

Research-in-Brief



IWPR Publication # ^{B236}~~A126~~

February 2001

MAKING BIRTH CONTROL MORE ACCESSIBLE TO WOMEN: A Cost-Benefit Analysis of Over-the-Counter Oral Contraceptives

by Holly Mead, IWPR/GWU Research Fellow

Oral contraceptives (OCs) are one of the most effective forms of reversible contraception on the market. The birth control pill has a failure rate of .1 percent when used perfectly and a failure rate of between 3 percent and 6 percent for typical use (The Alan Guttmacher Institute 1998; Trussell *et al.* 1995). In comparison, condoms have a 2 percent to 16 percent failure rate and the diaphragm has a 6 percent to 18 percent failure rate. Furthermore, the Pill is the most popular form of reversible contraception with over 10.4 million women using it compared with 7.9 million women who use male condoms and 720,000 women who use diaphragms (The Alan Guttmacher Institute 1998).

The Food and Drug Administration (FDA) has been considering an Rx-to-OTC switch of oral contraceptives for several years based on the drug's extensive safety record. In June 2000, the agency held a public hearing to discuss the issue and examine the evidence both for and against the proposal. Switching the birth control pill to over-the-counter status would greatly benefit women by reducing access barriers imposed by the prescription requirement. Although the prescription regulation of drugs was implemented to protect consumers, Rx status of oral contraceptives may in fact prevent women from experiencing the benefits of the product. The medicalized status of the Pill adds little to the quality or safety of the product and, instead, makes it more difficult and costly for women to obtain an effective form of birth control. By lifting the prescription regulation of OCs and eliminating the need to see a physician, the government would provide women with a safe and effective birth control method at a lower cost and with no obligatory medical checkpoint. Increased access to this contraceptive would benefit society by reducing incidences of unintended pregnancies, decreasing women's risk of certain diseases, and eliminating psychological barriers that can prevent women from using the Pill.

The Institute for Women's Policy Research (IWPR) conducted a cost-benefit analysis to determine whether switching oral contraceptives to OTC status is more beneficial to women and society than continuing to regulate them as prescription drugs. IWPR estimated the costs and benefits to all individuals including sexually active women, pharmaceutical companies, and society in general. By weighing the positive impacts against the negative impacts, the Institute calculated whether the OTC birth control pill proposal would improve the overall welfare of society.

Potential Impacts of OTC Oral Contraceptives

Over-the-counter distribution of birth control pills would result in a number of potential benefits mainly due to the larger number of women who would be using the drug. A survey conducted by Louis Harris and Associates found that 20.4 percent of sexually active women who currently do not use the Pill would be very likely to switch to that form of birth control if it were available over-the-counter (1993). With over 34 million sexually active women currently not using the Pill (Henry J. Kaiser Family Foundation 1996), a 20.4 percent increase would result in approximately 6.96 million new users for a total of 17.4 million women using the Pill.

With a larger population of oral contraceptive users, women and society at large would see lower incidences of unwanted pregnancies, decreased risk of certain reproductive health problems, and lower financial and time costs associated with seeing a physician for refills. Women and their partners would also experience the psychological benefits of having easier access to such an effective form of birth control. In addition, pharmaceutical companies would see a large increase in revenues generated from wider distribution of the drug.

Table 1. Medical Savings from Averted Unplanned Pregnancies for Potential OTC Oral Contraceptive Users¹

Pregnancy Outcome	Number of Outcomes	Average Price	Best Savings Estimate (in millions)
Induced Abortion	219,679.69	\$380.50	\$83.59
Spontaneous Abortion/Miscarriage	57,360.00	\$727.00	\$41.70
Ectopic Pregnancy	4,671.05	\$3,899.50	\$18.21
Term Pregnancy	185,440.86	\$10,430.50	\$1,934.24
Total Savings			\$2,077.74

¹ Calculations assume a three percent failure rate for oral contraceptives.

Sources: IWPR calculations based on data from the Henry J. Kaiser Family Foundation 1996; Louis Harris and Associates 1993; Trussell *et al.* 1995.

While OTC oral contraceptives would have a positive impact on society because of the wider use of a safe and effective form of birth control, an increase in the number of women using the Pill would also have some negative effects. Increased marketing costs for pharmaceutical companies, the potential for higher out-of-pocket costs for women, and increased incidences of adverse events for both the general population and those groups that are at higher risk of negative side effects would likely occur. Women who would choose to forego their annual gynecological exams following a switch would also face increased risk of undiagnosed health problems and a delay in treatment of conditions that could be detected during an exam.

