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**CONTROLLING CONTRACEPTION: THE CASE FOR OVER-THE-COUNTER
AVAILABILITY OF NONEMERGENCY ORAL CONTRACEPTIVES**

by

Sarah Wright, Class of 2011

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ABSTRACT

The Food and Drug Administration (FDA) currently categorizes nonemergency oral contraceptives as prescription-only instead of nonprescription, or over-the-counter, drugs. The time has come for the FDA to reconsider this decision and allow oral contraceptives to be prescribed on an over-the-counter basis. The high safety level of oral contraceptives, numerous studies indicating that greater misuse of oral contraceptives will not occur if they are available over-the-counter, and an assessment of collateral factors relating to oral contraceptive use support this conclusion. Additionally, should the FDA create a new class of behind-the-counter drugs, considerations of access, cost, privacy, and pharmacist interference with women's right to make their own birth control determinations indicate that it would still be more appropriate to designate oral contraceptives as over-the-counter drugs rather than to move them to this new category.

How did we get ourselves into such a mess? In my view, what has brought out the harsh, controlling streak in so many people is that emergency contraception has to do with sex, and that the resultant commingling of sex with politics and morality is highly corrosive. Why does sex get people's backs up? Like all powerful forces—terrorism, hurricanes, pandemics—the power of sex can seem appalling, terrifying, something that must therefore be controlled at all costs.
- Frank Davidoff, *Sex, Politics, and Morality at the FDA: Reflections on the Plan B Decision*¹

I. INTRODUCTION

Historically, the issue of access to contraceptives in the United States has been a highly contentious one. The enactment of the 1873 Comstock Act, which criminalized so much as importing, mailing, or transporting in interstate commerce any form of literature about birth control or any device designed for preventing conception or causing abortion,² established the tone for future battles over freedom of choice and morality in relation to contraception. Ever since the introduction of oral contraceptives (OCs) in the early 1960s, the “Pill” has only been available to women in the United States who have obtained a prescription for it from a physician.³ In spite of scientific advancements over the past few decades which have greatly enhanced the safety of OCs, the considerable positive side effects of using OCs, and studies from other countries which indicate that on the whole over-the-counter (OTC) prescription of OCs is generally safe and efficacious for women, the Food and Drug Administration (FDA) has not yet elected to move OCs from the prescription-only category of drugs to the nonprescription OTC drug category. In this paper, I will make the case that the FDA should reclassify OCs from prescription drugs to OTC drugs. I will then argue that even if the FDA creates a new class of behind-the-counter (BTC) drugs, a step which has been debated over the past decade, OCs

¹ Frank Davidoff, *Sex, Politics, and Morality at the FDA: Reflections on the Plan B Decision*, 36 HASTINGS CTR. REP. 20, 25 (2006).

² See generally James Trussell et. al., *Should Oral Contraceptives Be Available Without Prescription?*, 83 AM. J. PUB. HEALTH 1094 (1993).

³ *Id.*

should still be identified as OTC drugs rather than BTC drugs.

II. A BRIEF HISTORY OF THE DISTINCTION BETWEEN PRESCRIPTION AND OTC DRUGS

The 1938 Federal Food, Drug, and Cosmetic Act (FD&C Act), which provides the backbone of modern food and drug law, does not set forth any guidelines for distinguishing between prescription and OTC drugs.⁴ Within half a year of the 1938 Act's passage, however, the FDA promulgated regulations outlining the distinction between these two drug categories.⁵ Under these regulations and the FD&C Act as it then stood, any drug for which adequate usage directions could be provided to the public through the drug's labeling was to be sold OTC, and all other drugs were to be prescription only.⁶ In 1944, the FDA amended the 1938 regulations to clarify the distinction between prescription/nonprescription drug status.⁷ In a show of support for the FDA's regulations, Congress echoed the FDA's chosen method of distinguishing between prescription and OTC drugs in the 1951 Durham-Humphrey Amendments to the FD&C Act.⁸

The Durham-Humphrey Amendments added section 501(b)(1) to the FD&C Act.⁹ Section 501(b)(1) provides that prescription drugs are ones which meet one or more of the following criteria: (A) habit-forming drugs listed in section 502(d) of the Act and their derivatives; (B) drugs unsafe for use except under the supervision of a licensed practitioner; and

⁴ Alan H. Kaplan, *Over-the-Counter and Prescription Drugs: The Legal Distinction Under Federal Law*, 37 FOOD DRUG COSM. L.J. 441 (1982).

⁵ *Id.*

⁶ Peter Barton Hutt, *A Legal Framework for Future Decisions on Transferring Drugs from Prescription to Nonprescription Status*, 37 FOOD DRUG COSM. L.J. 427, 431 (1982).

⁷ *Id.* at 431-32.

⁸ *Id.* at 428.

⁹ *Id.* at 432.

(C) drugs limited to prescription sale under a New Drug Application (NDA).¹⁰ Because the first and third categories are clear-cut, the uncertainty as to whether a drug should be classified as prescription or OTC arises only as to the second category.¹¹ In assessing if a particular drug is unsafe for use except under the supervision of a practitioner, the FDA considers three primary factors: (1) its toxicity; (2) its potential for inducing a harmful effect; and (3) its method of use and/or any other measures necessary for its use.¹²

In a nutshell, the first of these factors, toxicity, refers to drugs that have a low safety margin and, as a result, need to have their concentration adjusted by a professional in order to prove effective yet safe for patient use.¹³ Standing alone, however, the possibility that toxicity would result from drug misuse is not enough to place a drug in mandatory prescription-only status.¹⁴ In many instances, labeling of OTC drugs to provide clear and sufficiently detailed information for use is fully capable of providing an effective alternative to requiring all drugs with any toxicity potential to be prescription-only.¹⁵

The second factor, the drug's potential for causing harmful effects, involves an assessment of the wide-ranging ways in which the drug might cause harm in addition to mere toxicity alone.¹⁶ The drug's potential for abuse, its interaction with food and other products, the likelihood of widespread use of the drug leading to patient tolerance or pathogenic resistance, the chance of tampering with OTC products, and the possibility of some OTC drug ingredients being used in counterfeit drug sales of drugs on the streets are just some of the potential ways in which

¹⁰ *Id.* at 433.

¹¹ *Id.*

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.* at 434.

