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MEDI-CULT: PRICING A RADICAL INNOVATION

This case was prepared by Research Associate Brian Rogers under the supervision of Professor Nirmalya Kumar as a basis for class discussion rather than to illustrate either effective or ineffective handling of a business situation.

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"This is the biggest revolution ever to hit artificial reproductive therapy!" exclaimed Henrik Krogen, president of Medi-Cult. Krogen was referring to In Vitro Maturation (IVM), a procedure and medium that his biotech company had developed for infertile couples, which significantly reduced the time needed to mature an egg from 30 days to just 2 days. The most important advantage of IVM was that it was a hormone-free treatment; it spared women the physical and psychological side effects caused by the 30 days of hormone stimulation required under the current In Vitro Fertilization (IVF) method.

In August 1998, the first baby using the IVM method was born, and the early success of IVM caught Medi-Cult by surprise. Initially, Krogen had thought the product would hit the market in the year 2001 or 2002. "Success rates with IVM were pathetic everywhere else in the world," Krogen explained. "We were caught somewhat by surprise. IVM hadn't really been included company-wise as something of strategic value."

Although Krogen was confident that IVM would revolutionize the way infertile couples have babies, he was uncertain of what price to charge for the new technology. If he priced it too low, he could sub-optimize potential profitability and risk having the credibility of his product questioned. If he priced it too high, he might attract only a limited number of the infertile couples who seek treatment each year, while perhaps making the industry more attractive for potential competitors.

As Krogen pondered what price to charge for a single dosage of IVM, he began to ask himself the following questions: (1) How would patients, governments, insurance companies, and health care providers receive IVM? (2) What price would the market bear? (3) What percentage of the market would IVM attract?

Company Background

Medi-Cult, a Danish biotechnology company, developed and manufactured cell culture media. Cell culture media allowed cells to exist and propagate outside their natural environment (the human body). In 1986, Professor Kjell Bertheussen developed and patented Synthetic Serum Replacement (SSR), a protein-free culture medium which could be substituted in the place of animal and human sera. SSR, unlike animal and human sera, effectively minimized the risk of transferring diseases to the embryo. This was considered a breakthrough in the field of Assisted Reproductive Technologies (ART), and a comfort to couples who wished to conceive through IVF.

In 1987, Bertheussen and a number of partners established Medi-Cult to exploit this proprietary cell culture technology in two major application markets. The first was a *clinical* application of cell culture in the field of ART. The second was an *industrial* application, where cells were used in the production of active pharmaceutical substances and marketed to the biopharmaceutical industry.

Three fully owned subsidiaries in France, Great Britain, and the United States were responsible for sales of Medi-Cult products in those countries. A fourth subsidiary, Amdex A/S, with headquarters in Copenhagen, had been created to supply highly innovative technologies to the international diagnostic industry. Medi-Cult serviced clients all over the world through its extensive network of 35 independent distributors, who had been awarded exclusive territories by the company. In August 1998, Medi-Cult hoped to strengthen its position in the US market by signing a letter of intent to acquire Unisyn, Inc., a Boston-based biopharmaceutical contract producer.

In 1997, Medi-Cult had total sales of DKK (Danish krone) 20,560,000 or roughly US$3 million. (*Refer to* ***Exhibit 1*** *for more data*.) Practically all the sales revenues in 1997 came from IVF products. Forecasted growth was estimated at 30% to 40% for 1998. The company, which had been listed on the Oslo stock exchange since 1996, had not turned a profit in recent years.

Henrik Krogen, president of Medi-Cult, was a 42 year old, dynamic, technically trained executive with extensive sales and marketing experience in the pharmaceutical industry. Medi-Cult employed 53 people and was fully operational, with its own R&D, patents, and manufacturing. Ten of its 53 employees were dedicated exclusively to R&D.

