



# A Difficult Proposition: Oral Contraceptives' Switch from Prescription to Over-the-counter Status

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## Introduction

A movement for increased personal autonomy and individual empowerment has seeped into all aspects of this country's social, political, and economic life. The extent of this movement's influence is clearly visible in the confluence of perhaps surprising bedfellows: the politics of the Food and Drug Administration and a 1951 amendment to the 1938 Food, Drug, and Cosmetic Act, the establishment of contraception use as a fundamental privacy right in constitutional law, and the increasing power of feminists and reproductive rights advocates on the democratic process.<sup>1</sup> What is responsible for this phenomenon? The latent, but nonetheless real, controversy over the potential switch of oral contraceptives from prescription only drugs to drugs available over-the-counter. The aborted initiative to produce such a switch demonstrates that the line separating individualism from paternalism in the realm of scientific and medical technology is not as bright as one would think.

### Statutory Authority and Legislative History for Prescription to Over-the-Counter Switches

Prior to 1951, and arguably even after 1951, the classification of a drug as prescription or non-prescription has been rife with uncertainty. The 1938 Federal Food, Drug and Cosmetic Act (the FD&C Act) failed to include criteria for categorizing a drug as prescription or over-the-counter.<sup>2</sup> In response to this omission, FDA created the concept of federal mandatory prescription status through regulations promulgated in 1938 which

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<sup>1</sup>It is arguable that women's rights and reproductive rights advocates have suffered a major set back following the *Casey* decision in 1992. See *infra* Note 101

<sup>2</sup>Wion, Ann H. *Rx to OTC Switch. The Process and Procedures*. 19 Drug Info. J. 119 (1985).

were later amended in 1944.<sup>3</sup> Yet until Congress codified these regulations in the 1951 Durham-Humphrey Amendments to the FD&C Act, different manufacturers made different choices about whether to market the same drug as prescription or over-the-counter.<sup>4</sup> Motivated by a desire to eliminate this confusion, Congress included section 503(b)(1) to the FD&C Act when it enacted the Durham-Humphrey Amendments.<sup>5</sup> Section 503(b)(1) defines a prescription drug as:

- A drug intended for use by man which-
- (A) is a habit-forming drug to which section 502(d) applies; or
  - (B) because of its toxicity or other potentiality for harmful effect or the method of its use, or the collateral method necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or
  - (C) is limited by an approved application under section 505 to use under the professional supervision of a practitioner licensed by law to administer such drug.

Thus, under the statute, a drug must be classified as prescription only if it falls under one of three categories: (1) habit-forming, (2) not safe for use except under medical supervision because of the drug's toxicity, potentially harmful effects, or method of use, or (3) limited to prescription status under new drug applications (NDAs). Since the first category is limited to 17 specified habit-forming chemicals, or their derivatives, listed in section 502(d) and since the third category refers to those new drugs which are limited to prescription status when FDA approves an NDA for drugs falling within the second category, it is the second category which effectively controls future determinations of drugs as either prescription or over-the-counter.<sup>6</sup> Thus, a potential prescription to over-the-counter switch for oral contraceptives must be first scrutinized under the

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<sup>3</sup>Hutt, Peter Barton. *A Legal Framework for Future Decisions on Transferring Drugs From Prescription to Nonprescription Status*. 37 Food Drug Cosm. L.J. 427 (1982). 427, 428.

<sup>4</sup>See supra Note 2 at 119.

<sup>5</sup>See supra note 2 at 119.

<sup>6</sup>See supra note 3 at 433

second component of section 503(b)(1).

But what did Congress intend by promulgating the criteria of the second component of section 503(b)(1) and did Congress envision that drugs such as oral contraceptives would potentially be available over-the-counter? Since the birth control pill was introduced in 1960, nine years after the passage of section 503(b)(1), the question of oral contraceptives specifically never arose in the amendment's legislative history. Interestingly enough, however, there was committee testimony regarding human hormones.<sup>7</sup> The then FDA Federal Security Agency Associate Commissioner, George P. Larrick, offered the following testimony regarding potent drugs:

When the medicines are administered by skilled physicians they cure many ailments. Most of these drugs, however, are quite potent and capable of doing harm when misused. ... Female sex hormones, called estrogens, are very useful in the hands of skilled physicians, but in a case under the Food and Drug Act in California recently, where the drugs were sold without prescription, eminent medical authorities testified that improper use is capable of stimulating the growth of incipient cancer; it may impair fertility and cause hemorrhage from the uterus.<sup>8</sup>

The Associate Commissioner's testimony demonstrates what one congressman articulated as the goal of the amendment: "...to protect the public in the use of potent medicines which should be sold on prescription..."<sup>9</sup> In passing the 1951 amendment, Congress was indeed motivated by the desire to protect public health. But Congress also recognized that the prescription/over-the-counter status of a drug may change on the basis

