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## Can I See Some ID? Banning Access to Cosmetic Breast Implant Surgery for Minors Under Eighteen

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# CAN I SEE SOME ID? BANNING ACCESS TO COSMETIC BREAST IMPLANT SURGERY FOR MINORS UNDER EIGHTEEN

KATHERINE COHEN COOPER\*

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## I. INTRODUCTION

Under U.S. law, parents are granted broad power and control over their children's bodies. In the healthcare setting, the law vests parents with decision-making authority for most medical decisions.<sup>1</sup> This general rule applies when minors seek to undergo body modification through cosmetic surgery, such as breast implants.<sup>2</sup> Thus, a consenting parent who finds a willing provider to perform breast implant surgery on a minor can authorize this invasive, but elective, surgery on the child's behalf.

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<sup>1</sup> *Parham v. J.R.*, 442 U.S. 584, 603 (1979) (noting that "parents can and must make" medical decisions regarding their teenage children); *see generally* Lawrence Schlam & Joseph P. Wood, *Informed Consent to the Medical Treatment of Minors: Law and Practice*, 10 HEALTH MATRIX 141, 148–52 (2000) (explaining that doctors must obtain parental consent prior to performing most medical procedures on minors).

<sup>2</sup> Diana Zuckerman & Anisha Abraham, *Teenagers and Cosmetic Surgery: Focus on Breast Implant and Liposuction*, 43 J. ADOLESCENT HEALTH 318, 322 (2008) (stating that an adolescent under eighteen can undergo cosmetic surgery, including breast implants, as long as there is parental consent).

Omnipresent media reports and other cultural portrayals of cosmetic surgery performed on youth indicate that the parental authority to consent to breast implant surgery on behalf of minors is real and exercised, rather than simply theoretical. One news report, for example, profiled several teenaged girls who received breast implants.<sup>3</sup> These teens were sometimes offered breast implants as gifts from parents to celebrate a momentous birthday or a graduation.<sup>4</sup> Others indicated that their parents had consented to the procedure to help the teen remedy issues with low self-esteem, or to improve her overall happiness.<sup>5</sup>

Regardless of what motivates parents to consent to breast implant surgery for their children, the available data show that parents are doing so in growing numbers. For example, between 2010 and 2011 the number of breast implant surgeries performed on young women ranging from ages thirteen to nineteen increased four percent.<sup>6</sup> In a nation where hundreds of thousands of breast implant surgeries are performed each year across the general population,<sup>7</sup> year-to-year increases of this magnitude can equal thousands of additional surgeries performed each year.

In many situations it is perfectly reasonable, and in fact preferable, to allow parents to consent to medical interventions on the behalf of their minor children. Parents enjoy a constitutional liberty interest in directing the upbringing of their children; it is presumed that parents will act in the best interests of their children when they substitute their experiences and judgment for a child's in making important life decisions.<sup>8</sup> This article highlights, however, that when it comes to providing consent for their children to undergo medically unnecessary breast implant surgery, the rationales underlying the presumption of deference to parents and medical providers fail. Because there are reasons to believe this traditional consent framework will not protect the best interests of minors who seek breast implants, this article argues that it is appropriate for the federal government to mandate a national minimum age of eighteen for receiving breast implants.

This article begins in Part II by providing a brief background on breast implant surgery and its prevalence amongst minors. Part III outlines representative situations in which the federal government sets a national minimum age for access to products or procedures that can be unsafe for minors. Part IV illustrates scenarios where national age minimums are not deemed appropriate. Part V explores the rationales underlying both the use and rejection of age restrictions; it explains why a national minimum age for breast implants would serve similar policy goals as other age-based access controls. Part VI specifically addresses two primary counterarguments: highlighting why it is appropriate to impinge on both the physician-patient

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<sup>3</sup> John Stossel, *Why Are Parents Buying Their Girls the Gift of Surgery?*, ABC NEWS (July 16, 2007), <http://abcnews.go.com/2020/story?id=875821#.ULk6oYXLQ7A>.

<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

<sup>6</sup> AM. SOC'Y OF PLASTIC SURGEONS, *American Society of Plastic Surgeons 2011 Plastic Surgery Statistics Report* 14 (2012), [http://www.plasticsurgery.org/Documents/news-resources/statistics/2011-statistics/2011\\_Stats\\_Full\\_Report.pdf](http://www.plasticsurgery.org/Documents/news-resources/statistics/2011-statistics/2011_Stats_Full_Report.pdf) [hereinafter *ASPS 2011 Statistics Report*].

<sup>7</sup> *Id.* at 8.

<sup>8</sup> See *infra* text accompanying notes 181–190.

relationship and parental autonomy in the context of breast implants for minors. Finally, Part VII concludes the article.

## II. BACKGROUND ON BREAST IMPLANT SURGERY AND ITS PREVALENCE AMONGST MINORS

### A. *The Basics of Breast Implant Surgery*

Plastic surgery procedures are typically segmented into two subgroups: reconstructive and corrective.<sup>9</sup> Reconstructive surgery is designed to “correct a clear abnormality.”<sup>10</sup> For example, the correction of a cleft lip or palate is considered reconstructive surgery. On the other hand, corrective or cosmetic surgery is “defined as surgery to improve a ‘normal’ appearance.”<sup>11</sup> Corrective and cosmetic surgeries are performed solely for aesthetic reasons and include procedures such as rhinoplasty (colloquially called a “nose job”) and breast implant surgery.<sup>12</sup>

Breast implants are medical devices implanted underneath breast tissue or the chest muscle. Cosmetically, breast implants are used to increase breast size. Two types of breast implants are approved for sale by the Food and Drug Administration (FDA) in the United States: saline-filled and silicone gel-filled.<sup>13</sup> The FDA has formally approved saline-filled breast implants for women eighteen and older, and silicone gel-filled implants for women twenty-two and older.<sup>14</sup> Notably, however, it is legal for doctors to perform breast implant surgery using either type of implant in minors under eighteen as an “off-label” use with parental consent.<sup>15</sup>

Breast implant surgery is typically performed on an outpatient basis and requires general anesthesia.<sup>16</sup> During the procedure, the breast implant device is placed inside a pocket created under the breast tissue or in the pectoralis major muscle of the patient.<sup>17</sup> Immediately following the breast implant surgery, patients typically experience postoperative discomfort for several days, must wear a surgical bra for

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<sup>9</sup> Kuni Simis et al., *After Plastic Surgery: Adolescent-Reported Appearance Ratings and Appearance-Related Burdens in Patient and General Population Groups*, 109 PLASTIC & RECONSTRUCTIVE SURGERY 9, 9–10 (2002); see also Derrick Diaz, *Minors and Cosmetic Surgery: An Argument for State Intervention*, 14 DEPAUL J. HEALTH CARE L. 235, 238 (2012).

<sup>10</sup> Zuckerman & Abraham, *supra* note 2, at 318.

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> *Medical Devices: Breast Implants*, FDA, <http://www.fda.gov/medicaldevices/Productsandmedicalprocedures/implantsandprosthetics/breastimplants/default.htm> (last updated Sept. 17, 2013).

<sup>14</sup> Zuckerman & Abraham, *supra* note 2, at 319.

<sup>15</sup> *Id.* Off-label use of this kind is permissible pursuant to the FDA’s policy of approving medical products only for the specific uses for which they have been proven safe and effective, simultaneously allowing physicians to determine if they want to use those products for other medical purposes. *Id.*

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

two weeks, and are instructed to avoid strenuous exercise for four to six weeks.<sup>18</sup> Beyond the general risks of undergoing any surgery involving intravenous anesthesia, many other complications can arise from breast implant procedures, specifically. Most commonly, patients may experience capsular contracture, a tightening or hardening of the scar tissue surrounding the implant, causing the breast to feel hard and painful.<sup>19</sup> Also common are implant ruptures, leaking, postoperative bleeding, loss of nipple sensation, scarring, and infection.<sup>20</sup>

Furthermore, the medical risks of breast implants steadily increase in the years following the implant surgery. Breast implants last approximately ten years within the body, and the likelihood of a capsular contracture or related complication requiring surgery occurring increases over time.<sup>21</sup> Thus, an adolescent who receives breast implants may require repeated surgeries, with all of the previously mentioned associated risks, throughout her lifetime.<sup>22</sup> Additionally, breast implant surgery has been shown to increase the likelihood of insufficient lactation for breastfeeding.<sup>23</sup> Breast implants also interfere with preventative or diagnostic mammography, as mammography procedures increase the likelihood of implant leakage and rupture, and breast implants may lead to a failure to detect approximately fifty-five percent of cancerous breast tumors.<sup>24</sup> Overall, the FDA has estimated that forty percent of patients who undergo breast implant surgery experience at least one serious complication within three years.<sup>25</sup>

#### *B. Prevalence of Breast Implant Surgery in the United States*

According to statistics compiled by the American Society of Plastic Surgeons (ASPS), 1.6 million cosmetic surgical procedures were conducted in the United States in 2011.<sup>26</sup> Breast implant surgery has held the title of most common cosmetic surgical procedure since 2006.<sup>27</sup> A total of 307,000 breast implant surgeries were performed in 2011, an increase of 4% from 2010.<sup>28</sup> The national average surgeon or physician fee for a breast implant surgery is \$3,388; as such, U.S. expenditures on breast implant surgery totaled \$1,040,725,840 in 2011.<sup>29</sup>

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<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> *Id.*

<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> Stossel, *supra* note 3.

<sup>26</sup> *ASPS 2011 Statistics Report*, *supra* note 6, at 5.

<sup>27</sup> *Id.*

<sup>28</sup> *Id.* at 8.

<sup>29</sup> *Id.* at 20.