In addition to internal R&D, Medi-Cult also had a virtual R&D network, in which they contracted with academic institutions for particular projects. These institutions worked up new products, technologies, and documentation, which were then brought back to Medi-Cult for evaluation, testing of reproducibility, and product formulation. Medi-Cult prided itself on its partnerships with doctors, scientists, and biotechnological manufacturers throughout the world, and viewed these relationships as key to staying on the cutting edge of research in this highly competitive field. The development of IVM and its clinical success was one such example of the synergy achieved between Medi-Cult and its R&D network.

Assisted Reproductive Technologies

In 1998, about 6% of the Western population suffered from reduced fertility. On average, infertility is equally split between men and women. In most cases, the female partner is 100% healthy; however, it is usually the female, not the male partner, who undergoes treatment for infertility.

In Vitro Fertilization

The IVF method is better known as the "test tube method," though neither egg nor sperm see the inside of a test tube. The four steps in the IVF treatment are as follows: (*Refer to diagram in **Exhibit 2***.)

Step 1 - Hormonal Stimulation

Only one of the 1,000 eggs a woman develops every month matures completely. Using hormone stimulation, more eggs are matured, thus increasing the chance of pregnancy. Hormonal stimulation lasts approximately 30 days and can require up to 50 self-administered injections. Some women are unable to administer the injections themselves, necessitating a daily visit to the clinic; later in the process, two daily visits are required.

The injection of these hormones is often accompanied by side effects such as general discomfort, reduced sexual desire, and extreme mood swings. About 50% of the women suffer from nausea; 10% become sick because of over-stimulation. In extreme cases, hormonal stimulation may lead to very serious, potentially life-threatening problems resulting in 2% of women requiring an average of 5 days of hospitalization. Because of the potential for side effects, all infertility patients are closely monitored during the stimulation process and have to submit bi-weekly blood samples to the clinic.

Step 2 - Egg Aspiration

Egg aspiration lasts only ten minutes. During this stage, the more mature eggs are removed, examined, and placed in a nutrition fluid.

Step 3 - Fertilization

After four hours in an incubator, the eggs are fertilized with the male sperm. Cell division begins 18 hours later.

Step 4 - Embryo Transfer

Forty-eight hours later, the embryos are transferred to the uterus. This transfer takes just a few minutes.

The Market for In Vitro Fertilization

In 1998, the worldwide market for IVF encompassed approximately 350,000 procedures (also called cycles); according to estimates, these cycles resulted in 50,000-100,000 births. (*Refer to **Exhibit 3** for details on the market.*) According to Medi-Cult, growth in the number of cycles was estimated at 5% to 10% per year. Of these cycles, 15% to 40% could be lost to non-stimulated cycles or to freezing.

The total cost for an IVF cycle varied significantly from country to country. For example, in the USA, the total cost of the IVF treatment was $8,000-$10,000, and $4,000-$5,000 for the rest of the world. (Table A provides a breakdown of the cycle cost for a typical patient.)

Table A: Cost for IVF Cycle

	Cost of IVF Treatment (a)	Cost of Hormones [1] (b)	Lab Work (c)	Misc. Costs [2] (d)	TOTAL COST (a+b+c+d)
USA	$4,000-$6,000	$3,000	$500	$500	$8,000-$10,000
Rest of the World	$2,000-$3,000	$1,500	$300	$200	$4,000-$5,000

[1] The hormones are usually directly purchased by the patient at a pharmacy while the rest of the costs (IVF treatment, lab work, etc.) are billed to the patient or alternative payer by the hospital/clinic.

[2] Miscellaneous costs include additional doctor visits, ultrasound monitoring, workdays lost, and hospitalization. Note: this cost varies as hormone injections affect some women more than others.

Source: Medi-Cult

IVF is not always successful--on average, three to five attempts are made before a child is born. Because the extensive hormone treatment under the IVF method is so unpleasant and sometimes dangerous, women dislike it and often give up after the first attempt. As a result, fewer children are born because most women are unwilling to undergo IVF treatment three to five times to become pregnant.

