

1-1-2011

## Legitimizing radical new medical services

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### Recommended Citation

Nanette C. Clinch, A Osland, and C Wang. "Legitimizing radical new medical services" *Journal of Applied Business and Economics* (2011): 67-78.

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## **Legitimizing Radical New Medical Services**

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*Physicians enjoy considerable liberty in the creation of entrepreneurial ventures in the new frontiers of medicine. Professional societies may opine about a new procedure but professionals may feel free to ignore their counsel as well. Two case studies are used to discuss this method of new venture creation; the cases are trait selection through pre-implantation genetic diagnosis and female cosmetic genital surgery (FCGS), both controversial practices. We discuss the ethics and legitimacy of both and how one can use theory to analyze whether or not these are legitimate businesses and how to develop them.*

### **RELEVANT THEORY AND LITERATURE**

Three management and sociological theories are relevant here: industry life cycle model (Hofer, 1975; Hill & Jones, 2010), embeddedness theory (Granovetter, 1985; Zelizer, 1978), and institutional entrepreneurship theory (Maguire, Hardy, et al., 2004; Greenwood & Suddaby, 2006). The industry life cycle model depicts the various stages in an industry's evolution over time, from embryonic, growth, shaking-out, mature, and eventually to a decline stage. It delineates noteworthy strategic issues in each stage and helps us explain difficulties encountered in commercializing new services. The embeddedness theory emphasizes that economic activities such as commercializing a new technology are embedded within relational and cultural contexts. Cultural beliefs tend to enable as well as constrain economic actions. It also helps us explain the role of ethics as a social force in legitimating a business. The institutional entrepreneurship theory indicates the possibility that actors can take strategic action to influence or shape institutional structures or cultural beliefs to create a benign environment for their business. We also suggest that sensible strategic plans be developed to help legitimate the new businesses based on the theory of institutional entrepreneurship.

Legitimacy connotes the kind of social integration that commands public respect as a consequence of substantial ethical and legal approval. New technologies should not regard engagement with ethics or the law as a contest in which the values of others must yield to business interests but rather new technologies should conform to accepted ethical standards and legal requirements. The advantage of oversight for such complex technologies as genetically-engineered organisms and nanotechnology has been recognized by experts, even though the criteria for oversight varies (Kuzma, Najmaie, & Larson, 2009). Although legal

regulatory oversight can arise from or intensify after a health or safety crisis, oversight ideally arises in a pro-active manner, from the holders of the technological prowess: the makers themselves. This was demonstrated by the scientific community that conferred years ago at Asilomar in California, resulting in scientists pressuring government to intervene with guidelines to govern research on recombinant DNA (Kuzma et al., 2009, p. 547). Such a demand for oversight represents more than an effort to provide safety; it represents a conscientious ethical decision to develop technologies in accord with what is best for humanity.

If new technologies are to be incorporated into society with public approval, it would seem logical that both experts within a field (not just a business) as well as governmental agencies should be brought into the dialogue of what merits pursuit. For example, Wall and Brown (2010, p. 30e1), criticized the “trend toward prepackaged surgical procedures” being shaped by commercial interests.

Ethical concerns associated with genetically engineered organisms, such as impact on social systems, rights of consumers to understand the products or services, health and safety, and “opportunities to object to the technology on moral grounds” (Kuzma et al., 2009, p. 550) can be extended to other new technologies. Trait selection is one such case.

## **TRAIT SELECTION CASE**

In February 2009, Dr. Jeff Steinberg announced that his clinic, The Fertility Institutes, based in Los Angeles, would use pre-implantation genetic diagnosis (PGD) to help prospective parents select their babies’ hair and/or eye color. Immediately after the media coverage of the initiative, some doctors expressed doubts regarding its technical feasibility, and some religious groups and bioethicists questioned its ethics. Amidst ethical controversies and technological uncertainty, Steinberg faced challenges to legitimate the trait selection business.

### **Legitimizing Trait Selection as a New Technology**

When a new technology, PGD in this case, lays a foundation to a potential new line of business (e.g., the trait selection business), strategic entrepreneurs need to learn how to deal with issues peculiar to the embryonic stage of an industry. Furthermore, a technology is not always value neutral, but can involve ethical controversies. Entrepreneurs should assess the ethical implications of the technology and formulate strategies to shape the institutional environment to their advantage by overcoming the presenting hurdles.

#### *Hurdles*

The hurdles Steinberg faced included undeveloped technology, lack of customer demand, the threat of regulation, and ethical dilemmas. According to the *industry life cycle model*, technology in an embryonic stage, the earliest stage of the life cycle of an industry, is usually immature. Entrepreneurs need to focus on improving and eventually perfecting the technology to provide quality products or services. In the case of trait selection, regardless of ethical controversies, the technology that Steinberg plans to use to deliver his announced service is far from mature. Sean Tipton of the American Society for Reproductive Technology commented, “Nobody can do this right now” (Salamone, Dillon & Pesce, 2009). Even Steinberg himself acknowledged that “it’s not perfect science because eye and hair colors are not perfect genetics” (Salamone, et al., 2009). It seemed that he had not been able to use PGD to identify accurately and consistently genetic materials that determine a baby’s hair and eye pigmentation. Failure to deliver what he promised would definitely compromise the viability of his proposed business.

