

Too Young to Decide? The FDA's Role in Regulating Breast Augmentation in Adolescents

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Abstract: In 2006, the FDA set a minimum age requirement of 18 for saline-filled breast implants and 22 for silicone breast implants. As a result, adolescent women who do not meet the age requirement are unable to receive implants for augmentation or reconstructive purposes. The FDA reasons that the age requirement will allow women sufficient time for their breast tissue to develop and will prevent adolescents from making an emotionally immature decision. This age limitation affects all adolescents considering augmentation procedures whether one is considering augmentation to align with their new gender identity, to enhance their breasts solely for cosmetic reasons, or to gain a new sense of confidence after receiving a mastectomy due to breast cancer. This case explores the purpose, structure, and approval process of the FDA and examines the varying motivations of adolescent women electing to undergo breast enhancement. Is the FDA limiting the population of women that can undergo breast augmentation by setting a legal age requirement for surgery? Does this affect an adolescent's control over her bodily autonomy? How does the legal age requirement affect options available to younger transgender individuals and cancer patients? Do teens consider cosmetic breast augmentation procedures for the right reasons?

Susan and the FDA

After years of disappointment and unfulfilled expectations, Susan's struggles motivated her to act. Since Susan could remember, she had always been uncomfortable with her small breasts and looked forward to finding a solution. At the age of 9, Susan was taken to a family doctor when her breasts began to swell. She distinctly remembers her mother saying, "maybe you are going to get breasts after all" (Davis 1995, 124). To Susan and her mother's surprise, the swelling disappeared, and her breasts were not developing. It wasn't until a summer several years later, when Susan was 17, that she began to consider the possibility of receiving a breast augmentation procedure. While at the swimming pool with her mother, Susan noticed scars running along the sides of her mother's breasts.

So, I asked: "Where did those scars come from?" And she said: "Well, I guess the time has come to tell you. I had my breasts enlarged." "Oh," I said. "Can I have it done, too?" I had already been thinking about it for a while anyway, like whether something could be done for me. And...from then on, we just never stopped talking about it (Davis 1995, 124).

Although Susan's mother was ready to support Susan's decision to receive breast implants, she warned her daughter that the operation was not a perfect solution. Susan's mother also informed her that she comes from "a long line of flat-chested women," all of whom have had breast augmentations. With this newfound information of her family's history with breast implants, Susan decided to consult an aunt who had five breast corrections, all unsuccessful. Despite her aunt's warning against surgery, Susan still wanted to go through with the procedure. She reasoned, "I am a different person and maybe it will work for me" (Davis 1995, 124). Susan relayed her enthusiasm about the possibility of receiving implants to her mother in hopes that she would receive her mother's support and encouragement.

Fortunately for Susan, her mother was encouraging and began to educate Susan about the logistics of the surgery and what to expect. She then accompanied Susan to a family doctor and a plastic surgeon to learn more about the procedure and to discuss the optimal time to undergo the surgery. During this encounter, Susan realized her age "might be construed as problematic" (Davis 1995, 124). Susan was quickly informed by her plastic surgeon that, at age 17, she would not be able to receive silicone breast implants. As dictated in 2006 by the Food and Drug Administration¹ Susan would have to wait until she was 22 to receive silicone breast implants to allow time for her breast tissue to fully develop. Due to the FDA's age restriction, Susan was unable to receive implants as a teenager.

Before I talked to my mother I just thought it would be a lot more difficult, I had no idea how it went. And I thought, yeah, it wouldn't be possible, especially at my age. When I found out about the operation, that's when I started asking around...But I would have taken the step anyway. It just would have been a few years later. I'm sure glad I can do it now, though (Davis 1995, 124-125).

According to Susan, her decision to receive the surgery remained the same five years later and her thought process and emotional maturity regarding this procedure were unwavering between the ages of 17 and 22 (Davis 1995, 120-125).

