

**The Plan B Age Restriction Violates a Minor's Right  
to Access Contraceptives**

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## Introduction

Every year nearly 750,000 teenagers get pregnant, and more than two-thirds of those teenagers who decided to have their baby will not graduate from high school.<sup>1</sup> In light of these statistics, it is no surprise that the United States has the highest rate of teenage pregnancy in the Western industrialized world.<sup>2</sup> Teen pregnancy has clearly created a financial burden, costing the United States at least seven billion dollars annually.<sup>3</sup> The majority of teenage pregnancies in the United States are unintended as well.<sup>4</sup> The rising rate of unwanted teenage pregnancies, therefore, is a serious societal problem and cannot be ignored.<sup>5</sup>

Plan B, also known as the “morning after pill,” is a safe, reliable, and effective emergency contraceptive, which prevents pregnancy if taken within seventy-two hours of unprotected sex or a birth control failure.<sup>6</sup> In August 2006, the Food and Drug Administration (FDA) issued a decision to allow the sale of Plan B as an over-the-counter emergency contraceptive.<sup>7</sup> However, in approving the sale of Plan B, the FDA also required women under the age of eighteen to first obtain a prescription for the drug from a physician.<sup>8</sup>

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<sup>1</sup> Pregnant Teen Help, <http://www.pregnantteenhelp.org/articles1.html> (last visited Jan. 19, 2010).

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

<sup>4</sup> See J. Trussell & E.G. Raymond, *Emergency Contraception: A Cost-Effective Approach to Preventing Unintended Pregnancy* (2009), <http://ec.princeton.edu/questions/ec-review.pdf>.

<sup>5</sup> Anna Pikovski Krishtul, *The FDA's Recent About Face: Plan B Age Restriction is Unlawful Rulemaking and Violates Minors' Due Process Rights*, 81 TEMP. L. REV. 303, 303 (2008).

<sup>6</sup> Pharmacy Access Partnership, *What Consumers Need To Know About Obtaining Plan B Over-the-Counter in Pharmacies* (2009), <http://www.pharmacyaccess.org/pdfs/ConsumerFAQsOTC.pdf>.

<sup>7</sup> See Krishtul, *supra* note 5, at 303.

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

The United States Supreme Court recognizes a fundamental due process right to access contraceptives.<sup>9</sup> It is the general position of this paper that the age restriction placed on women under the age of eighteen to obtain Plan B without a prescription, therefore, is a violation of that group's constitutional rights.<sup>10</sup> Notably, many believe that the FDA was unduly influenced by political considerations under the Bush Administration when the FDA placed an age restriction on Plan B.<sup>11</sup> Recently, in *Tummino v. Torti*, a federal judge found overwhelming evidence indicating that the FDA's decision to place an age restriction on Plan B was arbitrary, capricious, and an abuse of discretion not in accordance with the law.<sup>12</sup> As a result, the judge ordered the FDA to allow seventeen year-olds access to Plan B without a prescription, and to reconsider its ban on nonprescription sales to minors as young as eleven years-old.<sup>13</sup>

This Article seeks to address the legal tension that exist since the FDA reclassified Plan B from prescription to nonprescription status for women eighteen years of age and older, but continued to restrict access to minors. Part I of this Article is a broad overview of the competing constitutional rights of the parents, the State, and the female minor in need of contraceptives. This part will also discuss the constitutional rights of the State to regulate and protect adolescent sexual activity while balancing the parents' rights to decide how to raise their child. Part II describes how the Fourteenth Amendment protects a minor's right to privacy, including her decisions concerning contraceptives and procreation. Part III argues from a legal perspective why female

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<sup>9</sup> *Carey v. Population Serv. Int'l*, 431 U.S. 678, 685 (1977) (recognizing the right to decide whether or not to have a child was first explicitly recognized in *Griswold v. Connecticut*, 381 U.S. 479 (1965), finding a statute that prohibited the use of contraceptives to be unconstitutional).

<sup>10</sup> See Krishtul, *supra* note 5, at 303-04.

<sup>11</sup> See John Riley, *Plan B For Minors*, NEWSDAY, Mar. 24, 2009, at A6.

<sup>12</sup> *Tummino v. Torti*, 603 F. Supp. 2d 519, 549-50 (E.D.N.Y. 2009).

<sup>13</sup> *Id.* at 550.

minors are entitled the right to access Plan B without a prescription and without parental consent.

## **I. Competing Constitutional Rights- Whose Decision Is It?**

### **1. A Minor's Right is Limited**

The Supreme Court has ruled that minors are protected by the Constitution and are entitled to the same constitutional rights as adults.<sup>14</sup> However, the Supreme Court has ruled that the “State has a somewhat broader authority to regulate the activities of children than of adults.”<sup>15</sup> Children are afforded the same constitutional guarantees against government deprivations in the same manner that adults are protected.<sup>16</sup> Nonetheless, the Supreme Court has given three reasons why the constitutional rights of children should not be equated with the rights of adults.<sup>17</sup> First, the State is entitled to “adjust its legal system to account for children’s vulnerability.”<sup>18</sup> Second, the State may limit the freedom of children because an assumption is made that children, unlike adults, lack the ability to make critical decisions in an informed, mature manner.<sup>19</sup> Third, the Supreme Court acknowledges the importance of the parental role in child-rearing<sup>20</sup> and, thus, justifies limiting the freedom of minors since “the child is not merely the creature of the state; those who nurture him and direct his destiny have the right, coupled with the high duty to recognize and prepare him for additional obligations.”<sup>21</sup> A duty to prepare a child for “additional obligations” is interpreted by the Supreme Court to include raising a

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<sup>14</sup> *Planned Parenthood of Cent. Missouri v. Danforth*, 428 U.S. 52, 75 (1976).

<sup>15</sup> *Prince v. Massachusetts*, 321 U.S. 158, 170 (1944).

<sup>16</sup> *Bellotti v. Baird*, 443 U.S. 622, 635 (1979).

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

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

<sup>19</sup> *Id.* (“minors often lack the experience, perspective, and judgment to recognize and avoid choices that could be detrimental to them”).