The PGD procedure needs to extract one or two cells from a three-day-old embryo for genetic diagnosis. The loss of the cells may damage the embryo and lead to irreversible side effects on it and, eventually, the person developing from it. Since few babies resulting from the PGD procedure have reached adulthood yet, more time is needed to evaluate accurately the implications of the PGD procedure for their health. Therefore, some medical practitioners believe that the PGD technology is still in an experimental stage (Kalfoglou, 2005).

The PGD procedure is subject to misdiagnosis. For example, cells extracted from an embryo may have different genetic compositions from cells left intact in the embryo. Thus, results from the diagnosis may not be generalized to other cells. For example, genes related to blue eyes may be found in an extracted and diagnosed cell, but may be missing from intact cells in an embryo.

No representative sample about misdiagnosis is available. But according to research based on convenience samples, the misdiagnosis rate is rather high; one study reported that three of seven pregnant PGD patients were misdiagnosed (Kalfoglou, 2005).

Until Steinberg and his colleagues can improve their PGD technology to increase diagnostic accuracy, the trait selection business may not be able to take off.

In the embryonic stage of an industry, there is usually a low demand for a new product or service. Potential customers tend to be unaware of or unfamiliar with the product or service. Entrepreneurs need to invest heavily in marketing. In addition, lacking the economies of scale, the price of the product or service tends to be high, which suppresses demand.

Furthermore, as mentioned earlier, the immature technology in trait selection may not serve a customer's needs well. Since results are not necessarily guaranteed, prospective parents would face an ethical or emotional dilemma if a conceived baby turns out to be different from what they ordered.

To use PGD to select traits, prospective parents need to go through the *In Vitro Fertilization* procedure, which may cause physical and psychological discomfort. Moreover, the healthy embryos will be discarded simply due to the lack of potential for specific hair or eye color, which could cause moral qualms among some prospective parents who believe that an embryo deserves to grow to fruition. Healthy embryos are routinely discarded by fertility clinics because usually only one or two are expected to grow into children in the implantation phase. Physical and psychological inconvenience and moral ambiguities tend to suppress demand from potential customers though there are many willing customers for PGD should the parents be fearful of a genetic disease or have a specific gender preference, a big part of Steinberg's business.

It is likely that prospective parents' preference for a certain hair or eye color is influenced by public opinion as conveyed through the media. The aesthetic taste of the public may be fickle. A fashionable eye color may cease its popularity after a short while. The fluidity of taste poses a risk to the prospective parents that traits selected for their children might be out of fashion at some point.

The genetic pool of parents defines the range of the possible physiological features that can be found in their descendants. Some Caucasians (e.g., Scandinavians) can more readily have blue eyes and blond hair, for example. If there is no genetic disposition for some trait in prospective parents of other ethnicities, the PGD procedure won't be able to help them to bear a child with that trait unless they use sperm or eggs from donors.

To leap over the customer demand hurdle, entrepreneurs need to help customers to overcome the fear of physical and psychological uneasiness related to the IVF procedure and to ease the moral qualms about the disintegration of screened-out embryos. They could also attempt to expand the portfolio of traits available for selection, thereby increasing the size of potential customers who may insist on using their own sperm and/or eggs. Perhaps athletic parents would choose to order extremely tall boys, technology permitting.

There is no federal or state legislation that prohibits or limits non-medical trait selection practices in the United States, although gender selection for non-medical purposes is illegal in Canada and the UK (see [http://www.fertilityfactor.com/infertility\\_sex\\_selection.html](http://www.fertilityfactor.com/infertility_sex_selection.html)). However, there is no assurance that federal or state legislatures won't regulate or even ban them in the future. Since these practices are ethically controversial, representatives from various religious groups voiced their objection. For example, Rabbi Mark Popovsky (2007) argued that gender selection and other trait selections are unethical according to Judaism. Viewing children as gifts from God, the Vatican denied that prospective parents have a right to select a child's traits through medically assisted procreation (Trujillo, 2010, p. 6). Out of the consideration of social justice, some jurists and ethicists reason that trait selections may give children conceived with the PGD method unfair advantages over those conceived through sexual intercourse. Ethical controversies cast doubts on the legitimacy of the trait selection business. Religious

groups and social activists in favor of regulation or a ban on it may mobilize in state or federal legislatures to pass restrictive statutes.

### *Ethics*

PGD trait selection has emerged from advances in biotechnology, where the inter-disciplinary aspects pose new dilemmas (Poitras & Meredith, 2008, p. 314). Ethical and legal opinions about the practice of trait selection tend to vary according to people's religious backgrounds and theological and philosophical understandings about life.

First, there is no consensus about when a life is considered to begin. If implanted in a womb, an embryo cultured *in vitro* will potentially develop into a child. When an otherwise healthy embryo is disintegrated or destroyed due to the lack of characteristics desired by prospective parents, the child that would have developed out of it is not given a chance to survive. People who believe that an embryo is the beginning of a life would consider such destruction equivalent to an abortion.

Second, it is reasonable to assume that prospective parents tend to favor some traits over others. For example, blue eyes might be preferred over brown eyes. Groups of people with screened-out traits might feel discriminated against and victimized. The trait selection business might suggest the existence of a bias against people with certain physical characteristics and, even worse, help to reinforce it.