*C. Prevalence of Breast Implant Surgery Amongst Minors in the United States*

Although data for minors is not precisely segmented, ASPS found that people age thirteen to nineteen had the least number of cosmetic procedures in 2011, constituting two percent of total surgeries.<sup>30</sup> Specifically, 8,892 breast implant surgeries were performed on patients aged thirteen to nineteen in 2011, which constituted three percent of the total number of breast implant surgeries performed that year.<sup>31</sup> Although patients aged thirteen to nineteen may represent a small proportion of the total number of patients undergoing breast implant surgeries in the United States, the number of these breast implant surgeries performed on women thirteen to nineteen increased four percent from 2010 to 2011.<sup>32</sup> The American Society for Aesthetic Plastic Surgery (ASAPS) has also gathered statistics regarding the prevalence of breast implant surgery among minors. The ASAPS report states that 125,397 cosmetic surgeries were performed on patients under eighteen in 2010, representing 1.3% of the total number of cosmetic surgery patients.<sup>33</sup> Furthermore, the report indicates that 4,153 breast implant procedures were performed on women under the age of eighteen in 2010, also constituting 1.3% of the total number of breast implant surgeries conducted in that year.<sup>34</sup> A cosmetic bilateral breast implant was the most frequently requested surgery amongst minors aged eighteen and under, at forty-seven percent.<sup>35</sup>

### III. REPRESENTATIVE SITUATIONS IN WHICH THE FEDERAL GOVERNMENT MAINTAINS AGE-BASED REGULATIONS

*A. Tobacco Products*

Tobacco sales represent one major area in which the federal government has successfully mandated a nationwide minimum age, although this federal oversight is a fairly recent accomplishment. In Philip J. Hilts' book on the history of the FDA, *Protecting America's Health*, Hilts describes the years leading up to the FDA's first statements asserting authority to regulate tobacco products. Hilts notes that "[t]he FDA had not actively pursued the subject before, not because Congress had prevented it, or because of anything in the law, but simply because it was a hornet's nest. There was no nastier political tangle."<sup>36</sup> Despite the stacked political odds, the FDA proceeded to investigate the subject of tobacco, addiction, and public health throughout the early 1990s. Based on this research, the FDA determined that:

the problem was not just that a drug was intentionally being delivered to smokers, but that the companies initially hooked smokers when they were

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<sup>30</sup> *Id.* at 6.

<sup>31</sup> *Id.* at 14.

<sup>32</sup> *Id.*

<sup>33</sup> AM. SOC'Y FOR AESTHETIC PLASTIC SURGERY, COSMETIC SURGERY NATIONAL DATA BANK 10 (2010), [http://www.surgery.org/sites/default/files/Stats2010\\_1.pdf](http://www.surgery.org/sites/default/files/Stats2010_1.pdf).

<sup>34</sup> *Id.*

<sup>35</sup> *Id.* at 12.

<sup>36</sup> PHILIP J. HILTS, *PROTECTING AMERICA'S HEALTH: THE FDA, BUSINESS, AND ONE HUNDRED YEARS OF REGULATION* 292 (2003).

children. At bottom, smoking was a *pediatric disease*, even if the illness and death finally struck during adulthood. Thus, ultimately, the object of planned FDA regulation was not to ban smoking or to go after adult smokers, but simply to try to reduce the number of children who started.<sup>37</sup>

In 1996, as a culmination of these years of study and analysis, the FDA promulgated a rule that regulated cigarettes and smokeless tobacco as medical devices and prohibited the sale of nicotine-containing cigarettes and smokeless tobacco to individuals under the age of eighteen.<sup>38</sup> The access restrictions and advertising controls contained in these regulations were designed to reduce children's and adolescents' easy access to cigarettes and smokeless tobacco and to significantly decrease the amount of positive imagery making these products so appealing to that age group.<sup>39</sup>

The FDA's cigarette regulations were challenged in *Coyne Beahm, Inc. v. FDA*.<sup>40</sup> Although the Supreme Court ultimately struck down the FDA's rules in *FDA v. Brown & Williamson Tobacco Corp.*,<sup>41</sup> holding that Congress had excluded tobacco products from the FDA's jurisdiction, it was the subject-matter of the rules, rather than the manner of regulating their sale, that was primarily problematic. In *Brown & Williamson*, the Court clearly noted that under 21 U.S.C. § 360j(e) the FDA may restrict the sale, distribution, or use of a device it has jurisdiction to regulate "if, because of its potentiality for harmful effect or the collateral measures necessary to its use, [the FDA] determines that there cannot otherwise be reasonable assurance of its safety and effectiveness."<sup>42</sup>

After this first regulatory attempt failed, there was no nationwide minimum purchase age for tobacco products until March 2010, when the FDA issued a final rule prohibiting the sale of cigarettes or smokeless tobacco to people younger than eighteen.<sup>43</sup> This rule was authorized by the Family Smoking Prevention and Tobacco Control Act of 2009 (the Act); the Act amended the Federal Food, Drug, and Cosmetic Act (FDCA) to provide the FDA with jurisdictional authority over tobacco products and required the FDA to issue new rules identical to those it originally

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<sup>37</sup> *Id.* at 294.

<sup>38</sup> Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,396 (Aug. 28, 1996) (to be codified at 21 C.F.R. pts. 801, 803, 804, 807, 820 and 897). The FDA determined that cigarettes and smokeless tobacco were combination products consisting of a drug (nicotine) and device components intended to deliver nicotine to the body, which FDA may regulate as a drug/device combination product using the Federal Food, Drug, and Cosmetic Act's (FDCA) drug authorities, device authorities, or both. *Id.* at 44,400.

<sup>39</sup> *Id.* at 44,396.

<sup>40</sup> *Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374, 1400 (M.D.N.C. 1997).

<sup>41</sup> *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 156 (2000).

<sup>42</sup> *Id.* at 129.

<sup>43</sup> Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 75 Fed. Reg. 13,225, 13,225 (Mar. 19, 2010) (to be codified at 21 C.F.R. pt. 1140).



promulgated in 1996.<sup>44</sup> The Congressional findings supporting the Act focused on the adverse health effects tobacco products pose for children, the prevalence of tobacco advertising and marketing geared towards adolescents, and the need for comprehensive restrictions on the sale of tobacco products given the failure of past efforts focused solely on advertising and marketing restrictions.<sup>45</sup>

### B. Human Subjects Research on Minors

Federal regulations also restrict the ability of minors to participate in biomedical research.<sup>46</sup> Laws governing human subjects research in the United States grew out of various ethical guidelines and conventions developed by international organizations and tribunals beginning after World War II. The Nuremberg Code (the Code), developed in 1947 at the conclusion of the Nuremberg Military Tribunal trials, first addressed participation in biomedical research.<sup>47</sup> Although the Code did not explicitly address guidelines for children as research subjects, the Code did emphasize the importance of voluntary, informed consent.<sup>48</sup> As such, the guidelines specify that human subjects participating in research must “have the legal capacity to give consent; should be so situated as to be able to exercise free power of choice . . . and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.”<sup>49</sup> Thus, while the Code did not impose explicit age restrictions for participation in biomedical research, following its principles of voluntary consent would generally prevent participation in biomedical research by minors. It appeared that children could not meet the Code’s standards for enlightened decision-making because they lacked the statutory or common law capacity to give consent to medical treatment and because they were viewed as unable to comprehend the subject matter of research and engage in an informed decision-making process.<sup>50</sup>

The World Medical Association’s Helsinki Declarations were the first international guidelines to make specific recommendations for children’s participation in research.<sup>51</sup> In 1975, “Helsinki II” explicitly categorized children as a

<sup>44</sup> Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 102, 123 Stat. 1776, 1778–79 (2009) (codified as amended in scattered sections of 5 U.S.C., 15 U.S.C., and 21 U.S.C. (2006)).

<sup>45</sup> *See id.*

<sup>46</sup> *See generally* 45 C.F.R. § 46.101 (2009).

<sup>47</sup> TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10, 181–82 (U.S. Gov’t Printing Office, 1949) [hereinafter THE NUREMBERG CODE]; *see also* Leonard H. Glantz, *Research with Children*, 24 AM. J.L. & MED. 213, 213 (1998).

<sup>48</sup> THE NUREMBERG CODE, *supra* note 47, at 182.

<sup>49</sup> *Id.*

<sup>50</sup> Leonard H. Glantz, *The Law of Human Experimentation with Children*, in CHILDREN AS RESEARCH SUBJECTS: SCIENCE, ETHICS, AND LAW 105, 111–13 (Michael A. Grodin & Leonard H. Glantz eds., 1994).

<sup>51</sup> Ann E. Ryan, *Protecting the Rights of Pediatric Research Subjects in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use*, 23 FORDHAM INT’L L.J. 848, 869 (2000).

class of legally incompetent research subjects.<sup>52</sup> In 1989, “Helsinki IV” urged that, in situations where a minor child was in fact able to give consent, the child’s consent should be required in addition to the consent of the minor’s parent or legal guardian.<sup>53</sup> The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use’s “Guidelines for Good Practice” suggested that human subjects who could not provide informed consent should not participate in non-therapeutic research unless certain conditions, such as low risks relative to benefits, were met.<sup>54</sup>

Beyond these international ethical statements, the current U.S. regulatory framework governing children’s participation in human subjects research was also shaped by a series of disturbing incidents involving children as research subjects. One of the most infamous examples of this abusive treatment of underage research subjects occurred at the Willowbrook State School, a residential facility for mentally disabled children.<sup>55</sup> From the 1950s through the 1970s, children living at Willowbrook were experimentally infected with hepatitis and observed over the natural course of the disease.<sup>56</sup>

As the result of this history, federal laws governing human research subjects provide for enhanced protections when children are research participants.<sup>57</sup> The mandate of 45 C.F.R. § 46 applies to human subjects research that is conducted or supported by any federal department or agency and to entities that receive federal funding for research, including universities.<sup>58</sup> The regulation categorizes research into four categories according to degrees of risk and benefit.<sup>59</sup> Research not involving greater than minimal risk is the most permissive category.<sup>60</sup> “Minimal risk” means “that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”<sup>61</sup>

Research involving greater than minimal risk, but presenting the prospect of direct benefit to the individual subjects, may be funded if an Institutional Review Board (IRB) finds that:

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<sup>52</sup> *Id.* at 870.