Estimating Benefits of OTC Oral Contraceptives

Reduction in Unintended Pregnancies

The potential reduction in unintended pregnancies is the most significant benefit that would result from an Rx-to-OTC switch of oral contraceptives. Based on a ten percent national rate of unintended pregnancies (Henry J. Kaiser Family Foundation 1996), approximately 481,553 women would become pregnant unintentionally in the population of 6.96 million potential new OTC OC users if they continue to use another form of birth control.¹ Assuming a three percent failure rate for oral contraceptives (based on data examining typical use of the Pill), a total of 467,105 of these pregnancies would be averted if all 6.96 million potential new OTC OC users start using the Pill.

To measure the benefits of these averted pregnancies,

IWPR estimated the cost savings associated with preventing four possible pregnancy outcomes: abortion, miscarriage, ectopic pregnancy, and term pregnancy. Costs associated with these outcomes include the costs of all medical treatments and procedures from time of conception. Costs of term deliveries include prenatal care, delivery and newborn hospitalization, and other medical costs that end at the time of discharge from the delivery facility (Trussell *et al.* 1995).²

The OTC birth control pill would serve an important public health interest by reducing the number of abortions by approximately 220,000 a year. This would result in a total savings to society of \$83.6 million (see Table 1). In addition, wider distribution of the Pill would lead to a reduction of about 185,000 term pregnancies, which would save society \$1.93 billion in medical costs. Finally, the OTC Pill would avert approximately 62,000 miscarriages and ectopic pregnancies, which would lead to a savings of \$59.9 million. The total savings to society associated with the reduction of unintended pregnancies would be substantial at \$2.08 billion.

Protective Health Benefits

Use of oral contraceptives is associated with a reduction in the risk of several reproductive health conditions including ovarian cysts, ovarian cancer, benign breast disease, endometrial cancer and pelvic inflammatory disease (Trussell *et al.* 1995; Ashraf, Arnold, and Maxfield 1994; Petitti 1994). To determine the protective benefit of the birth control pill, IWPR calculated the reduction in incidences

of disease based on the difference in rates of disease for OC users and non-users and applied this number to the population of potential OTC OC users (Petitti 1994). To measure this benefit, we calculated the cost savings associated with the reduction in disease based on average medical costs of each disease (Trussell *et al.* 1995; Barnes *et al.* 1995; Ashraf, Arnold, and Maxfield 1994).

Society would see the greatest cost savings from the reduction in incidences of pelvic inflammatory disease (PID). Wider use of the Pill would lower the number of cases of PID by approximately 11,000 and would save society over \$69.2 million in medical costs (see Table 2). Incidences of benign breast disease would decrease by about 8,000 leading to a cost savings of \$5.4 million. Society would save about \$4.1 million in costs associated with lower incidences of ovarian cysts and about \$5.9 million associated with a decrease in endometrial and ovarian cancers. Total medical costs saved due to the protective effect of OTC oral contraceptives would equal \$84.5 million.³

Time and Cost Savings from Physician Visit

Women who would eliminate their annual ob/gyn exams altogether and women who see their physician more than once a year for prescription OC refills would experience a time and cost savings from the Rx-to-OTC proposal be-

cause they would no longer need to see a medical professional to obtain their birth control pills.

In the population of women who currently use the Pill (10.4 million women), 7.9 percent or 822,390 women see their physician four times a year for OC refills, 34.7 percent or 3.61 million see their physician two times a year for refills and 49.3 percent or 5.13 million see their physician once a year for refills.⁴ Assuming the average cost of a physician's visit is \$85 and that women will continue to see their physician at least once a year (American Medical Association 1996), women who see their physician four times a year for refills would see an individual cost savings of \$255 per year for a total savings of \$209.7 million for the population. Women who see their physician two times a year for refills would see an individual cost savings of \$85 per year for a total cost savings of \$307 million for the population. In addition, approximately 2.1 million women would eliminate their annual gynecological visits altogether for an individual cost savings of \$85 per year and a total cost savings of \$178.54 million (Louis Harris and Associates 1993). Overall, the savings to women who either stop seeing their physician annually or reduce their visits to once a year would equal about \$695.3 million.