¹⁵ *Id.*

¹⁶ *Id.* at 435.

a drug available OTC might cause harm.¹⁷ As with toxicity, adequate consumer labeling can address some of these concerns, namely those relating to potential for abuse and interaction.¹⁸

The third factor, method of use and additional measures necessary for use, is the most far-reaching of these considerations.¹⁹ The legislative history of the 1951 Amendments indicates that the prescription/nonprescription status assessment was meant to cover any threat to public health in general.²⁰ Thus, this factor reaches all aspects of the circumstances under which a particular drug is used, including issues of social policy.²¹ The possibility of layperson self-diagnosis of conditions, the need for doctors to supervise the administration of a drug and subsequent patient progress, the realities of the medical and pharmaceutical professions, overarching social policy goals, and the desire of drug companies to reap enhanced profits through widespread OTC drug availability are all relevant considerations in this assessment process.²² Additionally and perhaps most importantly, adequate labeling once again plays a major role in the analysis.²³ Indeed, of all of the considerations relating to both this factor and the others, the most important by far are the drug's margin of safety, its potential to be abused if made available OTC, and the availability of sufficient labeling.²⁴

The majority of the remainder of this paper will focus on applying these three factors to the prescription/OTC status determination for nonemergency OCs. First, the safety of OTC use of OCs will be addressed. Second, the high level of efficacy and relatively low potential for harmful effects resulting from OTC sales of OCs will be set forth. I will then argue that the

¹⁷ *Id.* at 435-36.

¹⁸ *Id.* at 435.

¹⁹ *Id.* at 436.

²⁰ *Id.* at 433.

²¹ *Id.*

²² *Id.* at 436-39.

²³ *Id.* at 438.

²⁴ *Id.* at 440.

method of use and other collateral measures pertaining to OTC use of nonemergency oral contraceptives do not provide sufficient reason to keep OCs prescription-only. Because some of the same considerations are involved in each of these areas, some issues may be appropriate for consideration in one or more of these sections and either be discussed from slightly different perspectives in each category or only covered in one section. My brief final argument will be that should the FDA create a new class of behind-the-counter (BTC) drugs, OCs should still be identified as OTC drugs rather than BTC drugs.

III. FACTOR ONE IN PRESCRIPTION/OTC ANALYSIS: TOXICITY AND MARGIN OF SAFETY

OCs are currently some of the most well-studied drugs in existence, and research indicates that while as with most drugs OC use entails some risks, it can also lead to many significant benefits.²⁵ Indeed, research has shown that in addition to safeguarding women from unintended pregnancies and the resultant health risks, OCs protect against a wide variety of conditions including pelvic inflammatory disease, ectopic pregnancy, iron deficiency anemia, primary dysmenorrhea, and benign breast disease.²⁶ OC use also reduces the incidence of ovarian cancer in users by a staggering 30-50% and provides protection against endometrial cancer proportional to the duration of use and for up to 15 years after discontinuation.²⁷ One of the most recent studies has even indicated that women who use oral contraceptives at some point in their lives face a significantly lower risk of death resulting from any cause, including heart

²⁵ Trussell, *supra* note 2, at 1095.

²⁶ *Id.*

²⁷ Helen Rees, *Acquiring the Pill: Safety Issues*, 2 REPROD. HEALTH MATTERS 41 (1994).

disease and cancers, compared with women who have never taken them.²⁸ It seems plausible that this latest finding may turn out to be due at least some extent to the fact that many women who do not use oral contraceptives may choose not to do so because they already engage in other health-threatening behaviors such as smoking which render OC use riskier for them.

Nonetheless, on the whole, the benefits of OC use are striking.

Safety risks relating to OC use include some possibility of increasing a woman's chance of getting breast cancer, although most studies show no overall impact of OC use on this risk, and a possible link to increased rates of cervical neoplasia.²⁹ As for cardiovascular disease, it appears to be unrelated to low-dose OC use, at least when users are subject to screening.³⁰ Even if a causal relationship does exist between OC use and these conditions, however, considering the many positive effects of OC use and thinking in terms of overall safety, it may actually be healthier for women to use OCs for at least some time than to abstain from utilizing them altogether.

A limited number of conditions for which OC use is contraindicated currently exist. The World Health Organization (WHO) advises women with a history of venous disease or thrombosis, heart disease, stroke, heart attack, liver problems, and migraine headaches avoid using OCs.³¹ The WHO also recommends that women with breast cancer, heavy smokers aged over 35, pregnant women, women taking certain anticonvulsant medications, and women who

²⁸ *Women on the Pill Live Longer: Study*, Reuters, Mar. 12, 2010, <http://www.reuters.com/article/idUSTRE62B01R20100312>.

²⁹ Trussell, *supra* note 2, at 1095.

³⁰ David A. Grimes, Editorial: *Over-the-Counter Oral Contraceptives—An Immodest Proposal?*, 83 AM. J. PUB. HEALTH, 1092 (1993).

³¹ Carrie Tatum et. al., *Valuable Safeguard or Unnecessary Burden?: Characterization of Physician Consultations for Oral Contraceptive use in Mexico City*, 71 CONTRACEPTION 208 (2005).

will be facing lengthy periods of immobilization avoid OC use.³² Screening for the WHO's set of contraindications to OC use generally does not require any medical examination.³³ As determined by the WHO, physical exams, including a Papanicolaou examination, breast or cervical exams, and sexually transmitted infection (STI) screenings are not necessary for women to commence using OCs properly and safely.³⁴

Labeling could easily warn women of these risk factors, and potential OC users are themselves in by far the best position to know key information such as their ages and whether or not they smoke. The low rates of known or potential contraindications among women seeking to obtain OCs for the first time indicates that once again, a simple clear warning on the OC package relating to the need to see a physician if one has these conditions or develops certain symptoms upon OC use which may be indicative of the existence of these conditions would more than suffice to promote user safety. One 1988 -1989 study of women in Senegal who underwent mandatory laboratory testing for cervical cancer, diabetes, high cholesterol, anemia, and liver function problems before they received oral contraceptive pills for the first time found that under 3% of the 410 women who requested the contraceptives had medical contraindications to their use.³⁵ Such a low rate of potential contraindications is an encouraging sign that OTC prescription of OCs would not pose serious danger to women's health.

A comparison of the safety of OCs with that of drugs which already enjoy OTC status also weighs in favor of making OCs available over-the-counter. Statistics indicate that aspirin, which is widely available OTC and can even be found in vending machines, is more deadly than

³² *Id.*

³³ *Id.* at 209

³⁴ *Id.*

³⁵ John Stanback, *Safe Provision of Oral Contraceptives: The Effectiveness of Systematic Laboratory Testing in Senegal*, 20 INT'L FAM. PLAN. PERSPS. 147 (1994).