<sup>53</sup> *See id.* at 872–73.

<sup>54</sup> *Id.* at 920–21.

<sup>55</sup> Susan Lederer & Michael Grodin, *Historical Overview: Pediatric Experimentation*, in *CHILDREN AS RESEARCH SUBJECTS: SCIENCE, ETHICS, AND LAW* 15, 17 (Michael A. Grodin & Leonard H. Glantz eds., 1994).

<sup>56</sup> *Id.*

<sup>57</sup> *See generally* 45 C.F.R. § 46.101 (2009).

<sup>58</sup> *See id.*

<sup>59</sup> OFFICE FOR HUMAN RESEARCH PROTECTIONS, DEP’T OF HEALTH & HUMAN SERVICES, INSTITUTIONAL REVIEW BOARD GUIDEBOOK: CHAPTER VI SPECIAL CLASSES OF SUBJECTS (1993), available at [http://www.hhs.gov/ohrp/archive/irb/irb\\_chapter6.htm](http://www.hhs.gov/ohrp/archive/irb/irb_chapter6.htm) (last updated 1993).

<sup>60</sup> *Id.*

<sup>61</sup> 45 C.F.R. § 46.102(i) (2009).

(a) The risk is justified by the anticipated benefit to the subjects; (b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and (c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians . . . .<sup>62</sup>

Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition, may be funded if an IRB finds that:

(a) The risk represents a minor increase over minimal risk; (b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations; (c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and (d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians . . . .<sup>63</sup>

The language of these regulations suggests that research on children that involves greater than minimal risk is generally inappropriate, even with parental consent to participation. At least one court has taken a firm stance on this issue. In *Grimes v. Kennedy Krieger Inst., Inc.*,<sup>64</sup> the Court of Appeals of Maryland held that parents simply cannot consent to the participation of a child in non-therapeutic research in which there is any risk of injury or damage to the health of the subject.<sup>65</sup>

On the other hand, it is the policy of the National Institutes of Health (NIH) that children should be "included in all human subjects research conducted or supported by the NIH unless there are scientific and ethical reasons not to include them."<sup>66</sup> This policy is driven by the need to develop scientific data regarding the risks and benefits of medical treatments for children. The best way to obtain this data is through clinical trials conducted on children, rather than relying solely on extrapolated data obtained from adult clinical trials.<sup>67</sup> Thus, there is a fundamental tension between the scientific and societal goals for medical research that will benefit broad population segments and the rights of individual children participating in biomedical research. While excluding children from medical research could be

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<sup>62</sup> 45 C.F.R. § 46.405 (2009).

<sup>63</sup> 45 C.F.R. § 46.406 (2009).

<sup>64</sup> *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807 (Md. 2001).

<sup>65</sup> *Id.* at 858.

<sup>66</sup> *NIH Policy and Guidelines on the Inclusion of Children as Participants, in Research Involving Human Subjects*, NAT'L INSTITUTES OF HEALTH (Mar. 6, 1998), <http://grants1.nih.gov/grants/guide/notice-files/not98-024.html>.

<sup>67</sup> *Id.*

considered “an injustice to them as members of a community . . . their inclusion as individual participants in research may be an illegality to each of them.”<sup>68</sup>

### C. Female Genital Mutilation

According to World Health Organization estimates, over 140 million women and girls have undergone female genital mutilation (FGM) worldwide, with the practice occurring primarily in Africa, Asia, and the Middle East, as well as in some immigrant communities in North America and Europe.<sup>69</sup> Although FGM is performed for diverse and complex reasons, for many practitioners and in many cultures the surgeries are thought to add to the beauty of women and to ensure their marital prospects.<sup>70</sup> Despite these cultural rationales, there is a powerful global movement resisting the practice of FGM. In the United States, the Federal Prohibition of Female Genital Mutilation Act outlaws FGM at the federal level.<sup>71</sup> Many states also have specific anti-FGM criminal statutes.<sup>72</sup> The laws at the state level vary tremendously: some forbid FGM entirely, some ban the practice when performed on minors under eighteen, and some impose criminal liability on the parental act of consenting to the procedure.<sup>73</sup>

The federal anti-FGM statute criminalizes the conduct of the individuals who perform FGM on minors, providing that “whoever knowingly circumcises, excises, or infibulates the whole or any part of the labia majora or labia minora or clitoris of another person who has not attained the age of 18 years shall be fined under this title or imprisoned not more than 5 years, or both.”<sup>74</sup> The federal law also contains two defenses: first, where the operation is “necessary to the health of the person on whom it is performed, and is performed by a person licensed in the place of its performance as a medical practitioner” and second, when the operation is done for reasons of medical necessity “on a person in labor or who has just given birth.”<sup>75</sup> Finally, the statute states that, when applying the first medical necessity defense, “no account shall be taken of the effect on the person on whom the operation is to be performed of any belief on the part of that person, or any other person, that the operation is required as a matter of custom or ritual.”<sup>76</sup> While the number of

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<sup>68</sup> Bernard M. Dickens, *The Legal Challenge of Health Research Involving Children*, 6 HEALTH L.J. 131, 132 (1998).

<sup>69</sup> See Sara Corbett, *A Cutting Tradition*, N.Y. TIMES (Jan. 20, 2008), [http://www.nytimes.com/2008/01/20/magazine/20circumcision-t.html?\\_r=0](http://www.nytimes.com/2008/01/20/magazine/20circumcision-t.html?_r=0).

<sup>70</sup> See Richard A. Shweder, *What About Female Genital Mutilation? And Why Understanding Culture Matters in the First Place*, in ENGAGING CULTURAL DIFFERENCES: THE MULTICULTURAL CHALLENGE IN LIBERAL DEMOCRACIES 216, 224–25, 234–35, 242 (Richard A. Shweder et al. eds., 2002).

<sup>71</sup> See 18 U.S.C. § 116(a) (2000).

<sup>72</sup> See Holly Maguigan, *Will Prosecutions for “Female Genital Mutilation” Stop the Practice in the U.S.?*, 8 TEMP. POL. & CIV. RTS. L. REV. 391, 393 (1999).

<sup>73</sup> See *id.* at 410.

<sup>74</sup> See 18 U.S.C. § 116(a) (2000).

<sup>75</sup> See 18 U.S.C. § 116(b)(1)–(b)(2) (2000).

<sup>76</sup> See 18 U.S.C. § 116(c) (2000).

prosecutions under this statute has been quite low,<sup>77</sup> convictions can lead to a variety of collateral consequences for families involved, including deportation from the United States and the termination of parental rights.<sup>78</sup>

#### IV. SITUATIONS IN WHICH AGE-RELATED ACCESS CONTROLS ARE INAPPROPRIATE

##### A. *Over-the-Counter Diet Drugs*

The FDCA empowers the FDA with the statutory authority to regulate the safety, efficacy, and labeling of prescription and nonprescription drugs.<sup>79</sup> Congress has codified the distinction between prescription and over-the-counter (OTC) drugs, explaining that a prescription drug is so designated “because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug.”<sup>80</sup> Accordingly, while prescription drugs must be dispensed by a pharmacist, OTC drugs can be sold in any retail establishment on open shelves.<sup>81</sup>

Generally, OTC drug manufacturers are able to market their drugs without FDA preapproval by complying with a drug monograph designated by the FDA.<sup>82</sup> As such, the FDA does not review each OTC drug product and label, but requires manufacturers to produce labels that follow specific format and content guidelines. For example, OTC drug labels must include information about ingredients, directions for proper use, and warnings against unsafe use and side effects.<sup>83</sup> Beyond these basic requirements, the FDA can establish specific warnings for products that may cause harm under proper use,<sup>84</sup> or require reasonable warnings to reduce foreseeable risks of harm posed by the product. For example, in 1998, the FDA observed that the availability in the marketplace of multiple container sizes of OTC laxative drugs containing sodium phosphates had caused consumer confusion, leading to accidental overdosing and consumer deaths.<sup>85</sup> Given this potential for misuse, the FDA required an additional warning stating that “[t]aking more than the recommended dose in 24 hours can be harmful.”<sup>86</sup>

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<sup>77</sup> See Maguigan, *supra* note 72, at 406.

<sup>78</sup> Elaine M. Chiu, *The Culture Differential in Parental Autonomy*, 41 U.C. DAVIS L. REV. 1773, 1804 (2008).

<sup>79</sup> 21 U.S.C.A. § 371(a) (West 2012).

<sup>80</sup> 21 U.S.C. § 353(b)(1)(A) (2012).

<sup>81</sup> Jennifer L. Pomeranz et al., *Over-the-Counter and Out-of-Control: Legal Strategies to Protect Youths From Abusing Products for Weight Control*, AM. J. PUB. HEALTH e1, e2 (2012).

<sup>82</sup> 21 C.F.R. § 330.1 (2012).

<sup>83</sup> 21 C.F.R. § 201.66(c)(2), (4)–(5) (2012).

<sup>84</sup> 21 C.F.R. § 201.66(c)(5)(ii)(B), (E) (2012).

<sup>85</sup> 21 C.F.R. § 201.307(a) (2012).

<sup>86</sup> 21 C.F.R. § 201.307(b)(2)(i) (2012).