As a result of the FDA's regulations, Susan was faced with the reality of waiting another five years before receiving her breast augmentation procedure. The FDA's decision to set a minimum age requirement on breast implants was determined in 2006. In a nine to six vote, the FDA set a minimum age requirement of 22 for women seeking breast augmentation surgery with silicone breast implants and 18 for augmentation with saline-filled implants (FDA 2018). The FDA reasoned that since breasts can continue to develop until a woman's early 20s, women should be required to wait until their later adolescent years to ensure the best post-surgical results. Additionally, the FDA was concerned that younger patients wishing to undergo augmentation would not have developed the emotional maturity to make an educated medical decision and would not accurately weigh the possible complications of the procedure. Those in opposition to the age limit argued that it prevented women from making decisions regarding their bodily autonomy (Kessler 1992). In addition to breast implants, the FDA has also set age requirements for treatments such as hormone therapy for transgender candidates seeking sex reassignment surgery, which requires an individual to be 18 years or older.

¹ The Food and Drug Administration is a federal agency of the United States Department of Health and Human Services, one of the United States federal executive departments. It is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biologics, and medical devices (FDA n.d.).

Is the FDA unreasonably limiting the population of women that can undergo breast augmentation by setting a legal age requirement for surgery? Does this affect an adolescent's control over her bodily autonomy?

Evolution of Saline and Silicone Breast Implants

Surgeons first performed breast augmentations in the early 1950s in Japan, but they were not commercially successful until the early sixties. During this time a topless cocktail waitress, Carol Doda, working in San Francisco became an “instant media star in the late fifties when she allowed twenty shots of silicone to be injected directly into her breasts” (Davis 1995, 25). Women's initial enthusiasm for this method quickly faded when physicians started to discover cysts and gradual decaying of the skin in patients who had elected to receive these injections. As a result, new techniques and materials began to evolve during the mid-20th century when breast augmentation procedures were executed using materials such as Teflon, Ivalon sponge, petroleum jelly, beeswax, and liquid silicone. After thousands of procedures, the FDA prohibited the use of these materials in the United States once they were found to cause local tissue reactions, firmness, and breast distortion. Modern breast implants, which began as 2-component prosthetic devices manufactured with silicone elastomer shells filled with stable filling materials such as saline or silicone gel, did not reach consumers until 1962. In response to the popularity of gel implants for augmentation, researchers and plastic surgeons began to approve and support women's decision to receive breast reconstructive surgery in the 1970s due to the changing epidemiology of breast cancer: more women were having more mastectomies² at younger ages and they were living longer after surgery (Jacobson 1998).

Plastic surgeons first used saline-filled implants in France in 1965. Manufacturers developed these implants in order to allow a non-inflated implant to be introduced through a small incision. Although many women elected to use saline implants for augmentation, aggressive overfilling led to a more spherical breast shape and resulted in unnatural firmness. Another disadvantage of “saline-filled implants is that the consistency on palpation is similar to that of water instead of the more viscous feel of natural breast tissue” (Gabriel and Maxwell 2017, n.p.). The number of saline-filled augmentation procedures quickly declined as silicone implants became a better alternative.

In contrast to saline-filled implants, silicone implants proved highly successful at reducing the incidence of capsular contracture, which is a response of the immune system to foreign materials in the human body that cause a wide range of medical complications such as extreme breast pain, scar tissue, and infection. However, the commercial success of silicone implants was not achieved until the fifth-generation of implant models during the late 1990s when the FDA determined that the safety and effectiveness of silicone implants was properly demonstrated. The first generation of silicone gel implants was similar to that of saline-filled implants as they were both found to cause high contracture rates due to the quality of the shells and lack of cohesivity of the silicone gel. These devices were constructed using thick, smooth silicone elastomer as a 2-piece envelope with a seam along the periphery. In order to reduce the incidence of capsular contracture in the second-generation, manufacturers used a thinner, seamless shell and constructed them using a rounder shape with a less viscous gel to provide a more natural feel. Surgeons soon discovered that the second-generation caused bleeding of microscopic silicone molecules due to their thin and permeable shell.

² A surgical operation to remove a breast (Newman 2017).

The third and fourth generations of silicone gel-filled implants were developed in the 1980s and were designed to improve the strength and permeability of the shell. Rather than using a thin-layered shell, manufacturers designed shells consisting of multilayers of silicone elastomer. Although the multilayers of silicone elastomer reduced bleeding, it wasn't until the fifth-generation of gel devices that the FDA concluded that the safety and effectiveness of the device was in accordance to the regulations set by the 1976 Medical Device Amendment³. The fifth-generation focused on the inclusion of a textured surface, which would result in a more anatomically correct shaped implant filled with a more cohesive gel. Finally, after various unsuccessful clinical trials, the FDA approved the fifth-generation as a Class III⁴ device for the three top US manufacturers: Sientra, Allergan, and Mentor. Each manufacturer contributed its own shape and style to their personally designed silicone-gel implant (Gabriel and Maxwell 2017, n.p.).