OCs.³⁶ Acetaminophen ingestion results in approximately 56,680 visits to the emergency department and 26,256 hospitalizations, as well as 458 deaths, in the United States every year.³⁷ Even cigarettes, which end over a thousand lives each day, are much more readily available to the public than OCs, which offer so many positive health effects for women.³⁸

Now that the vast majority of OCs prescribed are low-dose products, it is particularly unnecessary for a professional to calculate the precise level of OC that is safest for a woman before she starts using the drug.³⁹ The majority of serious medical concerns about OCs in the past concerned pills containing 50 micrograms of oestrogen, not newer low-dose models.⁴⁰ In the 1960s and 70s, higher dose OCs were associated with an increased risk of strokes, heart attacks, and the formation of blood clots.⁴¹ Stroke and heart attack risks with low-dose OCs seem to be limited to women aged 35 and older who smoke, however, and blood clot formation risks are now lower as well.⁴² Epidemiological research over the past several decades also strongly indicates that the low-dose OCs now in use are safe and effective enough to be marketed without prescription to be self-administered by women.⁴³ Family planning experts no longer even recommend that an initial OC product selection be based on choosing an “ideal” product because the effects of the most widely prescribed OCs are so similar.⁴⁴ It is typical for clinicians to prescribe a standard initial product, often the one that is the cheapest or most readily available,

³⁶ *Id.*

³⁷ Alastair J.J. Wood et. al., *A Sad Day for Science at the FDA*, 353 NEW ENG. J. MED. 1197, 1998 (2005).

³⁸ *Id.*

³⁹ Trussell, *supra* note 2, at 1096.

⁴⁰ Rees, *supra* note 27, at 41.

⁴¹ *Id.*

⁴² *Id.*

⁴³ M. A. Shah, *Over-the-Counter Use of Oral Contraceptives in Kuwait*, 73 INT’L J. GYNECOLOGY & OBSTETRICS 243, 244 (2001)

⁴⁴ Trussell, *supra* note 27, at 1096.

since few women would face health difficulties as a result of using any of the low-dose OCs currently on the market.⁴⁵

If any problems do arise following initial OC use without a prescription, package labeling can instruct women to consult a clinician upon the occurrence of certain symptoms. To support adequate safety for OTC OC users, labels should include a clear explanation of OC contraindications, instructions for performing breast self-exams and for checking blood pressure, and descriptions of danger signs for possible adverse reactions.⁴⁶ Labels should also inform OC users that they should consult a clinician before using OCs if they have any doubts about whether they should be using the drug.⁴⁷

IV. FACTOR TWO IN PRESCRIPTION/OTC ANALYSIS: EFFICACY AND LOW POTENTIAL FOR HARMFUL EFFECTS AS OTC DRUG

Reclassifying OCs as OTC drugs would not only be a good idea because of the high safety margin of OCs, but also because of the minor potential for OCs made available over-the-counter to cause harmful effects. The most immediate concern regarding harmful effects resulting from reclassifying OCs as OTC drugs is that doing so might lower the overall efficacy of the drugs due to women being less inclined to follow the instructions for their use properly in the absence of having to interact with a medical professional in order to obtain the OCs. In response to this concern, it is first important to note that the efficacy of OCs among perfect users will not be impacted in any way by a shift from prescription to OTC status and that when used perfectly, only about one in a thousand combined estrogen-progestin pill OC users will become

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ *Id.*

pregnant each year.⁴⁸ Typical, or imperfect, use results in a significantly higher risk of pregnancy; studies vary, however, as to exactly how high this risk is for imperfect users.⁴⁹ Imperfect use includes skipping OC pills and failing to use a backup method of contraception in the event that pills are missed, if antibiotics or anticonvulsants are taken, or upon the advent of vomiting or severe diarrhea.⁵⁰

A number of possible causes exist for missed pill imperfect OC use. These possibilities include failing to start a new package of pills in a timely fashion, halting pill use mid-cycle, interrupting pill use for one or more cycles, missing pills by mistake, taking pills significantly later than the recommended time, and taking triphasic pills in the wrong order.⁵¹ Current research indicates that missed-pill noncompliance is common even in places where women must currently visit clinicians to obtain a prescription for OCs.⁵² One of many studies supporting this conclusion, which monitored the OC use of 612 women in a United States public health department family planning clinic, found that only 42% of these women always took a pill each day, only 17% always took a pill at the same time each day, and only 60% of those who missed pills used backup contraception.⁵³

The only real question remaining concerning missed pills, then, is whether such dismal rates of optimal OC use would decrease even further if women were not required to obtain a prescription to use OCs. Considering that high patient flow in physicians' offices frequently precludes lengthy discussions regarding OC use and that in the offices of affiliates of the Planned Parenthood Federation of America, Inc. most counseling on OC use is currently performed by

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.*

mid-level clinicians and counselors instead of by physicians,⁵⁴ any assumption that OC users' compliance levels will suffer in the absence of physician counseling seems at best highly speculative. Moreover, discontinuation of OC use has been found to be linked to the occurrence of side effects, to pill packaging (with 28-day packs inspiring greater discontinuation than 21-day packs), and to pill phasing (with more discontinuation occurring with monophasic than triphasic pills).⁵⁵ Physicians cannot prevent certain side effects from occurring, alter pill packaging, or change pill phasing schedules through consultation alone. Thus, their input on such matters would be of little real value to women who choose to skip or discontinue pill use due to these factors.

While the majority of pregnancies that occur during a woman's OC use are probably a result of missed-pill noncompliance, there are two other significant factors which reduce the efficacy of OCs: interactions with other drugs, particularly anticonvulsants and antibiotics, especially rifampin, and diarrhea or vomiting, including when associated with bulimia or other eating disorders.⁵⁶ Package labeling already instructs women to use backup contraception under these circumstances, but many women do not follow the instructions.⁵⁷ It is questionable whether women even read, or if they do, comprehend, such instructions; one English study showed that half the respondents did not know that OC efficacy could be reduced by diarrhea/vomiting or by taking antibiotics.⁵⁸

Several studies support the conclusion that OC users' compliance levels will not face a precipitous decline in the absence of physician counseling prior to use. Many of these studies

⁵⁴ Grimes, *supra* note 20, at 1093.

⁵⁵ Tatum et. al., *supra* note 31, at 209.

