinical results"
- Medical presenters would show 20mg oral dos improved ability of 81% of men over extended period of time, even **36** hours after taking drug
 - **Viagra effect lasted four hours after dosing, new treatment offered men significantly greater window of opportunity for intimacy**
- Other benefits of Cialis over V
 - Cialis not affected by food intake
 - Generally favorable safety profile
 - Rare for visual irregularities (side effect of V)
- In prep for 2002 launch, brand council convened to discuss how to differentiate Cialis and how to promote drug once approved

Commented [1]: Target segment: men with women wanting long intimate experiences.

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- Needed to clearly identify target market for drug and position it against competition
- Contemplating 3 approaches:
 - "Niche": specific/narrow segment would be identified and targeted
 - "Compete": head-to-head with Viagra positioning
 - "Beat": come up with differentiated positioning to pursue broad market

ED - Treatable Condition

- Medical condition rarely discussed in public - erectile dysfunction (ED).
 - Process by which increased blood can flow is impaired
 - Associated with:
 - Medical disease
 - Medications
 - Smoking
 - Alcohol consumption
 - Psychological factors (20% of cases)
 - Stress
 - Depression
- **30MM in U.S. and 150MM worldwide experience chronic ED**
 - **50% of all men between 40 and 70 experience ED**
- Viagra stats - \$10 per pill retail
 - Prescription medicine, once daily
 - 30min to 1 hour onset time
 - Requires stimulation
 - Half-life three to five hours
 - Improve 80% of men suffering from ED **(find those 20%!!)**
- Side effects:
 - Facial flushing
 - Headaches
 - Indigestion

Commented [2]: Large demographic segment - easy to carve out niche

- Blue-tinted vision

Viagra's Launch

- Successful launch in April 1998
 - 600,000 prescriptions filled in first month
 - Brand name became common noun for symptom it treated - ED
 - Pfizer used **Bob Dole** (75 y old well known politician) to support on TV, urging men to have checkups
 - Emerged as hero displaying rare combination of determination, courage, and humor.

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- Six months after launch, things went south!
 - FDA received reports of 130 deaths; over half were cardiovascular related (YIKES)
 - Scripts plummeted immediately
- Needed to combat legitimate safety fears
 - Retest the drug to assure policy makers & general public drug was not dangerous
 - Follow-up study in Sweden confirmed no difference between placebo and Viagra group in heart attack rate
 - Concerted effort to communicate findings to decision makers and experts in medical community
 - \$53MM advertising blitz, sales forces made 700,000 doctor visits to push medication in 1999
 - Turned around downward spiral - sales topped \$1B

Commented [3]: Responded to outside market forces pushing product down.

Developing the Next ED Drug

- ICOS, small biotech start-up in Bothell, WA
- Discovered during early experiments
 - Onset time of 30 mins, half-life of over 17 hours (significantly greater than V)
 - Inhibition of certain enzyme caused V blue-vision side effect - this was not a part of Cialis drug
- ICOS had no experience in FDA registration trials, **no marketing capabilities** - found a partner

The Lilly ICOS Joint Venture

- George Rathmann, CEO of ICOS, knew ICOS would need clinical development and marketing capabilities to become self-sufficient

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- Sidey Taurel, CEO of Lilly: "Successful alliances are more critical than ever to our strategy. We are working hard to be recognized as the pharmaceutical industry's premier partner by consistently creating value for our partners and for Lilly."
- Promising results of IC351, committed management of ICOS, earnest desire to leverage Lilly resources made it mutually attractive alliance.
- Profits from drug would be split 50/50 between the companies
- Product team formed, faced with several challenges:
 - Medical side:

- Phase II human trials required completion
- Phase III human trials needed to be designed and carried out
- Marketing side:
 - **Sense of urgency with respect to the need for conducting market research**
 - ICOS did not have capability to do this yet, would use Lilly as "scaffolding" to build its own competence.