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

<sup>21</sup> *Pierce v. Soc’y of Sisters*, 268 U.S. 510, 535 (1925).

child with “moral standards, religious belief, and elements of good citizenship.”<sup>22</sup> The State gives deference to parents because the underlying assumption is that parents know what is best for their child and parents will do whatever they can to protect their child from harm.<sup>23</sup>

## **2. A Parent’s Right to Raise His or Her Child**

It is well established that parents have a fundamental constitutional right to raise their children as they see fit.<sup>24</sup> The Supreme Court held in *Meyer v. Nebraska* that parents have a liberty interest protected by the Fourteenth Amendment, which includes the right to “establish a home and bring up children.”<sup>25</sup> Two years later, in *Pierce v. Society of Sisters*, the Supreme Court found that an Oregon statute “unreasonably interfere[ed] with the liberty of parents and guardians to direct the upbringing and education of children under their control.”<sup>26</sup> In *Prince v. Massachusetts*, the Supreme Court stated that “it is cardinal with us that the custody, care and nurture of the child resides first in the parents, whose primary function and freedom include preparation for obligations that the [S]tate can neither supply nor hinder.”<sup>27</sup>

More recently in *Troxel v. Granville*, the Supreme Court acknowledged the extensive precedents, which established parents’ right to raise their children without State interference.<sup>28</sup> Therefore, parents have the constitutional right to raise a child in accordance to their own morals and beliefs, especially in regards to adolescent sexuality

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<sup>22</sup> *Wisconsin v. Yoder*, 406 U.S. 205, 233 (1972).

<sup>23</sup> *See id.*

<sup>24</sup> *See, e.g., Meyer v. Nebraska*, 262 U.S. 390, 399 (1923).

<sup>25</sup> *Id.*

<sup>26</sup> *Pierce*, 268 U.S. at 534-35.

<sup>27</sup> *Prince*, 321 U.S. at 158.

<sup>28</sup> *Troxel v. Granville*, 530 U.S. 57, 66 (2000); *see also* Joshua A. Douglas, *When Is A “Minor” Also An “Adult”?: An Adolescent’s Liberty Interest in Accessing Contraceptives From Public School Distribution Programs*, 43 WILLAMETTE L. REV. 545, 553 (2007) (discussing parental rights).

and birth control, because the Due Process Clause of the Fourteenth Amendment protects the parents' fundamental right to make decisions concerning the care, custody, and control of their children.<sup>29</sup>

## **2. The State's Interest to Protect the Health, Safety, and Welfare of the Child**

While the Supreme Court acknowledges a parent's fundamental right to raise his or her child,<sup>30</sup> the State has "an independent interest in the well-being of its youth."<sup>31</sup> Part of the State's police power is to promote public health, safety, and welfare.<sup>32</sup> The law recognizes that parents do not always make the best decision for their children.<sup>33</sup> *Parens patriae* provides the State a wide range of power to interfere and limit parental authority in relation to things that would affect the child's welfare.<sup>34</sup> If the State views a parental decision or act to be harmful to a child, the State will exercise its *parens patriae* and police power to protect the health, safety, and welfare of the child.<sup>35</sup>

The State recognizes that confidential access to reproductive health care is essential for adolescents because many minors would avoid contraceptive services if forced to involve or notify their parents.<sup>36</sup> Currently, no state law exists that explicitly mandates parental consent or notification when a minor seeks contraceptive services.<sup>37</sup>

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<sup>29</sup> *Troxel*, 530 U.S. at 66; *see also* Douglas, *supra* note 28, at 553.

<sup>30</sup> *See Yoder*, 406 U.S. at 231-34.

<sup>31</sup> *Ginsburg v. New York*, 390 U.S. 629, 640 (1968).

<sup>32</sup> *See e.g., Pierce*, 268 U.S. at 534-535; *see also Yoder*, 406 U.S. at 231-234.

<sup>33</sup> *See e.g., Danforth*, 428 U.S. at 74 (ruling that "the State does not have the constitutional authority to give a [parent] an absolute" right over another person, even if that person is a minor").

<sup>34</sup> *Pierce*, 268 U.S. at 534-35.

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

<sup>36</sup> *See e.g.,* Rachel K. Jones, et al., *Confidential Reproductive Health Services for Minors: The Potential Impact of Mandated Parental Involvement for Contraception*, 36 PERSP. ON SEXUAL AND REPROD. HEALTH 182, 182 (2004) (explaining that mandatory parental involvement for adolescents threatens the rights of minors to access reproductive health care).

<sup>37</sup> *Id.* at 183 (a minor's right to access contraceptives varies state to state, for example, certain categories of minors are permitted such as those who are parents, emancipated, etc.).

Twenty-five states and the District of Columbia have laws that grant minors access to confidential contraceptive services.<sup>38</sup>

One visible effort by the State exercising its broad *parens patriae* and police power is through the 1970 enactment of Title X of the Public Health Service Act (Title X), which is the only federally funded family planning program.<sup>39</sup> Title X supports clinics that provide reproductive services to anyone on a confidential basis.<sup>40</sup> Many parents have attacked this statute claiming that Title X undermines their parental authority and violates their right to be notified if their child seeks contraceptive services.<sup>41</sup> In 1981, Congress amended Title X to require providers to encourage minors to seek family participation when seeking contraceptive services.<sup>42</sup> The House of Representatives attempted to pass the Parental Notification Act of 1998, an amendment to Title X, which would require the clinics to notify parents prior to giving adolescents contraceptives.<sup>43</sup> After two years of debate, the sponsors of the proposed Title X amendment dropped their bill in exchange for a \$50 million federally funded abstinence education program.<sup>44</sup>

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<sup>38</sup> Encyclopedia of Everyday Law, *Treatment of Minors*, <http://www.enotes.com/everyday-law-encyclopedia/treatment-minors> (last visited Jan. 21, 2010).

<sup>39</sup> Jones, et al., *supra* note 36, at 183 (stating that any clinics receiving federal funding must provide confidential reproductive health services for adolescents).

<sup>40</sup> Planned Parenthood, *Title X Family Planning Funding*, <http://www.plannedparenthoodaction.org/campaigns/626.htm> (last visited on Jan. 21, 2010).