⁵⁶ Trussell, *supra* note 2, at 1097.

⁵⁷ *Id.*

⁵⁸ *Id.*

focus on examining compliance rates in the numerous countries in which OCs are available on an OTC basis. One such study involved trained simulated patients who attended appointments with Mexico City public and private physicians in order to request OC prescriptions. Immediately upon the completion of each of these appointments, the simulated patients filled out a checklist concerning the information provided and examinations performed by the physicians.⁵⁹ The results showed that many physicians failed to ask women questions regarding contraindications and to give them instructions for proper OC use.⁶⁰ Furthermore, the majority of the physicians also failed to discuss the possible side effects of OC use with the patients; only in about half of all consultations did the provider explain that the woman might gain weight, and other side effects such as headaches, irregular bleeding between periods, and bleary vision were discussed at even lower rates.⁶¹ Perhaps most critically, in 71.1% of the consultations, the providers neglected to tell the patients that any side effects typically go away after a few menstrual cycles.⁶² While the Mexico City consultations may well differ significantly from United States ones in respect to the information supplied, this study still indicates that trained medical professionals who are in possession of all of the key information regarding OC use sometimes perform very poorly in actually disseminating this information to patients.

Moreover, even assuming that physicians do disseminate all of the key information relating to OC use and possible side effects during women's visits to obtain prescriptions, it is highly questionable whether women will actually recall the information so provided well enough to act on it. A 1982 FDA study concluded that a full 40% of patients surveyed could not recall their doctor explaining how much medication to take, how to take their medication, or what to do

⁵⁹ Tatum et. al., *supra* note 31, at 208.

⁶⁰ Tatum et. al., *supra* note 31, at 211.

⁶¹ *Id.*

⁶² *Id.*

in the event that they forgot to take it.⁶³ Due to such natural forgetfulness, it may well be an inefficient use of the time of both health care professionals and their patients to keep OCs prescription-only based on the faulty assumption that meaningful information which the patients will be able to readily recall when they need it is exchanged in these interactions.

Another recent study from Kuwait, where OCs are available on an OTC basis, further demonstrates that OTC availability does not lead to lower efficacy results due to improper use or discontinuation. A fourth of the Kuwaiti women studied commenced OC use without first consulting a doctor, and half bought OCs from a pharmacy.⁶⁴ The researchers determined that the duration of first-time OC use did not differ based on whether a woman consulted with a physician prior to initiating use.⁶⁵ Also tellingly, approximately the same percentages of women who bought OCs over-the-counter and women who obtained OCs after consulting with a physician became pregnant due to imperfect use during the period studied.⁶⁶ Based on these findings, consultation with a physician does not appear to bolster the proper use of OCs or even encourage women to utilize the method for a longer period of time than they would in the absence of such advisement.

Returning to Mexico, an analysis of a national stratified probability sample of 15,000 households in which all women aged 15 to 49 were asked to provide detailed histories of their contraceptive use for a nearly five-year period, which turned up 4,253 women who used contraceptives in that time frame, also found that physician/patient interaction is not a key factor

⁶³ Martha Williams-Deane, *Current Oral Contraceptive Use Instructions: An Analysis of Patient Package Inserts*, 24 FAM. PLA. PERSPS. 111, 114 (1992).

⁶⁴ Shah, *supra* note 43, at 243.

⁶⁵ *Id.* at 248-49.

⁶⁶ *Id.*

in keeping compliance rates from falling.⁶⁷ Women in Mexico were able to obtain their contraceptives from a physician, from a family planning clinic, or from a commercial drugstore where no questions were generally asked and no safety information was provided.⁶⁸ The researchers' actual findings contrasted sharply with their initial hypothesis, which was the users obtaining OCs from private physicians or clinics rather than directly from the drugstores would have higher continuation rates and lower pregnancy rates due to the information and support received from the provider.⁶⁹ Women who obtained OCs directly from a drugstore with no physician interaction did not in fact have lower rates of continuation of use, and rates of pregnancy while using OCs remained similar, at 2-3%, for all three of the source methods.⁷⁰ Interestingly, less educated and illiterate women did not have substantially higher failure rates than did the other OC users.⁷¹

Some individuals involved in the prescription/OTC debate argue that improved provider-client communication, not the elimination of provider-client communication, is what is needed to improve OC use efficacy rates.⁷² Sweden's switch to OTC distribution of OCs in the mid-1970s, which led to a decline in compliance with proper use until the trend was reversed by the passage of additional regulations to require the midwives responsible for OC distribution to counsel and educate women before giving them the drugs, is cited as an example of the need for greater interaction between health care professionals and women receiving OCs.⁷³ This point, however,

⁶⁷ Jerald Bailey et. al., *Effect of Supply Source on Oral Contraceptive Use in Mexico*, 13 *STUD. FAM. PLAN.*, 343 (1982).

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *Id.* at 345.

⁷¹ *Id.* at 346.

⁷² Amy Allina and Francine M. Coeytaux, *Over-the-Counter Distribution of Oral Contraceptives*, 2 *REPROD. HEALTH MATTERS* 34, 37 (1994).

⁷³ *Id.*

fails to take into account the striking manner in which the Internet has revolutionized access to information in recent years. Today, women with questions about how to use birth control properly or about whether certain symptoms were a normal result of OC use can simply either go to the website of their OC manufacturer or perform a basic search on google.com for, say, “Do oral contraceptives cause headaches?” and quickly find the sought-after information.

To provide women with additional information and support regarding OCs without continuing to require prescriptions, one idea is to require the installation of computer-based displays in locations where OCs are sold which are designed to provide answers to any and all OC-related questions. Computer programs to help women select the absolute best OC choice for them based on their personal preferences and capacity to pay could be included, as could a variety of videos addressing proper OC use for all brands carried, instructions on what to do in the event of improper use, and information on all of the symptoms that users stand a substantial risk of encountering. Women would surely appreciate the convenience and anonymity of receiving advice from a nonjudgmental computer screen at the time most convenient to them, and since younger, more technologically savvy women make up the majority of Pill users,⁷⁴ the computer format would feel highly natural to them.⁷⁵

Studies already show that doctors and patients alike find interactions via Internet videoconferencing highly satisfactory.⁷⁶ While viewing purely prerecorded materials is not quite the same thing as interacting with a live doctor through videoconferencing, this does illustrate that direct in-person interaction between patients and physicians is not particularly necessary to

⁷⁴ Williams-Deane, *supra* note 62, at 111 (80% of current OC users are under the age of 30).