In 2007, the FDA approved Orlistat, the first OTC diet drug.<sup>87</sup> Orlistat is designed to prevent the absorption of fat from food to achieve weight-loss; its effects are similar to laxatives.<sup>88</sup> The FDA approved prescription strength Orlistat for weight management at a dosage of 120 milligrams nearly a decade earlier.<sup>89</sup> The OTC version of Orlistat, marketed under the name Alli, is indicated for weight loss in overweight adults aged eighteen years and older in a dosage of sixty milligrams, half that of prescription strength.<sup>90</sup> Although Alli's labeling indicates that it is approved only for overweight adults, the FDA does not enforce this requirement, and Alli can be freely purchased in retail establishments and online without age or weight verification.<sup>91</sup>

Because OTC weight management drugs like Alli are available without any real retail access controls, minors under eighteen are free to purchase these drugs and ignore age restrictions outlined in the product labeling. Indeed, abuse of diet pills by adolescents is a well-documented national public health problem.<sup>92</sup> Data indicates that, in 2011, six percent of adolescent girls and four percent of adolescent boys reported past-month use of diet products without physician advice.<sup>93</sup> Although diet drugs such as Alli are widely available on store shelves and advertised directly to consumers, abuse of OTC weight management products can cause serious health problems such as fluid and electrolyte disorders, cardiac arrhythmia, stroke, and hepatic and renal failure.<sup>94</sup>

While OTC diet drugs like Alli are currently accessible to minors, despite labeled contraindications, commentators have called for increased regulatory controls to limit access and abuse of these drugs by youths. Such suggestions include designating Alli as behind-the-counter (BTC) pharmacy-only status, which would enable age verification by pharmacists.<sup>95</sup> Despite these calls for increased regulation and tighter access controls for minors, the fact remains that teenagers are generally able to obtain easy access to OTC diet drugs. This is likely so because the FDA has explicitly considered the safety profile of diet drugs such as Alli, deemed them to be generally safe without the supervision of a physician, and therefore considers the benefits of widespread availability to outweigh the potential for misuse in the marketplace.

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<sup>87</sup> Pomeranz et al., *supra* note 81, at e1.

<sup>88</sup> *Id.*

<sup>89</sup> *Id.*

<sup>90</sup> *Alli Approved Drug Label*, FDA, <http://www.accessdata.fda.gov/drugsatfdadocs/label/2007/021887lbl.pdf> (last visited May 3, 2013). Alli's label defines "overweight" as having a body mass index (BMI) of approximately 27. Pomeranz et al., *supra* note 81, at e4.

<sup>91</sup> Pomeranz et al., *supra* note 81, at e4.

<sup>92</sup> See Heidi Michels Blanck et al., *Use of Nonprescription Dietary Supplements for Weight Loss is Common Among Americans*, 107 J. AM. DIETETIC ASS'N 441, 441; see also *Mobility and Morality Weekly Report: Youth Risk Behavioral Surveillance*, SURVEILLANCE SUMMARIES (CDC/Office of Surveillance, Epidemiology, & Laboratory Services, Atlanta, GA), June 8, 2012 [hereinafter *CDC Youth Risk Report*].

<sup>93</sup> Pomeranz et al., *supra* note 81, at e1.

<sup>94</sup> *Id.*

<sup>95</sup> *Id.* at e4.

### B. Indoor Tanning Beds

The use of tanning beds by minors has come under increased scrutiny in recent years. Studies indicate that exposure to tanning beds when young is particularly harmful; for example, exposure to indoor tanning appliances can lead to an especially high increased risk for skin cancer when the age of first exposure is below twenty years of age.<sup>96</sup> Moreover, statistics indicate that the use of tanning beds by minors is quite prevalent; an FDA advisory committee panel found in 2010 that forty to sixty percent of teenage girls surveyed had used tanning beds in the prior year, despite being aware of the associated risks of skin cancer.<sup>97</sup> To respond to this growing problem, many states have enacted legislation that regulates the use of tanning facilities by minors. Eleven states ban the use of tanning beds for minors under a specified age, typically fourteen years; twenty-one states have opted instead to require only parental consent for minors under eighteen.<sup>98</sup> Only California and Vermont ban all minors under eighteen from using tanning beds,<sup>99</sup> while New Jersey has a similar ban for minors under the age of seventeen.<sup>100</sup> The federal government, however, has not imposed a national age restriction for tanning beds.

Although the FDA has not imposed a nationwide minimum age requirement for indoor tanning, the FDA has authority under 21 U.S.C. § 360j(e) to require that a device be restricted to use “upon such other conditions as the Secretary may prescribe in such regulation, if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness.”<sup>101</sup>

This “upon such other conditions” language would allow the FDA to restrict the use of tanning beds to persons over the age of eighteen as long as the restriction is essential to the safe and effective use of tanning beds.<sup>102</sup> Critics of proposed national age restrictions on tanning bed use argue that the government should not have more of a say in a teenager’s life than his or her own parents; they also suggest that minimum age requirements will “drive teens to riskier alternatives like home units and beaches.”<sup>103</sup> On the other hand, advocates of these rules stress the limitations of

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<sup>96</sup> INT’L AGENCY FOR RESEARCH ON CANCER, WORLD HEALTH ORG., EXPOSURE TO ARTIFICIAL UV RADIATION AND SKIN CANCER 49 (2006), available at <http://www.iarc.fr/en/publications/pdfs-online/wrk/wrk1/ArtificialUVRad&SkinCancer.pdf>.

<sup>97</sup> Damali Thomas, *Is That Tanning Bed a Death Bed?*, DAMALI THOMAS BLOG, <http://damalithomas.com/fun-stuff/is-that-tanning-bed-a-death-bed/> (last visited Feb. 21, 2014).

<sup>98</sup> *See Indoor Tanning Restrictions for Minors: A State-by-State Comparison*, NAT’L CONFERENCE OF STATE LEGISLATURES, <http://www.ncsl.org/issues-research/health/indoor-tanning-restrictions.aspx> (last updated Feb. 2014).

<sup>99</sup> *Id.*

<sup>100</sup> Ashley Hayes, *NJ Bans Minors from Tanning Beds*, CNN (Apr. 2, 2013), <http://www.cnn.com/2013/04/02/health/new-jersey-tanning-minors>.

<sup>101</sup> 21 U.S.C. § 360j(e)(B) (2012).

<sup>102</sup> Veronica Knapp, *FDA’s Regulation of Tanning Beds: How Much Heat?*, 66 FOOD & DRUG L.J. 25, 42 (2011).

<sup>103</sup> Hayes, *supra* note 100.

parental consent laws, noting that parental consent is often insufficient to protect minors because parents, like their teenage children, do not understand or do not take sufficient account of the risks of indoor tanning.<sup>104</sup> Overall, although indoor tanning can be highly dangerous to the health of minors, tanning beds are widely viewed as an everyday consumer product. As such, it appears that public sentiment favors leaving their use and popularity to the regulation of the marketplace.

### C. *Caffeine in Food, Beverages, and Dietary Supplements*

Caffeine is a pervasive ingredient in foods, beverages, and medicines sold in the United States. While most adult users can regularly ingest caffeine with few short-term or long-term health effects, caffeine use can contribute to mental and physical health conditions amongst minors, and early caffeine addiction can lead to experimentation with more serious, illicit drugs.<sup>105</sup> Nevertheless, caffeinated products are relatively unregulated. Federal regulatory requirements for caffeine vary greatly depending on whether the caffeinated product is classified as a food, drug, or dietary supplement.

The FDA defines “food” as any article, or component of such article, “used for food or drink.”<sup>106</sup> When caffeine is added as an ingredient to existing products, such as soda, or when foods and beverages such as coffee and chocolate contain caffeine naturally, caffeine as an additive is classified as a food.<sup>107</sup> The FDCA states that caffeine is “generally recognized as safe when used in cola-type beverages in accordance with good manufacturing practice.”<sup>108</sup> For beverages, the acceptable amount of caffeine allowable is 0.02% of the total content.<sup>109</sup> Although caffeine does not have to be listed as an ingredient when it is a natural component of the food, solids or beverages to which caffeine is artificially added must list caffeine as an ingredient on product labeling.<sup>110</sup> Manufacturers can evade even these fairly limited regulatory requirements by marketing their caffeinated products as dietary supplements, rather than food.<sup>111</sup> Dietary supplements are regulated by the Dietary Supplement Health and Education Act of 1994 (DHSEA).<sup>112</sup> High-caffeine energy

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<sup>104</sup> Knapp, *supra* note 102, at 42.

<sup>105</sup> James G. Hodge, Jr. et al., *The Consumable Vice: Caffeine, Public Health, and the Law*, 27 J. CONTEMP. HEALTH L. & POL’Y 76, 78 (2010).

<sup>106</sup> Dietary Supplement Health and Education Act of 1994, 21 U.S.C. § 321(f) (1994).

<sup>107</sup> Hodge, Jr. et al., *supra* note 105, at 102.

<sup>108</sup> 21 C.F.R. § 182.1180(c) (2010).

<sup>109</sup> 21 C.F.R. § 182.1180(b).

<sup>110</sup> *Why Isn’t the Amount of Caffeine a Product Contains Required on a Food Label*, FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194317.htm> (last updated Dec. 30, 2009).

<sup>111</sup> See Chad J. Ressig et al., *Caffeinated Energy Drinks: A Growing Problem*, 99 DRUG & ALCOHOL DEPENDENCE 1, 2 (2008).