Marketing Competence at Lilly

- In 1990, marketing needed to be integrated into product development and introduction - reasons for shift:
 - 1. Big pharma embracing high-risk high-return strategy
 - Product development concentrated on finding next "blockbuster drugs"
 - Focused on "first" or "best-in-class" vs. "me-too" alternatives
 - 2. Industry resources being increasingly allocated to development of "quality-of-life" medicine; these were not typically covered by most health plans
 - Male baldness
 - Male ED
 - Skin rejuvenation
 - 3. FDA revised rules on prescription drug promotion
 - Facilitating direct-to-consumer (DTC) advertising
 - **Granted pharma companies ability to use TV media**
 - Influence demand for offerings beyond traditional detailing of doctors
 - Nearly 1/3 of adults talked to doctors about drugs on TV, 44% receiving prescripti

Commented [4]: CEO instructed employees not to bother with any drug not topping \$500MM in annual sales

Commented [5]: TV was a good avenue - fairly anonymous, could be on multiple channels, patients could seek out doctors on their own

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GMSO

- Lilly mgmt got marketing involved in product development cycle, to not run into problems with ethical/regulatory obligations
- Global Marketing Sales Organization (GMSO) created
 - Global Marketing Planning (GMP)
 - Global Market Research (GMR)
 - Global Marketing Sales Training (GMST)
- Initial stage of product planning:
 - 1. Funnel ideas for research project based on ongoing input from sales reps visiting physicians and market needs identified by GMR
 - 2. GMP would **forecast** market potential to see if projects should be termed or moved along
 - Projects progressing would get product team with medical, marketing, registration, and logistics functions
 - 3. Phase III clinical trials would get completed; end goal to register drug with FDA
 - Results of trial would impact medical claims that could be made about drug; **marketing function would plan trials, but more importantly, role was to translate medical implications of drug into future commercial success.**
- Mark Kershnik, executive director of GMP: "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."

Commented [6]: segmentation analysis

Affiliates

- Lilly organized efforts geographically by creating distinct affiliates with regional responsibilities
 - Primary affiliates:
 - U.S.
 - Europe (five major countries)
 - Canada
 - Australia
 - Mexico
 - Brazil
- Brand councils held in Indianapolis (Lilly HQ)
 - Product team would present vision for positioning and branding of new drug
 - Lay out key drivers of success
 - **GMSO would prepare sales forecasts and common reporting format for post-launch tracking**
- Given U.S. market was particularly important, U.S. affiliate brand was made integral part of product team marketing function

Commented [7]: Measurement of success - does this come up later?

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Understanding the ED Market

- Pre-req for successful launch was up-front market research, even if launch was 3-4 years down the road
- One of biggest challenges was name for new drug
 - Global marketing director advocated neutral name to not convey strong connotations
 - Branding meaning could be molded after team understood market better

Physicians

- In early 1999 preliminary conjoint study was performed with 350 doctors, evenly split between urologists and PCPs
- Study revealed key findings:
 - *Efficacy* (fraction of patients whom drug was effective): most important attribute
 - *Safety* was next important (combined with effi for 70% importance)
 - *Duration* (how long one dosage of drug can improve ability to achieve erection): relative importance less than 10%
 - *Onset time*
 - *Side effects*
- Get sense of attitudes towards treatment of ED, interviews conducted with physicians at medical conferences
 - Knowledge varied between urologists and PCPs
 - Urologists were familiar with medical causes of ED, comfortable speaking about it
 - PCPs were not comfortable discussing sexual problems with patients during annual checkups
 - True even if patient suffered from disease associated with ED
 - Expressed apprehension about prescribing drug like Viagra to patient entrusting them with health (due to recent deaths from using drug)
 - Inability to perform sexually was secondary to potential risks arising from drug

- Of those who prescribed medication, close to 90% said patient initiated request for drug, and they would not follow up on drug's success

Commented [8]: influencers in DMU; figure out how to get them on board with drug.

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Patients

- Brown pushed for better understanding of ED patient perspective (this is important!)
- June 1999, GMR took six-month study to explore consumers in U.S., France, Germany, Italy, Spain, and the U.K, viewed ED and treatment
 - **2,172** out of 32,644 (6.7%) suffered from ED and sought treatment.