Women who currently see their doctor more than once a year to obtain OC refills or who would forego their annual

Table 2. Medical Savings Associated with the Protective Benefits of Increased Over-the-Counter Oral Contraceptive Use

Health Condition	Reduced Incidences of Disease	Average Price	Best Savings Estimate (in millions)
Ovarian Cysts	3,131.50	\$1,313.50	\$4.11
Benign Breast Disease	8,002.70	\$669.00	\$5.35
Endometrial Cancer	139.17	\$15,373.00	\$2.14
Ovarian Cancer	347.94	\$10,749.00	\$3.74
Pelvic Inflammatory Disease	11,152.00	\$6,204.00	\$69.19
Total Medical Savings			\$84.53

Sources: IWPR calculations based on data from Ashraf, Arnold, and Maxfield 1994; Barnes *et al.* 1999; Louis Harris and Associates 1993; Petitti 1994; Samuels, Stryker, and Smith 1994; Trussell *et al.* 1995.

exam altogether would also see an opportunity cost savings of time if the Pill were to become an OTC drug. To measure the value of this benefit, IWPR assumed the alternative use of the time spent in the physician's office would be work and that the value of time saved should, therefore, equal the average wage rate for women. Assuming the average wage rate is \$12/hour and the average amount of time spent at the doctor's office is 1½ hours (including travel time), women who currently see their physician four times a year for OC refills would save 4.5 hours per year or \$54 for a total opportunity cost savings of \$44.4 million for the population.⁵ Women who see their doctors twice a year for refills would save 1.5 hours per year or \$18 for a total opportunity cost savings of \$64 million for the population. For the population of women who would eliminate their annual ob/gyn visits altogether, a total of 3.15 million additional hours would be spent working for a \$37.8 million savings. Overall, the opportunity cost savings to women who either reduce or eliminate their physician visits would equal \$147.2 million.

Revenue to Pharmaceutical Companies

Manufacturers of oral contraceptives would see an increase in revenues from the product due to its wider distribution as an OTC drug. The higher revenues would come primarily from the increased user population, because pharmaceutical companies would be unlikely to increase the price of oral contraceptives once available OTC. Based on a mid-point price of \$26 per month, an annual cost of \$312 per woman and an estimate of 6.96 million new users, pharmaceutical companies would see an increase in revenue of about \$2.17 billion (de Boer and Herings 1993; American Medical Association 1996; Dailard 1999).

Psychological Benefits

Women would also experience significant psychological benefits if access to the birth control pill were improved through an Rx-to-OTC switch. Women who rely on less effective forms of contraception would rest easier knowing they have access to a highly effective method without the hassle and cost of seeing a physician. Eliminating the requisite physician visit also removes the psychological barrier of having to undergo a pelvic exam, which becomes a significant obstacle for many women. Finally, with lower rates of unplanned pregnancies, fewer women would have to cope with the difficult and stressful decisions associated with an unwanted pregnancy. Unfortunately, no study has attempted to determine women's willingness to pay for reduced anxiety and stress levels, making it difficult to measure these benefits in monetary terms. These benefits, however, are real and often significant for women and should be considered in the overall

analysis of the policy proposal. Therefore, we represent them with a "+" sign in the cost-benefit analysis and consider the issues qualitatively when formulating our policy recommendations.

Estimating Costs of OTC Oral Contraceptives

Health Risks

Use of oral contraceptives is associated with an increased risk of certain adverse health events including myocardial infarction, thrombotic stroke, hemorrhagic stroke, pulmonary embolism/thrombophlebitis and gallbladder disease (Trussell *et al.* 1995; Ashraf, Arnold and Maxfield 1994; Petitti 1994).⁶ Increasing the population of oral contraceptive users would increase the incidences of these events and the associated medical costs.⁷

The largest costs would come from the higher incidences of pulmonary embolism and venous thromboembolism in the larger OC user population. Approximately 2,800 more of these adverse events would occur at a cost of \$15.9 million (see Table 3). The medical costs associated with the increase in thrombotic stroke would also weigh heavily on society. Costs would equal about \$15.5 million for approximately 1,400 additional events. Higher incidences of myocardial infarction and hemorrhagic stroke would increase medical costs by about \$4.2 million and \$1.6 million, respectively, while the increase in gallbladder disease would increase costs by \$7.5 million. In total, medical costs associated with adverse events in the larger population of OC users would equal \$44.62 million.

