

# Oral Contraceptives and Women's Health in Japan

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**J**APAN APPROVED THE USE OF LOW-dose oral contraceptives (OCs) on June 16, 1999, after more than 35 years of debate. The main concerns of the Japanese Ministry of Health and Welfare, which contributed to the delayed approval of a low-dose OC, have been cardiovascular adverse effects, a declining birth rate, the deterioration of sexual morality, and the spread of sexually transmitted diseases (STDs). In this article, we analyze how the past resistance to approval of OCs reflects deeper problems in health services for women in Japan. We then explore the expected results of the approval and those actions by government and professional bodies that will be necessary to ensure a positive impact of OCs on women's lives.

## HISTORY

Two types of high-dose OCs ( $\geq 50$   $\mu$ g ethinyl estradiol) were approved for therapeutic use, but not for contraceptive purposes, in Japan in the late 1950s. A high-dose OC was first approved for contraceptive purposes in the United States by the Food and Drug Administration in 1960. Japan's Ministry of Health and Welfare planned to approve a high-dose OC for contraception in 1965, but postponed approval because of the allegation that OCs would lead to sexual immorality.<sup>1</sup> In addition, in the early 1960s after the thalidomide tragedy, the ministry became very cautious in its review of new drugs.<sup>2</sup> At the same time, certain women's groups became active in protest-

ing the adverse effects of high-dose OCs. In response, the ministry avoided approving OCs in the 1960s. Opposition to OCs also came from officially designated physicians who perform abortions in Japan.<sup>3</sup> (Japan legalized abortion in 1948 with the Eugenic Protection Law, which was revised to the Maternal Body Protection Law in 1996.) Private gynecologists, who perform most induced abortions in Japan, earn large fees from abortions, currently estimated to total \$400 million annually.<sup>4</sup> Opposition to OCs in the 1960s also came from family planning organizations and health professional associations that benefited from condom sales.<sup>3</sup> Attitudes of Japanese health care professionals toward OCs became more positive during the next 20 years.<sup>3</sup> Generational changes resulted in different concerns and priorities in family planning organizations and health care professional associations. The abortion rate declined throughout the 1960s and 1970s, and the birth rate declined after the second baby boom in the 1970s, so that OCs seemed less of a threat to physician incomes from abortion and obstetric practices. Moreover, physicians in Japan are allowed to sell prescrip-

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tion drugs, and obstetrician-gynecologists had obtained control over the therapeutic use of high-dose OCs when they were designated prescription drugs in 1971. Approval of OCs for contraception, therefore, was increasingly perceived as a potential source of additional income for obstetrician-gynecologists. However, perhaps most important was the fact that millions of women throughout the world had used OCs without serious health consequences.

Efforts to approve OCs in Japan started again in the early 1980s, when phase 3 safety studies of 2 types of low-dose OCs were initiated by the Japan Family Planning Association. Then, in 1985, the Japan Association of Obstetricians and Gynecologists and the Japan Society of Obstetrics and Gynecology urged the Ministry of Health and

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Welfare to conduct its own safety study of OCs. In 1987, after 2 years of intensive discussions, the Ministry of Health and Welfare started phase 3 studies with more than 5000 volunteers.<sup>2</sup> The studies concluded that low-dose OCs were effective contraceptives and that the incidence of adverse effects was low.<sup>5,6</sup> However, according to a March 18, 1992, press report, the Ministry of Health and Welfare shelved approval of OCs, although no official statement was issued. After the press questioned the decision, the ministry explained that Japan needed to look into the relationship between low-dose OCs and STDs.<sup>7</sup>

According to press reports, the reason for not approving a low-dose OC was concern that it would discourage condom use and facilitate spread of human immunodeficiency virus (HIV) infection. At that time (1992), the number of reported new acquired immunodeficiency syndrome (AIDS) cases was 61, and the number of HIV cases was 442.<sup>8</sup>