<sup>41</sup> See Jones, et al., *supra* note 36, at 182 (parents argue that giving a minor the right to consent to reproductive services without parents' knowledge will undermine parental authority, and family values).

<sup>42</sup> Krishtul, *supra* note 5, at 320 (requiring clinics to encourage minors to discuss their family planning services with their parents).

<sup>43</sup> *Id.* (requiring clinics "to give parents a written notification unless the minor obtained judicial permission to bypass parental notification).

<sup>44</sup> *Id.* (discussing legislative efforts to limit a minor's access to reproductive services funded by the federal government).

## II. The Fundamental Right to Access Reproductive Services

### 1. The Right to Privacy Protected by the Fourteenth Amendment

In *Griswold v. Connecticut*, the Supreme Court ruled that the Bill of Rights created “zones of privacy” that protect against government invasions in an individual’s private life and home.<sup>45</sup> Under the Due Process Clause of the Fourteenth Amendment, the Supreme Court has stated that each person is entitled to “a right of personal privacy, or a guarantee of certain areas or zones of privacy.”<sup>46</sup> Although the Constitution does not explicitly mention any “right of privacy,” the Supreme Court has recognized this right as a liberty protected by the Fourteenth Amendment.<sup>47</sup> The right to privacy guarantees an individual “the interest in independence in making certain kinds of important decisions.”<sup>48</sup> The government may not interfere with important decisions protected by the right to privacy, such as child-rearing<sup>49</sup>, education,<sup>50</sup> marriage,<sup>51</sup> family,<sup>52</sup> procreation,<sup>53</sup> and contraception.<sup>54</sup>

If the government restricts a constitutional right, the restriction must go through a strict scrutiny analysis to ensure that no undue burden is imposed on any individual.<sup>55</sup> To

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<sup>45</sup> *Griswold v. Connecticut*, 381 U.S. 479, 484-85(1965).

<sup>46</sup> *Roe v. Wade*, 431 U.S. 678, 684 (1977) (quoting *Roe v. Wade*, 410 U.S. 113, 152 (1973)).

<sup>47</sup> *Id.*

<sup>48</sup> *Id.* at 684 (quoting *Whalen v. Roe*, 429 U.S. 589, 599-600 (1977)).

<sup>49</sup> *Prince*, 321 U.S. at 166.

<sup>50</sup> *Pierce*, 268 U.S. at 535.

<sup>51</sup> *Loving v. Virginia*, 388 U.S. 1, 12 (1967) (stating that “marriage is one of the ‘basic civil rights of man’”).

<sup>52</sup> *Griswold*, 381 U.S. at 484-85 (Connecticut statute prohibiting married people from using and limiting the doctors’ ability to help the couple obtain contraceptives was unconstitutional).

<sup>53</sup> *Skinner v. Oklahoma ex rel. Williamson*, 316 U.S. 535, 541-42 (1942) (holding that procreation is one of the basic civil rights of man).

<sup>54</sup> *Eisenstadt v. Baird*, 405 U.S. 438, 447 (denying an unmarried individual access to contraceptives was a violation of the Equal Protection Clause under the Fourteenth Amendment).

<sup>55</sup> See Samantha Harper, “*The Morning After*”: *How Far Can States Go to Restrict Access to Emergency Contraception?*, 38 COLUM. HUM. RTS. L. REV. 221, 248 (2006) (discussing contraception as a fundamental right).

survive the strict scrutiny analysis, the government has the burden to show that the restriction is justified by a compelling state interest and is narrowly tailored to only further that compelling interest.<sup>56</sup>

## **2. An Individual's Right to Access Contraceptives**

In *Eisenstadt v. Baird*, the Supreme Court held that a right to access contraceptives without government interference is recognized as part of an individual's right to privacy.<sup>57</sup> Furthermore, the Supreme Court found that access to contraceptives is important when an individual wants to exercise her fundamental right to make decisions regarding procreation.<sup>58</sup> Any governmental restriction on the distribution and sale of contraceptives nevertheless burdens an individual's freedom to make decisions concerning procreation and thus, is subject to the strict scrutiny analysis.<sup>59</sup>

In *Planned Parenthood of Central Missouri v. Danforth*, the Supreme Court ruled that the Constitution protected minors with a similar due process right to privacy.<sup>60</sup> However, the Supreme Court found that any governmental restriction on a minor's fundamental right is allowed only if it serves "any significant state interest ... that is not present in the case of an adult."<sup>61</sup>

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<sup>56</sup> *Carey*, 431 U.S. at 686 ("where a decision as fundamental as that whether to bear or beget a child is involved, regulations imposing a burden on it may be justified only by compelling state interests, and must be narrowly drawn to express only those interests").

<sup>57</sup> *Eisenstadt*, 405 U.S. at 354-55; see also *Griswold*, 381 U.S. at 484-86 (finding no rational basis for the different standards of treatment between married and unmarried individuals concerning a right to use contraceptives).

<sup>58</sup> *Carey*, 431 U.S. at 687-88.

<sup>59</sup> *Id.* at 688-89 (stating that regulation is only justified by a compelling state interest, that is narrowly tailored for that legitimate state interest because the right to access contraceptives is a constitutionally protected right).

<sup>60</sup> *Danforth*, 428 U.S. at 75.

<sup>61</sup> See *Carey*, 431 U.S. at 675 (examining whether a significant state interest exists when requiring parental consent to justify the State's imposed burdens on a minor's right to privacy).