Cost to Women at Higher Risk of Adverse Events

Some health care providers have expressed concern that women who are highly contraindicated for the Pill will use it if a physician is not involved in screening out at-risk groups. These women would face an increase in adverse events due to use of the drug. Specifically, an increase in cardiovascular (CV) events, including myocardial infarction, stroke and pulmonary embolism, in women over the age of 35 who smoke 15 or more cigarettes per day would likely occur.⁸ To measure this increased risk, IWPR estimated the number of women among the 6.96 million new users who would be contraindicated for OC use (i.e. heavy smokers over the age of 35) and calculated the added cost to society based on their increased risk of adverse events. The estimated increase in CV incidents for the contraindicated population is about 7.6 events. Based on an average cost of CV events of \$11,020.5 million (Ashraf, Arnold and Maxfield 1994), the total medical costs to society would be \$83.8 million.⁹

Table 3. Medical Costs Associated with Adverse Health Effects of Increased Over-the-Counter Oral Contraceptive Use

Adverse Health Events Due to OC Use	Increased Incidences of Disease	Average Price	Best Savings Estimate (in millions)
Myocardial Infarction	347.96	\$11,964.49	(\$4.16)
Thrombotic Stroke	1,391.75	\$11,141.26	(\$15.51)
Hemorrhagic Stroke	139.18	\$11,141.26	(\$1.55)
Pulmonary Embolism/ Venous Thromboembolism	2,783.54	\$5,707.60	(\$15.89)
Gallbladder Disease	1,739.71	\$4,316.16	(\$7.51)
Total Medical Savings			(\$44.62)

Sources: IWPR calculations based on data from Ashraf, Arnold, and Maxfield 1994; Louis Harris and Associates 1993; Petitti 1994; Samuels, Stryker, and Smith 1994; Strom *et al.* 1986; Trussell *et al.* 1995.

Costs of Foregone Ob/Gyn exam

Many health professionals have expressed concern that switching the birth control pill to over-the-counter status would cause women to stop seeing their health care providers for their annual gynecological exams. Without an annual check-up, women may delay the diagnosis and treatment of health problems such as STDs, which could lead to more serious and costly health problems including pelvic inflammatory disease. In addition, undiagnosed precursor conditions such as cervical dysplasia (which is often detected with pap smears) could develop into advanced stages of cancer if not identified and treated promptly.

The cost of foregoing annual pelvic exams is difficult to quantify, however, because predictions of the percentage of long-term health problems that could be prevented with annual exams or the cost savings that would result from early intervention in a disease do not exist. Instead, IWPR attempted to measure the cost by doubling the risk factor of those health conditions (or their precursor conditions) that could be detected during a gynecological exam, including ovarian cysts, ovarian cancer, endometrial cancer, breast cancer and cervical cancer in the population of women who would forego their annual gynecological visits (Petitti 1994; American Cancer Society 1997; Coker, Harlap and Fortney 1993).¹⁰ To measure the increased risk

in long-term health problems associated with STDs, IWPR doubled the risk of pelvic inflammatory disease – the most common and most serious consequence of undiagnosed STDs – in the population of OC users who stop seeing their ob/gyns regularly (Petitti 1994). The average expense of each condition was then used to determine the overall cost of the potential increase in incidences.

Doubling the risk of breast cancer, cervical cancer and pelvic inflammatory disease in the population of women who would eliminate their annual gynecological exam altogether results in the greatest cost to society. Medical costs for these diseases would equal \$317.4 million, \$43.7 million and \$41.7 million, respectively (see Table 4). Higher incidences of endometrial and ovarian cancers in this population would cost society about \$3.6 million total, while the higher risk of ovarian cysts would cost about \$828,000. The total cost to society associated with undiagnosed problems and the delay in treatment of more serious conditions would equal \$407.2 million.

Marketing Costs of OTC Oral Contraceptives

Unlike with Rx drugs, a launch of an OTC product requires significant advertising and promotional support because companies must rely on consumers to make their own purchasing choices. To estimate the amount of marketing sup-

Table 4. Medical Costs Associated With Increased Risk of Undiagnosed Disease in Women Who Use Over-the-Counter Oral Contraceptives and Forego Annual Physical Exam

Adverse Health Condition	Increased Incidences of Disease ¹	Best Cost Estimate (in millions)
Ovarian Cysts	630.13	(\$0.83)
Ovarian Cancer	210.04	(\$2.26)
Endometrial Cancer	84.02	(\$1.29)
Breast Cancer	20,458.27	(\$317.43)
Cervical Cancer	2,814.59	(\$43.67)
Pelvic Inflammatory Disease	6,721.40	(\$41.70)
Total Medical Savings		(\$407.18)

¹ Increased incidences are due to delayed diagnosis and treatment of precursor health conditions.