Understanding Breast Augmentation Procedures and Possible Risks

In the standard breast augmentation procedure, regardless of the type of implant used, “an incision is made on or under the breast. This incision provides access to a retro-mammary space⁵. In the retro-mammary space, the surgeon dissects a ‘pocket’ and then places the implant inside that pocket” (Bircoll 2008, n.p.). Prior to placing an implant in the retro-mammary pocket, the surgeon will remove the implant from the sterile container, fill the implant, and ensure that there are no holes or other deformities present in the implant. The surgeon tests the integrity of the implant by squeezing it in its inflated state. In order to insert the implant, the surgeon then rolls the implant into a tightly-rolled “cigar-like structure, and forces the rolled implant, with the aid of an instrument, into the pocket in the retro-mammary space. Finally, the surgeon fills the implant with silicone or saline through a filling tube with a self-sealing valve before the incision is closed (Bircoll 2008, n.p.).

According to the American Society of Plastic Surgeons, possible breast augmentations surgery risks include bleeding, hematoma, infection, and changes in breast sensation. In a study conducted in 1995, a group of medical doctors followed 87,501 women for 14 years after their implantation. The research team found that 516 women were confirmed as having definite connective-tissue diseases in the breast. However, the researchers concluded that there was no association between silicone breast implants and connective-tissue diseases (Colditz et al. 1995). A similar study was conducted in Olmsted County, Minnesota, where researchers identified complications that occurred after the initial procedure and after any subsequent implantation. The researchers defined a complication as “a surgical procedure performed for any of the following reasons: capsular contracture; rupture of the implant; hematoma or bleeding; infection or seroma of the wound; chronic pain; extrusion, leakage, or sweating of the implant; necrosis of the nipple, areola, or flap; and wound rupture. Through the study, researchers discovered that complications occurred in 24% of women observed. The most frequent problem was capsular contraction, followed by plant rupture, hematoma, and wound infection. However, many of these complications occurred within 5 years of the procedure and were less “frequent among patients

³ Prior to the passage of The Medical Device Amendment of 1976, Congress debated how to best ensure that consumers have access, as quickly as possible, to new and improved medical devices and, at the same time, prevent devices that are not safe and effective from entering or remaining on the market. The Amendment dictated that the FDA classify all medical devices that were on the market at the time of enactment into one of three classes based on risk (low, moderate, and high risk) (Johnson 2016).

⁴ Class III devices are considered high risk and include heart valves and breast implants (FDA 2018).

⁵ Retromammary space is a loose areolar tissue that separates the breast from the pectoralis major muscle. It is often the site of breast implantation due to its location away from key nerves and structures that support the breast (Bircoll 2008).

who received implants for cosmetic reasons than among those who received implants after mastectomy for cancer or for cancer prophylaxis” (Gabriel, Woods, and O’Fallon 1997, n.p.). Regardless of the type of implant, plastic surgeons advise their patients of these known risks and complications, emphasize the ephemeral nature of breast implants in that they are not guaranteed to last a lifetime, and inform patients that future surgery may be required to replace one or both implants.

In addition to these risks, more complications are present for adolescent candidates who elect to undergo breast augmentation procedures. One of the main concerns about plastic surgery on younger women is that their bodies are still developing. The average girl gains weight between the ages of 18 and 21, and therefore, according to the FDA, it is likely she will change her desire for breast augmentation during this crucial developmental time due to the positive correlation between weight gain and breast size. Also, since breast implants typically last 10 years, an adolescent will need repeated surgeries throughout her lifetime. Breast implants also can increase the chances of insufficient lactation when a woman tries to breastfeed after giving birth, which is a relevant consideration for adolescents seeking to have children in the future (Zuckerman 2005).