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<sup>7</sup>11 Legislative History of the Food, Drug & Cosmetic Act 26, (1979) 26, 114  
*Hearings before the Comm. on Interstate and Foreign Commerce* H.Rep. Sess. 1, 82d. Cong. (1951), *Statement of George P. Larrick*

<sup>8</sup>*Id* at 115

<sup>9</sup>11 Legislative History of the Food, Drug and Cosmetic Act 26 (1979), 26, 324  
*H.R. Debate*, 82d Cong. 1st Sess. (1951)

of new information.<sup>10</sup> As Congressman Durham explained during committee hearings regarding the amendment, any prescription drug may be administratively changed to over-the-counter when its prescription status is no longer necessary to protect the public health.<sup>11</sup> Congressional intent was to prevent dispensation of “harmful drugs” without the supervision of medical professionals, not to prevent self-medication which utilized relatively safe drugs such as aspirin or “Mothersill’s seasick pills.”<sup>12</sup>

Regarding determination of a drug’s prescription or over-the-counter status under section 503(b)(1), Congress intended extensive inquiry to occur.<sup>13</sup> Although recognizing that many drugs were not “toxic” or “poisonous,” Congress still deemed the potential of these drugs to have an ill effect upon a human being and their potential to threaten the public health as relevant factors influencing determination of the drugs’ prescription/non-prescription status.<sup>14</sup> <sup>15</sup> Thus, although Congress was weary of vesting excessive power in a government agency and in the agency’s commissioner,<sup>16</sup> the combination of (1) a broad range of permissible inquiry accompanying determination of a drug’s prescription/non-prescription status, and (2) the less than mathematical requirements of section 503(b)(1), has created a process in which a drug’s status rests largely on the judgment of FDA.<sup>17</sup>

### **FDA Consideration of a Prescription-Over-the-Counter Switch for Oral Contraceptives**

Although generally a conservative agency, FDA initiative since the 1980s to change drugs from prescription

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<sup>10</sup>See supra Note 3 at 433

<sup>11</sup>See supra Note 7 at 38

*Statement of Hon. Carl T. Durham, A Representative in Congress from North Carolina*

<sup>12</sup>See supra Note 9 at 351

<sup>13</sup>See supra Note 3 at 433

<sup>14</sup>See supra Note 9 at 338

<sup>15</sup>See supra Note 3 at 433

<sup>16</sup>See supra Note 8 at 317-318, 326, 329, 333, 337

<sup>17</sup>*The Impact of the Rx-to-OTC Switch Process-Present and Future.* 19 Drug Info. J. 85 (1985) 85, 201

to over-the-counter suggests, for many, a new FDA policy toward over-the-counter status.<sup>18</sup> FDA seems more willing to acknowledge the ability of laypersons to safely and effectively utilize drugs which heretofore have been limited to prescription status.<sup>19</sup> Congruent with this more recent policy, FDA on January 21, 1993 announced in the *Federal Register* an open committee discussion of the Fertility and Maternal Health Drugs Advisory Committee (a committee which reviews and evaluates data on the safety and effectiveness of marketed and investigation human drugs for use in the practice of obstetrics and gynecology) to be held on February 4 and 5, 1993, to discuss issues related to providing oral contraceptives without prescription.<sup>20</sup> The issues scheduled for discussion at the Feb. 4-5 session were to include whether labeling can provide adequate instruction on the use of oral contraceptives, whether an over-the-counter Pill would place women at a higher risk of contracting sexually transmitted diseases, and whether over-the-counter availability would affect the contraceptives' efficacy.<sup>21</sup> On January 28, 1993, one week after the posted *Federal Register* notice of the committee review, FDA canceled the session.<sup>22</sup> The over-the-counter oral contraceptives advisory committee review was never rescheduled.

FDA's abrupt cancellation of the committee review was allegedly ordered by top FDA officials and sparked public speculation as to the reasons for the agency's retreat.<sup>23</sup> An FDA spokesman said Commissioner David Kessler's office gave the order to cancel the meeting while staffers explore a broader agenda and consult with outside groups about their concerns.<sup>24</sup> The press reported that an outpouring of discontent from medical

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<sup>18</sup>Kaplan, Alan H. *Over-the-Counter and Prescription Drugs: The Legal Distinction under Federal Law*. 37 Food Drug Cosm.L.J. 441 (1982) 441, 445

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

<sup>20</sup>58 FR 5400, 5401

<sup>21</sup>F-D-C Reports—"The Pink Sheet," Feb. 1, 1993

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

<sup>23</sup>*Talks Canceled on Making "Pill" Nonprescription*. The Wall Street Journal, January 28, 1993 at B1