Sources: IWPR calculations based on data from the American Cancer Society 1997; Ashraf, Arnold, and Maxfield 1994; Coker, Harlap, and Fortney 1993; Fireman *et al.* 2000; Louis Harris and Associates 1993; Peltti 1994.

port companies would spend to launch OTC oral contraceptives, the Institute examined the advertising and promotional budgets (as a percentage of sales) of the OTC launches of several analogous goods in the feminine yeast infection and gastrointestinal categories.

Assuming OC producers will spend 4.5 percent of annual product sales on advertising (a midpoint value calculated from ad budgets of the analogous goods) and total OC sales are \$268.6 million ("OTCs: Contraceptives" 1999), manufacturers will spend approximately \$12.1 million to launch oral contraceptive brands into the OTC market.¹¹ According to the Physician's Desk Reference, 30 different brand name OCs are available in the prescription market. Assuming that the manufacturers of all 30 brands choose to launch OTC versions, the total cost in increased marketing of OTC OCs to the pharmaceutical industry would be \$362.88 million.¹²

Costs to Low-Income Women

Low-income women and women without health insurance

who have regular interactions with the health care system to obtain birth control pills may suffer from an Rx-to-OTC switch of the pill. Health professionals have expressed concern that these women would either lose access to free or subsidized care or choose to forego regular physicals, which would put their health at risk. In addition, providers are concerned that OTC status may actually create barriers to birth control access for disadvantaged women. Women whose insurance plans pay for prescription OCs are likely to lose coverage if the Pill becomes available OTC. Without insurance coverage, women will pay larger out-of-pocket costs. Furthermore, many uninsured, low-income women obtain subsidized OCs from public clinics. Pharmaceutical companies, however, are unlikely to continue offering clinics discounted prices if the product becomes available over-the-counter. The costs to low-income women are difficult to measure and should not be valued based on efficiency goals. But because they are important to the overall conclusion of the study, IWPR represented these impacts in the analysis with a "-" sign and considered them when formulating the policy recommendations.

Table 5. Overall Net Benefits to Society From OTC Oral Contraceptives

Benefits and Costs to Society	Best Estimate (in millions)
Benefits of OTC Oral Contraceptives	
Increase in revenue for producers	\$2,171.00
Saved monetary cost of MD visit	\$695.29
Saved opportunity cost of time	\$147.24
Reduction in unintended pregnancies and their outcomes (medical cost savings)*	\$2,077.74
Health benefits associated with OC use**	\$84.53
Lower anxiety levels associated with OC use	+
Total Savings	\$5,175.80
Costs of OTC Oral Contraceptive Use	
Cost of OCs to consumers	(\$2,171.00)
Health risks associated with OC use***	(\$44.62)
Increased risk of undiagnosed disease****	(\$407.18)
Higher incidences of adverse events in at-risk women	(\$83.76)
Increased cost of marketing OTC OCs	(\$405.00)
Cost to low-income women	-
Lives lost in contraindicated women ¹	-
Total Costs	(\$3,111.56)
Net Benefit to Society	\$2,064.24

* refer to Table 1; ** refer to Table 2; *** refer to Table 3; **** refer to Table 4.

¹ See footnote 3.

Sources: IWPR calculations based on data from the American Medical Association 1996; Ashraf *et al.* 1994; Dailard 1999; de Boer *et al.* 1993; Louis Harris and Associates 1993; Schiff 1999; Schwingl *et al.* 1999.

Results

Total benefits to society from a policy that would allow the distribution of oral contraceptives without a prescription would approximate \$5.2 billion (see Table 5). The majority of this benefit would be derived from the \$2.08 billion in medical savings from preventing unplanned pregnancies. An additional \$842.5 million in savings would

come from the financial and time costs many women would eliminate once distribution of the Pill was released from the direction of a physician (\$695.3 million and \$147.2 million, respectively). Society would also save about \$84.5 million in medical costs from the protective health benefit of the Pill. Although measuring the psychological benefit of OTC OCs is difficult, it should be included in the analysis qualitatively to highlight its importance when consid-

ering implementation of the policy. Women who use the pill would experience lower levels of anxiety if their access to one of the most effective forms of birth control were improved.

While pharmaceutical companies would also benefit significantly from an OTC birth control pill due to an increase in total revenue of about \$2.17 billion, this gain would be directly offset by the cost to consumers of having to pay for the Pill.¹³ However, basing an analysis on revenue data slightly understates the overall gain to society because it cannot measure the social and psychological gains associated with the proposal.