The Ministry of Health and Welfare also feared that approval of new contraceptives might further decrease the already low fertility rate in Japan.<sup>2</sup> Between 1950 and 1996, the total fertility rate in Japan decreased from 3.65 to 1.43.<sup>9</sup> Government officials worried that the low birth rate could have a serious impact on the Japanese economy.<sup>10</sup> However, Japan's birth rate has been declining steadily since the end of World War II. This is similar to what has happened in other industrialized countries, regardless of the types of contraceptives used. For this reason, it is unlikely that adoption of OCs in Japan would have a significant independent impact on the birth rate. Indeed, most of the recent decline in the birth rate is attributed to the delayed age of marriage for Japanese couples.<sup>11</sup> Economic reasons also contribute to couples' decisions to have smaller families.<sup>12</sup> According to a 1998 family planning survey conducted by the *Mainichi Newspapers*, more than 40% of married women gave financial constraints as the main reason for not having more children.<sup>13</sup>

The debate over OCs began to change in the 1990s. In 1993, 4 organizations called for the Ministry of Health and Welfare to approve a low-dose OC immediately: the Japan Association of Obstetricians and Gynecologists, Japan Family Planning Association, Japan Society of Obstetrics and Gynecology, and Family Planning Federation of Japan. Following the International Conference on Population and Development in Cairo in 1994, many public meetings on low-dose OCs were held throughout Japan. In 1995, a women's group, including 24 members of the Diet, lobbied the ministry for approval of a low-dose OC.

In September 1995, an expert committee set up by the Ministry of Health and Welfare concluded that the spread of HIV might not be directly related to use of OCs, which suggested that approval would follow. However, in October 1995 international concerns were raised about thrombotic adverse effects of third-generation low-dose OCs. The Ministry of Health and Welfare responded by setting up another expert committee, which then concluded that these adverse effects were not a major problem.

The ministry presented the issue to the Public Health Advisory Committee in March 1997. In June, that committee came to 2 conclusions about OCs and STDs. First, it is difficult to prove a direct relationship between OCs and STDs. However, STDs can be expected to spread after the approval of OCs, unless approval is accompanied by the promotion of primary prevention. Second, the following measures are important for the primary prevention of STDs: further promotion of condom use, dissemination of information on STDs, STD surveys, and counseling by health care professionals.

Based on this ambiguous recommendation from the Public Health Advisory Committee (neither supporting nor opposing OC approval), the ministry's Central Pharmaceutical Affairs Committee stated in late 1997 that it would approve low-dose OCs on the condition that, when a physician prescribed a low-dose OC, tests for STDs

would be recommended, possible adverse effects of OCs would be explained, and the importance of condom use for the prevention of STDs would be stressed. The committee also decided to conduct an open forum on approval of OCs followed by a nationwide survey of STDs after approval.

In March 1998, the Central Pharmaceutical Affairs Committee postponed approval to discuss concerns about low-dose OCs and cervical cancer, potential environmental pollution due to residues of the hormonal drug in urine, and possible teratogenic risks of OCs. The strongest concern centered on the environmental issue. Later in that year, the news media reported that OCs might be approved at the committee meeting on March 3, 1999, but approval was once again postponed. The ministry explained that more time was needed to finalize the prescription guidelines. Finally on June 16, 1999, 10 different types of low-dose OCs from 9 pharmaceutical companies were approved and became available on September 2, 1999.

In striking contrast to the decades-long debate about OCs, sildenafil citrate (Viagra; Pfizer Inc, New York, NY) was approved on January 25, 1999, only half a year after a pharmaceutical company applied to the Ministry of Health and Welfare for approval and without clinical trials performed in Japan. The news media and women's groups alleged that the ministry used a double standard for sildenafil and OCs, and pressure by these groups may have contributed to the ultimate approval of OCs in June 1999.

This historical review shows that multiple factors shaped Japan's delay in OC approval: the economic interests of the existing contraceptive system (physicians who perform abortions and various groups related to condom sales); the Ministry of Health and Welfare's fear of being blamed for any problems associated with OCs (such as adverse effects, declining birth rates, or increase in incidence of HIV/AIDS); cultural acceptance of abortion as a form of contraception; and the male dominance of Japanese society with its associated gender bias (for example, the proportion

of women among members of the Diet was 7.6% in 1997 and among all physicians, only 13% in 1996<sup>9,14</sup>).