<sup>24</sup>*Oral Contraceptives' Move to OTC Hits Major Obstacle*. Washington Drug Letter. February 1, 1993, at 5

and family planning groups led FDA to cancel the advisory committee meeting.<sup>25</sup> Answering allegations of FDA's backing away from a controversy, FDA deputy commissioner for external affairs responded that the meeting was canceled after FDA officials decided that the agenda was not broad enough and that the agency had not consulted with a wide enough range of groups.<sup>26</sup>

Given the cancellation of the oral contraceptives review, what motivated the scheduled meeting of the advisory committee in the first instance? Under "switch-regulation," first promulgated by FDA in 1956 and later codified in 21 CFR 310.200, any interested party may petition FDA to exempt a drug that is restricted to prescription use under the terms of its NDA from its prescription use limitations.<sup>27</sup> The Commissioner may also initiate review of a drug, which may result in over-the-counter status for the drug if FDA determines that prescription status is no longer necessary to protect the public health.<sup>28</sup> Although the Fertility and Maternal Health Drugs Advisory Committee was not to review any specific company's application at its Feb. 4-5 meeting,<sup>29</sup> helping to organize the scheduled meeting was R.W. Johnson Pharmaceutical Research Institute, the research arm of Ortho Pharmaceutical Corp., producer of the top-selling oral contraceptive brand, Ortho-Novum.<sup>30</sup> Apparently, FDA had approached Ortho Pharmaceutical to help organize the meeting.<sup>31</sup>

Estimates predicted that if sold without a prescription, Johnson and Johnson's birth control pill sales could double to \$500 million.<sup>32</sup> Pill sales of other firms producing oral contraceptives, such as American Home, Bristol-Myers Squibb, Monsanto and Warner-Laambert, would also increase; according to outside analysts, a

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

<sup>26</sup> *Supra* see Note 23

<sup>27</sup> *Supra* see Note 2 at 120-121

<sup>28</sup> *Id.* at 121

<sup>29</sup> F-D-C Reports- "The Pink Sheet." January 25, 1993

<sup>30</sup> *Birth Control Pills May Not Require a Prescription.* Washington Post Health. January 19, 1993

<sup>31</sup> *FDA: OTC Birth Control Issue Needs Broad-Based Input.* Dickonson's FDA. February 15, 1993 at 8

<sup>32</sup> *Supra* see Note 23

prescription to over-the-counter switch would double the oral contraceptive market to close to \$1.6 billion.<sup>33</sup> Responding to the cancellation of the advisory committee's meeting, Ortho stated that any discussion of switching oral contraceptives to over-the-counter status should be made in the best interests of women's health and take into account all viewpoints.<sup>34</sup>

### History and Development of "the Pill"

In 1950, the Planned Parenthood Federation of America invited an American biologist, Dr. Gregory Pincus, to develop an ideal contraceptive.<sup>35</sup> Planned Parenthood contributed \$2,100 to the project and another \$20,000-\$30,000 was raised from government and private sources before the research actually began.<sup>36</sup> A pill was developed containing estrogen and progestin, synthetic hormones similar to those produced naturally in a woman's body, which worked by suppressing the release of eggs from a woman's ovaries.<sup>37</sup> After clinical trials on 6,000 women in Puerto Rico and Haiti, the first commercially produced birth control pill, Enovid-10, was marketed in the United States.<sup>38</sup> The first oral contraceptives contained 100 mcg to 175 mcg of estrogen and up to 10 mg of progestin, higher levels than in today's pills, and they were 99 percent effective when used properly.<sup>39</sup>

The pill was available prior to 1960, but not as a drug marketed for contraception. Searle initially asked

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<sup>33</sup>Supra see Note 24

<sup>34</sup>Supra see Note 21

<sup>35</sup>Snider, Sharon. *The Pill: 30 Years of Safety Concerns*. FDA Consumer Magazine. Dec. 1990

<sup>36</sup>*Id.*

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

<sup>38</sup>*Id.*

<sup>39</sup>*Id.*

for FDA approval of a drug for treating menstrual disorders only.<sup>40</sup> Searle knew of the drug's contraceptive effects, but conducted additional testing before applying for permission to market the pill as a contraceptive.<sup>41</sup> Thus, FDA first licensed oral contraceptives for treatment of solely menstrual disorders and required a warning on the package which stated that women taking the drug would not ovulate.<sup>42</sup> Not surprisingly, in 1959 many women suddenly developed "menstrual disorders" which required treatment with the pill.<sup>43</sup> Acceptance of the pill among American women occurred quickly. Within two years of its introduction as an oral contraceptive, approximately 1.2 million women were taking the pill, 5 million within five years, and by 1973, about 10 million.<sup>44</sup> In the early 1980s, use of the pill dropped to 8.4 million following reports of possible harmful side effects.<sup>45</sup> With the introduction of a low-dose pill on the market, use once again rose to approximately 10.7 million in 1990.<sup>46</sup> With 80 percent of women born after 1945 having used the pill at some point, it is the most popular method of non-surgical contraception.<sup>47</sup>