FDA Evaluation Process

The FDA is divided into three main units: The Center for Drug Evaluation and Research (CDER), the Center for Biologics⁶ Evaluation and Research (CBER), and the Center for Devices and Radiological Health (CDRH)⁷. Each of these three units is assigned to evaluate new drugs, biologics, or devices, depending on their specified concentration. Breast implants are evaluated under the Center for Devices and Radiological Health and follow the evaluation process as specified by the medical device unit. In order to be legally marketed in the United States, medical devices are subject to review by the FDA. Medical devices are classified into one of three risk-related categories, as required under the Medical Device Amendments of 1976, which provided the FDA with three defined classes of medical devices based on the risk to patients posed by the devices (Johnson 2016). Class I devices are regulated using the FDA’s specific guidelines of the listed general controls, which are “sufficient to provide reasonable assurance of safety and effectiveness of a device” (National Academy of Sciences 1992, n.p.). General controls allow the FDA to prohibit misbranded devices, ban certain devices, restrict the sale, distribution, or use of certain devices, and require annual records, reports, and inspections. Class I devices are “low risk” and include elastic bandages, hand-held surgical instruments, and examination gloves. Similarly, Class II devices are also subject to general controls.

Yet, unlike Class I devices, Class II devices must also adhere to potential regulation by “special controls,” which include special labeling requirements, mandatory performance standards, and post-market surveillance (Johnson 2016). Class II devices are considered to be of moderate risk to patients and include devices such as powered wheelchairs, infusion pumps, and surgical drapes. Class III devices, which includes saline and silicone breast implants, require well-controlled investigations and other appropriate tests to provide assurance of the device’s safety and effectiveness. Regardless of the device’s class, all submitted products must provide

⁶ Biological products are regulated by the FDA and are used to diagnose, prevent, treat, and cure diseases and medical conditions. Biological products, such as vaccines and therapeutic proteins, are a diverse category of products and are generally large, complex molecules. These products may be produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell, and are often more difficult to characterize than small molecule drugs (FDA n.d.).

⁷ The Center for Devices and Radiological Health is responsible for protecting and promoting public health by ensuring the patients and providers have continued access to safe, effective, and high-quality radiation-emitting products (FDA n.d.)

premarket notification to the FDA explaining the sponsor's desire to market the device. The FDA will then proceed to evaluate the device, according to its class criteria.

FDA Advisory Committee

During President Reagan's administration, Congress passed a final rule on New Drug and Antibiotic Regulations (NDA) to improve the evaluation process of drugs, biologics, and devices⁸. As a result of this new policy, the FDA agreed to use outside experts, as they believed experts would "add to the quality and credibility to the decision-making process" (National Academy of Sciences 1992, n.p.). The FDA supported the decision to include outside experts for the purpose of supplementing the agency's internal expertise and helping the agency staff remain up-to-date with advancing technology by encouraging the collaboration between staff and trusted professionals. Additionally, advisory panels would provide grounds for public discussion on pressing consumer concerns (National Academy of Sciences 1992). However, ultimately it is the FDA, not the advisory committee, who has the final say on whether a product will eventually reach the market.

The Advisory Committee is comprised of individuals in the medical field whose expertise include human and veterinary drugs, vaccines, food, and medical devices. As a committee, their main role is to supplement the FDA's decision on whether a product should be warranted for general consumer use or whether certain restrictions on products should be enforced, such as the case with age requirements for breast implants. Typically, the advisory panel includes a chair, several FDA members, a consumer, industry, and a patient representative. Experts with special knowledge of the particular product under evaluation may also be invited to weigh in on committee decisions. Although not officially apart of the committee, Congress and the public aid in the screening for conflicts of interest and the use of waivers for some conflicts.

Teenage Motivations for Breast Surgery

Despite the age restrictions set by the FDA, there are a variety of reasons that motivate young adolescents to desire breast augmentation procedures once they are of age. Breast augmentation is the most popular cosmetic procedure that adolescents want (Zuckerman 2005) due in part to the "media playing an essential role in making it acceptable for an ever-growing population" (Davis 1995, 18). Magazines like *Vogue*, *Cosmopolitan*, and *Self* regularly feature advertisements for cosmetic surgery and often contain "personal testimonies of the 'before' and 'after' variety, which depicts women's experiences with various kinds of operations" (Davis 1995, 19). As a result, adolescents compare their bodies to those of their peers and celebrities portrayed in popular media, which may include changing clothing or hairstyle and, for some, surgical transformations (Corcoran and Jordan 2013, 68). Once a teen receives affirmation from her peers, it's likely that her psychological need for a bodily transformation will increase substantially. For example, "a teen may wear a padded bra and receive compliments on her dress, thus reinforcing an already existent belief that larger breasts would make her more attractive" (Corcoran and Jordan 2013, 68). Peers and media influence a teen's acceptance of cosmetic surgery and aid in its portrayal as a simple and "no big deal" procedure. A New York plastic surgeon, Dr. Norman Rowe, estimates that her practice consists of 20-30% of women in their late