⁷⁵ See Tamar Lewin, *If Your Kids Are Awake, They're Probably Online*, N.Y. TIMES, Jan. 20, 2010, at A1.

⁷⁶ See, e.g., *Study Finds Virtual Doctor Visits Satisfactory for Both Patients and Clinicians*, http://www.eurekalert.org/pub_releases/2009-05/mgh-sfv051409.php.

achieve satisfactory information provision. This is important because compliance with proper OC use procedures is linked with the woman's satisfaction with the clinician, the absence of side effects, establishing a daily pill taking routine, and reading the information distributed with the OC packaging.⁷⁷ The latter three of those elements clearly fall outside the scope of provider-patient interactions, and if videoconferencing with doctors can lead to patient satisfaction, it seems at least possible that interacting with a "clinician" computer program designed to provide information could also engender an appropriate degree of patient satisfaction.

In a somewhat different vein, it is possible that patient satisfaction with OCs sufficient to encourage their continued use can be achieved by giving women greater control over their birth control options, which might be accomplished simply by giving OTCs over-the-counter status in the first place. Women choosing to obtain OCs over-the-counter do not have to depend on a physician to choose their first contraceptive for them, they are acting on their own behalf, and they are somehow arranging to have the cost of the drug covered.⁷⁸ A combination of all or some of these factors may encourage women to feel more responsible for their behavior, making them more inclined to persist in taking OCs and enduring any resulting side effects.⁷⁹

In order for package labeling to translate into women using OCs properly at high rates, it is necessary for such labeling to be complete, to have a user-friendly format, and to achieve a high degree of readability.⁸⁰ To be complete, OC package insert instructions should tell users when to start their first packs of pills, give advice on what to do when pills are missed, and discuss the need for back-up contraception use.⁸¹ A national survey of OC users showed a strong

⁷⁷ Shah, *supra* note 43, at 250.

⁷⁸ Bailey, *supra* note 66, at 347.

⁷⁹ *Id.*

⁸⁰ Williams-Deane, *supra* note 62, at 114.

⁸¹ *Id.*

preference for the inclusion of longer, more detailed information in package inserts.⁸² Women particularly favored the inclusion of more information relating to the potential side effects and health hazards of OC use.⁸³ As for formatting, the labeling should be printed in a typeface that is appropriately clear, large, and dark.⁸⁴ It should also include subject headings that are clearly differentiated from the surrounding text so as to make instructions easy to locate.⁸⁵ In terms of readability, it is essential to keep the average reading level at the fifth-to-sixth grade standard for health education materials so that the average woman can comprehend the instructions.⁸⁶

Lastly, recent case law indicates that even the judicial system is becoming increasingly amenable to the view that OCs are appropriate for women to use without first interacting with physicians. Several courts have held that drug manufacturers have a duty to warn consumers directly of the dangers associated with OC use.⁸⁷ In essence, this means that the courts are inclined to view the woman's role in electing to use OCs as being so important that her physician's role as a "learned intermediary" in prescribing the drug alone is not by itself enough to absolve the drug manufacturers of liability. Through downplaying the physician's role in OC use decisions, the courts are displaying their recognition that the tide is turning toward regarding OC usage determinations as the primary province of the users themselves.

⁸² Michael Mazis et. al., *Patient Attitudes About Two Forms of Printed Oral Contraceptive Information*, 16 MED. CARE, 1045, 1049-50 (1978).

⁸³ *Id.* at 1049.

⁸⁴ Williams-Deane, *supra* note 62, at 114.

⁸⁵ *Id.*

⁸⁶ *Id.*

⁸⁷ Teresa Moran Schwartz, *Consumer Warnings for Oral Contraceptives: A New Exception to the Prescription Drug Rule*, 41 FOOD DRUG COSM. L.J. 241 (1986).

V. FACTOR THREE IN PRESCRIPTION/OTC ANALYSIS: METHOD OF USE OR COLLATERAL MEASURES NECESSARY TO USE

The final factor in making the prescription/OTC determination, namely considering method of use and collateral measures pertaining to use, requires an extremely broad analysis.⁸⁸ This analysis includes an inquiry into social policy issues and the circumstances relating to a particular drug's use.⁸⁹ On the very broadest level, making OCs available over-the-counter would eliminate an important obstacle to their use by combating the incorrect presumption held by many women that OC use is dangerous.⁹⁰ The very fact of their ready availability would signal to women that OCs are in fact quite safe for them to take.

Perhaps the most important issue to consider in this regard is the great boon that women, and society as a whole, receive as a result of OC use. Pregnancies, and negative pregnancy-related health consequences, can disrupt women's lives and result in substantial societal costs.⁹¹ The beneficial effects of OCs are becoming increasingly more important as social shifts have resulted in the earlier onset of sexual activity by teenagers. In the 1990s, 50% of teenagers had sex by age 18, compared with 27% of members of this age group in the 1950s; by age 20, the proportions were 76% and 61%, respectively.⁹² In spite of this increase, pregnancy rates among sexually experienced teenagers decreased by 19% between 1972 and 1990, indicating that increased contraceptive use has played an important role in preventing large numbers of teenage pregnancies.

As more teenagers engage in earlier sexual activity, it becomes ever more critical for

⁸⁸ Hutt, *supra* note 6, at 433.

⁸⁹ *Id.*

⁹⁰ Trussell, *supra* note 2, at 1097.

⁹¹ James G. Kahn, *Pregnancies Averted Among U.S. Teenagers by the Use of Contraceptives*, 31 FAM. PLAN. PERSPS. 20, 33 (1999).

⁹² *Id.* at 29.

reliable methods of birth control to be easily accessible in order to prevent unwanted pregnancies, pregnancy-related complications, and increased numbers of abortions. One study concluded that the likely number of pregnancies averted by adolescent contraceptive use is approximately in the 750,000 to 1.25 million range,⁹³ which would translate into the prevention of approximately 480,000 live births, 390,000 abortions, 120,000 miscarriages or stillbirths, and 10,000 ectopic pregnancies each year.⁹⁴ Considering these staggering numbers, making contraceptives such as OCs widely available is the cost-effective thing to do. The average annual cost for each adolescent at risk of unintended pregnancy and using no method of contraception is estimated to be \$5,758 over five years in the private sector and \$3,079 in the public sector.⁹⁵ In contrast, the cost of providing such teenage girls with a contraceptive method such as an implant costs approximately \$1,533 in the private sector, which represents an estimated savings of \$4,301.⁹⁶

One recent report, which compiled research estimating the cost of health care, housing assistance, food stamps, child welfare services, and lost revenue due to lower taxes paid by teenage mothers, found that United States taxpayers spent at least \$9.1 billion in 2004 for costs linked to teenagers having children.⁹⁷ If an ounce of prevention is truly worth a pound of cure, as the old saying goes, then promoting the availability of OCs to stave off such costs is surely the intelligent choice to make.