Although oral contraceptives were well received and are still widely used today, concern over side effects plagued, and continue to surround, the pill's use. Because of the millions of healthy women worldwide who have used oral contraceptives since their introduction, short-term and long-term use of these drugs is a public health issue of maximum proportions.<sup>48</sup> Not surprisingly, oral contraceptives have been scrupulously monitored and studied over the last 36 years. According to FDA, more studies have been done on the pill to look for side effects than have been done on any other medicine in history.<sup>49</sup>

In 1965, galvanized by reports of blood clotting in several women taking the pill, FDA awarded a research

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<sup>40</sup>Tribe, Lawrence H. *Abortion. The Clash of Absolutes*. New York: W. W. Norton & Company; 1992, at 218

<sup>41</sup>*Id.*

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

<sup>43</sup>*Id.*

<sup>44</sup>Supra see Note 35

<sup>45</sup>*Id.*

<sup>46</sup>*Id.*

<sup>47</sup>Supra see Note 40

<sup>48</sup>Grimes, David A. *The Safety of Oral Contraceptives: Epidemiologic Insights From the First 30 Years*. 166 Am. J. Obstet. Gynecol. 1950 (1992)

<sup>49</sup>Supra see Note 35

grant to investigate exactly how widespread the problem was.<sup>50</sup> At the same time, the agency established the Advisory Committee on Obstetrics and Gynecology, FDA's first advisory committee, to review the drugs and to investigate their effect on blood clotting.<sup>51</sup> In 1966, the advisory committee reported that it found no scientific data to prove the pill unsafe at the time.<sup>52</sup> The committee cautioned, however, that the pill was not in use long enough at the time of the review to draw valid conclusions about any potential carcinogenic effects.<sup>53</sup> A World Health Organization scientific group, which conducted independent studies, confirmed the advisory committee findings.<sup>54</sup>

Concern over the pill's alleged and real side effects, however, continued to brew. Following British studies in 1968 which found an increased incidence of blood clots among pill users, FDA added information about the results of those studies to the product labeling for oral contraceptives.<sup>55</sup> A year later the labeling was revised to include the results of U.S. studies which confirmed the earlier British studies.<sup>56</sup> In 1969, the results of ongoing research revealed that risks of blood clots, heart attack, and stroke were directly related to the level of estrogen in different versions of the pill.<sup>57</sup> In 1970, FDA issued a bulletin to doctors about the danger of blood clots and advised prescribing the lowest effective dose of estrogen possible (the 1969 research results indicated that the same level of contraceptive effectiveness could be attained utilizing only 50 mcg of estrogen).<sup>58</sup>

FDA also once again revised the product labeling to include the "lowest effective dose" and for the first time, required that information for patients about the drug's risks be included in every package of oral contraceptives.<sup>59</sup>

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<sup>50</sup> *Id.*

<sup>51</sup> *Id.*

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

<sup>53</sup> *Id.*

<sup>54</sup> *Id.*

<sup>55</sup> *Id.*

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

<sup>57</sup> *Id.*

<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

By the mid-1970s, most women were taking oral contraceptives with estrogen levels of 50 mcg or less.<sup>60</sup> The amount of progestin in the drugs had also decreased to between 2.5 and 15 mg.<sup>61</sup> In 1982, a new version of the pill, the “biphasic” pill was introduced, to be followed in 1984 by three “triphasic” pills. These “multiphasic” pills are low-dose oral contraceptives in which the ratio of progestin to estrogen changes during the 21 day cycle the pill is taken.<sup>62</sup> In 1988, urged by FDA, the drug companies still manufacturing high-dose estrogen pills voluntarily withdrew from the market all remaining contraceptives containing over 50 mcg of estrogen.<sup>63</sup> Most pills prescribed today contain 30 to 35 mcg of estrogen and .5 to 1 mg progestin (in 1973-1974, FDA approved several low-dose pills containing as little as 20 mcg).<sup>64</sup> Oral contraceptives today pose fewer risks than childbirth for women under age 35.<sup>65</sup>

### Safety Issues and Compliance with Section 503(b)(1)

Traditional safety concerns may no longer justify restricting oral contraceptives to prescription status under section 503(b)(1). There is at least enough scientific evidence to warrant a review of the drug’s current prescription status - a review not unlike the one originally scheduled by the FDA in 1993, but then canceled. Most versions of the oral contraceptive pill today have one-third or less estrogen and one-tenth or less progestin as the oral contraceptive pills of the 1960s.<sup>66</sup> Most of the known side effects of the pill today are