⁸ Prior to the final rule on the NDA, applicants were submitting low-quality applications, which delayed the approval of many drugs, devices, and biologics. The new ruling was made to improve the efficiency of the agency's drug approval process and to improve the agency's dealings with applicants for marketing approval of new drugs and antibiotic drugs. The improvements help applicants prepare and submit higher quality applications and permit the FDA to review them more efficiently with fewer delays (US National Library of Medicine National Institute of Health 1982).

teens and early twenties, saying, “With the young patients I think that they just have to make sure it’s what they want and not a knee-jerk response and not keeping up with what whoever is doing” (Wischhover 2015, n.p.).

Celebrities also play a significant role in an adolescent’s decision to undergo cosmetic surgery. Many adolescents “exhibit some degree of celebrity worship⁹...and there exists a positive correlation between celebrity worship and the acceptance of cosmetic surgery among females” (Corcoran and Jordan 2013, 68). Clinical psychologist Dr. Judy Rosenberg believes teenagers seek cosmetic surgery as a mechanism to deal with emotional issues such as confidence and self-esteem:

Our culture makes it so socially acceptable to seek plastic surgery, and because celebrities create the idea that if you are beautiful and perfect you will be rich, famous, and loved, teens easily associate this plastic surgery “solution” as a pathway to feeling better (Olya 2015, n.p.).

This correlation between celebrity worship and increased rates of cosmetic surgery stems from sociocultural theories of body image, which “suggest that body dissatisfaction results from unrealistic societal beauty ideals, and one way of transmitting these ideals is through the mass media” (Hargreaves and Tiggemann 2004, n.p.). Body dissatisfaction especially affects girls during adolescence since body image becomes one of the most important aspect of an adolescent girl’s self-esteem. This dissatisfaction results from current unrealistic standards of female beauty which place emphasis on thinness coupled with large breasts. These images help to explain the popularity of breast augmentation procedures among teenage girls (Hargreaves and Tiggemann 2004).

Lauren, who is 25 and is a size 32A bra, thought of getting a breast augmentation when she was only 16, but changed her decision after listening to her mother’s advice:

I wanted to do it when I graduated from high school. My boyfriend had broken up with me and he had always made comments about how little my boobs were and the stuff I could do to make them bigger. Then I thought, “Yeah he is kind of yucky for pressuring me” (Wischhover 2015, n.p.).

Lauren’s mother asked her whether she “wanted to be with a guy who only wants to date [her] because [she has] big boobs” (Wischhover 2015, n.p.). After taking time to consider her mother’s contrasting perspective, Lauren decided not to receive breast implants: “I can pretty much wear anything and now I never have to wear a bra. It’s wonderful and I save a ton of money” (Wischhover 2015, n.p.). Lauren recognized her initial motivations for receiving implants were shortsighted and no longer views breast augmentation as a viable solution.

Perspectives of Feminist Clinical Therapists

The increase in cosmetic surgery in the U.S. makes the decision to undergo surgeries such as breast augmentation seem “normal” and discourages many women from thinking twice about electing to undergo this procedure. Women of all ages who are unaware of the alarming statistics regarding the number of cosmetic surgeries performed per year in the U.S., often times

⁹ “Celebrity worship” is defined as a parasocial, or one-sided relationship, wherein an individual admires or identifies with a celebrity (Corcoran and Jordan 2013, 68).

seek the advice of clinical therapists whom they hope will help them understand their motivations underlying their decision for cosmetic surgery. Prior to undergoing a body transformation, many apprehensive women make an appointment with female therapists who specialize in helping women decide whether they are electing to receive cosmetic surgery for the right reasons. Feminist therapists promote the core belief that gender socialization shapes one's behavior and therapists utilize this premise to ask a client a series of questions, such as whether she thinks gaining conventional beauty will bring new love into her life or keep an old love alive, in order to unravel why women want to change what is normal about their bodies (Dingman 2012).