Medi-Cult participated in the market by supplying the IVF media used in steps 2, 3, and 4 of the IVF method. The price of a single dose of IVF medium, sufficient for one cycle, was about $50 per cycle. (In Table A, this price was included in the cost of IVF treatment.) Medi-Cult estimated its variable costs of production and testing to average approximately 30%. Medi-Cult remained the market leader in the IVF media market, despite aggressive competition from other European IVF media companies. The company was growing at 35% even though their pricing had increased 30% over the previous three years.

In Vitro Maturation and its Development

In Vitro Maturation, a delicate procedure involving the collection of immature oocytes (eggs) from the ovary, used the same procedure as used for IVF, but without the prior hormone stimulatory regimen. Step 1 of IVF was unnecessary, but Steps 2, 3, and 4 remained the same. Once collected, the oocytes were matured outside the body (in vitro) with the help of hormones and a single dosage of the patented maturation medium developed by Medi-Cult. After two days of maturation in the laboratory, the eggs were fertilized by the partner's sperm and replaced into the woman's uterus, as with existing IVF procedures.

Since IVM eliminates the hormonal stimulation step from the IVF procedure, the cost of the hormones for patients falls by 90%. Furthermore, lab work and miscellaneous costs also drop by about 50% since there is less monitoring of patients and fewer complications. The success rate of IVM is the same as IVF; therefore, patients can also expect to undergo three to five attempts before having a child. The success of IVM depends on following both the unique clinical procedures as well as using the maturation medium developed by Medi-Cult.

Table B: Cost for IVM Cycle

	Cost of IVF Treatment [1] (a)	Cost of Hormones (b)	Lab Work (c)	Misc. Costs (d)	TOTAL COST (a+b+c+d)
USA	$4,000-$6,000	$300	$250	$250	$4,800-$6,800
Rest of the World	$2,000-$3,000	$150	$150	$100	$2,400-$3,400

[1] These costs reflect the various steps of IVF treatment such as the initial doctor visit, tests, egg aspiration, fertilization, and embryo transfer which still have to be performed with the IVM. It however does not include the cost of Medi-Cult's IVM maturation medium.

Source: Medi-Cult

Customers

Infertile Couples

In recent years, infertile couples sought out information exhaustively, and were therefore well informed about the various treatments available to assist them in having a child. Although they consulted with physicians and clinics, many couples had made up their mind beforehand about which treatment they wished to have. Since having a baby using IVF could be prohibitively expensive, the decision to undergo treatment one or more times often depended on whether medical insurance or the government would cover some or all of the expenses.

Doctors

Svend Lindenberg, a physician at Herlev Hospital in Denmark, believed that patients would choose IVM because the process was very easy for the patient to comprehend and easy to participate in, and because there was no risk of hyper-stimulation from hormones. Dr. Lindenberg also believed doctors were likely to recommend IVM because no prescriptions were required, no artificial menstrual cycles were needed, and because their patients would complain less of discomfort.

Clinics

Initially, Medi-Cult planned to select certain clinics as part of its rollout plan, since the company viewed clinics as the critical link to the market. Before Medi-Cult shared its technology with clinics, the clinics would have to sign a franchising agreement in which the clinic agreed to buy the IVM media exclusively from Medi-Cult for a pre-determined period of time. The clinic would also agree not to develop its own IVM technology. Furthermore, clinics would have to agree to follow Medi-Cult protocols and quality requirements to the letter, report their results, and observe strict confidentiality.

For Medi-Cult, a potential drawback in attracting doctors and clinics was that they tended to resist signing agreements. To prevent competitors from seizing the technology and producing their own IVM media, secrecy was paramount. Dr. Lindenberg believed that doctors and clinics would still be drawn to IVM if Medi-Cult assured them that the IVM method would be continuously refined, and if doctors and patients were kept educated about the process. Despite these restrictions, Dr. Lindenberg hypothesized that clinics would embrace the IVM method quickly. They would adopt the IVM method primarily because patients had a tendency to flock to clinics that were on the cutting edge, and also because there was also a certain prestige factor in being one of the first clinics to offer such an innovative technology.