### 3. A Minor's Right to Access Contraceptives

In 1977, the Supreme Court finally addressed a minor's due process right to access contraceptives in *Carey v. Populations Services International*.<sup>62</sup> Under the Due Process Clause of the Fourteenth Amendment, the Supreme Court concluded that any limitations on the distribution of contraceptives that burdens a minor's right to decide whether to prevent conception or terminate a pregnancy, is justified only by a compelling state interest and must pass constitutional scrutiny.<sup>63</sup>

The Supreme Court reviewed the constitutional validity of a New York statute, which made it a crime: "(1) for anyone to sell or distribute contraceptives to minors under the age of sixteen; (2) for anyone other than a licensed pharmacist to distribute contraceptives to a person over the age of fifteen; and (3) for anyone to advertise or display contraceptives."<sup>64</sup> The State argued that the statute was constitutional because minors could obtain contraceptives from a physician.<sup>65</sup> Therefore, the State argued that the distribution and sale of contraceptives were not completely prohibited from minors.<sup>66</sup>

Second, the State argued that the burden was "constitutionally permissible as a regulation of the morality of minors, in furtherance of the State's policy against promiscuous sexual intercourse among the young."<sup>67</sup> The State did not present any medical evidence to support its argument that limiting the distribution of non-prescriptive contraceptives to minors affected their sexual behavior.<sup>68</sup> The State simply asserted that

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<sup>62</sup> *Id.* at 687.

<sup>63</sup> *Id.*

<sup>64</sup> *Id.* at 681-82.

<sup>65</sup> *Id.* at 698.

<sup>66</sup> *Id.*

<sup>67</sup> *Id.* at 692.

<sup>68</sup> *Id.* at 697.

the contraceptive restriction “serve[s] to emphasize to young people the seriousness with which the State views the decision to engage in sexual intercourse at an early age.”<sup>69</sup>

The Supreme Court held that the New York statute was unconstitutional and recognized a minor’s right to privacy, which included her ability to make her own reproductive choices.<sup>70</sup> The Supreme Court found that regulating “the morality of minors” was not a significant State interest.<sup>71</sup> Because the State did not present any evidence that limiting a minor’s access to contraceptives would “substantially discourage early sexual behavior,” the Supreme Court ruled that any burden to exercise a fundamental right must be rationally connected to the State’s policy and “require[ed] more than a bare assertion.”<sup>72</sup>

When limiting the distribution of contraceptives to those over the age of sixteen to pharmacists, the Supreme Court ruled that this also significantly burdens an individual’s right to decide whether to use contraceptives and affected her decision involving procreation.<sup>73</sup> Although this burden was not as restrictive as a complete ban to the distribution of contraceptives, the Supreme Court recognized that “the restriction of distribution channels to a small fraction of the total number of possible retail outlets renders contraceptive devices considerably less accessible to the public, reduces the opportunity for privacy of selection and purchase, and lessens the possibility of price competition.”<sup>74</sup> Although the State had a valid interest in protecting an individual’s health, the Supreme Court found this statute created a burden on an individual to exercise

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<sup>69</sup> *Id.*

<sup>70</sup> *Id.*

<sup>71</sup> *Id.* at 694.

<sup>72</sup> *Id.* at 695-96.

<sup>73</sup> *Id.* at 689 (citing *Eisenstadt*, 405 U.S. at 461-64).

<sup>74</sup> *Id.* at 689.

her right to privacy and was not rationally related to the “State’s interest in protecting health.”<sup>75</sup>

### **III. The Plan B Age Restriction Violates A Minor’s Right to Access Contraceptives**

The Supreme Court has long recognized that the right to access contraceptives is a constitutionally protected right and is well established in past precedents such as *Roe v. Wade*, *Griswold*, and *Eisenstadt*.<sup>76</sup> With a minor’s right to privacy, the Supreme Court has distinguished a difference between the right to use a nonhazardous contraceptive such as Plan B and the right to have an abortion.<sup>77</sup> Unlike Plan B, an abortion implicates a “significant State interest” because the State has an interest in protecting a potential life as well as the mental and physical health of a pregnant minor.<sup>78</sup> Currently, the Supreme Court has not rendered a decision that requires parental notification or consent concerning a minor’s right to access contraceptives.<sup>79</sup> Because Plan B does not cause an abortion, the FDA should remove the age restriction that limits and violates a minor’s right to access this emergency contraceptive.<sup>80</sup>

#### **1. Requiring a Prescription is an Undue Burden on a Minor’s Right to Make Important Decisions Concerning Procreation**

The FDA’s decision to require minors ages sixteen years and younger to access Plan B through a prescription is not a complete ban on the distribution of

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<sup>75</sup> *Id.* at 690 (citing *Eisenstadt*, 405 U.S. at 464).

<sup>76</sup> *Planned Parenthood v. Casey*, 505 U.S. 833, 852-53 (1992) (“We have no doubt as to the correctness of [the *Griswold*, *Eisenstadt*, and *Carey*] decisions. They support the reasoning in *Roe* relating to the woman’s liberty because they involve personal decisions concerning not only the meaning of procreation but also human responsibility and respect for it”).

<sup>77</sup> *Id.* at 694.

<sup>78</sup> *Id.*

<sup>79</sup> See Harper, *supra* note 55, at 250-51 (discussing Supreme Court precedent that rejects attempts by the State to police premarital, extra marital, or even teenage sex).

<sup>80</sup> See *id.* at 251 (prohibiting or limiting the distribution of contraceptives for moral reasons is not a compelling state interest justified by the burden on minors).

contraceptives.<sup>81</sup> However, minors are still burdened by this less than complete ban.<sup>82</sup> The Supreme Court has found that this significant burden, which infringes an individual's right to make a decision concerning procreation "must pass constitutional scrutiny."<sup>83</sup> When Plan B is only available to minors through prescription, this restriction creates an undue burden that affects their right to privacy and to access contraceptives.<sup>84</sup>

Requiring a prescription from a physician or health care provider significantly limits a minor's access to Plan B because this inevitably delays her ability to take the emergency contraceptive from a few hours to more than a day.<sup>85</sup> Because Plan B is an extremely time-sensitive drug, any delay of even a few hours greatly compromises the effectiveness of this emergency contraceptive.<sup>86</sup> Within the seventy-two hour time frame to take Plan B, the FDA is requiring a minor to contact a doctor, schedule an appointment, go to the appointment to get the prescription, go to the pharmacy, and get the prescription filled by a pharmacist.<sup>87</sup> An additional barrier to access Plan B occurs when a minor needs to see a doctor on the weekend or evening. Since most providers are closed on the weekends and evenings, the minor is forced to wait a few days before being seen by a physician and further compromises her ability to access Plan B.<sup>88</sup>

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<sup>81</sup> Memorandum from Andrew C. Von Eschenbach, Acting Comm'r, FDA (Aug. 23, 2006), available at <http://www.fda.gov/CDER/drug/infopage/planB/avermemo.pdf> (hereinafter Eschenbach Memorandum).