Feminist therapists discourage surgeries such as breast augmentation as they believe women choose to undergo the procedure for the wrong reasons. "Feminist critics of cosmetic surgery once focused on beautification, but now they address cosmetic surgery as an identity intervention" (Dingman 2012, 187). In other words, feminist critics of cosmetic surgery attempt to determine whether women feel a surgical transformation will change how they view themselves by improving their overall self-confidence. Cosmetic surgery attracts women who are willing to invest in correcting flaws with the hope on the part of surgeons that these consumers will want more correction afterward and various additional procedures (Heyes 2007). Breast augmentation surgery promises its recipients that it will transform their appearance, but according to feminist critics, neglects to point out that this transformation is by no means permanent.

In order to address these complex and multi-dimensional facets, a feminist therapist first seeks to understand why a client is seeking therapy. Once the therapist identifies the initial reason for their visit, which usually relates to feelings of inadequacy and discomfort with body image, a feminist therapist determines whether the client is looking for validation of the logic she used to arrive at the decision, or whether she wants to be talked out of her decision to receive this surgery. Therapists can then proceed to treat any underlying issues. Some of these treatments include unplugging the television, removing mirrors, and spending time contemplating how valuable a woman is to herself, her family, and society (Dingman 2012).

Young Cancer Patients and Breast Augmentations

Although many women elect to receive breast augmentations solely for cosmetic reasons, other women view this procedure as a momentous step in combatting their fight with cancer. The history of reconstructive surgery of the breast is closely correlated to the history of breast cancer. Plastic surgeons worked since the late 1800s to find procedures that reduced the extent of scarring and restored the image of the breast in response to the "[increasing] trend toward women undergoing mastectomy at younger ages, combined with the perception that breasts were most important to young women" (Jacobson 1998, 1256). Mastectomies coupled with augmentation became popular in the 1970s, around the time of the development of silicone breast implants, after a series of "psychological studies had developed the idea of a postmastectomy syndrome marked by anxiety, insomnia, depressive attitudes, occasional ideas of suicide, and feelings of shame and worthlessness" (Jacobson 1998, 1257). Researchers identified these symptoms due to a sense of mutilation and loss of feelings of femininity following mastectomy and found that women suffered more psychological effects from losing their breasts than they did after being diagnosed with cancer (Asken 1975). Physicians perceived the need for reconstruction among cancer patients to be psychological as women felt treatment for femininity was essential after they had been damaged by surgical mutilation. Cancer patients

were portrayed as “psychologically healthy, but needing this procedure to recover from the physical disease. Support from politically powerful groups of breast cancer activists—who had successfully tied increased federal funding for research with official recognition of the personal suffering of breast cancer patients—added legitimacy to this argument” (Jacobson 1998, 1258).

Though breast cancer is rare among younger women, it has been reported to occur in 4% of women under the age of 30 (Kong 2017). According to a 2015 Rethink Breast Cancer report, “young women have more aggressive forms and stages of breast cancer,” meaning they also require more aggressive forms of treatment, and are more likely than older women to experience depression, body image, anxiety, sleep, and marital dissatisfaction (Kong 2017, n.p.). Young women also are faced with many non-medical challenges that other diagnosed women may not be as prone to, such as dating challenges and problems with fertility. After receiving a mastectomy, only women 22 years of age or older are offered the option of receiving an augmentation procedure with silicone implants due to the age requirements set by the FDA.

Just eight weeks prior to her 21st birthday, Bianca Innes was diagnosed with Grade 3 breast cancer. Only seven weeks after her diagnosis, the cancerous lump had tripled in size. She was the youngest patient, with no family history of cancer, her doctors had ever seen:

At the time I was just devastated, I was thinking “how has this happened to me?” I’m only 20, I’m at a university and I’m so happy and healthy, and now I have cancer. I’ve learned to be really positive about it because I can’t change it. It’s turned my life upside down and changed me for the better. It’s allowed me to just live each day (Gillespie 2017, n.p.).