Third, research (Langlois, Kalakanis, Rubenstein, Larson, Hallam, & Smoot, 2000) shows that children and adults who are attractive receive more favorable judgment and treatment at the hands of others than unattractive children and adults, even when the individuals being so judged or treated are known. The same research suggests that attractive individuals tend to display more appealing behaviors and traits than less attractive individuals. If trait selection is available, selection of appealing traits and features by prospective parents is likely to give their children unfair advantages over children who were conceived through sexual intercourse.

Fourth, some religious traditions consider children as gifts from God. Parental love should not be conditioned on what traits children have. Trait selection is likely to set a precondition for parenthood. If willingness to parent a child is based on his/her characteristics, it violates humanity; the very existence of some children without the desired traits would be cast into doubt. The children might not like their blonde hair or blue eyes that were specifically selected by their parents, but they are grounded in these trivial physical characteristics. This disrespects human dignity.

An ethical view in favor of trait selection reasons that it is a procreation liberty as implied in a constitutional right to privacy. A person has a right to avoid reproduction (e.g., abortion) as well as a right to procreate. If it is legal to abort a fetus, there is no legal ground to prohibit destroying embryos not chosen for implantation. However, some theorists contend that though it is constitutional to have a baby, to customize it may go beyond the constitutional protection (Wolfe, 2008). Eventually, the legality of trait selection will depend on how a supreme court interprets the constitution of a given jurisdiction, be it a state or country. Of course, a government might preemptively pass legislation stipulating that such practices are illegal.

It may be plausible that public opinion disapproves of the trait selection business. However, it is not clear whether the opinion can translate into the regulations that ban the practice. Political entrepreneurs who intend to solicit support from religious groups or conservative constituents may raise an issue on the trait selection business to gain political capital. However, even if there were federal or state regulations that proscribe the trait selection business, Steinberg, his colleagues, and some patient advocacy groups could challenge the legitimacy of the ban in courts.

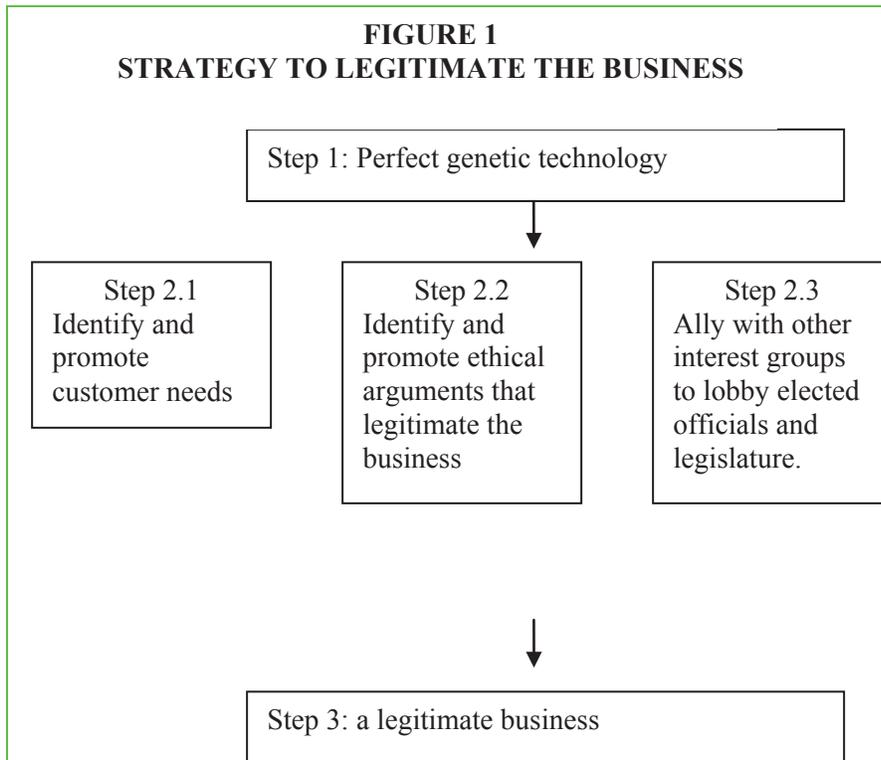
The *embeddedness* theory highlights the difficulty of a business in being accepted as legitimate when it contradicts ethical beliefs held by part of the society. As federal or state legislatures may regulate or ban the business, entrepreneurs need to pay institutional costs, lobbying for changes in legislation in their favor or challenging a ban in court by resorting to rights protected by the constitution. Furthermore, the entrepreneurs need to frame or reframe their business in favorable ethical, philosophical, or even religious principles or terms, seemingly difficult in the case of trait selection.

### SWOT analysis

Using *SWOT analysis* to legitimate their business, Steinberg needs to analyze opportunities and threats in the external environment and identify strengths and weaknesses. He needs to identify major stakeholders who are important to legitimate the trait selection business. His *in vitro* fertilization and PGD expertise are strengths. He may apply some of this expertise to the proposed non-medical trait selection service. Other strengths are his current customer base and former patients that may refer potential clients. One of the weaknesses is reliability of the trait selection technology. Another is that he may not have time or resources to forge coalitions with the interest groups that may be important in defending his course if opposing parties mobilize to ban the proposed trait selection business. One opportunity in the external environment is a potential new market. If Steinberg could improve the technology to increase its accuracy and reliability, he might become a first mover in the new market segment. He might build up customer loyalty and enjoy price premiums. As mentioned above, major threats include technological uncertainty, lack of customer demand, threat of regulations, and ethical controversies.