<sup>82</sup> *See id.*

<sup>83</sup> *Carey*, 431 U.S. at 697 (finding a burden on the "right to decide whether to bear children" is a narrow exception that must pass the constitutional scrutiny analysis).

<sup>84</sup> *See Carey*, 431 U.S. at 689 (finding factors such as access, price, privacy of selection, and purchase are important considerations taken by the Supreme Court when reviewing a burden on a constitutional right).

<sup>85</sup> *See Jones, et al., supra* note 36, at 183 ("Barriers such as limited mobility, restricted financial independence and lack of information about contraceptives, including where to obtain them, are more pronounced for adolescents younger than 16, than they are for 16 and 17 year-olds.").

<sup>86</sup> Harper, *supra* note 55, at 249 (discussing the limitations the on sale and distribution of emergency contraceptives amounts to an infringement of the right).

<sup>87</sup> *Id.*

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

Second, the prescription requirement infringes a minor's right to privacy regarding the selection, purchase, and price of Plan B.<sup>89</sup> For example, some states allow a physician to breach patient-physician confidentiality to notify the parents when he or she has prescribed contraceptives to their minor child.<sup>90</sup> In some states, a physician has a right to refuse to prescribe Plan B to a minor and a pharmacist has the right to refuse to fill a valid prescription based on his or her own moral or religious beliefs concerning contraceptives.<sup>91</sup> In addition, a minor may already be in a vulnerable state because she is worried about the potential problem of being pregnant after the failure of another contraceptive method or she may have been raped.<sup>92</sup> Both situations create additional stress on the minor while she attempts to access the emergency contraceptive.

Third, many financial considerations play a role in determining the level of access minors have to the emergency contraceptive.<sup>93</sup> Many prescription drug plans do not provide full coverage for contraceptives and this creates a financial barrier for minors who cannot afford Plan B through the private sector.<sup>94</sup> Plan B as a prescription drug increases the cost for minors between \$30 and \$125.00.<sup>95</sup> In addition, several private insurance agencies require numerous and complicated billing procedures that require a

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<sup>89</sup> See *Carey*, 431 U.S. at 689 (finding factors such as access, price, privacy of selection, and purchase are important considerations taken by the Supreme Court when reviewing a burden on a constitutional right).

<sup>90</sup> See Angela Diaz, et al. *Legal and Ethical Issues Facing Adolescent Health Care Professional*, 71 THE MOUNT SINAI J. OF MED. 181, 182 (describing barriers for minors when seeking family planning/reproductive health services).

<sup>91</sup> See Diaz, et al., *supra* note 90, at 182 (“a physician’s own values may affect his ability to provide care to a patient”); Harper, *supra* note 55, at 250-51.

<sup>92</sup> Harper, *supra* note 55, at 250-51 (discussing various situations where a minor may be vulnerable and reluctant to seeing a health care provider).

<sup>93</sup> Linda Hock-Long, et al., *Access to Adolescent Reproductive Health Services: Financial and Structural Barriers to Care*, 35 PERSP. ON SEXUAL AND REPROD. HEALTH 144, 144-45 (2003) (stating adolescents’ access depends on the extent they have health insurance coverage (public or private), the ability to pay directly for services or access to family planning programs).

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

<sup>95</sup> Harper, *supra* note 55, at 250-51 (“The cost of prescription drugs is higher than that of a nonprescription drug.”).

health care provider to disclose treatments in order to receive compensation.<sup>96</sup> Also, a breach of confidentiality concerning a minor's contraceptive treatment may occur when the parents pay for the insurance plan because most minors are dependents listed under their parents' health insurance.<sup>97</sup> Besides difficulty paying for health care fees, a minor may not be able to travel to an alternative health care facility that provides public assistance.<sup>98</sup> For these reasons, having Plan B available only through prescription significantly burdens minors by restricting their access, increasing their costs, and taking away their consumer privacy.<sup>99</sup>

## **2. The Age Restriction on Plan B Serves No Compelling State Interest**

The age restriction on Plan B is a severe limitation that significantly burdens a minor's right to make a decision concerning procreation because the government has not shown a compelling state interest justifying why minors must have a prescription to access Plan B.<sup>100</sup> First, the FDA argues that Barr Pharmaceuticals, the manufacturer of Plan B, did not conclusively prove that this emergency contraceptive could be used safely and effectively by minors under the age of seventeen without a physician's supervision.<sup>101</sup> Second, the FDA expressed concerns that allowing minors over-the-counter access to Plan B would increase sexual promiscuity and that minors would use Plan B as a primary method of contraception.<sup>102</sup>

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<sup>96</sup> Diaz, et al., *supra* note 90, at 184 (describing how health care finances create additional challenges to patient confidentiality when physicians render treatment to minors).

<sup>97</sup> *Id.*

<sup>98</sup> *Id.*

<sup>99</sup> *See Carey*, 431 U.S. at 689 (finding factors such as access, price, privacy of selection, and purchase are important considerations taken by the Supreme Court when reviewing a burden on a constitutional right).

<sup>100</sup> *See id.* 688 (regulation is "may be justified only by a 'compelling state interest' ... and ... must be narrowly drawn to express only the legitimate state interests at stake").

<sup>101</sup> Eschenbach Memorandum, *supra* note 81, at 1.

<sup>102</sup> *See Kristul*, *supra* note 5, at 313 (The FDA scientific staff granted approval of Barr Pharmaceutical's preliminary proposal to market Plan B without a prescription to women ages sixteen and older, but a senior

Here, the FDA’s reasons for limiting minors’ access to Plan B are similar to the State’s rationale for limiting the distribution of contraceptives to minors in *Carey*.<sup>103</sup> The FDA has not presented any scientific evidence that minors cannot use Plan B safely and effectively without supervision by a physician.<sup>104</sup> Moreover, the Supreme Court has held that any attempt to “regulate a minor’s morality” is not a compelling governmental interest to justify the FDA’s age restriction on Plan B because this infringes a minor’s fundamental right to access contraceptives.<sup>105</sup> The FDA’s decision to restrict a minor’s right to access Plan B is a constitutional violation and, thus, Plan B should be available to everyone without a prescription.