## EFFECTS OF OC APPROVAL

Approval of OCs is likely to have various consequences in Japan. These will include positive effects as well as some health risks.

### Cardiovascular Adverse Effects

Approval of low-dose OCs provides an opportunity to reduce health risks from the current use of 5 types of high-dose OCs in Japan. In addition, the development of prescription guidelines should improve the screening of medical eligibility for OC use.

Even though high-dose OCs were never approved for contraceptive use, in 1971, Prime Minister Kakuei Tanaka said, "The safety of the pill is not fully established, so pharmaceutical companies should not be allowed to include contraception as an indication for the use of the hormonal drug. However, a physician who prescribes the hormonal drug as a contraception on his own responsibility should not be punished by law."<sup>7</sup> Ironically, before approval, the government expressed more concern about the adverse effects of low-dose OCs that were not approved than about the adverse effects of high-dose OCs that were already being used for contraception by approximately 1% of Japanese married women.

Low-dose versions of OCs were developed following studies in the 1970s and 1980s showing that high-dose preparations had adverse health effects, notably on the cardiovascular system. While women in other countries have had access to low-dose OCs, Japanese women have been restricted to use of the riskier high-dose preparations. A 1997 report from Gifu Prefecture showed that 1.3% of women older than 35 years were still using and 7.1% had at some time used a high-dose OC as a contraceptive.<sup>15</sup> In addition, the report noted that 44.6% of current users of high-dose OCs were smokers, compared with 15.3% of those who had never used OCs. The risk of ischemic

and thrombotic stroke is higher with high-dose OCs.<sup>16,17</sup> Moreover, the risk of cardiovascular adverse effects is higher for women older than age 35 years who smoke, and such women are advised to choose other methods of contraception.<sup>17</sup> If current users of high-dose OCs switch to a low-dose OC and if the medical eligibility for OC use is adequately screened, health risks associated with OCs should be significantly reduced in Japan.

### Unintended Pregnancies and Abortion

The Allan Guttmacher Institute reported in 1999 that the proportion of unplanned births was as high as 52% in Japan compared with 19% in France and 30% in the United States.<sup>18</sup> Against this background, Maruyama et al<sup>4</sup> have calculated that 28% of abortions in Japan could be prevented by the approval of a low-dose OC. Oddens and Lolkema<sup>19</sup> have predicted a 13% to 58% reduction in the rate of unintended pregnancies, depending on rates of OC use.

Data on abortions in Japan show that women have a high rate of unintended pregnancies. The official abortion rate in Japan in 1994 was 11.8 (number of abortion cases per 1000 women aged 15-49 years) (TABLE 1).<sup>20</sup> Although Japan's official total abortion rate is lower than the other 2 regions in Table 1, other data show much higher rates in Japan. For example, a national survey of women in Japan es-

timated the abortion rate between May 1995 and May 1996 to be 34 for single women and 21 for married women.<sup>23</sup>

The abortion rate among teenagers has been increasing. The proportion of abortions in women younger than age 25 years among all abortions increased from 18.2% during 1976-1980 to 29.7% during 1991-1995.<sup>20</sup> Sexual mores among younger Japanese have been changing in recent years, and a survey showed that the percentage of women aged 16 through 19 years and 20 through 24 years who approved of premarital sex increased from 45% and 56%, respectively, in 1973 to 88% and 89%, respectively, in 1993.<sup>24</sup> In association with these changes, the proportion of single women who have experienced premarital sex has increased from 35% to 49% during the past 8 years.<sup>13</sup>

Women in their late 20s and 30s in Japan continue to have high abortion rates, which reflects inadequate contraception use, despite the fact that most women in this age group are married and have better access to reproductive information and services than younger, unmarried women. In the United States and in England and Wales, the age-specific abortion rates each have a sharp peak in the 20-to-24 year-old group and then decline for older age groups.<sup>21,22</sup> In Japan, by contrast, the age-specific abortion rates for women in their late 20s and 30s are as high as the rate for women in their early 20s and do not decline until women reach their 40s