<sup>112</sup> Dietary Supplement Health and Education Act of 1994, 21 U.S.C. § 321(g)(1) (1994).



drinks are commonly sold as dietary supplements in order to avoid the FDA's limitations on caffeine content in soft drinks and food labeling requirements.<sup>113</sup>

Finally, the FDA defines drugs as any article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease."<sup>114</sup> Drugs that contain caffeine are subject to stricter regulatory controls than caffeinated products classified as food or dietary supplements.<sup>115</sup> For example, the FDA limits the permissible caffeine content in OTC pain medicines to no more than sixty-five milligrams per dose<sup>116</sup> and requires OTC drugs containing caffeine to include warning labels.<sup>117</sup> Given the FDA's varied approaches towards food, dietary supplements, and drugs, it is possible for the manufacturers of caffeinated products to avoid governmental controls by carefully crafting their marketing and advertising strategies. What is more profound is that, regardless of whether a caffeinated product is categorized as a food, drug, or dietary supplement, these products "may be purchased by adults, adolescents, and children at nearly every grocery, convenience store, or pharmacy in the United States. There are no national limitations on the sale or consumption of most . . . caffeinated products to children."<sup>118</sup> Thus, while minors lack the capacity to make fully informed decisions about consuming caffeinated products, and are more negatively impacted by excessive caffeine use than adults, minors are able to purchase most caffeinated products to the same extent as adults.<sup>119</sup>

While limiting the sale of heavily-caffeinated products to children (in particular to children under the age of twelve, who the FDA has advised should avoid excess caffeine consumption) could be a feasible regulatory tactic, access restrictions on food products are generally highly unpopular.<sup>120</sup> New York City Mayor Michael Bloomberg, dubbed "chief of the national food police," has received backlash for his regulatory proposals related to soda.<sup>121</sup> Often, food regulations that single out a

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<sup>113</sup> Anne Harding, *Labels Urged for Caffeinated Energy Drinks*, REUTERS (Sept. 30, 2008, 12:00 PM), <http://www.reuters.com/article/idUSTRE48T5VC20080930>.

<sup>114</sup> 21 U.S.C. § 321(g)(1).

<sup>115</sup> Gwendolyn Prothro, *The Caffeine Conundrum: Caffeine Consumption and Regulation in the United States*, 27 CUMB. L. REV. 65, 77 (1997).

<sup>116</sup> *Id.* at 79.

<sup>117</sup> 21 C.F.R. § 340.50(a) (2010). These warnings include the following: the recommended dose of this product contains about as much caffeine as a cup of coffee; limit the use of caffeine containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heartbeat; for occasional use only; not intended for use as a substitute for sleep; if fatigue or drowsiness persists or continues to recur, consult a (select one of the following: "physician" or "doctor"); do not give to children under 12 years of age; directions, for adults and children twelve years of age and over, oral dosage is 100–200 mg not more often than every three to four hours. 21 C.F.R. § 340.50(c)–(d).

<sup>118</sup> Hodge Jr., et al., *supra* note 105, at 106.

<sup>119</sup> *Id.* at 109.

<sup>120</sup> *Id.* at 111.

<sup>121</sup> Editorial, *Food Police on Patrol*, BOSTON HERALD (Oct. 12, 2010), [http://bostonherald.com/news\\_opinion/opinion/editorials/2010/10/food\\_police\\_patrol](http://bostonherald.com/news_opinion/opinion/editorials/2010/10/food_police_patrol).

particular product or ingredient as unsafe or unhealthy are viewed as arbitrary and unproductive.<sup>122</sup> Moreover, the fact that caffeine is found in countless varieties of the foods and beverages we consume makes access controls as a regulatory technique highly burdensome for both retailers and consumers.

V. A NATIONAL MINIMUM AGE REQUIREMENT FOR BREAST IMPLANTS SERVES THE SAME POLICY GOALS THAT OTHER AGE-RELATED ACCESS CONTROLS ARE DESIGNED TO FURTHER

A. *Similarities to Federal Age Restrictions on Tobacco Products*

As discussed above, the quest to impose a national minimum age for the purchase of tobacco products was motivated by two primary concerns. First, the age restrictions were deemed appropriate because a key public health issue related to smoking was an expressly pediatric concern: reducing the risk that minors would begin smoking at a young age and subsequently become lifelong smokers. Second, federal legislation and regulation imposing age controls for tobacco products were driven by concerns that children were both especially vulnerable to, and the express targets of, destructive industry marketing.<sup>123</sup> Concerns about minors undergoing breast implant surgery share similar themes. Breast implant surgery poses unique health and safety risks when the patient is an adolescent.<sup>124</sup> Moreover, evidence suggests that teenagers are highly vulnerable to images in the media depicting cosmetically enhanced models and feel enormous pressure to “meet a culturally defined ideal of beauty.”<sup>125</sup> Like age controls for tobacco, therefore, banning access to breast implant surgery for minors under eighteen would be designed to protect minors from a uniquely pediatric health concern. Age restrictions in both scenarios would provide enhanced protection when minors are targeted by pervasive media or advertising images and would prevent serious and scientifically proven health consequences from occurring in youths.

B. *Similarities to Federal Age Restrictions in the Context of Human Subjects Research Involving Children*

The regulatory framework governing the participation of children in biomedical research highlights a rationale for federal intervention on the behalf of minors that is particularly relevant in the context of breast implant surgeries for patients under the age of eighteen. As discussed above, the regulations that control human subject research embody a keen skepticism towards parents who give permission to enroll their children in research trials that would expose the minor to risks without the promise of an individualized benefit in return.<sup>126</sup> In this way, these regulations seem to indicate that federal intrusion into the parent-child relationship can be tolerated where parents intend to expose their children to unnecessary physical risks. This

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<sup>122</sup> See *id.*

<sup>123</sup> See *supra* text accompanying notes 44–45.

<sup>124</sup> See *infra* text accompanying notes 147–47.

<sup>125</sup> Alicia Ouellette, *Body Modification and Adolescent Decision Making: Proceed with Caution*, 15 J. HEALTH CARE L. & POL'Y 129, 150 (2012) [hereinafter Ouellette, *Body Modification*].

<sup>126</sup> See *supra* text accompanying notes 57–58.

governing principle is highly applicable in the context of parents who provide consent for their minor children to undergo medically unnecessary breast implant surgery. Thus, in both situations, parental consent that would subject a child to physical risk without the promise of individualized physical benefit for that child should be closely scrutinized.

### C. *Similarities to Federal Age Restrictions on the Practice of FGM*

Like FGM, breast implant surgery invades the bodily integrity of children to achieve permanent change in their sexual organs, involves a major surgical procedure, and carries the risk of serious side effects. FGM and breast implant surgery are also similar because the parents who consent to both procedures may share similar motivations. According to Professor Elaine M. Chiu, parents who consent to breast implant surgery want “to enhance the social acceptability of their children . . . [and] attain beauty, as measured by the dominant culture.”<sup>127</sup> Chiu also notes that both procedures are integral to identity; in the case of breast implants, many girls and their parents turn to breast implant surgery as a means for the child to attain self-esteem and confidence.<sup>128</sup> Despite these numerous similarities, however, practitioners who perform FGM surgery on minors are subject to criminal prosecution, while it is entirely legal for physicians to perform breast implant surgery on individuals under the age of eighteen as an off-label use.<sup>129</sup> A lesson that could be gleaned from the example of FGM is that the federal government disfavors serious surgical procedures that invade the bodily integrity of minors when done primarily for cultural purposes, rather than based on medical need. Parental consent on behalf of a minor for both FGM and breast implant surgery is a decision “that subordinate[s] the child’s interests for the sake of the parent” and for the sake of conforming to societal norms.<sup>130</sup> As such, the two procedures should be treated in a legally similar manner.

### D. *Differences from Permissive Access to OTC Diet Drugs*

OTC drugs that can have harmful effects on minors are freely available to consumers of all ages in retail establishments, but this permissive access scheme is designed to further broader policy goals. The principle underlying the regulatory balance between OTC and prescription medicines is that, when OTC drugs are generally recognized as safe, allowing access to them on a fairly unrestricted basis furthers the interests of protecting the public’s health and relieving pharmacists and the public from burdensome restrictions on dispensing drugs.<sup>131</sup> Thus, for OTC drugs, the FDA has explicitly considered the safety profile of the drug for all population segments that could access it in the marketplace and has decided that the

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<sup>127</sup> Chiu, *supra* note 78, at 1811.

<sup>128</sup> *Id.*

<sup>129</sup> Zuckerman & Abraham, *supra* note 2, at 319.

<sup>130</sup> Alicia Ouellette, *Shaping Parental Authority over Children’s Bodies*, 85 IND. L.J. 955, 984 (2010). [hereinafter Ouellette, *Shaping Bodies*].

<sup>131</sup> Drug Approvals: Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an Over-the-Counter Drug Product, 70 Fed. Reg. 52,050, 52,051 (Sept. 1, 2005) (to be codified at 21 C.F.R. pt. 310).

benefits of widespread access outweigh the need for restrictions on dispensing it. On the other hand, breast implants are highly-regulated medical devices. When the FDA approved saline-filled breast implants for women over eighteen and silicone gel-filled implants for women over twenty-two, they determined that there was insufficient evidence to show that breast implants are safe and effective for minors. The FDA made no explicit determination whatsoever that minors should be able to access breast implants in its approval process. Thus, off-label breast implant surgeries performed on minors only occur when physicians, who have been given broad flexibility by the FDA in the realm of off-label use, determine, on a case-by-case basis, that these procedures are scientifically supported and in the best interests of a patient. Like the flexibility built into the OTC versus prescription drug dichotomy, the flexibility built into the off-label paradigm is designed to protect the public's health and make sure people have access to treatments that will be medically beneficial to them. With off-label access to breast implants, however, this flexibility is unwarranted. The health of a minor may be compromised by undergoing breast implant surgery at a young age, and the minor patient is not physically harmed if she is unable to access the procedure until after she reaches the age of majority.