[Exhibit 5]

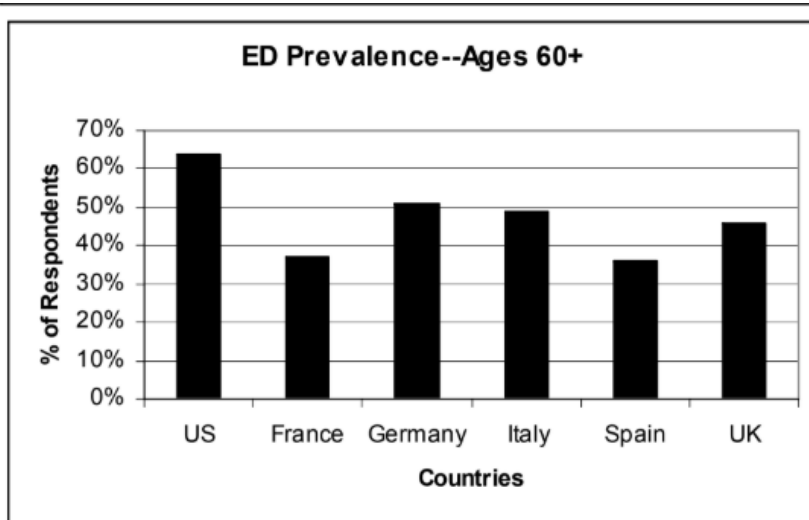


Exhibit 6 Demographic Indicators of ED Patients

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 Partner						
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.

- To find drivers of consumer behavior, follow-up was sent to those screened with ED
 - Younger men: expressed higher levels of embarrassment - waiting for it to go away
 - Older men: normal phenomenon of aging and created reluctance to seek treatment
 - Spouse or sexual partners were most highly cited reasons for ED patients to seek treatment

Commented [9]: influencers to DMU

- Satisfaction was mixed among the groups:

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.

- Subjects were asked about their interest in trying Cialis in the future (based on written profile)

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.

Commented [10]: Go after Germany, UK, and US patients for Viagra dropouts

- Mark Blakely, GMR, conducted in-depth interviews with ED patients:
 - "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 female partner."
 - "... what started as a relatively noncritical physical condition spirals into a psychological anxiety problem considerably affecting the individuals identity and 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."

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Partners

- Market research was also conducted on ED partners
 - 104 interviews with women married to ED sufferers between 35 and 65
 - Split roughly in half between male partner using Viagra and those who hadn't consulted with doctors
 - Common aspect of response was lack of information regarding ED prevalence and potential reasons for its occurrences
 - Some believed it was work-related stress

- Other related it to medical conditions like diabetes
 - **Several believed they were the cause due to no longer being attractive**
- Outcomes of ED:
 - Less hugging, less kissing, less physical intimacy
 - More tense when partner began showing signs of ED
 - Joint discussions were uncomfortable and "off limits"
- Partners satisfaction was mixed (YIKES)
 - "My partner must awkwardly ask me if he should take the pill,"
 - "Once my partner takes the Viagra tablet, I no longer feel I can refuse having sex."
 - "Because my partner must ultimately take the tablet, I usually don't initiate sex"
 - Despite these grievances, most women preferred them to take V vs. nothing at all

Commented [11]: Power is removed from the relationship; target partners of sufferers of ED and let them bring it to their significant others to remind them of their fertility and ability to please them.

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Recent Competitive Developments

- As Cialis team moved forward in terms of clinical trials, FDA submission, and marketing research, competitors:
 - Viagra was aggressively promoted
 - Bayer, new competitor, was on the horizon

Pfizer - Pumping Up the Marketing Machine

- Pfizer set industry record in 2000 with **EIGHT products generating sales more than \$1B each!!**
 - In 2002 company would invest \$5.3B in R&D (up from \$4.8B)
 - Known for marketing prowess, in particular, fierce and sustained marketing campaigns **post launch**
 - **Employed largest sales force in industry, 30,000 salespeople**
 - Philosophy was about poise and aggressiveness, Pfizer hired ex-soldiers, former Army officers, West Point graduates
- Marketing strategies:
 - Direct-to-consumer advertising (\$108M in 2000 for Viagra alone)
 - Mark Martin with #6 Taurus - visit doctor and see if six-pack free sample was right for them
 - Print ads with couple in 30s/40s with female partner prompting male partner to see doctor
 - Reminded the reader Viagra was proven treatment by emphasizing that **9 million** men have used drug
- Sales reached nearly \$1.5B in 2001, with margins of 90%.
- For every 1M patients, 30,000 had untreated diabetes, 140,000 had untreated high blood pressure, 50,000 had untreated heart disease.