Governments and Insurance Companies

Reimbursement of infertility treatments by insurance companies and governments was low because infertility patients were not considered "diseased." In the UK, the patient had to pay almost all of the cost for infertility treatment. In contrast, the French authorities allowed four free attempts (cycles) per patient; beyond this, the patient had to pay for any additional treatments. In Denmark, infertility treatments given by private practice had to be paid out of pocket by the patient, while the first three treatments given by public clinics were free of charge, with medication and hormone costs reimbursed up to 75%. In the USA, reimbursement was low; the amount that insurance companies were willing to pay varied from state to state, company to company, and procedure to procedure.

There was not much information available on the regulation of fertility by governments. Medi-Cult was in a difficult position because the IVM medium could not be sold without government approval, and because the cost to the

patient was significantly increased if governments and insurance companies elected not to cover the costs of fertility treatment. Furthermore, there may even be pressure on Medi-Cult to keep the price of the IVM medium low so that insurance companies could move funding to other disease areas or increase the total number of couples receiving the treatment.

Competition

Medi-Cult was likely to face two different types of competition. The first type of competition would come from the large pharmaceutical companies such as Ares-Serono, Organon, Ferring, and Whyeth-Ayerst, which supplied the hormones used in IVF. At Ares-Serono, an estimated $500 million in sales revenues came from reproductive health products; at Organon, 13% of their estimated $1.1 billion in sales revenue came from infertility drugs. In Medi-Cult's estimation, these large pharmaceutical manufacturers would lose out because the IVM process significantly reduced the need for hormones. Furthermore, Medi-Cult believed that the drug companies stood to lose $200-$300 million in new business, which was growing by 25%-50% annually. Medi-Cult suspected that upon launching IVM, these pharmaceutical giants would discredit the process, demand product approval for it, threaten withdrawal of research funds from clinics who adopt it, and stop all sponsoring of congresses for fertility physicians.

A second type of competition was likely to come from companies, which like Medi-Cult, also developed and manufactured cell culture media. Medi-Cult suspected that these biotech companies would develop their own product and clinical procedure. In Europe, for example, it is not possible to patent a process, although it is possible to patent a maturation medium. Medi-Cult worried that competitors would break Medi-Cult's IVM medium patent by using molecular modeling (also known as reverse engineering). At any rate, Medi-Cult expected to have a two to three year advantage by being the first to market since any company that wished to introduce a competing product or process would have to undertake the clinical trials and document live births.

Market Launch

Medi-Cult was considering using a Hub and Spoke approach to get to the market with the least possible delay. The central hub would consist of the Copenhagen University Institute of Human Reproductive studies, seven Danish clinics, and the Medi-Cult IVM Task Force. Secondary hubs would consist of the clinics trained at the central hub and supported by the primary spokes of information. The secondary hubs would then train tertiary centers.

The secondary training hubs would be carefully selected clinics in Norway, Sweden, Spain, Germany, France, Belgium, Italy, Israel, and the United Kingdom. These centers would be chosen based on their throughput, (i.e., above 300 cycles per year) and their willingness to enter into an agreement to operate under a Medi-Cult IVM-franchise. To expedite the IVM launch, Medi-Cult planned to recruit a

business development manager and a scientific director for the special IVM Task Force.

Medi-Cult would be marketing IVM medium in the form of a single dose sufficient for one cycle. In addition, the company would be providing training, upgrading, technology development, and quality control to the clinics involved. Medi-Cult planned to produce IVM like any other IVF medium, and had calculated the cost to produce a single dose of IVM medium to be slightly more expensive than its current cost of producing IVF medium. No extra investment would be incurred by Medi-Cult in the production set-up as sufficient in-house capacity was available and the company was already producing similar products.