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

<sup>61</sup> *Id.*

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

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

<sup>64</sup> *Id.*

<sup>65</sup> Trussell, James. *Should Oral Contraceptives Be Made Available Without Prescription?* 83 Am. J. Public Health 1094 (1983) 1094, 1097

<sup>66</sup> Buring, Julie E. *Low-Dose Oral Contraceptives and Stroke*. 335 New England Journal of Medicine 53, July 4, 1996 at 53-54

not medically serious.<sup>67</sup> They include possible nausea, breakthrough bleeding, mood changes, weight gain, breast tenderness, and eye dryness.<sup>68</sup> These side effects usually subside within the first three months of use.<sup>69</sup> Since the amount of estrogen in oral contraceptives has been thought to be chiefly responsible for increased risk of venous thromboembolism, myocardial infarction, and both ischemic and hemorrhagic stroke (blood clots, heart attacks, and strokes), the low-dose drugs considerably reduce these risks.<sup>70</sup>

As reported by the *New England Journal of Medicine*, oral contraceptives, when used by healthy women of childbearing age do not increase the risk of stroke.<sup>71</sup> The majority of studies have found no association between breast cancer and oral contraceptive use, although several recent reports have suggest that this cancer is diagnosed more frequently in young women who have used oral contraceptives.<sup>72</sup> Given the latest reports, the risk of increased breast cancer needs to be further explored. Earlier studies linking high-dose oral contraceptives and cardiovascular disease are no longer relevant to the low-dose drugs currently.<sup>73</sup> Recent studies on low-dose contraceptives have not suggested a link between oral contraceptive use and myocardial infarction or stroke.<sup>74</sup>

In addition to considerable evidence indicating the safety of low-dose contraceptives, sophisticated epidemiological studies have revealed the benefits of oral contraceptive use. Accompanying the benefit of effective

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<sup>67</sup>See supra Note 35

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

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

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

<sup>71</sup>See supra Note 66

<sup>72</sup>Coker, Harlap, Fortney. Oral contraceptives and reproductive cancers: weighing the risk and benefits. *Fam Plann. Perspect.* 1993;25:17-21

<sup>73</sup>See supra Note 65 at 1094-1095

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

contraception, oral contraceptives protect against the development of ovarian and endometrial cancers, pelvic inflammatory disease, and ectopic pregnancy.<sup>75</sup> The drugs are also commonly used to prevent heavy and irregular menstrual periods.<sup>76</sup> Oral contraceptives protect against the development of iron deficiency anemia, primary dysmenorrhea, functional ovarian cysts, and benign breast disease.<sup>77</sup> Prevention of osteoporosis, toxic shock syndrome, and rheumatoid arthritis has also been linked to the use of oral contraceptives.<sup>78</sup>

Although lower estrogen levels in today's oral contraceptives translate to lower toxicity levels in the drug, and thus demonstrate less reason to keep oral contraceptives prescription under section 503(b)(1) because of their toxicity, some safety issues remain unsettled and may be enough in themselves to generate opposition to the drug's possible switch to over-the-counter status. Contributing to the opposition is concern over use of the pill by women in high risk groups. Although the studies indicate the pill's relative safeness for healthy, non-smoking women, the risk of serious illness and death increases for certain groups.<sup>79</sup> Women who smoke, especially those over 35, have significantly increased risk of heart attack and stroke, increasing with age.<sup>80</sup> Women who are obese or have underlying health problems have an increased risk of experiencing serious side effects.<sup>81</sup> Women who have a history of blood clots, heart attack, stroke, liver disease, or cancer of the breast or sex organs are too high risk use oral contraceptives.<sup>82</sup> Thus, the possibility of harmful effects befalling women in high risk groups who use the pill may necessitate maintaining oral contraceptives as prescription drugs under section 503(b)(1)(B).

Proponents of a switch, however, argue that keeping oral contraceptives as prescription drugs does not

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<sup>75</sup>See supra Note 48 at 1954

<sup>76</sup>*Id.*

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

<sup>78</sup>See supra Note 65 at 1095

<sup>79</sup>See supra Note 66

<sup>80</sup>*Id.*

<sup>81</sup>*Id.*

<sup>82</sup>*Id.*

substantially decrease the likelihood that high risk individuals will use the pill any more so than if oral contraceptives were available over-the-counter. Switch supporters offer as evidence a study where women screened themselves for contraindications to oral contraceptives as accurately as clinicians.<sup>83</sup> Carefully designed package labeling, according to proponents, can provide enough information for women to make an intelligent decision regarding the use of the drug.<sup>84</sup> Women can identify contraindications in their own medical histories and they are capable of conducting breast self-examinations and of obtaining their own blood pressure reading (at a supermarket for example) prior to using oral contraceptives without medical supervision.<sup>85</sup> Yet, although possible, the chances of women actually following the entire screening procedure are lower than the probability of its complete execution by a physician. Contrary to one study's results, reliance on self-screening undoubtedly poses a greater health risk than screening procedures performed by physicians.