### Unresolved Business Issues

Technology improvement, marketing, and the regulatory threat are concerns. Legitimization of the trait selection business is depicted below (see Figure 1):



### Epilogue

For now, Steinberg has postponed the new business initiative (Daily Record, 29 July 2010). It is not clear if or when he will provide the trait selection business but the controversies will likely continue if he goes ahead with the trait selection business. In contrast, Female Cosmetic Genital Surgery (FCGS) is ongoing.

## FCGS CASE

Few object to cosmetic procedures to enhance appearance to compensate for apparent shortcomings or reconstructive surgery to remedy serious problems, including those involving female genitalia. However, through photos and films, porn stars may well contribute to the establishment of a standard look for female genitalia and the worry women may feel about superfluous, cosmetic and heretofore private issues; they undergo risky procedures of dubious benefit. Women get photos of female genitalia for comparison from pornography and now also from plastic surgeons' websites. Is FCGS a legitimate business? Will sheer numbers in the marketplace determine a standard look for genitalia? What role do the professional societies play in determining what's acceptable? What will the courts decide once claims for malpractice and damages become common? Will advocacy groups play a role? Later we will discuss the options activists might have.

### Legitimizing FCGS as a New Technology

The following is a brief situational overview:

1. The Second Global Symposium on Cosmetic Vaginal Surgery was held on September 23-25, 2010 in Las Vegas. The International Society of Cosmetogynecology is the professional society ([www.iscgyn.com](http://www.iscgyn.com)).
2. The numbers of surgeries performed are hard to determine because as of late 2010 the American Society of Plastic Surgeons had not as yet published specific statistics on FCGS.
3. Malpractice suits will no doubt occur, typical of medicine in general and perhaps especially in the case of a seemingly risky set of procedures performed for what some doctors would call frivolous ends.
4. Advocacy groups, including the New View Campaign ([www.fsd-alert.org](http://www.fsd-alert.org)), have begun to make their voices heard.
5. The Royal Australian and New Zealand College of Obstetricians (RANZCOG) has publicly opposed FCGS (Braun, 2010, p. 1393).
6. At least one professional society in the US has expressed its opposition; the American College of Obstetricians and Gynecologists (ACOG) (February 2007) cautioned against "vaginal rejuvenation," "designer vaginoplasty," "revirgination," and "G-spot amplification" procedures.

ACOG stated that they are "are not medically indicated, nor is there documentation of their safety and effectiveness" and that "it is deceptive to give the impression that any of these procedures are accepted and routine surgical practices." It warned of "potential complications, including infection, altered sensation, dyspareunia (pain), adhesions, and scarring." The report indicated that there was wide variation in the external appearance of female genitalia. ACOG (September 1, 2007) was "concerned with the ethical issues associated with the marketing and national franchising of cosmetic vaginal procedures. A business model that controls the dissemination of scientific knowledge is troubling," We believe this is in reference to the practice of training other surgeons for a fee but not publishing the results or practices in the medical press."

Liao and Creighton (2007, p. 1091) discussed women's requests for FCGS: "... our patients sometimes cited restrictions on lifestyle for their decision. These restrictions included inability to wear tight clothing, go to the beach, take communal showers, or ride a bicycle comfortably, or avoidance of some sexual practices. Men, however, do not usually want the size of their genitals reduced for such reasons." The authors, with a clear bias against FCGS, referred to the current market orientation as a demand for "designer vaginas" (p. 1090). They pointed out that in their study of 50 premenopausal women there were significant variations in the size, shape, length, color, folds or wrinkles, and symmetry of the various parts of female genitalia. Yet women approached the physician with a standard view as though they were going to have their hair freshly styled; they brought along desirable images ("usually from advertising or pornography", p. 1091).

One letter following the Liao and Creighton article in *BMJ*, from the editor of *Reproductive Health Matters*, stated: "If a woman (probably African) asks for her own or her daughter's genitals to be excised

for traditional reasons, it is refused as a criminal offense. Yet if a woman thinks her own genitals are an abnormal shape or size, the surgery is provided” (Berer, 30 June 2007, p. 1335). A significant difference between the two practices is that FCGS is voluntary whereas traditional female genital cutting is often imposed on young African girls.

### *Hurdles*

Plastic surgeons as strategic entrepreneurs offering a new technology, such as FCGS in this case, need to learn how to deal with issues peculiar to the embryonic stage of an industry. Furthermore, FCGS presents ethical controversies, and entrepreneurs should formulate strategies to shape the institutional environment to their advantage.

In the case of FCGS, regardless of ethical controversies, the technology is far from mature. Peer reviewed published studies have not been done. Failure to deliver what plastic surgeons promise would compromise the viability of FCGS. Furthermore, if women are harmed, lawsuits could result as well as regulatory action.

Potential customers tend to be unaware of or unfamiliar with a new product or service such as FCGS. Entrepreneurs need to invest heavily in marketing, which has clearly begun, as a cursory Google search (February 7, 2011) for “female cosmetic genital surgery” resulted in “about 375,000 results.” In addition, lacking the economies of scale, the price of a new product or service tends to be high, which usually suppresses demand. Women may be aware of this new service yet remain unconvinced of its importance; perhaps they don’t watch enough pornography to have adopted a standardized view of genitalia or they simply accept individual differences in this private matter. The rate of market growth is unclear, but surgeons are promoting FCGS.