**Table 1.** Age-Specific Abortion Rates\* in 1994 in Japan, the United States, and England and Wales†

Age Group, y	Japan	United States	England and Wales
<20	<20 y: 6.4	<15 y: 2.0 15-19 y: 24.0	<15 y: 3.4 15 y: 7.1 16-19 y: 22.0
20-24	17.1	39.0	25.4
25-29	15.8	25.0	18.6
30-34	18.6	14.0	12.6
35-39	18.1	7.0	8.0
≥40	40-44 y: 8.0 45-49 y: 0.8	≥40 y: 2.0	40-44 y: 3.0 ≥45 y: 0.2
Total	15-49 y: 11.8	15-44 y: 21.0	15-44 y: 14.4

\*The abortion rate in each age group is (total number of abortions in each age group/total number of women in each age group) × 1000.

†Japanese material according to the annual abortion report from the Ministry of Health and Welfare<sup>20</sup>; US material, report from the Centers for Disease Control and Prevention<sup>21</sup>; English and Welsh material, annual abortion report from the Office for National Statistics.<sup>22</sup>

**Table 2.** Contraceptive Methods Used by Japanese Women\*

Contraceptive Method	Married Women, %	Unmarried Women, %
Condom	77.8	95.1
Basal body temperature	8.2	16.7
Rhythm	8.4	4.4
Withdrawal	7.4	5.4
Intrauterine device	3.1	0.5
Oral contraceptive	1.1	0
Sterilization		
Man	1.2	NA
Woman	4.6	0
Douche	1.1	1.5
Other	0.8	4.4
No answer	2.6	0.5

\*According to a 1998 newspaper survey by the *Mainichi Newspapers*.<sup>13</sup> Multiple answers up to 2 were given. NA indicates not available.

(Table 1). The recent approval of OCs has the potential to reduce abortion rates for 2 age groups in Japan: young single women and older married women.

### Sexually Transmitted Diseases

Japanese health authorities are concerned that incidence of STDs will increase after OC approval because OC use could result in a decline in the use of condoms.<sup>25</sup> This is an important public health concern, especially since condoms in Japan are currently used mostly for contraception and frequently are not used in high-risk sexual relationships.

In 1998, condoms were the contraceptives of choice for 77.8% of married women and 95.1% of single women (TABLE 2),<sup>13</sup> but surveys suggest that condom use may not be regular enough to prevent STD transmission. In 1996, Munakata and Tajima<sup>26</sup> used a modified Japanese edition of the World Health Organization–Partner Relation Questionnaire and analyzed Japanese risk behaviors leading to HIV infection. This study revealed that 19% of men and 8% of women with steady partners had sex with occasional partners during the previous year. A similar study reported that 19.1% of men and 4.2% of women aged 20 through 59 years had more than 1 sexual partner in the previous year.<sup>27</sup> Of the men surveyed, 53.6% complained that the use of a condom reduced the enjoyment of sex, and only 25.8% of re-

spondents who had sex with occasional partners in the previous 4 weeks had always used a condom. This high degree of risky sexual behavior among Japanese men and women suggests a lack of awareness of STD risks.

Existing data suggest that STDs are already common in Japan. One study of women who underwent induced abortions in Hokkaido between 1986 and 1993 showed that the detection rate of *Chlamydia trachomatis* antigen was 5.6% for married women and 15.2% for unmarried women.<sup>28</sup> Another study reported that the seroprevalence of *C trachomatis* among pregnant women was 29.2% in 1997.<sup>29</sup> In both studies, the seropositive rates were higher in younger women.

The number of reported new AIDS cases increased from 61 in 1992 to 250 in 1997,<sup>8</sup> indicating the concern that reduced use of condoms could increase HIV transmission in Japan. Much greater and more focused efforts need to be put into the prevention of STDs and HIV transmission. Oral contraceptives are more effective contraceptives than the condom and may create more opportunities for women to be screened for STDs.<sup>30</sup> But public health education will need to emphasize the use of condoms for STD and HIV prevention, particularly in relations with occasional partners.