The pill's method of use is another factor to be considered when determining whether oral contraceptives should remain prescription under section 503(b)(1). Oral contraceptives must be taken daily on a 21-day or 28-day cycle, with a possibility of different pills to be taken on different days in the cycle, depending on the version of the drug used. It is not, at least to the novice user, a necessarily simple procedure. Concern over the potential switch of the pill's prescription status includes the fear that without medical consultation, imperfect use of oral contraceptives will increase, thus resulting in the decrease of the drug's efficacy.<sup>86</sup>

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<sup>83</sup>See supra Note 65

<sup>84</sup>*Id.*

<sup>85</sup>*Id.*

<sup>86</sup>*Id.*

The efficacy of oral contraceptives does depend on the extent and type of imperfect use.<sup>87</sup> Imperfect use includes missing pills, failing to use backup contraception if pills are missed, taking antibiotics or anticonvulsants while on the pill, and disregarding any vomiting or severe diarrhea which occurs.<sup>88</sup> Evidence suggests that many oral contraceptive users miss pills even though they visit a physician to obtain a prescription and that pill users often ignore cautions on package labeling which warn against particular drug interactions.<sup>89</sup> Consequently, proponents of a switch argue that the possibility of pill use non-compliance should not be an obstacle to the drug's over-the-counter availability since this non-compliance is a phenomenon even under the drug's current prescription only status.<sup>90</sup> Switch proponents concede that imperfect use of oral contraceptives will increase without clinical consultations, but with more user-friendly package labeling, the increase of non-compliance would not be great and certainly would not be enough to outweigh the benefits of making oral contraceptives available over-the-counter.<sup>91</sup> The balancing of risks versus benefits for an oral contraception switch is difficult and it is what makes the proposition of such an event so controversial.

### **Protecting the Public Health**

Uncertainty remains over the effects of the pill's lower toxicity levels, the feasibility of women self-screening to avoid known harmful effects, and the probability of non-compliance with the drug's method of use. Yet it is true that every drug carries an element of risk. Enough evidence exists, demonstrating the relative

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

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

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

<sup>90</sup> *Id.*

<sup>91</sup> *Id.*

safety of low-dose contraceptives, to justify an exemption for oral contraceptives from section 503(b)(1)'s literal definition of a prescription drug. Such a decision is within FDA's power and discretion, but it is complicated by considerations reaching beyond facial compliance (subject to statutory interpretation) with section 503(b)(1). As articulated by a former FDA General Counsel, drugs such as oral contraceptives generate sufficient public concern for reasons other than toxicity, as to make determination over the drugs' prescription/nonprescription status difficult.<sup>92</sup>

FDA's mandate is to protect the public health. This was also Congress's intention when amending section 503(b)(1). Yet the means to accomplishing this awesome task are not always clear and they often diametrically oppose one another. How does an agency recognize an individual's ability to self-medicate, and ease access to medicinal drugs, while protecting the same individual from the harmful effects of the drug's potency, or from even him or herself? These questions have divided the medical community and women's rights advocates within their own ranks, and they are a recurring theme in the debate over a switch to over-the-counter oral contraceptives.

### *Women's Health and Autonomy*

For many women's rights and family planning advocates, switching the status of oral contraceptives to over-the-counter is a political issue which signifies the increase of women's autonomy. Full and independent access to oral contraceptives liberates women to make their own decisions regarding when, or if, to have children.

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<sup>92</sup>Hutt, Peter B. *Drugs for Self-Medication in the Future: Their Source and the Social, Political, and Regulatory Climate*. 19 Drug Info. J. 1995 (1985), 195, 196

Health and safety issues notwithstanding, contraception has come a long way from its unlawful practice under the 1873 Comstock Act.