*E. Differences from Permissive Access to Consumer Products Such as Tanning Beds and Caffeine*

The objections to a national minimum age for tanning bed use highlight a key theme that frequently runs through the discourse associated with age-related product access controls: critics often argue that parental oversight should be the primary control on youth behavior.<sup>132</sup> Although it is hardly compelling to suggest that parents should be free to authorize their children to use indoor tanning beds when there is scientific and medical consensus that tanning beds are “as carcinogenic as plutonium, arsenic, mustard gas, or cigarettes,”<sup>133</sup> reasoning along these lines is potentially more persuasive in the context of tanning beds than it would be in the context of breast implants for minors. Like breast implants, tanning beds are regulated by the FDA as medical devices.<sup>134</sup> Tanning beds are Class I medical devices. Class I devices are subject to minimal oversight; tanning beds are in the same category of medical devices as elastic bandages and examination gowns.<sup>135</sup> Breast implants, on the other hand, are Class III medical devices, the most stringently regulated category of medical devices.<sup>136</sup> Tanning beds, therefore, are

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<sup>132</sup> See, e.g., Michelle Kay Pulley, *Government Tan Lines: Examining the Reach and Effectiveness of Federal and State Efforts to Protect Consumers from the Dangers of Indoor Tanning*, 36 PEPP. L. REV. 1161, 1200 (2009) (noting that critics of age-related access controls to tanning beds “argue that restricting teen tanning is equivalent to telling parents how to raise their kids”).

<sup>133</sup> Dennis Owens, *PA Lawmaker Wants to Ban Minors from Tanning Beds*, ABC27 (Apr. 8, 2013, 9:47 PM), <http://www.abc27.com/story/21912430/lawmakers-wants-to-ban-under-18s-from-tanning-beds>.

<sup>134</sup> 21 C.F.R. § 878.4635(a) (2010).

<sup>135</sup> 21 C.F.R. § 880.5075 (2010); 21 C.F.R. § 880.6265 (2010).

<sup>136</sup> *Regulatory History of Breast Implants in the U.S.*, FDA, <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm064461.htm> (last updated Sept. 25, 2013).

more like ordinary consumer products than breast implants. Given that parents have a broad liberty interest in overseeing the everyday rearing of their children,<sup>137</sup> it makes more sense to secure the primacy of parental control and authority in the context of tanning than it does when a child has a rare confrontation with choices regarding cosmetic breast implant surgery.

The parental choice rationale is even stronger when it comes to caffeine, which is a pervasive consumer good, and a fixture in everyday life. The example of caffeine also highlights some additional differences between regulation of the stimulant and breast implants. While the scientific evidence suggests that caffeine is not seriously dangerous for children in its common usages,<sup>138</sup> breast implant surgery carries significant health risks for minors. Moreover, practically speaking, strict age-based access controls for breast implants would be less onerous than similar restrictions on caffeine. The political backlash that would likely erupt if minors were banned from accessing caffeine makes it hard to imagine that age-based access controls for the stimulant would be effective or successful. Age-based access controls targeting physicians and designed to safeguard minors from unnecessary and proven safety risks would be a different scenario altogether.

#### VI. PROTECTING MINORS FROM ACCESSING BREAST IMPLANT SURGERY WARRANTS IMPINGEMENTS ON PHYSICIAN AND PARENTAL AUTONOMY

##### A. *Deference to Physicians Is Inappropriate in the Context of Breast Implants for Minors*

The Food and Drug Administration Modernization Act of 1997 affirms the longstanding principle of the FDA regulatory regime that the Agency must not “limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.”<sup>139</sup> In certain circumstances, such as when a very ill patient could benefit from a newly-discovered indication of an approved drug, or when the patient is a member of a population group that is infrequently included in clinical trials that amass safety and effectiveness data, “off-label use by prescribers is often appropriate and may represent the standard of care.”<sup>140</sup> Given the need for flexibility and the desire to promote innovation when it is in the best interests of patients, the FDA merely constrains off-label use by physicians thusly: physicians using “a product for an indication not in the approved labeling . . . have the responsibility to be well informed about the product, to base its

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<sup>137</sup> See *infra* text accompanying notes 181–78.

<sup>138</sup> See Hodge Jr., et al., *supra* note 105, at 77.

<sup>139</sup> 21 U.S.C. § 396 (2010).

<sup>140</sup> FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: RESPONDING TO UNSOLICITED REQUESTS FOR OFF-LABEL INFORMATION ABOUT PRESCRIPTION DRUGS AND MEDICAL DEVICES 2 (2011), <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf>.

use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects.”<sup>141</sup>

While there are indeed many good reasons to provide the medical profession with a significant degree of deference when it comes to off-label uses, it is not true “that physicians need to be unfettered in their prescribing practices to achieve maximal patient welfare.”<sup>142</sup> In fact, off-label uses “for which there is little to no good evidence of safety or efficacy is antithetical to patient welfare and represents anachronistic medical ethics.”<sup>143</sup> This section sets forth the reasons why breast implant surgery for minors falls into this latter category of off-label use, justifying regulatory intrusion into the doctor-patient relationship in order to better protect the best interests of minor patients.

### 1. There Is No Evidence Breast Implant Surgery Is Safe for Minors

Although a policy of non-interference with the physician-patient relationship is warranted in situations in which intrusions would impede sound medical judgment and stifle innovation, this rationale fails where the proposed off-label use is not supported by sound medical evidence of safety. Currently, there is no scientific evidence supporting off-label use of breast implants for minors. As discussed earlier, the FDA has approved saline-filled breast implants for women ages eighteen and older and silicone gel-filled implants for women ages twenty-two and older.<sup>144</sup> One reason that these medical device approvals carry age specifications relates to the fact that, for both saline-filled and silicone gel-filled breast implants, the core clinical studies used by manufacturers to obtain FDA approval did not involve younger research subjects.<sup>145</sup> For example, the information in Allergan's Premarket Approval (PMA) application for its saline-filled implant indicates that the studies were conducted on women over the age of eighteen.<sup>146</sup> In the PMA for Allergan's silicone-filled implant product the minimum age of patients is not specified, but the mean age of the subjects in the core study was thirty-four.<sup>147</sup> Because PMA submissions “must provide valid scientific evidence collected from human clinical trials showing the device is safe and effective for its intended use,” the FDA could not approve the devices for an unstudied population group.<sup>148</sup>

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<sup>141</sup> *Off-Label and Investigational Use of Marketed Drugs, Biologics, and Medical Devices: Information Sheet*, FDA, <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm> (last updated Aug. 10, 2011).

<sup>142</sup> Philip M. Rosoff & Doriane Lambelet Coleman, *The Case for Legal Regulation of Physicians' Off-Label Prescribing*, 86 NOTRE DAME L. REV. 649, 680 (2011).

<sup>143</sup> *Id.*

<sup>144</sup> *See supra* text accompanying note 14.

<sup>145</sup> *PMA P990074: FDA Summary of Safety and Effectiveness Data*, FDA (May 10, 2000), [http://www.accessdata.fda.gov/cdrh\\_docs/pdf/P990074b.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf/P990074b.pdf).

<sup>146</sup> *Id.*

<sup>147</sup> *PMA P020066: FDA Summary of Safety and Effectiveness Data*, FDA (Nov. 17, 2006), [http://www.accessdata.fda.gov/cdrh\\_docs/pdf2/P020056b.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020056b.pdf).

<sup>148</sup> *Learn if a Medical Device Has Been Cleared by the FDA for Marketing*, FDA, <http://www.fda.gov/MedicalDevices/ResourcesforYou/Consumers/ucm142523.htm> (last updated Apr. 24, 2009).

Of course, this lack of clinical trial evidence is not dispositive, as almost all off-label uses will, by definition, lack evidentiary support in PMA submissions and approval studies. What sets breast implant surgery for minors apart is that, on top of the lack of clinical trial data suggesting the safety and efficacy of these surgeries conducted on minors, there is affirmative evidence that minors are more vulnerable physically and mentally to adverse effects related to breast implants. First, in addition to the serious side effects associated with all breast implant surgeries, regardless of the age of the patient, there are specific risks associated with performing breast implant surgery on adolescents whose bodies are still developing. The bodies of teenaged girls continue to mature into adulthood; growth charts indicate that most girls gain weight between the ages of eighteen and twenty-one, which may affect a girl's desire or need for breast implant surgery.<sup>149</sup> In addition, because breast implants only last in the body for an average of ten years, minors who have breast implant surgeries will necessarily have to undergo successive operations across their lifetimes.<sup>150</sup> In addition to the health risks posed by these additional surgeries, there will also be significant financial burdens for minors who, at a young age, sign on to carry the burden of breast implant maintenance with them for a lifetime. One plastic surgeon interviewed for an article in the New York Times described her fee structure: "she charges about \$7,000 for breast augmentation; roughly \$5,000 to remove implants; roughly \$7,500 to replace old implants; and roughly \$9,000 for surgery in which she removes implants and performs a breast lift using the patient's own tissue."<sup>151</sup>

There is also reason to believe that, psychologically and mentally, minors are particularly inappropriate candidates for breast implant surgeries. As a general matter, research indicates that individuals who are drawn to cosmetic surgery in the first place are particularly vulnerable to reckless behavior. As many as fifteen percent of "patients seeking cosmetic treatments suffer from body dysmorphic disorder, a severe mental disorder that affects body perception and often leads sufferers to seek multiple unnecessary surgeries."<sup>152</sup> Further, women who have received breast implants are twice as likely as women of the same age who did not undergo surgery to commit suicide or die from substance abuse.<sup>153</sup> Moreover, unlike other medical decisions, cosmetic surgery decisions are highly susceptible to peer influence.<sup>154</sup> Adolescents are especially vulnerable to images in the media depicting cosmetically enhanced models and feel enormous pressure to "meet a culturally defined ideal of beauty."<sup>155</sup> It is precisely this pressure that motivates teen girls to

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<sup>149</sup> Diana Zuckerman, *Teenagers and Cosmetic Surgery*, VIRTUAL MENTOR (Mar. 2005), <http://virtualmentor.ama-assn.org/2005/03/oped1-0503.html>.

<sup>150</sup> Chiu, *supra* note 78, at 1810.