Henrik Krogen's Dilemma

"With IVM, we can't lose," Krogen concluded. He added, "I don't want to kill the market with a high price, but I don't want to undershoot the market either." Even though Medi-Cult was losing money, Krogen was under no pressure to set any particular price for IVM. Confident of his product, Krogen began considering his pricing options for the March 1999 launch of IVM.

Krogen knew that it would be very difficult to claim that the cost of production would justify its price. There was no tradition for pricing media at this level, and everybody would know that the cost to produce the IVM medium was insignificant, when compared to the current price for medication. But still, Krogen contemplated whether IVM should be priced according to the product's perceived value. A high launch price could signal the enhanced benefits of IVM over the existing IVF method and potentially generate greater profits. Alternatively, a low launch price could motivate faster adoption of the IVM method by clinics since they could obtain a greater share of profits.

Krogen also wondered if a single uniform price should be set worldwide, or whether the price should vary from country to country. To help make this decision, Krogen solicited from Medi-Cult managers in Denmark, France, UK and the USA their judgments on: (a) the lowest realistic price and expected first year sales volume at that price; (b) a "medium" price and expected sales volume at that price; and (c) the highest realistic price and anticipated sales volume at that price. (*Refer to* ***Exhibit 4*** *for results*.) Traditionally, drug prices had differed widely across countries, resulting in some shipment of products from low to high price countries. However, with the introduction of the Euro on January 1, 1999, market analysts expected greater harmonization of prices within Europe.

Krogen felt that the pricing strategy also needed to address the question of the appropriate long-term evolution of prices. One option was to keep real inflation-adjusted prices stable over time as this enhanced the legitimacy of the initial launch price. Alternatively, if Krogen opted for a high initial price, he could lower prices as competition materialized--or, if he selected a low initial price, he could increase prices as uncertainties about the new IVM method faded and the Medi-Cult method became the established industry standard. In the latter case, for example, "improved" versions could be launched by Medi-Cult at higher prices.

Last but not least, the reaction from the big pharmaceutical companies also had to be considered since the increased use of IVM would translate into losses of revenue for the drug companies.

There were many unanswered questions, but one thing Krogen knew for sure: infertile couples would place a high value on his product because it was easy to use, safer than the current IVF method, and would help them achieve their ultimate dream--to have a child.

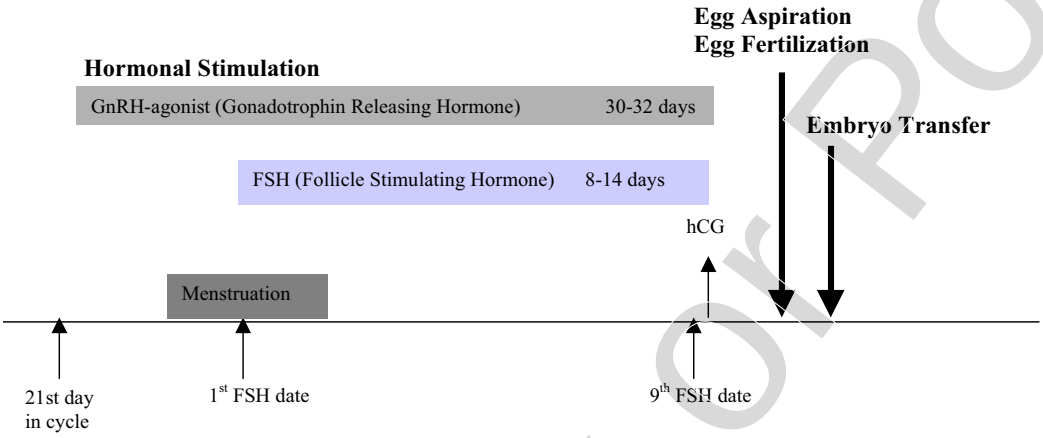
Exhibit 1
Medi-Cult Financial Information 1996-1997