The Comstock Act criminalized the import, mail, or transport in interstate commerce any literature about birth control or any device designed to prevent conception or cause abortion.<sup>93</sup> In the 1936 case, *United States v. One Package*, the Supreme Court slightly loosened the vice of the Comstock Act by allowing products (diaphragms), which may be used by competent physicians to promote the well being of their patients, to flow in interstate commerce.<sup>94</sup> Women, as opposed to physicians, were evidently not permitted to promote their own well-being. Shadows of the Comstock Act lingered on until in 1965, five years after oral contraceptives were first marketed, *Griswold v. Connecticut*, the famous contraceptives case, marked the modern era's recognition of a fundamental privacy right to plan pregnancy.<sup>95</sup> <sup>96</sup> The trend toward greater access to contraceptives continued with *Eisenstadt v. Baird*<sup>97</sup> in 1972 and *Carey v. Population Services Int'l* in 1977.<sup>98</sup>

While access to contraceptives liberalized, women's rights and reproductive rights advocates enjoyed tremendous success with the hallmark *Roe v. Wade* decision in 1973.<sup>99</sup> The Court in *Roe v. Wade* held that women

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<sup>93</sup>See supra Note 72

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

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

<sup>96</sup>*Griswold v. Connecticut*, 381 U.S. 479 (1965). The Court in *Griswold* protected the right of married persons to use contraceptives by striking down a statute which made criminal the use of contraceptives and the aiding or counseling of others in their use.

<sup>97</sup>*Eisenstadt v. Baird*, 405 U.S. 438 (1972). The Court broadened the contraceptive aspect of privacy to reach unmarried couples.

<sup>98</sup>*Carey v. Population Services Int'l*, 431 U.S. 678 (1977). The Court in *Carey* struck down a New York statute which prohibited anyone but a licensed pharmacist from distributing contraceptives to persons over 16 and which entirely prohibited the sale or distribution to minors under the age of 16, except by prescription.

<sup>99</sup>*Roe v. Wade*, 410 U.S. 113 (1973)

have a Fourteenth Amendment fundamental right to privacy and that therefore the legislature has only a limited right to regulate, and may not completely prohibit, abortions.<sup>100</sup> This, for many women, meant the power to control one's own body - it meant autonomy. Yet in 1992, this autonomy was drastically curtailed by the Court in *Planned Parenthood of Southeastern Pennsylvania v. Casey*.<sup>101</sup> *Casey* overturned abortion's status as a fundamental right.<sup>102</sup> As a result, states may now restrict abortions as long as a woman's right to choose is not unduly burdened. With greater restriction on abortion, a woman's ability to plan and control pregnancy is vastly impaired.

The loosening of restrictions on contraceptive use in the modern era, partnered with the recent setback for women's right to choose abortion, should have sent family- planning and reproductive rights advocates clamoring for a switch from prescription to over-the-counter status for oral contraceptives. Such a switch would increase availability of the drug to women by reducing obstacles, such as the time and cost of doctor's visits and the general stigma of prescription drug use, and thus giving women more control over their own bodies and reducing the number of unwanted pregnancies. Over-the-counter status for oral contraceptives would allow women to regain some of the momentum toward autonomy they experienced following *Griswald*, but lost after *Casey*.

Yet surprisingly, many representatives of women's groups oppose the oral contraceptive switch to over-the-counter status and these representatives expressed their dissatisfaction with the proposal to FDA following

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<sup>100</sup>*Id.*

<sup>101</sup>*Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992)

<sup>102</sup>*Id.*

the scheduled Feb. 4-5 review meeting.<sup>103</sup> They oppose the switch on a number of counts, Medicaid coverage being one of them. Medicaid will not cover nonprescription birth control pills.<sup>104</sup> Consequently, without reimbursement, over-the-counter oral contraceptives, for many low-income women, will become cost prohibitive, may actually reduce the pill's use among these women.<sup>105</sup> Lower income women's access to contraception is a valid concern, however, it may be possible for physicians to still write a prescription for the drugs, perhaps thus enabling women to be reimbursed for the expense.

Another reason some family-planning advocates oppose a switch in prescription status of oral contraceptives is the potential decrease in consultations with physicians. Switch opponents argue that women who have not consulted clinicians may be scared off by unexpected side-effects and may stop using the pill, creating more unwanted pregnancies.<sup>106</sup> It is possible, however, that women experiencing these side effects would then visit physicians rather than just stop oral contraceptive use. Opponents also fear that a switch would result in deterioration of women's overall health because of more infrequent visits with physicians. The medical director of Planned Parenthood Federation was quoted as saying, "[w]e've been using the pill as bait to get women in for other medical tests."<sup>107</sup> Yet the "bait" theory angers supporters of the switch, eliciting responses such as, "[t]hat's like saying we're going to put condoms on prescription so we can test men for cancer of the testes."<sup>108</sup> It is indeed possible that with more women using over-the-counter oral contraceptives, these women will be more conscious of their physical health and may actually be more likely to consult with physicians than if they were not using oral contraceptives at all.