As an immature technology, FCGS may not serve a customer’s needs well. Since results are not necessarily guaranteed, prospective patients could face practical or emotional dilemmas; if the procedure doesn’t work, they may experience constant or intermittent pain and discomfort in sexual relations, perhaps requiring additional surgeries and procedures, at personal expense.

Physical and psychological inconvenience and moral ambiguities tend to suppress demand from potential customers. Some women clearly want “designer vaginas” but other women don’t share a uniform view as represented by the exposed porn star, stripper or images on surgeons’ websites. The aesthetic taste of the public may be fickle; a fashionable view of genitalia may cease its popularity and the fluidity of taste poses a risk to women that select permanent cosmetic changes.

Caucasian women comprise approximately 75% of women receiving plastic surgery in the US in 2009 (American Society of Plastic Surgery, 2010). Appealing to non-white women could broaden the appeal of FCGS.

To leap over the customer demand hurdle, entrepreneurs need to help customers to overcome the fear of physical and psychological uneasiness related to FCGS. Some potential customers with genitalia that interfere with tightly fitting garments (e.g., bikinis, yoga shorts, & tight shorts) may not accept the porn standard but still prefer smaller genitalia. Before and after images are provided by plastic surgeons on the Internet.

A business wants to hire the best practitioners, but will the best and brightest plastic surgery residents seek out FCGS? It’s too soon to know as FCGS is an immature technology.

Gloria Bachmann expresses her concern as a physician that patients might think an abnormality is being addressed and they need to be informed they are receiving cosmetic surgery not reconstruction for abnormal function (Goodman, Bachmann, Johnson, Fourcroy, Goldstein, A., Goldstein, G. & Sklar, 2007, p. 271). Yet if patients anticipate greater sexual gratification, functionality becomes a motivation. How much gratification is realistic might be obscured by the very terminology:

FCGS...includes labia minora reductions, vaginal tightening (“rejuvenation”), labia majora “augmentations”, pubic liposuction (mons pubix, labia majora), clitoral hood reductions, hymen “reconstruction”, perineum “rejuvenation,” and “G-spot amplification.” A confusing array of terms associated with even the same procedure has led to calls for standardized nomenclature in

this area, which eschews terms that are proprietary and strongly linked to commercialized medicine, such as laser vaginal rejuvenation (Braun, 2010, p. 1393).

A special source of revenue for this type of business could rest in the intellectual property opportunities. Some enterprises are already establishing their niche and are ready to license training to other practitioners. The business would have to consider the possible need to license trademarks. Braun (2010) provides an interesting illustration: “One of the surgeons most publicizing of FCGS, Dr. Matlock, appears not to have published anything about his trademarked techniques. However, they are highly marketed using (ostensibly) evidence-based claims about outcomes, and Matlock offers training (for a fee); trained surgeons can then advertise—and use—his techniques” (p. 1401).

Informed consent in medical procedures demands communication of health risks and what can and cannot be achieved. In 2007, six physicians with experience in “vulvar health” submitted opinions about how physicians should be guided in dealing with patients in the *Journal of Sex Health*. Michael P. Goodman stressed the importance of respecting the patient’s wishes, so long as the patient’s desire is not superficial (losing a “boyfriend”), but also admits, “Because the purpose frequently is ‘to be tight and bleed,’ an effective procedure is often the opposite of the meticulous surgery we would hope for: remove a wedge, retighten, and hope for as much scar tissue as possible to produce tearing and bleeding with next coitus. Egad! Not the type of surgery I’d like—but maybe just what the patient wants!” (Goodman, et al., 2007, p. 270).

Andrew T. Goldstein and Gail R. Goldstein described four areas for ethical concern: autonomy (patient choice not influenced by outsiders or physicians); non-maleficence (medical standard of care), beneficence (professional delivery of right patient outcome), and justice (equitable use of resources; cost of such elective procedures is carried by each patient and not borne by society through insurance plans) (Goodman, et al., 2007, pp. 272-273). Inadequate knowledge could compromise informed consent because FCGS is too new to anticipate the consequences (Braun, 2010).

What is in a woman’s best interests might not even be properly guided by current medical views on women’s sexual health. The New View Campaign (2010), mentioned above, argues that women and men have different sexual needs, women’s needs not being adequately recognized by prevalent medical standards. The New View Campaign would redirect attention to four main areas where sexual problems could be generated by the socio-cultural, political and economic context; partner relationships; psychological factors and medical factors. (See New View Campaign, Manifesto, 2010). What the New View Campaign decries as the medicalization of sex could, in some respects, be called the disempowering of physician ethics: the power of physicians to give or withhold medical intervention for the sake of avoiding harm, compromised by the pressure for profits. Profit-making is already a motivating factor for physicians.

Sklar warns (Goodman, et al., 2007) of using patient satisfaction as a gauge rather than medical benefit. FCGS could conceivably make people feel better psychologically but the surgery could result in untold harm later (pp. 274-275). Margins of risk acceptable in a utilitarian analysis might not be acceptable to an ethical physician (Liao, et al., 2009, quoted in Braun, 2010, p. 1400). The development of competitive and ethical alternatives through such a concerted effort may well be possible only through oversight, which is absent or ignored (e.g., ACOG) by the surgeons.