The true cost of teenage pregnancies, however, includes even greater losses to society in

⁹³ *Id.* at 31-32.

⁹⁴ *Id.* at 32.

⁹⁵ *Id.* at 33.

⁹⁶ *Id.*

⁹⁷ Kari Huus, *A Baby Changes Everything: The True Cost of Teen Pregnancy's Uptick*, MSNBC, Feb. 19, 2010, http://www.msnbc.msn.com/id/35448556/ns/us_news-the_elkhart_project/.

terms of lost educational opportunities and future earnings for teenage parents. Individuals who have children during their teenage years are less likely to get a high school diploma or to go on to college, they tend to earn less during their time in the workforce, and their unfortunate offspring are more likely to struggle to keep up with their peers.⁹⁸ Only 40% of teenage girls who give birth at age 17 or earlier finish high school, and an even larger gap exists when it comes to completion rates for higher education.⁹⁹ Consequently, teenage girls who have a baby at age 17 or younger earn approximately \$28,000 less on average in the 15 years following the birth than if they had delayed until just 20 or 21 to have a child, and teenage boys who become fathers to children of teenage mothers at age 17 or younger face the loss of a similar amount of income over the 18 years following the child's birth.¹⁰⁰

Furthermore, looking to future generations, the daughters of teenage mothers are three times more likely to become teenage parents themselves than are girls born to older mothers, and the sons born to teenage parents are more likely to be incarcerated.¹⁰¹ Both sons and daughters of teenage parents face an increased risk of both social and academic struggles.¹⁰² Those who believe that children thrive best in traditional family units in which both a mother and father are present ought to be particularly concerned with the prevention of teenage pregnancy. Eight out of ten teenage fathers do not marry the mothers of their first children, and such absentee fathers typically pay less than \$800 annually in child support.¹⁰³ Thus, on the whole, staving off the catastrophic ripple effects created by teenage pregnancies through making OCs more readily available to women is, from a social policy perspective, the correct course of action to adopt.

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ *Id.*

An examination of social issues relating to the prescription/OTC determination for regular use OCs must also include a look at the closely related concerns which emerged in the relatively recent debate over the prescription/OTC status of emergency OCs. In 1996, the FDA approved the emergency OC pills popularly known as “Plan B” for OTC sale.¹⁰⁴ The FDA’s choice to shift Plan B from prescription drug status to nonprescription drug status represented a complete about-face from the stance it took against making such a switch just three years earlier.¹⁰⁵ In an essay sharing his personal insights into the FDA’s consideration of making the change, former FDA consultant Frank Davidoff mentions that during the agency’s consideration of Plan B’s manufacturer’s application for approval of OTC marketing of the drug, the committees meeting to discuss the issue spent the majority of their time talking about the social, behavioral, and ethical issues relating to making the emergency OC so readily available.¹⁰⁶ This represented an unusual deviation from the standard practice of FDA committees to discuss making a prescription to OTC switch based primarily on the biological and clinical concerns raised by the change.¹⁰⁷

Five principal social objections to OTC availability of Plan B were raised in the committee meetings: 1) requiring prescriptions for emergency contraception is important in that it forces women to see doctors on a regular basis, who can provide for their overall health and supply them with information; 2) because the mechanism by which Plan B prevents pregnancy is not fully understood, implantation of fertilized ova might occasionally be interfered with, which some viewed as abortion; 3) increased promiscuity might result from OTC availability, leading

¹⁰⁴ Rob Stein, *FDA Approves Plan B’s Over-the-Counter Sale*, WASHINGTON POST, Aug. 25, 2006, <http://www.washingtonpost.com/wp-dyn/content/article/2006/08/24/AR2006082400559.html>.

¹⁰⁵ *Id.*

¹⁰⁶ Davidoff, *supra* note 1, at 20.

¹⁰⁷ *Id.*

to an increase in the spread of STDs; 4) OTC availability might discourage women from using other means of contraception; and 5) social and behavioral side effects associated with OTC availability might have a greater impact on very young women who might be less capable of following instructions for use.¹⁰⁸

After much discussion, the committee members voted overwhelmingly (23 to 4) that emergency contraception should be available to American women on an OTC basis.¹⁰⁹ Even the committee members voting against OTC status acknowledged that they were doing so for reasons other than Plan B's demonstrated safety and efficacy.¹¹⁰ Although not binding, the FDA rarely makes decisions contrary to advisory committee recommendations; in this instance, however, the FDA announced its decision that Plan B was not approved for OTC use in May 2004.¹¹¹ As documented by a report of the Government Accountability Office in November 2005, four unusual occurrences seemingly resulted in this determination.¹¹² First, the FDA staff members who ordinarily would have signed the denial of approval letter so disagreed with the decision that they refused to sign it.¹¹³ Second, high-level FDA management was more involved in the Plan B review than in reviewing any other OTC switch application.¹¹⁴ Third, the agency's decision not to approve the application may have been formulated before the scientific reviews of the drug were even completed.¹¹⁵ Finally, the rationale for the decision, namely that younger women would be unable to use Plan B appropriately, failed to follow the FDA's usual practice of

¹⁰⁸ *Id.* at 21.

¹⁰⁹ Wood, *supra* note 37, at 1197.

¹¹⁰ *Id.*

¹¹¹ Davidoff, *supra* note 2, at 22.

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ *Id.*

extrapolating data from older to younger adolescents.¹¹⁶

Strong suspicions existed that pressure from social conservatives led to the FDA's initial refusal to approve Plan B for OTC status. Indeed, W. David Hager, an obstetrician-gynecologist recruited directly by the second President Bush's White House to serve on the committees discussing Plan B approval, even said of the Plan B decision in one speech to a Christian college audience that "God has used me to stand in the breach for the cause of the Kingdom."¹¹⁷ Such statements by a White House recruitee suggest that pressure was placed on the FDA from the highest levels of the executive branch to reject Plan B's OTC approval.