The costs associated with OTC oral contraceptives totals about \$3.11 billion, which reduces the benefits of the Rx-to-OTC switch by more than half. The medical repercussions associated with delayed diagnosis and treatment of early stage cancers and precursor health conditions would be the most costly to society, totaling approximately \$407.2 million. Increased risk of adverse health events in the general population of OTC OC users would cost about \$44.6 million, which is only about half the amount society would save in medical costs from the protective effect of OC use. The higher risk of adverse events among women who are contraindicated for OC use would add about \$83.8 million in costs to society. The expense of marketing an OTC birth control pill is the second highest cost in the analysis. The pharmaceutical industry would likely spend about \$405 million to support the marketing of OTC oral contraceptives. Society would also face additional costs that cannot and should not be measured in dollars. Low-income women may face higher financial and personal costs following an Rx-to-OTC switch of the Pill, which should be considered in the policy making process.

In monetary terms the positive impacts of an OTC oral contraceptive substantially outweigh the negative impacts. The net benefit to society of an Rx-to-OTC switch of the Pill is \$2.06 billion. The cost savings associated with reduced unintended pregnancies, the protective benefit of OC use, and eliminating the obligatory physician visit are much greater than the costs of undiagnosed medical conditions, increased adverse events, and higher health risks.

Recommendations

Based on the cost-benefit results, IWPR recommends FDA approve the OTC status of the birth control pill. The public health benefits associated with reduced rates of unplanned pregnancies and abortions as well as the medical cost savings to society would substantially outweigh any risks of increased and undirected use of oral contraceptives.

If an OTC birth control pill were approved, the federal government should consider several complementary policies to address any potential problems resulting from the switch. FDA should require that OC manufacturers develop and sponsor an extensive educational campaign emphasizing the importance of annual pelvic exams as part of the terms of an Rx-to-OTC switch. Such a campaign would identify the risks women face when foregoing annual exams and would help reduce the social costs associated with undiagnosed diseases. The campaign could also highlight groups of women who are contraindicated for OC use and who are, consequently, at higher risk of adverse events and death.

The government should also mandate Medicaid coverage for over-the-counter birth control pills and require that all insurance companies include OTC OCs in their prescription plans. In addition, pharmaceutical companies should be encouraged to continue offering discounted OC prices to public clinics regardless of drug status to guarantee low-income women's ability to obtain the drug. These efforts would help eliminate any barriers an OTC switch might impose for poor women.

Finally, state and federal governments should develop a comprehensive health care plan to address health providers' concerns regarding the health of disadvantaged women. Relying on the secondary effects of a policy such as obligatory pelvic exams for prescription OCs to keep low-income women in contact with the health care system is not a sufficient strategy for improving the health of poor and disadvantaged women.

IWPR Research Fellow Holly Mead conducted the cost-benefit study of OTC oral contraceptives with the assistance of Bethany Snyder, IWPR Research/Administrative Fellow. The study was submitted to the Food and Drug Administration during a June 2000 public hearing examining the Rx-to-OTC switch proposal. Holly Mead is pursuing her Ph.D. in public policy at the George Washington University.

Endnotes

1 This calculation may underestimate the number of averted unintended pregnancies for the population of OTC OC users because the national rate of unintended pregnancies includes pregnancies that result from failed oral contraceptive use. The potential OC user population in this study does not currently use the Pill, which is an extremely effective form of contraception. Because they would be willing to switch to the Pill if it were available OTC, the assumption is they are currently using forms of reversible birth control that are less reliable than the Pill. Using methods such as condoms, the diaphragm or IUDs, which have higher failure rates than the Pill, could increase the likelihood of unplanned pregnancies in that population.

2 The Trussell *et al.* study (1995) provides a range of costs depending on

type of insurance provider (public versus private). IWPR used an average cost based on these ranges in the analysis.

3 IWPR chose to look at the costs and benefits of disease in terms of medical expenses rather than lives saved or lost to avoid the controversy of monetizing the value of a life. When the Institute quantified the numbers of lives saved and lost due to the switch of OCs to OTC status, we found that approximately 180 lives would be saved from the Pill's protective benefit against cancer and 204 lives would be lost due to death in contraindicated women. Because these estimates are only approximations at best, IWPR felt the figures were virtually comparable and that the difference need not be monetized. However, we represent the slightly higher number of lives lost as a "-" to ensure it is considered in the analysis (see Table 5).

4 Calculations based on survey data from Louis Harris and Associates (1993).

5 The average wage rate is calculated and rounded to the nearest dollar based on data from *The State of Working America 1998-1999* (Mishel, Bernstein, and Schmitt 1999).