### *Ethics and Oversight*

There is no federal or state legislation that prohibits or limits FCGS as yet in the United States. The FDA doesn’t regulate such procedures. However, there is no assurance that federal or state legislatures won’t regulate or even ban forms of FCGS in the future. Representatives from various feminist groups may eventually voice their objections and be heard. Ethical controversies cast doubts on the legitimacy of the FCGS business. Plastic surgeons performing it don’t feel constrained but the ACOG advised against the practice, as mentioned above. LaSandra Cooper, Senior Media Relations Associate of the American Society of Plastic Surgeons (ASPS) stated (email, November 1, 2010): “The ASPS has not released a formal position or statement on these procedures. We largely concur with the ACOG statement and defer to our OB-Gyn colleagues as these procedures are primarily in the scope of practice of the gynecologist.”

Fraudulent marketing could invite interventions from the Federal Trade Commission or pose dangers by attracting patients who are not good candidates for the surgery, perhaps for psychological reasons, bringing in public health agencies for oversight. Fraud, the intentional misrepresentation of material facts coupled with justifiable reliance by the patient, could be hard to prove; after all, everyone understands that promotional marketing celebrates the promise less than it discloses the risks and flaws. Television or radio ads extol the virtues of products and then quickly in nearly unintelligible voices or tiny print explain the risks. Braun (2010, p. 1398) reports “one group of surgeons” proclaimed a woman that had an FCGS procedure done later married a professional golfer. One wonders whether the union would have been reported had she married a caddy. Advertisements promising greater happiness are common; such claims are known as ‘puffing’ and they are legal. For FCGS, is the trust often placed in the medical profession being exploited? Claims of improved sexual pleasure and psychological well-being appear in the advertising for these procedures (Braun, 2010, pp. 1398-1399), but FCGS could damage highly sensitive nerve fibers contained within the labia minora, which are linked to sexual arousal and compromise sensitivity. Doctors warn of damaged labia (Triffin, 2010).

An ethical view in favor of FCGS reasons that such choices, however questionable in terms of risk, are essential to the constitutional right to privacy. A person has a right to express oneself with one’s body. The right to privacy under the United States Constitution has been interpreted by the United States Supreme Court to be concerned with issues involving family planning and personal decisions about intimate relationships (e.g., *Griswold v. Connecticut*, 1965; *Lawrence v. Texas*, 2003). Desires to reconstruct genitalia could easily be related to such privacy interests, particularly since sexual relationships, not just personal image, are implicated.

Entrepreneurial plastic surgeons would ideally frame or reframe their business in favorable ethical, philosophical, or even religious principles or terms. However, it would seem difficult to frame support for FCGS in this context. The frame commonly used is the desire to have genitalia that would be attractive to a porn star or stripper or at least not obviously visible in a bikini.

#### *Could FCGS Undermine the Experience of True Beauty?*

The emphasis on sexuality in modern culture drives aesthetics away from appreciation (and judgment) of beauty and toward anything that promises sensual excitement, eroticism becoming an easy standard for maximizing pleasure. The goal is not to be admired for beauty but to be admired as a sexual object. The aesthetics of FCGS are intertwined with its marketing (Triffin, 2010). That which is aesthetically pleasing is not necessarily beautiful; indeed, it may be just the opposite.

Defining beauty is, as Socrates noted, an arduous task, and even aesthetic theory, dealing with the arts, has no settled definition of the beautiful. However, philosophers and scholars have identified significant features that beauty displays. Beauty can help humans identify whatever is appropriate and good (Plato, *Hippias Major*). Beauty, the object of love, is related to perception and appreciation of perfect ideal forms that can be glimpsed in the imperfect realities of human existence (Plato, *The Symposium*). These propositions do not suggest that a woman’s beauty should be measured by how much carnal desire she provokes.

Scarry (1999) argues that beauty draws humans outside of themselves, allowing the experience of loving that which is the other. To encounter beauty is to long for that which is beyond the self. Beauty offers a vision of harmony, order, and truth that stimulates longing to find beauty in many things, which necessarily develops what Scarry describes as lateral disregard, the capability that allows beauty and its illuminating experiences to be sought in other places even where one might least expect to find it.

Cope (2007), in “Beauty: An Essential Characteristic of Civilized Culture,” concludes that someone without an ability to judge beauty will not be exposed to values that transcend the political, economic, and cultural spheres and will lack discernment in the face of conflicting demands. A holistic view of beauty enhances critical thinking. Elliot (2003) cautions that in America, excessive preoccupation with one’s looks or personality can result in failing to meet demanding expectations of how one presents oneself.

Incorporating aesthetics through artificial means not just into material things but into the body itself manipulates the way that beauty is experienced and understood and the way the body is experienced and understood as well. Is this a world where to function well is to exude sexuality? Braun writes:

Psychology provides a moral justification for cosmetic surgery, rendering it acceptable. Through reference to psychology, even aesthetic procedures can be reframed as about functionality and as a legitimate way to move beyond bodily distress. For instance, breast augmentation surgery has been identified as “a means of establishing congruency between the body and mind, or developing and embodied self that was comfortable” (2010, p. 1399).