The same social concerns which the FDA advisory committees discussed in relation to Plan B are extremely likely to crop up again in talks regarding shifting regular use OCs to over-the-counter status. Particularly if a Republican administration is in place at the time of the decision, a strong possibility also exists for social conservatives to allow their desire to impose their set of beliefs on women across the United States to cloud a fair assessment of the proper status of OCs. It is to be hoped that future FDA decisions on the prescription/OTC status of OCs will place stronger emphasis on their safety and efficacy instead of allowing social views with dubious measures of objective support to cloud the agency's judgment.

One more social policy argument that is sometimes brought up in support of keeping OCs prescription-only is that "birth control is a poor woman's ticket to health care," since a visit to a family planning clinic "is her annual exam, when she gets a Pap smear, blood pressure check, and general health information."¹¹⁸ This argument relies on the faulty presumption that in order to lure women in to have regular health examinations, the presence of an accompanying "carrot"

¹¹⁶ *Id.*

¹¹⁷ Davidoff, *supra* note 1, at 23.

¹¹⁸ Malcolm Potts and Cindy Pearson, *Should Birth Control Pills be Sold Over the Counter?*, 9 A.J. PUB. HEALTH, 20 (1995).

in the form of a prescription for OCs is necessary.¹¹⁹ It should be noted that men face no comparable coercion to undergo regular health screenings, yet no one seems to be suggesting that items such as male condoms ought to require prescriptions simply in order to induce men to come in for check-ups.¹²⁰ This argument is highly paternalistic in that it suggests that policymakers should be the ones who decide essentially to force women into seeing doctors on a regular basis to obtain OC prescriptions instead of allowing women to make decisions regarding doctor's visits for themselves.¹²¹

A related line of concern is that giving OCs over-the-counter status could jeopardize the very survival of family planning clinics. This is because financial support for such clinics is to a substantial degree based on reimbursement associated from contraceptive distribution, particularly OCs.¹²² The weight of this line of reasoning may be diminished by national health care reform measures which may alter the reimbursement system for family planning.¹²³

The manner in which insurance coverage of OCs might change upon their switch to OTC availability is another issue worthy of examination. Concerns have been raised that insurance policies which cover prescription drugs might no longer pay for OCs should they become available over-the-counter.¹²⁴ Moreover, some argue that OC manufacturers might stop offering steep price discounts to family planning clinics due to the move to OTC status, which might result in poor women who are currently able to gain access to OCs inexpensively being forced to pay higher, potentially unaffordable prices.¹²⁵ Others counter this point by arguing that

¹¹⁹ Trussell, *supra* note 2, at 1095.

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² Trussell, *supra* note 2, at 1097.

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ *Id.*

manufacturers would have a strong incentive to continue such discounts in an effort to create brand loyalty should OC distribution be increased through nonprescription approval of the drugs.¹²⁶ Whatever the shift in cost allocation for OCs upon their OTC availability, however, making OCs accessible without a prescription would almost certainly decrease the overall social cost of their use through eliminating the administrative costs associated with prescriptions and the costs associated with visiting a clinician to obtain OCs.¹²⁷

A final social concern relating to the OTC availability of OCs is that since OCs, unlike barrier methods, offer no protection from STDs, some individuals may choose to use only OCs for their contraceptive needs if the drugs become more available, thereby placing themselves at greater risk for contracting STDs. This concern does not, however, justify keeping OCs as prescription-only drugs. Sexually active individuals are at risk for STDs whether they use hormonal contraceptives, the withdrawal method, intrauterine devices, male and/or female sterilization, and, with respect to at least HIV infection, possibly also spermicides.¹²⁸ The proper public health response to counter the spread of STDs is increased education on recognizing and reducing the risk of contraction, not restricting of one or more methods of contraception.¹²⁹ One promising possibility for accomplishing this is for condoms and information on assessing STD risk to be included in all OC packages sold.¹³⁰

¹²⁶ *Id.*

¹²⁷ *Id.*

¹²⁸ Trussell, *supra* note 2, at 1095.

¹²⁹ *Id.* at 1096.

¹³⁰ *Id.*

VI. OCs SHOULD REMAIN OTC DRUGS RATHER THAN BECOME BTC (BEHIND-THE-COUNTER) DRUGS

Once the FDA decides to abandon the current physician's prescription-only system for OCs, a further question of whether OCs should become available over-the-counter or whether they belong in some new behind-the-counter distinction. While no such category currently exists, there has been discussion in recent years about possibly establishing a BTC category. In the event that a BTC category is established, OCs ought to remain in the OTC category, albeit possibly in a "restricted-sale" segment of the OTC category along with Plan B, instead of becoming BTC drugs in order to keep OC prices down, promote access to the drugs, and minimize the risk of pharmacist interference with women's OC use decisions.

In the FDA's notice of its upcoming November 14, 2007 public meeting to assess the need for this new classification of drugs, the agency defined the BTC class of drugs as "comprised of certain medications available behind the counter at the pharmacy without a prescription and require[ing] the intervention of a pharmacist before dispensing."¹³¹ BTC drugs could take three possible forms: a separate third class of drugs that is neither nonprescription nor prescription, prescription drugs, or nonprescription drugs.¹³² Prescription BTC drugs would require a prescription by the pharmacist rather than by a physician, whereas nonprescription BTCs would require pharmacist intervention without the issuance of an actual prescription before purchase of the drug.¹³³ Due to the current two-category system provided for by the FD&C Act, some argue that the FDA lacks the statutory authority to choose the first of these

¹³¹ Abram S. Barth, *Is Three a Crowd or Company?: Behind-the-Counter Drugs*, 63 FOOD & DRUG L.J. 865 (2008).

¹³² *Id.* at 867.

¹³³ *Id.*

options and create a separate, discrete BTC drug class.¹³⁴ Regardless of whether this argument is correct, Congress could still elect to provide for the creation of such a category through legislation if it so chose.¹³⁵

For clarity's sake, it is important to note that while certain OTC medications are already thought of as being "behind the counter," namely Plan B and drugs containing pseudoephedrine, these drugs are not in a formal BTC category and their current treatment is different from that which would occur if they were officially made BTC drugs.¹³⁶ Plan B and pseudoephedrine are only kept physically behind the pharmacy counter in order for age and quantity restrictions to be enforced.¹³⁷ These drugs do not require, as the proposed BTC class would, pharmacist counseling, consultation, or interaction and are frequently dispensed by members of the store's staff without any interaction between pharmacist and purchaser whatsoever.¹³⁸ In fact, should a true BTC class be created, it would be a good idea for Plan B and pseudoephedrine to be referred to as something along the lines of "restricted-sale" drugs to keep public, pharmacy, and insurance confusion to a minimum.¹³⁹

While it might in fact be a good idea for OCs to join these "restricted-sale" drugs in being physically placed behind pharmacist counters once they become available OTC in order to ensure that they will not be tampered with before their use, there is no need to require purchasers to interact directly with pharmacists before receiving OCs as would be the case with true BTC drugs. First and foremost, aside from the issue of whether OCs belong in a BTC class if BTC

¹³⁴ See, e.g., *Id.* at 868.