### WOMEN'S HEALTH IN JAPAN

The Ministry of Health and Welfare's past resistance to approval of a low-dose OC reflects deeper problems in the structure and culture of health services for women in Japan. There appears to have been a general disregard for women and their health needs. For example, none of the official discussions about the approval of OCs considered women's need for effective contraception. Realization of the benefits of a low-dose OC and minimization of potential harmful effects requires a reorientation of women's health services in Japan toward comprehensive improvement of women's health. This process will involve a number of steps.

First, there is the need to collect epidemiological data and document the

state of women's health in Japan. There is little information on unintended pregnancies. The official statistics on abortion are incomplete, mainly because of incentives for private physicians to underreport the number of abortions as a way of avoiding taxes.<sup>31</sup> Thus, as already mentioned, the abortion rate reported by women is about twice the officially reported rate. Concerns about a possible increase in STDs following introduction of OCs can only be substantiated by careful monitoring of these diseases and the implementation of appropriate preventive measures.

Second, gynecological practice must consider the dignity and rights of women patients. The current practice of gynecological examination in Japan symbolizes the disregard for women's needs and rights in that country. In some large hospitals and medical institutions providing gynecological cancer screening, a patient is examined on a special examination bed with a curtain that comes down to her abdomen, and her legs facing the section where the health staff are working. Examination rooms are structured so that the medical staff can easily move from one patient to another, but the curtain makes it impossible for a woman to see what the physician is doing or even who is there. This situation is an infringement of women's rights as patients, shows disregard for a woman's need for privacy, and contributes to women's reluctance to visit a gynecologist.<sup>32</sup> In a pilot study conducted in 1999 among 107 women aged 35 through 49 years with a response rate of 80%, 26% of respondents answered that they were reluctant to visit or do not visit a gynecologist even if they have something to discuss (A.G., unpublished data, 1999). Twelve women responded that they disliked the gynecological examination or clinics, or that they were ashamed. Among women older than 30 years, who are advised by the Ministry of Health and Welfare to receive a Papanicolaou test smear annually, only 14.8% received the test in 1996.<sup>9</sup> A survey conducted in 1988 among 1094 women older than age 30 years iden-

tified embarrassment as a significant barrier to cervical cancer screening.<sup>33</sup>

According to guidelines written by 6 professional organizations (Japan Association of Obstetricians and Gynecologists, Japan Family Planning Association, Japan Society of Obstetrics and Gynecology, Japan Society of Fertility and Sterility, Japanese Association for Infectious Diseases, and Japanese Society for AIDS Research),<sup>34</sup> a low-dose OC would require prescription by a gynecologist and a gynecological examination and other tests every 3 months. Neither these examinations nor the OC pills will be covered by health insurance. Submission to both the cost and the indignity of a pelvic examination every 3 months is likely to act as a major deterrent to women's use of OCs in Japan.

Third, women need to be educated about OCs and their adverse effects. Japanese women have never expressed a strong demand for a low-dose OC. When asked their opinions about OC approval in the 1998 survey conducted by *Mainichi Newspapers*,<sup>13</sup> 70% of women were unable to define their position. More than 60% of women claimed that they knew something about a low-dose OC, but only 13% indicated a wish to use this method of contraception, mostly because they were afraid of adverse effects.<sup>13,23</sup> This low demand may be due to repeated past publicity about the adverse effects of high-dose OCs and the lack of accurate public information about low-dose OCs.

Finally, women need to be enabled to take more responsibility for the control of their own fertility. The male condom remains the predominant means of contraception in Japan. Diaphragms and intrauterine devices, although available, are not in common use, in part because these female methods of contraception require a woman to understand the anatomical structure of her sexual organs and be comfortable handling her own genitalia.<sup>32</sup> Women need more opportunities to be informed of available contraceptive options, and receive thorough explana-

tions about each method, so that they can feel confident in choosing and using a method of contraception. Opportunities to provide reproductive health information exist in health promotion information networks, mothers' classes, maternal and child health care classes for young couples, and health guidance sessions. Expanded education of health care workers about reproductive health issues is essential.

Government approval of a low-dose OC represents a major advance for Japan after 3 decades of procrastination. However, the benefits of OCs can only be realized through a new emphasis on all aspects of women's health and the responsible promotion of OCs within this overall context.

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