Prospective patients, concerned that physicians might doubt their simple desire to look sensually erotic, may try to stress physical discomfort, answers that will result in approval being medically-indicated (Braun, 2010, p, 1399).

The Scottish philosopher Hume explained the human desire people feel to become whatever society will admire or envy. Unlike Aristotle’s ideal person anxious to contribute to a society that appreciates justice, compassion, temperance, and a well-lived life, Hume’s ideal person imitates what society deems attractive. MacIntyre explains:

Aristotle’s presupposed social context is one in which evaluation is primarily in terms of the achievement of the ends of activity; Hume is one in which evaluation is primarily in terms of the satisfaction of consumers. The individual envisaged by Aristotle engages in practical reasoning not just *qua* individual, but *qua* citizen, of a *polis*; the individual as envisaged by Hume engages in practical reasoning *qua* member of a type of society in which rank, property, and pride structure social exchanges (1988, p. 298).

Gever’s observations about the philosophical aspects of cosmetic surgery focus on Kant and Hume and bear quoting at length:

Following Kant, one aspires to metaphysical, universal, categorical virtues and suffers from guilt when unable to measure up. The alternative morality, theorized by Hume, is more pragmatic, based on what he regarded as natural virtues exemplified by social norms. The kind of moral opprobrium this system inculcates is shame, which comes about when one is excluded or ridiculed by others. Of course, shame understood as inadequate self-esteem also describes the feelings that motivate many to undergo cosmetic surgery (Gever, 2010, pp. 117-118).

What others ‘see in me’ in the blink of an eye may come to matter more than virtue. Cosmetic surgery responds directly to individuals competing to be the most beautiful (Healy, 2004). When physicians portray images of what constitutes good-looking female genitalia (Braun, 2006), society is urged to question all beauty in nature: perhaps nature is not really beautiful at all. Society might begin to expect a prescribed standard to resolve the question of beauty. Ease of reference to some authority displaces the individual analysis of beauty that could lead to moral growth.

Personal preferences of physicians who are unaware of the range of normal labial size could result in unnecessary surgery and risk (Braun, 2010, p. 1402), and “ideally, assessment should not be conducted by those with fiscal interest in the outcome” (p. 1398). The aesthetic notions informing these practices run into the ground the natural diversity of female genitalia (Braun, 2006).

Pornography has been identified as one of the sources women use when they discuss their desire for designer vaginas with plastic surgeons. But pornography leads to a degrading objectification of humanity, and the more pornography seizes from healthy sexuality, the more it portends disaster for loving relationships. Women have a right to equal treatment for women but such equality of treatment is at risk when they are treated as fungible objects whose basic humanity can be ignored while their utility as sexual objects predominates as in pornography.

For Nussbaum (1999), sex is not what causes objectification of sexual others resulting in their loss of humanity. Rather the desire to objectify the sexual other is due to deformed attitude regarding things and people.

Attending to the body and enjoying sexual functions is healthy behavior until happiness is viewed as consisting solely in sex and sexual attraction. Sexuality incorporates objectification, the desire for an orgasm as a desire to fall away from the self into a state of unconscious ecstasy, what poets for centuries

have often compared to a kind of loss of self, a death. Nussbaum, when describing how much sexuality rightly involves “intense focusing of attention on the bodily parts” (1999, p. 233), explains that this kind of mutually shared delight allows partners to become vulnerable and exposed without fear.

Yet when one partner’s feelings are simply those of inadequacy, when the entire sexual act is burdened by fears of how one’s genitalia appear, then healthy attention to bodily functions and parts during sex is converted into an unhealthy obsession. Attention to specific parts of the body allows those parts to insist a woman’s happiness be measured by how many stars are awarded to her for the up close screen shots of bedroom activity. Doctors advocating surgical procedures for genitalia communicate modes of evaluation:

...we’d argue that by offering these services, doctors are sending the message that there’s a right way for a vagina to look. While clicking through images of patients’ genitals on Power Point slides, the speakers made comments like “This is not so pleasant looking” and “Notice the aesthetic improvement.” One even defined cosmetic gynecology as “transforming female external genitalia to an aesthetically pleasing look”—implying it’s unpleasant to begin with. Appearance isn’t the only thing these M.D.s claim their procedures can improve; they also suggest they’ll boost male attraction (Triffin, 2010).

Dangers of objectification of women become evident when one considers Nussbaum’s “seven ways to treat a person as a thing”:

1. Instrumentality. The objectifier treats the object as a tool of his or her purposes
2. Denial of autonomy. The objectifier treats as the object as lacking in autonomy and self-determination
3. Inertness. The objectifier treats the object as lacking in agency, and perhaps also in activity
4. Fungibility. The objectifier treats the object as interchangeable (a) with other objects of the same type and/or (b) with objects of other types
5. Violability. The objectifier treats the object as lacking boundary integrity, as something that it is permissible to break up, smash, break into
6. Ownership. The objectifier treats the object as something that is owned by another, can be bought or sold, etc.
7. Denial of subjectivity. The objectifier treats the object as something whose experience and feelings (if an) need not be taken into account (Nussbaum, 1999, p. 218).