6 Because studies have found contradictory results regarding the net effect of oral contraceptives on breast and cervical cancer and the exact risk, if any, is not known, IWPR has not included these diseases in the analysis. IWPR included only those side effects that require hospitalization or long-term medical care.

7 Risk factors for each disease vary in the literature. IWPR calculations use a midpoint value of risk in determining total costs (Trussell *et al.* 1995; Petitti 1994; Ashraf, Arnold and Maxfield 1994, Strom *et al.* 1986).

8 Other groups of women contraindicated for OC use include women who are taking Rx drugs that could cause adverse effects when used in combination with OCs or women who have pre-diagnosed health conditions that could cause adverse effects when using OCs. In both cases IWPR assumed these women would be in contact with their physicians who would explain to them the risk factors of using oral contraceptives. Older women who smoke are the only group for whom medical guidance is not anticipated and who would, therefore, be at risk of self-prescribing OCs without knowing the consequences.

9 A average cost was derived from pricing information in the study conducted by Ashraf, Arnold and Maxfield (1994).

10 The risk factor used in this analysis is derived from risk in the general population of women.

11 Sales figures for the OC market are based on 1999 numbers.

12 It is unlikely that all 30 Rx brands will be launched in the OTC market. However, because IWPR has no way of knowing exactly how many would be switched to OTC status, we assume that all 30 brands will have drug store versions.

13 Insurance companies would also gain if OCs were switched to OTC status because most prescription plans would no longer cover the Pill. This gain, however, is only a transfer from insurers to women and is, therefore, not included as a separate benefit to society.

Works Cited

The Alan Guttmacher Institute. 1998. *Facts in Brief: Contraceptive Use*. New York: The Alan Guttmacher Institute.

American Cancer Society. 1997. *Breast Cancer Facts and Figures: Who Is at Risk of Developing Breast Cancer*. Atlanta, Ga.: American Cancer Society. Retrieved from: <http://www.cancer.org/statistics/97bcff/risks.html>.

American Medical Association/Planned Parenthood Federation of America. 1996. "You and the Pill." *Contra-*

ception Information Center. Retrieved from: <http://www.ama-assn.org/special/contra/support/ppfa/pill4.htm>.

Ashraf, Talat, Sharon Arnold, and Myles Maxfield. 1994. "Cost-Effectiveness of Levonorgestrel Subdermal Implants: Comparison with other Contraceptive Methods Available in the United States." *The Journal of Reproductive Medicine*, 39 (10): 791-798. October.

Barnes, M.N., and P.Y. Roland, M. Straughn, L.C. Kilgore, R.D. Alvarez, and E.E. Partridge. 1999 "A Comparison of Treatment Strategies for Endometrial Adenocarcinoma: Analysis of Financial Impact." *Gynecologic Oncology*, 73(3): 443-447. September.

Bittar, Christine. 1999. "First Generation Tackles Second Generation Challenge." *Brandweek*, S58. June 21.

Coker, Ann, Susan Harlap, and Judith Fortney. 1993. "Oral Contraceptive and Reproductive Cancers: Weighing the Risks and Benefits." *Family Planning Perspectives*, 25(1): 17-21. January/February.

Dailard, Cynthia. 1999. *U.S. Policy Can Reduce Cost Barriers to Contraception: Issues in Brief*. New York: Alan Guttmacher Institute.

De Boer, A. and R.M. Herings. 1993. "Editorial: Oral Contraceptives without Prescription." *Lancet*, 342(8877): 993. October.

Family Health International. 1999. *What are the Benefits and Risks of Combined Oral Contraceptives?* New York: Family Health International. Retrieved from: <http://www.ama-assn.org/special/contra/support/educate>.

Fireman, Bruce, Louis Fehrenbacher, Elisabeth Gruskin and Thomas Ray. 2000. "Cost of Care for Patients in Cancer Clinical Trials." *Journal of the National Cancer Institute*, 92: 136-142. January 19.

Henry J. Kaiser Family Foundation. 1996. *Contraception: Trends in Use, Safety and Effectiveness*. Menlo Park, Ca: Henry J. Kaiser Family Foundation. Retrieved from: <http://www.kff.org>.

Louis Harris & Associates. 1993. *Barriers to Pill Use*. (IRSS Study Number S932008) Chapel Hill, N.C.: Institute for Research in Social Sciences. Retrieved from: <http://www.irss.unc.edu>.