Out of the 266,120 women diagnosed with breast cancer each year, only eight will be between the ages of 20 and 24. At only 20 years old, Bianca was one of the few victims. At the age of 20, a breast cancer patient will experience side effects from chemotherapy, including nausea and possible infertility, and a sense of isolation from her peers. Bianca expressed her devastation after losing her hair from chemotherapy:

When you’re 20 you go out with your girlfriends and you spend hours doing your hair and makeup. It started getting to the stage where my hair was just falling out in clumps and it was just devastating. My dad shaved my head for me, and it was so hard (Gillespie 2017, n.p.).

Unlike other women her age, Bianca was faced with other challenging decisions, such as whether to improve her chances of survival by receiving a mastectomy. Yet, if she decided losing her breasts was the best option medically and emotionally, Bianca would have to wait another two years before she would be eligible for an augmentation procedure. The perceived loss of femininity is one of the hardest moments in a woman’s cancer battle. After losing her hair, Bianca was faced with the decision of whether she should elect to surgically remove her breasts, knowing that she would not be able to receive an augmentation procedure with silicone implants until she turned 22.

Adolescent Transgender Candidates for Breast Augmentation

With increasing awareness of gender dysphoria, the stigma surrounding sex reassignment surgery has begun to decrease in the United States. Current statistics estimate that gender

dysphoria occurs in almost 10% of the U.S. population (Morrison et al. 2016). As a result, more patients are starting to seek medical and surgical transition. Chest surgery, specifically, has become one of the most commonly performed gender reassignment surgeries. Chest surgery has been performed on transgender candidates since 1988, when the first sex reassignment surgery, a vaginoplasty coupled with a breast augmentation, took place (De Cuyoere 2005). Plastic surgeons have found that chest surgery can greatly increase the confidence and self-esteem of transgender individuals. For most transfeminine patients, breast augmentation (or breast reconstruction) greatly increases subjective feelings of femininity since mammoplasty provides a more feminine profile, facilitating adjustment to the gender identity (Claes, D'Arpa, and Monstrey 2018, 369-370). In accordance with this phenomenon, results of cohort studies have shown that the “gains in breast satisfaction, psychosocial well-being, and sexual well-being after augmentation are statistically significant and clinically meaningful to the patient shortly after surgery as well as in the long term” (Claes, D'Arpa, and Monstrey 2018, 370). Many plastic surgery programs now require some degree of training and education on transgender care to ensure that these candidates for chest surgery receive support from their physicians during their transition journey.

After consulting a plastic surgeon and informing them of their decision to receive top surgery, a transgender patient is evaluated on whether they have well-documented gender dysphoria, the capacity to make a fully informed decision and to give consent for treatment, and if they are of age. The capacity to make a fully informed decision and to give consent for treatment is used to evaluate non-transgender patients as well. This criterion, set by the World Professional Association of Transgender Health Standards of Care, also encourages feminizing hormone therapy 12 months prior to breast augmentation surgery. The hormone therapy treatment will only result in softly pointed breasts, as seen in young girls, will not cause full breast development, and include possible medical consequences such as weight gain, sleep apnea, blood clots, and infertility (Claes, D'Arpa, and Monstrey 2018, 370). Therefore, augmentation mammoplasties¹⁰ are the only alternative for transgender individuals to fully develop breasts during their transition.

Similar to breast implants, transgender individuals are unable to receive sex reassignment surgery (SRS) and hormone therapy until they are at least 18 years old. Although the FDA does not regulate SRS, it does set age limitations on when transgender women and men can receive testosterone or estrogen therapy. The clinical management of transgender and gender non-conforming youth “is a growing area in pediatric endocrinology and adolescent medicine with multiple questions and challenges” (Montano 2016, n.p.). Many medical and ethical aspects surround the issue of what risks are present in delaying transition until adulthood, whether children and adolescents are capable of making life-changing decisions, and what long-term psychological and medical consequences are of puberty suppression and cross-sex hormones¹¹. Available studies indicate that the incidence of mental health problems, such as anxiety, depression, and thoughts of suicide, among transgender and gender non-conforming youth is higher than in cisgender youth. This statistic emphasizes the struggles transgender youth encounter when they are unable to live as the gender with which they identify. In fact, “studies showed that transgender adults going through transition had worse baseline mental health than