Some of these views of things are appropriate for ordinary objects, discarded when they lose their utility. Yet even inanimate things can merit protection beyond utility. Photographs of loved ones have sentimental value, even when they fade. Pornography presents women as things: tools for sexual excitement, whose own interest, feelings, or activity is meaningless except insofar as their activity contributes to the objectifier’s erotic experience. Women in this context are interchangeable. Women in this context are broken up into their sexual parts. They have no boundaries and are completely accessible, completely destructible at will (See Nussbaum, 1999, pp. 218-239).

The problem with pornography is that the real face, the real person, does not matter: large breasted women can easily be substituted for large-breasted women: women are as fungible as cars, washing machines, and fuzzy toys (Nussbaum, 1999, pp. 234-235). The woman has no life beyond her sexual parts: “For what Playboy [sic] repeatedly says to its reader is, Whoever this woman is and whatever she has achieved, for you she is cunt, all her pretensions vanish before your sexual power. For some she is a tennis player—but you, in your mind can dominate her and turn her into cunt” (Nussbaum, 1999, pp. 235-236).

Even an FCGS enterprise that went to great lengths to avoid pornographic representations would not be able to overcome the influence of the cosmetic industry on women’s perceptions of their bodies. Women might not think they are searching for the porn star; rather, they want the exclusive five-star refurbishment. That could be read into desires for “a ‘neat’ vulva that resembles that of a prepubescent girl, a fleshy but smooth-skinned (and firm) vulva...a ‘nicely’ hooded and ‘contained’ clitoris” (Braun, 2010, p. 1401): innocent and smartly outfitted genitalia, nothing shameful here.

Gever (2010) contends that modern preoccupations with visual media lead inevitably to a propensity to be entranced by mutable appearance as opposed to substance and enduring values.

#### *How Does an Emphasis on Pornography Impact the Legitimacy of the Business?*

Berer (2010) introduces the position of Ivo Pitanguy, the father of reconstructive and cosmetic surgery in Brazil. His philosophy is that there is a right to beauty and harmony with one's own image and surroundings. But a narcissistic preoccupation with the reflection in the mirror can easily result, not harmony (Braun, 2006).

That pornographic magazines and hard-core DVDs might legitimately turn up on the physician's bookshelf alongside Grey's Anatomy is a dismal idea. According to Sklar (Goodman, et al., 2007, p. 274), while professionals differ on the right labial size, the issue of what is normal and abnormal is not resolved by the American Medical Association's distinction between cosmetic surgery (for improved self-image) and reconstructive surgery (to fix abnormalities). Preference for small genitalia in women contrasts with "size matters" for men. A new frontier for standardization of female genitalia adds yet another dimension to potential sources of stigmatization for women, already suffering from the onslaught of Madison Avenue images of artificial beauty.

#### ***SWOT Analysis, Unresolved Business Issues and a Strategic Plan***

To legitimize the FCGS business, plastic surgeons need to analyze opportunities and threats in the external environment and identify their own strengths and weaknesses. However, the only strength appears to be the surgeons' self reports of success. A profound weakness is the lack of peer reviewed research on the techniques employed and their outcomes. An opportunity is the customer base that keeps the surgeons busy and profitable but a real threat exists in terms of regulation and lawsuits from unhappy customers. The unresolved business issues include the following:

1. The technology is not mature in that it has not yet been presented in peer reviewed publications and the professional organizations are disapproving.
2. It's unclear what happens to women that undergo FCGS in the long run. Does sexual satisfaction improve? Is there residual pain?
3. Although regulatory bodies have not yet intervened they may.
4. Women's groups have not yet made their voices heard but they still may.

A strategic plan to legitimate it as a business could involve the following steps:

1. The first step is to perfect the technologies, a pre-requisite to the legitimacy of the business.
2. Entrepreneurs need to respond to customer need. Is there a need beyond a small group of women that accept the porn star standard?
3. They need to identify, develop, and disseminate ethical and legal theories to enhance the moral legitimacy of their business. Beyond privacy what ethical justification is there?
4. They need to ally with other interest groups to lobby elected officials and legislatures to fend off damaging policies and regulations. Would politicians want to support it and risk the wrath of women's groups? It would be difficult to step forward in support of such an unusual practice.
5. With reliable revenue from customers, moral support from ethical theories, and protection from laws and governmental policies, the business would be legitimate. But this is unclear at this point though some women and their surgeons have created a niche market.

#### *Epilogue*

The FCGS business is ongoing. Surgeons hold annual meetings. Eventually the number of procedures performed will be publicized.

## CONCLUSION

In sociological literature, there are three kinds of legitimacy that are considered relevant to the viability of a new line of business: cognitive, normative, and regulatory. Cognitive legitimacy is about whether stakeholders are aware of the needs supposedly to be filled by the proposed business; normative legitimacy is about whether the proposed business conforms to the ethical opinions upheld by the majority of the stakeholders; regulatory legitimacy is about whether regulatory agencies approve the proposed business. More often than not, normative legitimacy decouples from regulatory legitimacy. In the other words, a new line of business that is involved with ethical controversies may be unregulated or even endorsed by regulatory agencies. Consequently, entrepreneurs in this new line of business should focus on perfecting their products or services and on educating stakeholders about the utility of the products or services. In this article, two cases about new medical services are discussed, and a legitimizing strategy is proposed. However, trait selection was shown to be illegitimate as yet and although practiced, FCGS is not supported by the medical establishment and medical ethicists. Yet it is ongoing.

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