Mishel, Lawrence, Jared Bernstein, and John Schmitt. 1999. *The State of Working America 1998-1999*. Ithaca, New

- York: Cornell University. Retrieved from: www.epinet.org/books/swa.html.
- "Mile's Mycelex-7 Finishes 1992 with 14% Unit Share." 1993. *FDC Reports "The Tan Sheet,"* pp 14-15. March 1.
- "Ortho's OTC Monistat 7 Will Be on Pharmacy Shelves by Mid-March." 1991. *FDC Reports "The Pink Sheet,"* T&G-1 – T&G-2. March 4.
- "OTCs: Contraceptives." 2000. *Chain Drug Review*, p 40. January 3.
- "OTC Oral Contraceptive Benefit to 'Subgroups' Outweighed by Risk to Adolescents." 1994. *FDC Reports "The Tan Sheet,"* pp 6-8. June 6.
- "OTC Switches Raise Great Expectations." 1996. *Canadian Business and Current Affairs: Pharmacist News*, 4(1): 23, 27. February.
- Petitti, Diana. 1994. "Safety of Birth Control Pills." pp 77-116 in, Sarah Samuels and Mark Smith, eds., *The Pill: From Prescription to Over-the Counter*. Menlo Park, Ca.: Henry J. Kaiser Family Foundation.
- Samuels, Sarah, Jeff Stryker, and Mark Smith. 1994. "Over-the-Counter Birth Control Pills: An Overview." pp 1-20 in, Sarah Samuels and Mark Smith, eds., *The Pill: From Prescription to Over-the Counter*. Menlo Park, Ca.: Henry J. Kaiser Family Foundation.
- "Schering's Femcare OTC Antifungal Discounted 20% to Gyne-Lotrimin." 1992. *FDC Reports "The Pink Sheet,"* T&G-4 – T&G-5. June 15.
- Schiff, Isaac. 1999. "Introduction." *American Journal of Obstetrics and Gynecology*, 180(6): S341-S342. June.
- Schondelmeyer, Stephen and Judy Johnson. 1994. "Economic Implications of Switching from Prescription Status." pp 189-236 in, Sarah Samuels and Mark Smith, eds., *The Pill: From Prescription to Over-the Counter*. Menlo Park, Ca.: Henry J. Kaiser Family Foundation.
- Schwingl, Pamela, H.W. Ory, and C.M. Visness. 1999. "Estimates of the Risk of Cardiovascular Death Attributable to Low-Dose Oral Contraceptive in the United States." *American Journal of Obstetrics and Gynecology*, 180(1): 241-249. January.
- Sherif, Katherine. 1999. "Benefits and Risks of Oral Contraceptives." *American Journal of Obstetrics and Gynecology*, 180(6): S343-S348. June.
- Strom, B.L., R.N. Tamragouri, M.L. Morse, E.L. Lazar, S.L. West, P.D. Stolley, and J.K. Jones. 1986. "Oral Contraceptives and Other Risk Factors for Gallbladder Disease." *Clinical Pharmacology and Therapeutics*, 39(3): 335-341. March.
- Trussell, James, Joseph Leveque, Jaqueline Koenig, Robert London, Spencer Borden, Joan Henneberry, Katherine LaGuardia, Felicia Stewart, George Wilson, Susan Wysocki, and Michael Strauss. 1995. "The Economic Value of Contraception: A Comparison of 15 Methods." *American Journal of Public Health*, 85(4): 494-503. April.

For more information on IWPR reports or membership, please call (202) 785-5100 or e-mail iwpr@iwpr.org

The Institute for Women's Policy Research (IWPR) is a public policy research organization dedicated to informing and stimulating the debate on public policy issues of critical importance to women and their families. IWPR focuses on issues of poverty and welfare, employment and earnings, work and family issues, the economic and social aspects of health care and domestic violence, and women's civic and political participation.

The Institute works with policymakers, scholars, and public interest groups around the country to design, execute, and disseminate research that illuminates economic and social policy issues affecting women and families, and to build a network of individuals and organizations that conduct and use women-oriented policy research. IWPR, an independent, nonprofit organization, also works in affiliation with the graduate programs in public policy and women's studies at The George Washington University.

IWPR's work is supported by foundation grants, government grants and contracts, donations from individuals, and contributions from organizations. Members and affiliates of IWPR's Information Network receive reports and information on a regular basis. IWPR is a 501(c)(3) tax-exempt organization. Visit IWPR's web site: www.iwpr.org.