¹⁰ Breast augmentation—also known as augmentation mammoplasty—is a surgery to increase breast size (Mayo Clinic Staff 2018)

¹¹ Cross-sex hormones—like estrogen and testosterone—is a form of hormone replacement therapy in which sex hormones and other hormonal medications are administered to transgender or gender non-conforming individuals to more closely align their secondary sexual characteristics with their gender identity. Risks include: pulmonary emboli, blood clots, gallstones, elevated liver, enzymes, weight gain, male pattern baldness, sleep apnea, and infertility (Montano 2016).

did transgender adolescents going through transition” (Montano 2016, n.p.). The reason for this discrepancy may be due to the increased exposure of gender dysphoria, harassment, and discrimination that transgender adults experience as a result of waiting longer to receive SRS. Medically, some surgical procedures are more difficult to perform on a fully mature adult, such as breast removal surgery for a trans-male.

Additionally, not all adolescents reach their developmental milestones at the same age. A 14-year-old may be more cognitively functioning and advanced for their age in comparison to an 18-year-old, who may lack these skills. As a result of this variation, “an interdisciplinary team including clinicians and behavioral/mental health experts should help individuals through the process of characterizing their self-identified gender identity and support their eventual transition” (Montano 2016, n.p.). Although long-term data are not available to determine the optimal age for transition, some believe children and adolescents should have the ability to make these important decisions regarding their gender identity (Montano 2016, n.p.). In order to help minimize psychological consequences for children with gender dysphoria, clinicians recommend focusing on social, rather than physical, transition. For example, using the preferred name and pronouns along with gender-specific clothing and hairstyle can allow time for the child to confirm whether they want to proceed with SRS when they are older.

A 31-year-old transgender male, Charles Thomy, reflects on his emotional transition journey, which began after he graduated college:

At the end of this week, I will turn 31. I never thought I’d make it through my twenties, much less reach my golden birthday. In my 31 years on this earth, I have embodied many genders. I have lived two-thirds of my life as a female and a third as male. I graduated from high school as a girl and from college as a guy; those five years were the most difficult yet joyous and rewarding of my life. For 20 years, I was ashamed of how I felt and stuffed down what I thought was a terrible secret, only to be met with open arms and discover affirmation, validation, and love. After going through all of this—changing my name, my body, my presence in this world and the way I navigate it, I can just say that I feel human. And I know what it means to be alive (New York Times 2015, n.p.).

Like Susan, Charles also was required to wait until his college years before receiving his desired surgery. As previously referenced, Charles endured embarrassment, uncertainty, and shame for 20 years before he was physically able to change his body to coincide with his new gender identity.

Is the FDA rightly limiting the population of women that can undergo breast augmentation? How does the legal age requirement affect options available to younger transgender individuals and cancer patients? Do teens consider cosmetic breast augmentation procedures for the right reasons?

Who Should Decide?

The decision to receive a breast augmentation is a particularly challenging decision for adolescents, transgender women, and women recovering from breast cancer. Different medical and emotional consequences arise due to the many considerations and situations that would prompt a woman to consider breast implants. For Susan, having small breasts decreased her self-esteem and caused her to feel less confident around her family members who had all received breast augmentations. In contrast, Lauren was relieved that she was forced to wait to receive

breast implants, due to the age requirement, as she was only considering the procedure to please her boyfriend. After becoming of age, Lauren decided not to receive implants and, years later, states that she has not regretted her decision. At only 20 years old, Bianca was faced with the decision to receive a mastectomy after being diagnosed with breast cancer. Although the outcome of Bianca's story is unknown, if she decided that losing her breasts was the best option, Bianca would have to wait another two years before she would be eligible for silicone implants. Unlike the first three women, Charles had to wait years in order to begin his transition journey and suffered emotional trauma during his high school years as a result of not being able to start hormone therapy until he was of age.

This case explores whether or not a governmental agency has the right to make decisions regarding a woman's bodily autonomy. It analyzes how the specific women highlighted here felt prevented from making their own choice regarding whether or not to receive a breast augmentation procedure due to the specific guidelines and limitations set by the FDA. This case highlights the restrictions of governmental organizations like the FDA on women's autonomy regardless of whether a woman wants a breast augmentation for cosmetic reasons or whether she wants to regain the confidence she lost after suffering from breast cancer.

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