¹³⁵ See generally Daniel Healey, *Plan BTC: The Case for a Third Class of Drugs in the United States*, 63 *FOOD & DRUG L.J.* 375, 387-88 (2008).

¹³⁶ Barth, *supra* note 130 at 867-68.

¹³⁷ *Id.* at 868.

¹³⁸ *Id.*

¹³⁹ *Id.*

classes were in fact shown to be effective, the need for any kind of BTC class whatsoever remains unclear. A 1995 report by the Government Accountability Office (GAO) entitled “Value of Pharmacist-Controlled Class Has Yet to Be Demonstrated” examined variations on BTC classes already in existence in ten other nations.¹⁴⁰ The report reached the conclusion that there is insufficient data to link the creation of a BTC class of drugs to improved health incomes, lower cost, or expanded access.¹⁴¹ Additionally, the report found that while pharmacy counseling was mandated as a part of the BTC categorization plan in these other nations, it rarely occurred in practice.¹⁴² Considering these unpromising findings, the formation of any kind of BTC category, much less one including non-emergency OCs, seems unnecessary.

In some countries, including Canada as of 2008, Plan B is now available directly off the shelf as opposed to being kept behind the pharmacy counter.¹⁴³ This change eliminated privacy concerns created by requiring women to receive counseling from a pharmacist prior to receiving the drug, most notably that many pharmacies lack private consulting rooms and, in some areas, pharmacists recorded this very private information and stored it in patient files.¹⁴⁴ It was also estimated that the elimination of the consulting requirement might ultimately work to lower the cost of the drug, since the drug’s cost included dispensing and counseling fees added on by the pharmacies themselves to cover the additional services.¹⁴⁵ Since cost is certainly barrier to access, especially for younger women, and research suggests that these privacy issues constituted

¹⁴⁰ GAO, *Nonprescription Drugs: Value of a Pharmacist-Controlled Class Has Yet to Be Demonstrated*, GAO-PEMD-95-12 (1995).

¹⁴¹ *Id.* at 3.

¹⁴² *Id.* at 3.

¹⁴³ *Plan B Comes Out From Behind the Counter*, 178 CAN. MED. ASS’N. J. 1645 (2008).

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

an additional access barrier,¹⁴⁶ not placing OCs in a BTC category in the United States might well better serve women and society in general by increasing access to and use of OCs.

In addition to alleviating privacy and cost concerns, keeping OCs over-the-counter with, possibly, a “restricted sale” distinction but not making them BTC has the added benefit of limiting pharmacists’ ability to interfere, based on religious or other beliefs, with women’s decisions about their own bodies. Pharmacist refusals to fill prescriptions for birth control based on their personal beliefs are being increasingly reported around the world, including in the United States.¹⁴⁷ Pharmacists who refuse to dispense birth control also often refuse to transfer a woman’s prescription to a different pharmacist or refer her to another pharmacy so that she can obtain the medication.¹⁴⁸ Perhaps most disturbingly of all, some pharmacists have been known to confiscate prescriptions, mislead women about the availability of drugs, subject women to lectures on what, in the pharmacist’s view, constitutes morality, and/or to delay women’s access to the requested birth control drugs until the critical period for effective administration has passed.¹⁴⁹ Especially if a prescription BTC class is introduced in which women are required to obtain a pharmacist’s prescription rather than a doctor’s prescription in order to obtain OCs, pharmacist meddling poses a serious risk to women’s access to the drugs which allow them to control their reproductive destinies. Making OCs available over-the-counter instead of moving them to some variety of BTC classification is the best option for minimizing the risk of pharmacists interfering with women’s birth control decisions.

Even if OCs were classified as BTC drugs, both pharmacists’ ability to assess women’s

¹⁴⁶ *Id.*

¹⁴⁷ See Marcia D. Greenberger and Rachel Vogelstein, *Pharmacist Refusals: A Threat to Women’s Health*, 308 *SCIENCE* 1557 (2005).

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

risk for contraindications and the quality of the information passed along to the women by pharmacists would be questionable. In a study of OC provision in Jamaica, where low-dose OCs have been classified as BTC drugs to be dispensed only by pharmacists and requiring counseling about proper use since 2008,¹⁵⁰ a substantial number of mystery clients posing as new pill users were denied access to OCs even though they had no contraindications.¹⁵¹ Also troubling was the relevance of the information that the pharmacists passed along to the mystery clients, particularly regarding side effects of OC use. While the majority of pharmacists were knowledgeable about all aspects of pill use, as their responses to survey questions indicated,¹⁵² pharmacists tended to focus only on one side effect of use—namely, weight gain—which has actually been shown to be incorrectly attributed to OC use.¹⁵³ Costly, user-detering consultations which offer a significant opportunity for pharmacists to interfere with patients’ own birth control-related convictions simply do not seem to provide enough pros to outweigh the cons when it seems that the interactions may well prove so very unhelpful.

VII. CONCLUSION

In light of the FDA’s mission, which is supposed to involve prioritizing above all else the promotion of the public health through “promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner,”¹⁵⁴ the FDA has failed the citizens of the United States in the area of the drug status classification of

¹⁵⁰ Dawn Chin-Quee et. al., *Over-the-Counter Pill Provision: Evidence from Jamaica*, 37 *STUD. FAM. PLAN.* 99, 100 (2006).

¹⁵¹ *Id.* at 104

¹⁵² *Id.* at 106

¹⁵³ *Id.* at 108

¹⁵⁴ Section 903(b) of the FD&C Act, 21 U.S.C. § 393(b)(1) (added by Food and Drug Administration Modernization Act of 1997).

oral contraception. The public's health will be best promoted through increasing women's access to OCs, and this access should remain OTC instead of BTC in order to achieve optimal results in terms of promoting access, reining in costs, protecting privacy, and preventing pharmacist interference with women's reproductive choices.