<sup>151</sup> Natasha Singer, *Do My Breast Implants Have a Warranty?*, N.Y. TIMES (Jan. 17, 2008), [http://www.nytimes.com/2008/01/17/fashion/17SKIN.html?pagewanted=all&\\_r=0](http://www.nytimes.com/2008/01/17/fashion/17SKIN.html?pagewanted=all&_r=0).

<sup>152</sup> Ouellette, *Body Modification*, *supra* note 125, at 149.

<sup>153</sup> *Id.*

<sup>154</sup> *Id.*

<sup>155</sup> *Id.* at 150.

seek out cosmetic surgery, and studies indicate that peer influence is one of the most significant motivating factors for minors who wish to undergo cosmetic surgery.<sup>156</sup>

Finally, even though minors only consent to breast implant surgeries through the substituted judgment of their parents, it is nevertheless troubling that minors lack fully-formed decision-making capacity when making the request for cosmetic procedures and putting themselves in this sort of situation. Studies show that teen brains are not fully developed to make critical decisions.<sup>157</sup> For example, MRIs conducted on adolescents and adults indicate that adolescents “rely more on the amygdala, the area of the brain associated with the primitive impulses of aggression, anger, and fear. Adults, on the other hand, tend to rely on the frontal lobes, a cerebral area associated with impulse control and good judgment.”<sup>158</sup> In a similar vein, other research shows that the regions of the brain associated with risk assessment and impulse control do not fully develop until late adolescence or later.<sup>159</sup> Furthermore, studies show that adolescents are incapable of making cost-benefit analyses, score lower on measures of personal responsibility, and are less capable of viewing situations with a long-term perspective.<sup>160</sup> Because of this, minors take risks to a greater degree than do adults, undervalue the consequences of their actions, and tend to make poor judgments.<sup>161</sup>

## 2. Cosmetic Breast Implant Surgery Is, by Definition, Not Medically Necessary

Given the evidence that minors are generally inappropriate candidates for breast implant surgery, it cannot seriously be argued that there is a medical need urgent or important enough to counsel performing breast implant surgeries on minors in the face of these serious safety concerns. Indeed, breast implants for minors are wholly unnecessary. Breast implant surgery is quite unlike other medical interventions because it involves taking unnecessary physical risks that are not offset by any physical benefits.<sup>162</sup> Although it is possible that psychological or other intangible benefits may accrue to the cosmetic surgery patient, these theoretical benefits pale in comparison to the substantial risks of the medical procedure.<sup>163</sup> In addition, the role of the medical provider in the cosmetic surgery context is quite different, as compared to other medical interventions.<sup>164</sup> In general medical practice, physicians act according to professional guidelines, which restrict the use of invasive procedures to only “those that are medically effective as measured by objective scientific criteria.”<sup>165</sup> This guideline alone can serve as a “safeguard against

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<sup>156</sup> *Id.*

<sup>157</sup> Diaz, *supra* note 9, at 251.

<sup>158</sup> *Id.*

<sup>159</sup> *Id.*

<sup>160</sup> *Id.*

<sup>161</sup> *Id.* at 251–52.

<sup>162</sup> Ouellette, *Body Modification*, *supra* note 125, at 148.

<sup>163</sup> *Id.*

<sup>164</sup> *Id.* at 150.

<sup>165</sup> *Id.*



impulsive and reckless decision making.”<sup>166</sup> Cosmetic surgery, on the other hand, is not focused primarily on medical efficacy because its goals are to achieve “aesthetic and social improvement.”<sup>167</sup> While plastic surgeons are expected to perform only those surgeries that would benefit a patient, determining the degree to which a cosmetic procedure will benefit a patient is entirely subjective. Further, no study has shown that there is any long-term benefit of performing cosmetic surgery on minors.<sup>168</sup> While some plastic surgeons are certainly capable of exercising good subjective judgments in this terrain, “there is simply no guarantee that a professional adult decision maker committed to preserving the health of the adolescent can be counted on to counter impulsive risk taking by adolescents for body modification.”<sup>169</sup>

### 3. The Medical Profession May Be Amenable to Enhanced Regulation of Breast Implants for Minors

There are indications from within the medical profession itself that restrictions on the ability of physicians to perform breast implant surgery on minors may be acceptable. First, in 2004, the ASPS adopted an official stance against breast implant surgery for patients under age eighteen.<sup>170</sup> While this is not an enforceable standard, it suggests that at least certain medical professionals consider breast implant surgery performed on minors to run counter to medical ethics.

Statements made by physicians during the FDA panel hearings regarding breast implant approvals provide another indication that there is a degree of discomfort from within the medical profession when it comes to performing breast implant surgery on minors. During the General and Plastic Surgery Devices Panel hearing on saline breast implant approval, various stakeholders in attendance raised concerns about allowing young women access to breast implant surgery.<sup>171</sup> Several physicians noted that obtaining meaningful informed consent from teenagers and their parents can often be difficult. According to one speaker, this difficulty is largely related to the fact that the kind of information being given to potential breast implant surgery patients is largely “probabilistic information,” and “probabilistic thinking is the most abstract kind of thinking and the last one to develop in [the] range of skills and capacity that we have.”<sup>172</sup> Several physicians in attendance agreed with this sentiment based upon their personal interactions with younger patients. For example, Doctor Charles Bailey noted that, “with respect to interacting with the patients, it’s not uncommon to be sitting in front of a very young patient where you feel like

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<sup>166</sup> *Id.*

<sup>167</sup> *Id.*

<sup>168</sup> *Id.* at 151.

<sup>169</sup> *Id.*

<sup>170</sup> Chiu, *supra* note 78, at 1812.

<sup>171</sup> See generally MED. DEVICES ADVISORY COMM., FOOD & DRUG ADMIN., GENERAL & PLASTIC SURGERY DEVICES PANEL (2000), <http://www.fda.gov/ohrms/dockets/ac/00/transcripts/3596t3a.pdf> [hereinafter Transcript of Meeting Day Three, Part One].

<sup>172</sup> MED. DEVICES ADVISORY COMM., FOOD & DRUG ADMIN., GENERAL & PLASTIC SURGERY DEVICES PANEL (2000), <http://www.fda.gov/ohrms/dockets/ac/00/transcripts/3596t3b.pdf> [hereinafter Transcript of Meeting Day Three, Part Two].

nothing that you're saying is being heard."<sup>173</sup> Another speaker, Doctor Mark Jewell, agreed with this sentiment, stating

as your children are in the early 20s and certainly in the teens . . . it's immediate gratification now. Don't bother me with the details. I find that a lot of the younger people are not—I don't feel like they are really listening and so sometimes I will impose a second visit on them or have them, you know, spend more time reading over the material and come back and sort of show me that they have an understanding of it.<sup>174</sup>

Given that younger patients can have trouble properly processing information about risks and consequences related to breast implant surgery, it seems unlikely that they will be active and capable participants in the informed consent process alongside their parents and physicians. Although Dr. Jewell explicitly stated that he "would not operate on a 17-year-old,"<sup>175</sup> he noted that it is his practice to spend much more time discussing long-term problems associated with breast implant surgery with his "very young patients."<sup>176</sup> Specifically, Dr. Jewell tells these young patients that they will likely "have at least one or two deflations during the next 50 years and maybe more than that."<sup>177</sup>

Other speakers throughout the hearing offered additional concerns: that there is a lack of scientific data delineating the long-term health effects for young girls who have received breast implant surgery, and that young patients may suffer from emotional scars if their implants rupture or the patient finds out many years later that she will not be able to breastfeed her baby.<sup>178</sup> Finally, the speakers also hinted at issues related to the excessive influence of peer pressure on young girls seeking cosmetic surgery. Dr. Bailey noted that he sometimes saw young teens brought into the surgeon's office by "a mother who is pushing an implant on a daughter because of her early life experiences, or a boyfriend or a husband."<sup>179</sup> While Dr. Bailey stated that it was "not uncommon for [him] to refuse two or three patients a month based on some of these concerns," this is merely Dr. Bailey's personal policy, and not one that any other surgeon would have any obligation or duty to uphold.<sup>180</sup>

Overall, there are several reasons why self-regulation by medical professionals is insufficient to protect minors who wish to undergo breast implant surgery from harm. First, there is no evidence that breast implant surgery performed on minors is safe given both the limitations of scientific data and the unique vulnerabilities and risk profiles of minors. Second, cosmetic breast implant surgery is never medically

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<sup>173</sup> Transcript of Meeting Day Three, Part One, *supra* note 171, at 55.

<sup>174</sup> *Id.* at 73–74.

<sup>175</sup> *Id.* at 72.

<sup>176</sup> *Id.*

<sup>177</sup> *Id.* at 72–73.

<sup>178</sup> MED. DEVICES ADVISORY COMM., FOOD & DRUG ADMIN., GENERAL & PLASTIC SURGERY DEVICES PANEL 216–17 (2000), <http://www.fda.gov/ohrms/dockets/ac/00/transcripts/3596t3c.pdf> [hereinafter Transcript of Meeting Day Three, Part Three].

<sup>179</sup> Transcript of Meeting Day Three, Part One, *supra* note 171, at 56.

<sup>180</sup> *Id.* at 55–56.

necessary, so there are no public health concerns related to encouraging minors to delay their surgeries until after the age of majority. Finally, there are indications that the medical profession itself would approve of federal oversight and regulation of breast implant surgery for minors. Combined, these factors all support the notion that breast implant surgery performed on minors is a situation in which the doctor-patient relationship should not be considered inviolable.