### **3. Plan B is Safe and Effective For Minors to Use Without a Prescription**

The FDA’s rationale for placing an age restriction on Plan B is suspect for several reasons. First, the FDA completely disregarded the Joint Advisory Committee’s suggestion that Plan B did not require a health care professional’s supervision.<sup>106</sup> Second, the FDA never has requirements for an age-related marketing restriction, or pediatric studies for any approved over-the-counter medications.<sup>107</sup> Third, the FDA has never placed age-restrictions on any FDA-approved contraceptives prior to its Plan B

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agency officer denied the proposal stating that he was concerned that adolescents would use the emergency contraceptive.).

<sup>103</sup> See *Carey*, 431 U.S. at 694 (regulating “the morality of minors” is not a significant state interest and any burden to exercise a fundamental right must be rationally connected to the State policy “require[ing] more than a bare assertion).

<sup>104</sup> See *id.*

<sup>105</sup> See *id.*

<sup>106</sup> See Krishtul, *supra* note 5, at 313 (“Dr. Julie Beitz, the acting office director of the CDER, concluded that Plan B could be approved for over-the-counter sales absent an age registration because scientific data suggested the drug was safe and effective”).

<sup>107</sup> U.S. Government Accountability Office, Food and Drug Administration: Decision Process to Deny Initial Over-the-Counter Marketing of the Emergency Contraceptive Drug Plan B Was Unusual (2005), available at [www.gao.gov/new.items/d06109.pdf](http://www.gao.gov/new.items/d06109.pdf), at 30 (hereinafter GAO Report).

decision.<sup>108</sup> Finally, the FDA did not identify any issues that would warrant an age-related restriction during its initial review of Plan B as a prescription drug.<sup>109</sup> In sum, the FDA has not presented any scientific or medical evidence that supports its concerns that minors would take Plan B incorrectly without a physician's supervision.<sup>110</sup>

Pursuant to the United States Federal, Food, Drug, and Cosmetic Act (FDCA), the FDA has the authority to change access to a drug from prescription to over-the counter sale.<sup>111</sup> One way to change a drug's status from prescription to non-prescription is if the FDA determines the drug is safe, effective, and the drug's label provides clear, comprehensible, as well as adequate directions and warnings.<sup>112</sup> When a drug is under review to be switched from prescription to nonprescription sale, the FDA usually requests a recommendation from its Joint Advisory Committee, which is composed of members from the FDA's Nonprescription Drug Advisory Committee and another advisory committee with specialized knowledge in the specific drug under review.<sup>113</sup>

The FDA did not present any medical or scientific evidence that showed problems concerning the safety and effectiveness of Plan B to justify the age restriction.<sup>114</sup> On Dec. 16, 2003, the Joint Advisory Committee (members of the FDA's Nonprescription Drug Advisory Committee and Reproductive Health Drugs Advisory Committee)

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<sup>108</sup> *Id.*

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

<sup>110</sup> Eschenbach Memorandum, *supra* note 81, at 1 (The former FDA Commissioner, Von Eschenbach, did not use traditional FDA practices to determine that age eighteen is "is the more appropriate cutoff point to best promote and protect the public health.").

<sup>111</sup> *See generally* Krishtul, *supra* note 5, at 308 (describing how the FDA process when a prescription drug can switch to over-the-counter sale).

<sup>112</sup> *Id.*

<sup>113</sup> *See id.* at 312.

<sup>114</sup> United States of America Food and Drug Administration For Drug Evaluation Research, Nonprescription Drugs Advisory Committee (NDAC) In Joint Session With the Advisory Committee For Reproductive Health Drugs (ACRHD) Meeting, Dec. 16, 2004, at 395, available at <http://www.fda.gov/ohrm/dockets/ac/03/transcripts/4015T1.doc> (hereinafter Joint Committee Transcript).

recommended and approved Plan B for the over-the-counter sale in a vote of twenty-three to four.<sup>115</sup> Moreover, the Joint Advisory Committee approved Plan B for nonprescription use because it was “extraordinarily safe,” had a “wide safety margin,” and was the “safest produc[t] before the panel in four years.”<sup>116</sup> The four people who voted against Plan B’s over-the-counter sale stated that they did so for reasons other than safety and efficacy.<sup>117</sup> When reviewing drugs, safety and efficacy are the only factors that FDA members can consider when determining if a drug can be sold over-the-counter.<sup>118</sup>

When Plan B was under FDA review, an age restriction was never placed because the FDA will “not [] impose an age restriction for [Plan B] unless there were specific reasons to do so.”<sup>119</sup> Similar to other oral contraceptives, the FDA did “not have an age restriction [on Plan B] because most of the studies are done in a wide range of ages” and when the FDA “approved [contraceptives] according to the study population,” the youngest study participant was fourteen years- old.<sup>120</sup> When the FDA made the decision to make Plan B available without a prescription, the FDA determined that the emergency contraceptive was safe and effective for self-administration, regardless of the age of the person taking the medication.<sup>121</sup>

Plan B is a safe and reliable emergency contraceptive, which prevents pregnancies if taken orally within seventy-two hours of unprotected sex or contraceptive failure.<sup>122</sup> Plan B does not induce abortions, and if a fertilized egg is already attached to the uterus,

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<sup>115</sup> Joint Committee Transcript, *supra* note 114, at 395; *see also* Krishtul, *supra* note 5, at 312.

<sup>116</sup> Joint Committee Transcript, *supra* note 114, at 344-49.

<sup>117</sup> *Id.* at 361-95.

<sup>118</sup> 21. C.F.R. § 310.200(b).

<sup>119</sup> Joint Committee Transcript, *supra* note 144, at 351.

<sup>120</sup> *Id.* at 351-52.