Commented [12]: review the post purchase phase in lesson 2

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- One year after initiating treatment, only 25% of patients still used Viagra

Levitra from Bayer

- November 2000, German pharma giant Bayer released results of phase II clinical trial for Levitra
 - Effective at lower dosages than Viagra
 - Designed trials to focus on showing good results for diabetic men (**hard-to-treat segment**)
 - Duration was same of Viagra's (four to six hours)
- Bayer market research:
 - 76% of ED patients interested in new treatment (other than Viagra) that works reliably
- Encouraged by results, Bayer moved to commercialization
- 2001 had been disappointing for Bayer, 2% decrease in total sales and first ever net quarterly loss

Getting Ready for the Launch

- Success of Cialis was important for both parent companies
 - Lilly: expiration of Prozac in August 2001 (three years ahead) was straining earnings
 - ICOS: first drug launching after more than 10 years as company
- Both companies were content with functioning of joint venture
 - Lilly: brought experience and resources to table
 - ICOS: brought nimbleness and sense of urgency of start-up
- No duplication of effort nor sense of time squandered due to both companies being involved
- NDA submission for Cialis (after phase III trials) completed in record time

[pg. 12]

- Collaboration functioned exceptionally well working with scientific community during prelaunch
 - Worldwide opinion leaders from urologists, psychologists, other physicians focusing on men's health-issues
 - Advice was sought on clinical development plans, **how to position drug in market place**
 - Medical expert presented research findings at several key conferences

The Challenges Ahead

- Most medical activity associated with Cialis was completed with application to FDA in June 2001
- Several issues needed to be resolved for product team to present coherent strategy
 - 1. Agree on patient target market
 - Seemed logical to consider Viagra usage status in any segmentation scheme (since anyone discontinuing use of the drug probably didn't like it)
 - By end of 2001, estimated 6-7 million Viagra dropouts in U.S. (compared to 3 millions V users)
 - Age and comorbidities seemed potentially relevant as well

- Important to understand which product benefits to emphasize and how
 - Would the longer duration of Cialis be equally valued by all ED patients?
 - Was lack of interaction with high-fat meals important?
 - Should the answer to these questions differ for Europe vs. U.S.?
- 2. Emphasis to be placed on physicians vs. patients (due to limited marketing budget)
 - Without doctor signing for Cialis, no patient would be able to obtain it
 - Cialis was considered "quality-of-life" drug, doctors alone might not hold key to success
 - Should same benefits highlighted to doctors also be highlights to men suffering from ED?
- 2b. What role, if any, should partner play in marketing of Cialis?
 - Potential risk in alienating men if too many messages were directed to partners
- 3. Competitive pressures to take into account
 - Clinically both drugs were tolerated by patients (despite longer half-life of Cialis)
 - Viagra would take full advantage of five years being tried and tested
 - Viagra had passed initial "death-scary" episode, but how much effort would it take to convince doctors to switch?
- Give similarity of product profile of Levitra compared to Viagra, industry observers predicted Bayer would go for **niche strategy by targeting diabetic patients with ED**

[pg. 13]

- Cialis team was aware of analyst predictions for fierce marketing war between all three companies making ED drug in the US most heavily advertised category of pharma
- Several other decisions to make:
 - What is the price point for Cialis? Should it be priced higher than Viagra (\$10 per pill) because of longer duration or **lower due to drug not being covered by health insurance plans?**
 - Should Cialis ads also have sports-related theme? Feature celebrities, and which ones?
- "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." Brown, Blum, Beebe

Commented [13]: price lower to generate interest and conversion to the drug - then at later date drive up once market has been captured

Talk about how to differentiate between Europe and US - this will be key point of this case