*B. Deference to Parents Is Inappropriate in the Context of Breast Implants for Minors*

Parents have a fundamental constitutional right to the care and custody of their minor children. The Supreme Court has characterized this right as a liberty interest protected under the Due Process Clause of the United States Constitution and has affirmed the rights of “parents and guardians to direct the upbringing and education of children under their control.”<sup>181</sup> Accordingly, fit parents are granted the presumption that they will act in the best interests of their children. The rationale underlying this presumption is that parents have what children lack in “maturity, experience, and capacity for judgment when making difficult life decisions;” thus, “due to their natural bond, parents will act in the best interests of their children.”<sup>182</sup>

A parent’s liberty interest in the upbringing of his or her child encompasses medical decision-making on behalf of the minor child, as minors are generally considered to lack the ability to make mature decisions about their physical well-being. Informed consent in the medical decision-making context requires patients to understand a physician’s disclosure of relevant risks and to exercise competent judgment. Minors are considered legally incompetent of this sort of evaluation; instead, physicians obtain informed consent from “parents, who are presumptively deemed competent on behalf of the minor.”<sup>183</sup> Consequently, in most cases, a physician cannot legally treat an adolescent without parental consent.<sup>184</sup>

Although the consent of a parent is typically substituted for that of the minor patient, there are a few exceptions to this general rule, and parents are unable to dictate all of a child’s medical decisions. In certain circumstances, a state may substitute its judgment that a medical procedure is in a child’s best interests, even if parents do not consent. These situations are ones in which “emergent needs take priority over parental rights and adolescent incompetence.”<sup>185</sup> The first exception arises in the context of a medical emergency, defined as “any condition that requires prompt treatment to alleviate pain or in which delay of treatment could increase the risk to the health of the patient or, ultimately, anything causing the child to be frightened or hurt.”<sup>186</sup> A second form of exception exists in some jurisdictions that have created special rules for emancipated minors or “mature minors.” An emancipated minor attains legal adulthood before reaching the age of maturity and

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<sup>181</sup> *Pierce v. Society of Sisters*, 268 U.S. 510, 534–35 (1925).

<sup>182</sup> *Diaz*, *supra* note 9, at 251.

<sup>183</sup> *Id.*

<sup>184</sup> *Ouellette Body Modification*, *supra* note 125, at 133.

<sup>185</sup> *Diaz*, *supra* note 9, at 247.

<sup>186</sup> *Id.*

has the legal authority to consent to medical treatment without parental consent.<sup>187</sup> In addition, the common law “mature minor doctrine” holds that minors “of sufficient intelligence and maturity to understand and appreciate both the benefits and risks of the proposed medical or surgical treatment . . . may consent to the treatment without parental consent.”<sup>188</sup> Generally, the mature minor doctrine applies only to minors aged fourteen and above, who are deemed socially and psychologically mature enough to make their own healthcare decisions.<sup>189</sup> The third and final type of exception is made when minors seek out certain sensitive medical treatments, such as those for substance abuse, mental health, sexually transmitted diseases, and adolescent pregnancy.<sup>190</sup> When it comes to these types of adult-like interventions, the minor’s personal constitutional right to bodily integrity figures prominently in the equation and must be balanced against the parental liberty interest in the family and childrearing.

Several factors combine together to create the overall rationale underlying the rules detailed above. First, while adolescents are considered rights-bearing citizens, certain policy concerns at times require these rights to be circumvented. While it is true that “constitutional rights do not mature and come into being magically only when one attains the state-defined age of majority,” it is also true that the peculiar vulnerabilities of children, the inability of children to make informed and mature decisions, and the centrality of the parental role in childrearing must all be protected at the same time.<sup>191</sup> Therefore, a state’s interest in protecting minors validly justifies requirements that minors obtain parental consent before undergoing a medical procedure or that criminalize conduct involving minors that would be unconstitutional if applied to adults.<sup>192</sup> Another factor that leads courts and policymakers to restrict the ability of minors to make health care decisions is the idea that minors play an important role in an autonomous family unit, and it is the parents who have a constitutionally protected right of control over this domain.<sup>193</sup> In order to respect familial autonomy, parents are given broad discretion and authority to raise children as they see fit and make decisions about the care of their children without interference from the government. It is only when the state’s interest in protecting children outweighs parental liberty that the state can step in and “[take] the choice out of the hands of the parents” in the health care context, such as by requiring mandatory vaccinations or prohibiting procedures such as FGM.<sup>194</sup>

This legal framework suggests a presumption that parents, in consultation with doctors, are best situated to determine the best interests of the child. In the context of consenting to breast implant surgery on the behalf of a minor child, this presumption does not hold. Primarily, this is so because parental-physician decision-making in

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<sup>187</sup> *Id.* at 249.

<sup>188</sup> *Id.* at 250.

<sup>189</sup> *Id.*

<sup>190</sup> *Id.* at 247.

<sup>191</sup> Ouellette, *Body Modification*, *supra* note 125, at 137.

<sup>192</sup> *Id.*

<sup>193</sup> *Id.* at 139–40.

<sup>194</sup> *Id.* at 141.

this context can be marred by conflicts of interest. The philosopher Michael Sandel has written about the issue of parents seeking enhancements for their children; he notes that parenthood should involve an appreciation of “children as gifts as they come, not as objects of our design or products of our will or instruments of our ambition.”<sup>195</sup> Sandel does not imply that parents should “shrink from shaping and directing the development of their child;” on the contrary, he believes that parents have an obligation to heal their children and prevent sickness and injury.<sup>196</sup> The distinction as Sandel sees it, however, is that, while a parent who consents to casting a child’s broken leg does not reject the child as she came, a parent who consents to a medical intervention that is purely cosmetic fails to appreciate the child as a gift. The parent’s imposition of his or her will on the child distorts the parent-child relationship.<sup>197</sup> Thus, when a parent consents to an extreme medical intervention, geared toward shaping the child toward social acceptability but promising no demonstrable medical benefit, questions of conflicts of interest on behalf of the caregiver cause the weight to shift against applying the usual parent-doctor decision-making presumption to this decision.<sup>198</sup>

In fact, it would not be unprecedented to override parental consent in this sort of scenario. There are two situations in which the legal system has explicitly removed parental consent from the equation when there are concerns about the motivations parents have for consenting to medical interventions or procedures on behalf of their children. First, most courts have held that parental consent is insufficient to authorize procedures in which a child would serve as an organ donor; in these situations, judicial approval is necessary.<sup>199</sup> There are two reasons why courts typically displace parents as decision-makers in this context. First, parents frequently have conflicts of interest; the beneficiary of the proposed organ donation is often an ill family member, which makes it hard for parents to independently consider the best interests of the donor child.<sup>200</sup> Second, courts have stated that “extra caution is needed when a parent wants to consent to a medical procedure that offers no medical benefit to the child.”<sup>201</sup> In *Little v. Little*, for example, a Texas appellate court found that the mother of a fourteen-year-old girl could not authorize a transplant of her daughter’s kidney into her son; the court so held because parents can only authorize “medical treatment,” defined as “the steps taken to effect the cure of an injury or disease.”<sup>202</sup> Donation of a kidney was not considered medical treatment, even though it might

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<sup>195</sup> Michael J. Sandel, *The Case Against Perfection: What’s Wrong with Designer Children, Bionic Athletes, and Genetic Engineering*, in *ETHICAL ISSUES IN MODERN MEDICINE: CONTEMPORARY READINGS IN BIOETHICS* 890, 894 (Bonnie Steinbock et al. eds., 2009).

<sup>196</sup> *Id.*

<sup>197</sup> Ouellette *Shaping Bodies*, *supra* note 130, at 982–85.

<sup>198</sup> Anne Tamar-Mattis, *Exceptions to the Rule: Curing the Law’s Failure to Protect Intersex Infants*, 21 *BERKELEY J. GENDER L. & JUST.* 59, 88, 98 (2006).

<sup>199</sup> Rachel M. Dufault, *Bone Marrow Donations by Children: Rethinking the Legal Framework in Light of Curran v. Bosze*, 24 *CONN. L. REV.* 211, 220 (1991).

<sup>200</sup> Tamar-Mattis, *supra* note 198, at 94.

<sup>201</sup> *Id.*

<sup>202</sup> *Little v. Little*, 576 S.W.2d 493, 495 (Tex. Civ. App. 1979).

confer psychological benefits, because donation would not improve the physical health of the donor.<sup>203</sup>

Another area in which parental consent is considered inadequate to authorize a minor's medical intervention is when parents seek to permit the sterilization of their children. As with organ donation, potential parental conflicts of interest have played an important role in the development of this legal framework. Sterilization is typically proposed for developmentally disabled and mentally ill minors or incompetent adult children. Parents that seek to obtain sterilization for their children may be worried that the burden of that child's future unwanted pregnancy would fall on them; the desire to avoid this situation can mar the judgment of the parent and interfere with his or her ability to independently consider the child's best interests.<sup>204</sup>

Overall, although parents typically enjoy broad liberties when it comes to raising children and making important life decisions on their behalf, the risks to minors associated with breast implants are sufficient to warrant a degree of governmental interference in this relationship. This is especially so in the context of cosmetic surgery for minors. When parents consent to expose their children to real medical risks during purely cosmetic procedures, with only the promise of social or psychological benefits accruing to the child, their motivations may be marred by conflicts of interest. As such, enhanced scrutiny is necessary.

#### VII. CONCLUSION

This article has attempted to make sense of the policy rationales underlying the federal government's imposition of age-based access controls on consumer products, medical procedures, and other interventions. This article argues that banning breast implants for minors under the age of eighteen would serve similar policy goals to age restrictions successfully employed elsewhere, such as for tobacco products, participation in biomedical research, and female genital mutilation. While critics of age-based access controls will be quick to attack this proposal as unduly burdening the autonomy of physicians and parents, this article has also demonstrated that there are reasons to believe that the traditional parental-physician consent framework will not protect the best interests of minors who seek breast implants. As such, this article ultimately calls for consistency. Minimum age restrictions for breast implants would cause no harm for minor patients, but could avoid serious and unnecessary harms. Thus, age restrictions should be applied in the context of breast implant surgery for minors where the relevant policy concerns so dictate.

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<sup>203</sup> *Id.* at 498–99.

<sup>204</sup> Tamar-Mattis, *supra* note 198, at 96.