<sup>121</sup> *See* GAO Report, *supra* note 107, at 1 (“By law, FDA may approve the switch of a prescription drug to OTC status if use of the drug is safe and effective for self-medication in accordance with proposed labeling.”).

<sup>122</sup> *Id.* at 12 (discussing the chemical components of Plan B).

Plan B will not terminate the pregnancy.<sup>123</sup> The Plan B regimen is a two-pill dose of levonorgestel, which is a type of progestin and each pill contains .75 mg of levonorgestrel.<sup>124</sup> Plan B is most effective when the first pill is taken and the second pill is taken twelve hours after taking the first pill.<sup>125</sup> When Plan B is taken within the seventy-two hour window, this emergency contraceptive reduces the risk of pregnancy by eighty-nine percent.<sup>126</sup> Because Plan B is only levonorgestrel regimens, the temporary and minor side effects such as nausea, abdominal pain, menstrual changes, tiredness, dizziness, breast tenderness, and vomiting are reduced by fifty to seventy percent.<sup>127</sup> The most commonly reported side effect of Plan B was menstrual irregularities.<sup>128</sup>

All oral contraceptives (birth control pills), including the emergency contraceptive, contain the same label stating: “Safety and effectiveness of [trade name] have been established in women of reproductive age. Safety and efficacy are expected to be the same for post-pubertal adolescents under the age of 16 and for users 16 years and older.”<sup>129</sup> The FDA uses the same labeling for all oral contraceptives and nothing in its label explicitly mention any issue concerning safety or effectiveness as a result of the age of the person taking the medication.<sup>130</sup> The oral contraceptive label demonstrates the FDA’s assumption that ovulation will be suppressed for any female who has started

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<sup>123</sup> *Id.* at 12-13 (“[r]esearch has shown that levonorgestrel-only emergency contraception, such as Plan B, interferes with prefertilization events”).

<sup>124</sup> *Id.* at 12.

<sup>125</sup> *Id.*

<sup>126</sup> *Id.*

<sup>127</sup> David A. Grimes, et al., *Emergency Contraception Over-The-Counter: The Medical and Legal Imperatives*, 98 *OBSTETRICS & GYNECOLOGY* 151, 152 (2001) (arguing Plan B should be available without a prescription because it is safe and effective for self-administration); *see also* GAO Report, *supra* note 107, at 12.

<sup>128</sup> Grimes, et al., *supra* note 127, at 152 (“the side effects, although temporary and not serious, might be expected to deter frequent use”).

<sup>129</sup> GAO Report, *supra* note 107, at 30.

<sup>130</sup> *Id.*

menstruating, regardless of her age, after taking the medication.<sup>131</sup> Moreover, the FDA did not make any specific age-related inquiries regarding the drug's safety or effectiveness before the FDA approved Plan B for prescription use.<sup>132</sup> Since the FDA did not put an age-restriction on the prescription availability of Plan B, it does not make sense that the FDA would place an age-restriction on the Plan B over-the-counter sale.<sup>133</sup>

Any incorrect use of Plan B would not even come close to the health dangers or problems created by any incorrect use of other over-the-counter medications such as aspirin, antipyretics and analgesics.<sup>134</sup> For example, hundreds of deaths are recorded each year in the United States resulting from overdoses of aspirin, which is still available for over-the-counter sale to minors.<sup>135</sup> The risk of an overdose or abuse of Plan B is highly unlikely because this drug does not carry any ingredient with the potential for overdose or addiction.<sup>136</sup> Plan B is non-toxic, non-teratogenic, and does not pose any harm to the woman or embryo if this drug is mistakenly taken while pregnant.<sup>137</sup> Moreover, treatment is identical for all women and the over-the-counter dose of hormone is the same amount for the prescribed Plan B.<sup>138</sup> Thus, Plan B is arguably safer than other over-the-counter medications that are currently available to minors.<sup>139</sup>

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<sup>131</sup> *Id.*

<sup>132</sup> *Id.* at 31 (“There were no safety issues that would require age-related restrictions that were identified with the original NDA for prescription Plan B.”).

<sup>133</sup> *Id.* (“The label for prescription Plan B makes no age distinctions about the pharmacological processes of the drug, and prescription Plan B is available to anyone with a prescription.”).

<sup>134</sup> Grimes, et al., *supra* note 127, at 152.

<sup>135</sup> *Id.*

<sup>136</sup> *Id.* (“no deaths, suicides, or other serious consequences of an acute overdose of either hormone have been reported”).

<sup>137</sup> *Id.* at 152.

<sup>138</sup> *Id.*

<sup>139</sup> *Id.*

The argument that Plan B requires a physician’s supervision of a minor is faulty because the FDA would not have approved the over-the-counter sale of Plan B if the drug did not meet the “self-recognizable, self-limiting, and requires minimal intervention by a health care practitioner for treatment” elements required to switch a drug from prescription to over-the-counter sale.<sup>140</sup> The duration of treatment for Plan B is twenty-four hours (each pill is taken twelve hours apart) and the mild side effects are self-limited.<sup>141</sup> If any severe symptoms were to occur, these side effects are easily managed with over-the-counter analgesics or antiemetics.<sup>142</sup> Unlike other over-the-counter medications that require tailoring medicine doses based on the patient’s age, Plan B uses identical doses of progestin regardless whether it is sold over-the-counter or through a prescription.<sup>143</sup>

A woman will know after contraceptive failure or unprotected sex that she will need Plan B, and if this emergency contraceptive fails, the woman will be able to recognize on her own that she is pregnant.<sup>144</sup> Distinguishable from other over-the-counter medications, Plan B has simple and easy to follow instructions: take one pill immediately and take the other pill twelve hours later.<sup>145</sup> A physician monitoring a minor’s treatment of Plan B will not reduce the incident of side effects, will not increase

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<sup>140</sup> GAO Report, *supra* note 107, at 13-14 (“...the proposed OTC dose and administration schedule were identical to that for Plan B’s prescription use. The application also included an actual use study and a label comprehension study to assess potential users’ understanding of how to administer the product”).

<sup>141</sup> Grimes, et al., *supra* note 127, at 153.

<sup>142</sup> *Id.*

<sup>143</sup> *Id.* at 152.