STATEMENT OF INCOME		
Thousand DKK	1996	1997
1 US $ = 6.4 DKK (01.01.99)		
Net turnover	15,600	20,560
Production costs	5,786	8,053
Gross result	9,814	12,507
Sales and marketing costs	5,656	10,039
General and administrative costs	6,111	7,378
Research and development costs	2,001	4,981
Result before financial items	-3,954	-9,891
Financial items net	839	2,553
Result before extraordinary costs and tax	-3,115	-7,338
Extraordinary expenses	223	148
Result before tax	-3,338	-7,486

BALANCE SHEET		
Thousand DKK		
Fixed assets	2,034	3,385
Current assets	63,535	42,146
Assets in total	65,569	45,531
Equity	60,911	39,513
Long-term debt	776	0
Short-term debt	3,882	6,018
Liabilities and equity in total	65,569	45,531
Market capitalization	195,021	227,532
Share price, December 31 *(DKK)*	53	59

Source: Medi-Cult

Exhibit 2
IVF Process



The individual treatment may vary slightly compared to the above example.

On the first day of the woman's period, she contacts the clinic to set an appointment for her and her partner on the 21st day of her cycle. She will be given an ultrasound scan, both her and her partner will be instructed in injection technique, and the couple will be taken through the procedures to follow.

Hormonal Stimulation

On the 21st day of the cycle, the hormonal administration begins. GnRH agonist influences the production of superior sex hormones in the brain, which control the function of the ovaries and their production of other hormones. The GnRH agonist stops the woman's normal hormonal excretion for a short period of time. This hormonal pause is used to administer FSH which is normally excreted from the pituitary gland, allowing for control over the development of the eggs. Often several eggs are matured.

On the 9th FSH day, an ultrasound scan is performed and the following days are planned according to the results. The date for aspiration may even be decided. Otherwise a new control date is arranged and another injection is administered. In the above example, the ovulation inducing hormone, hCG, is injected the same evening.

Egg Aspiration and Fertilization

The male partner delivers a sperm sample. The eggs are then aspirated and fertilized.

Embryo Transfer

Two to three embryos are transferred to the uterus with the hope that one of them will adhere. The natural pregnancy process then begins.

Source: Ciconia

Exhibit 3
Estimated Number of IVF Cycles/Year

Europe		
France	33,000	
Germany	30,000	
Italy	27,000	
UK	25,000	
Benelux	15,000	
Spain	13,000	
Sweden	10,000	
Denmark	7,000	
Norway	4,000	
Finland	4,000	
		168,000
North America		
USA	80,000	
Canada	10,000	
		90,000
Rest of the world		**87,000**
TOTAL CYCLES WORLDWIDE		**345,000**

Source: Medi-Cult

Exhibit 4
Results of IVM Pricing Exercise

Country	Respondent	Potential Price Points								
		High Price			Medium Price			Low Price		
		Price [1]	Volume [2]	Market Share [3]	Price	Volume	Market Share	Price	Volume	Market Share
Denmark	Kristen Krag, Int'l Sales Director	DKK 12,000	325	5.0%	DKK 10,000	500	7.0%	DKK 8,000	1,200	17.0%
France	Denis Azra, General Manager	FF 8,000	500	1.5%	FF 5,000	650	2.0%	FF 4,000	900	3.0%
UK	Lesley Hutchins, General Manager	£900	2,000	8.0%	£700	3,000	12.0%	£500	4,000	16.0%
USA	Larry Fava, General Manager	$2,200	1,200	1.5%	$1,600	1,200	1.5%	$1,000	1,200	1.5%

[1] Price for a single dosage sufficient for one cycle
[2] Estimated number of IVM cycles for the first 12 months
[3] Percentage of total number of IVF cycles within that country

Currency Exchange Rates:

US$1 = FF 5.6 (French francs)
US$1 = £0.60 (British pounds)
US$1 = DKK 6.4 (Danish krone)

Currency Exchange Rates on 01.01.99
Source: Pacific Exchange Rate Service