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<sup>103</sup>F-D-C Reports - "The Pink Sheet," February 1, 1993

<sup>104</sup>See supra Note 24

<sup>105</sup>*Id.*

<sup>106</sup>*Id.*

<sup>107</sup>See supra Note 31

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

There is also another, somewhat dubious, yet critical, reason for Planned Parenthood's opposition to a switch in prescription status. Many family planning clinics raise a significant portion of their revenue from selling oral contraceptives.<sup>109</sup> The clinics buy the contraceptives from drug companies at a discount and then sell the pills at a higher rate.<sup>110</sup> If drug companies face a more competitive over-the-counter market, they may no longer provide low-cost pills to clinics.<sup>111</sup> Family-planning clinics will have difficulty replacing the millions of dollars of lost revenue necessary to subsidize their operations.<sup>112</sup> Unfortunately, this is a greater issue than just "the bottom line;" there is need for concern. Family-planning clinics are a tremendous resource for counseling, medical, and educational services. If the clinics' ability to provide these services are impaired, it is unlikely that government or private enterprise can replace their crucial role in maintaining the public health. This is actually one of the most compelling policy reasons in favor of maintaining oral contraceptives' current prescription only status.

### *Sexually Transmitted Diseases*

Sexually transmitted diseases are indeed to be feared and protected against. Many opponents of an oral contraceptives switch to over-the-counter status, offer the possibility of a rise in sexually transmitted diseases as a reason to maintain the drug's current prescription status. Japan's effort to contain the diseases, by completely banning oral contraceptives, is often used as ammunition by opponents in debates against advocates of the switch to over-the-counter status. But preventing the change of prescription status for birth control pills is not the answer to the sexually transmitted diseases problem, education is.<sup>113</sup> Concern over sexually transmitted diseases applies not only to the use of oral contraceptives, but also to all hormonal contracep-

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

<sup>110</sup> *Id.*

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

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

<sup>113</sup> See *supra* Note 65 at 1095-1096

tives, intrauterine devices, spermicides, cervical caps, sponges, and diaphragms.<sup>114</sup> In fact, as part of ongoing education efforts, FDA in 1993 notified the manufacturers of intrauterine devices, implantable and injectable contraceptives, and natural membrane condoms, as well as oral contraceptives, that labeling accompanying their products must state that they do not provide protection from sexually transmitted diseases, including AIDS.<sup>115</sup> FDA informed manufacturers that the information was to be displayed prominently in clear language for the consumer.<sup>116</sup> These are the efforts which protect against sexually transmitted diseases, not limiting the availability of a method of contraception.

### Conclusion

The choice between maintaining oral contraceptives at their current prescription drug status or switching the drugs to over-the-counter status, like so many other decisions in Food and Drug Law, has as much to do with science, as it does with politics and economics. If the second component of section 503(b)(1)(B) of the FD&C Act gave more formulaic guidance for determining which drugs were exempt from its reach, then determination of drugs' prescription/nonprescription status would be simpler. Yet if this were indeed the case, then the amended statute would not leave room to analyze the total social cost versus the total social benefit that a drug's availability over-the-counter would inspire. Protection of the public health, Congress's ultimate purpose for the FD&C Act and its 1951 amendments, would be difficult to achieve.

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<sup>114</sup>*Id.*

<sup>115</sup>FDA BULLETIN, Department of Health and Human Services, Food and Drug Administration, June 22, 1993

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

Although the pill's lower toxicity level translates to less risk of harmful side effects than was the case when it was first introduced in the 1960s, the pill is still not without its risks, especially for women with high risk group characteristics. Maintaining the pill's prescription status ensures a pre-use screening by a clinician and decreases the probability of oral contraceptive use by high risk consumers. This is a compelling reason to maintain the status quo, but is restriction of a contraceptive, especially with the establishment of contraception as a fundamental privacy right, the least costly solution to maintaining the public health? If we have any faith in the increasing intelligence of consumers and in information and education efforts such as package labeling and patient package inserts, perhaps increase in high risk women actually using oral contraceptives will not be as great as opponents of a switch to over-the-counter status predict.

With somewhat varying scientific data and less than bright-line statutory definition of a prescription drug, it is not surprising that FDA, in all of its discretion to make the prescription/nonprescription drug determination, would consider broader social and economic implications of an oral contraceptives switch to over-the-counter availability. Notwithstanding debate surrounding consumer's ability to use the drugs safely without physician consultations, concern regarding both the viability of family-planning clinics and the availability of the oral contraceptives to lower income women following a switch to over-the-counter status is probably the greatest impediment to such a switch. Regardless of one's political and social mores, the services which family-planning clinics contribute to the maintenance of the public health are undeniably crucial. Unless resources are found, or raised, in order to continue the operation of these clinics, or unless alternative comparable services are provided by some other means (perhaps manufacturers of oral contraceptives will make a charitable contribution), the combination of the loss of these services, with the decreased availability of the drug for lower income women (who arguably need the drug most), and the possible increase of harmful effects befalling high risk consumers, will make a switch to over-the-counter status for prescription drugs politically difficult, if not impossible.