<sup>144</sup> *Id.* (“Screening to recognize the indication for treatment is irrelevant.”).

<sup>145</sup> *Id.* (“In contrast, many over-the-counter medicines have more complicated instructions for use.”).

the effectiveness or efficiency of the medication, and therefore, professional monitoring is unnecessary.<sup>146</sup>

Finally, the FDA did not present any scientific or medical evidence that minors would use Plan B incorrectly. Before Barr Pharmaceuticals became the distributor of Plan B, Women's Capital Corporation conducted an actual use study with the FDA to determine whether "women would use the product appropriately and safely when it was dispensed using a simulated over-the-counter approach."<sup>147</sup> The study involved six groups from six different locations.<sup>148</sup> The two age groups were females ages sixteen and younger, and females ages seventeen and older.<sup>149</sup> Study results showed that "minors and less-educated women, were not substantially more likely than others to use the product in a contraindicated or incorrect manner and did not have notably higher risks of adverse events or pregnancy."<sup>150</sup> As the study proved, minors correctly and safely used Plan B without any physician's supervision.<sup>151</sup> Without presenting any evidence, the FDA's rationale for the age restriction of Plan B does not serve a compelling interest that justifies the burden placed on minors' access to Plan B.

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

<sup>147</sup> Elizabeth G. Raymond, et al., "Actual Use" Study of Emergency Contraceptive Pills Provided in a Simulated Over-the-Counter Manner, 102 *OBSTETRICS & GYNECOLOGY* 17-18 (2003) ("The Food and Drug Administration also reviewed the protocol, and a number of that agency's comments were incorporated into the study design and analysis plan.").

<sup>148</sup> *Id.* at 19 (Table 1 Characteristics at First Screening of Women Who Received Study Package).

<sup>149</sup> *Id.*

<sup>150</sup> *Id.* at 21-22.

<sup>151</sup> *Id.* at 23.

#### **4. Over-the-Counter Access to Plan B Does Not Increase Sexual Promiscuity Among Minors**

The FDA's concerns that over-the-counter access to Plan B will increase sexual promiscuity among minors is unsupported and the age restriction is the government's attempt to regulate the sexual behavior of minors.<sup>152</sup> The FDA's justification for the age restriction is analogous to the State's argument in *Carey*.<sup>153</sup> The FDA has not presented evidence to show that Plan B over-the-counter access will increase unprotected sex among minors nor has shown that minors will use more common reliable forms of contraceptives any less.<sup>154</sup> On the contrary, when the FDA Commissioner and the Acting Director expressed concerns regarding increased adolescent sexual activities, the FDA's Scientific Review Committee conducted additional studies to nevertheless conclude that "increased access to [Plan B] did not result in (1) inappropriate use by adolescents as a substitute form of contraception, (2) an increase in the number of sexual partners or the frequency of unprotected intercourse, or (3) an increase in the frequency of STDs."<sup>155</sup> Moreover, the Joint Advisory Committee voted seventy-eight to zero that based on the findings in an actual use study, minors would not use Plan B as a regular form of contraceptives if made available without a prescription.<sup>156</sup>

The FDA scientific review committee conducted five studies where all the participants received advance supplies of Plan B in order to assess the behavioral impact of over-the-counter access.<sup>157</sup> In one study with 2,090 participants ranging from the ages fifteen to twenty-four, showed "a decrease in unprotected sex among all age groups and

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<sup>152</sup> GAO Report, *supra* note 107, at 30.

<sup>153</sup> *See Carey*, 431 U.S. at 687.

<sup>154</sup> GAO Report, *supra* note 107, at 30.

<sup>155</sup> *Id.* at 26.

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

<sup>157</sup> *Id.* at 27.

no increase in the incidence of STDs compared to the baseline.”<sup>158</sup> In another study of 160 adolescent mothers, ranging from ages fourteen to twenty, the study did not reveal any increase in unprotected sex or any decrease in condom use among the participants.<sup>159</sup> A third study with 301 adolescent participants, ranging from the ages fifteen to twenty, showed similar results where there was no increase in unprotected sex or any decrease in condom use.<sup>160</sup>

The FDA’s assumptions that over-the-counter access to Plan B will increase adolescent promiscuity and decrease the use of regular methods of contraceptives is unfounded.<sup>161</sup> First, the FDA has chosen to ignore conclusive scientific evidence that proves access to Plan B without a prescription does not increase the health related risks among minors.<sup>162</sup> Second, the Supreme Court has rejected the government’s attempts to regulate sexual activity among minors finding that the burden placed on a minor’s right to access contraceptives is not justified by a compelling state interest.<sup>163</sup> In conclusion, the FDA must allow everyone over-the-counter access to Plan B because the prescription requirement is a severe limitation that affects a minor’s right to access contraceptives and her right to make decisions regarding procreation.<sup>164</sup>

## **Conclusion**

Individuals, including minors, are guaranteed the right to access contraceptives and to make decisions concerning procreation, all without undue burden from government restriction. The FDA’s decision to require minors to have a prescription to

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

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

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

<sup>161</sup> *Id.* at 26.

<sup>162</sup> *Id.* at 27.

<sup>163</sup> *See Carey*, 431 U.S. at 687.

<sup>164</sup> *See id.*

access Plan B is motivated by political pressures and attempts by the government to regulate adolescent sexual behavior. As such, limiting a minor's access to Plan B is not a compelling state interest as evidenced in *Carey*, and this governmental regulation creates a burden that infringes a minor's constitutional right to privacy.

The age restriction behind Plan B is not due to safety concerns, but rather exemplifies the FDA's fears of increase adolescent promiscuity that is unsupported by medical or scientific evidence. The FDA has ignored overwhelming evidence that shows minors can effectively and safely self-administrate Plan B responsibly. The FDA has not presented any evidence to show that minors will misuse Plan B. Because Plan B is an emergency contraceptive and does not induce abortions, the State does not have a compelling interest because "potential life" is not at issue. In summary, the FDA must allow a minor nonprescription access to Plan B because a prescription creates significant barriers without a justifiable State interest, and violates a minor's right protected under the Fourteenth Amendment.