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## The Pill in Japan: Will Approval Ever Come?

By Kunio Kitamura

In March 1998, decades of campaigning by Japanese reproductive rights advocates once more met with defeat, as the Japanese Ministry of Health and Welfare elected to delay indefinitely the licensing of the pill for use as a contraceptive in Japan. Over the years, through several failed attempts at changing this situation, health officials have cited numerous reasons for their position on the pill—among them concern over side effects, fears about the potential spread of sexually transmitted diseases (STDs) if pill use replaces condom use and, most recently, worries about the environmental effects of hormonal contraceptive use. In the end, though, Japan remains unique in banning one of the most widely used contraceptive methods in the world—as well as all other hormonal contraceptives.

Hormonal agents were first approved in Japan for noncontraceptive therapeutic uses in the late 1950s. In January, 1974, in response to a parliamentarian's request that the pill be approved for contraceptive purposes, the then Prime Minister, Kakuei Tanaka, refused to consider the proposal, citing safety concerns. He indicated, however, that the government did not prevent physicians from prescribing the pill for off-label purposes at their discretion and responsibility. In fact, based on the population of women of reproductive age, data from pharmaceutical companies and responses to a recent national survey on family planning, an estimated 200,000 women currently use medium- or high-dose formulations for contraception.<sup>1</sup> Low-dose pills, the safest of all types of oral contraceptives, remain inaccessible to Japanese women, a situation that is unlikely to change in the near future.

Wider availability of oral contraceptives seemed inevitable when, in 1990, a consortium of pharmaceutical companies applied for approval of the low-dose pill. However, as the approval process approached the final stages, a decision was delayed indefinitely, for fear that the pill's availability would increase the spread of AIDS and encourage "loose morals." The Central Pharmaceutical Affairs Council argued that women would stop using condoms and would have more sex once they had access to the pill, thus raising the risk of the spread of HIV and other STDs. Others attributed the decision, however, to underlying concerns about low (below replacement) fertility in Japan.

Several years of delay followed, but by the end of 1996, reproductive rights groups had grown optimistic about a policy turnaround: The Minister of Health and Welfare,

» [article in pdf](#)

» [table of contents](#)

» [search the FPP archive](#)

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Naoto Kan, publicly stated that the pill would be legalized in 1997. Then, in early 1997, a series of major reports appeared in the media exposing poor air-quality conditions surrounding plastic waste incineration sites and high levels of dioxin found among humans and wildlife residing near incinerators. Unfortunately, in the attention to environmental pollution that followed, newspaper reporters, and even a female gynecologist, equated oral contraceptives with endocrine disrupters (man-made chemicals that mimic the effects of estrogen) thought to cause environmental damage.

In November 1997, the female leader of a citizens' network protesting dioxin pollution wrote to the Central Pharmaceutical Affairs Council, urging the government to ban all production, sale and use of oral contraceptives in Japan, as well as to persuade other governments to do the same. This letter made headlines and ignited a debate among environmental groups and women's reproductive rights groups over whether oral contraceptives constitute an environmental threat.

Then, on March 2, 1998, the executive committee of the Central Pharmaceutical Affairs Council, which is under the auspices of the Ministry of Health and Welfare, announced that licensing of the low-dose pill would be delayed indefinitely, pending further studies. The committee specified that data were still needed on the potential association between pill use and cervical cancer, on possible environmental effects caused by endocrines released in the urine and feces of women taking the pill, and on possible health problems in children born to women who take the pill during pregnancy.\* (As a follow-up, in June 1998, the council created task forces to study the effect of the pill on long-term users and on their children, as well as on the environment.<sup>2</sup>)

Later that March, Japanese reproductive rights advocates, led by the Family Planning Federation of Japan (the country's International Planned Parenthood Federation affiliate), submitted an official statement to the Minister of Health and Welfare, Junichiro Koizumi. In the statement, the federation said that it would hold the government accountable for the public statement by the previous health minister announcing imminent approval. It also emphasized the importance of a woman's right to a wide array of contraceptive choices and the government's commitment to its Plan for the Year 2000 on Gender Equality, which guarantees reproductive rights and health. Advocates used the Program of Action formulated at the 1994 Cairo International Conference on Population and Development to press the government to fulfill its commitments.

One of the most discouraging aspects of this situation is the general ignorance about the pill and overall apathy among the Japanese public, including women of reproductive age. Results from the latest in a series of biannual national surveys on family planning (conducted by the newspaper *Mainichi Shimbun*) showed that only 7% of the female respondents aged 16-49 said they would use the low-dose pill if it were approved, while 54% said they would not want to do so, 35% were undecided and 4% did not answer the question.<sup>3</sup>

Respondents to that survey were also asked to select up to two reasons for their decision on whether they would use the pill. Among those who said they would, 46% said they would do so because it is highly effective, 41% because it is female-controlled, 38% because it does not interrupt sexual intercourse, 27% because it would

prevent women from having to resort to abortion, 9% because it has no major side effects and 5% because the method has demonstrated its success in other countries.

Among those who answered that they would not use the pill, 71% were worried about side effects, 34% were satisfied with their current method, 29% reasoned that by using the pill (instead of condoms or withdrawal), women would bear the burden of contraception, 14% believed that they would not be able to prevent HIV infection, 13% felt that taking a pill every day was too cumbersome and 12% replied that the pelvic exam needed for a pill prescription was too much trouble.

About 54% of respondents were current contraceptive users; of these, 78% relied on condoms, 17% on some form of fertility awareness, 7% on withdrawal, 5% on female sterilization and 3% on the nonhormonal IUD. Other methods used by fewer than 4% included vasectomy, oral contraceptives, douching and spermicides.

Given the higher failure rates associated with such methods as the condom and fertility awareness, it is no surprise that abortion is fairly common in Japan. In 1996, about 340,000 induced abortions were recorded by Japan's Ministry of Health and Welfare,<sup>4</sup> yet researchers believe that abortion reporting in Japan is incomplete, and that many more abortions are performed than are reported.<sup>5</sup> A recent analysis suggests that increased reliance on oral contraceptives would substantially decrease the number of unintended pregnancies occurring in Japan.<sup>6</sup>

Moreover, the need for contraceptives in Japan appears to be increasing. High school students are now having intercourse sooner and more often than in the past, and sexual relationships between school-aged girls and adult males are also becoming commonplace. However, Japanese couples say they do not talk to each other about contraception, and there is little indication among young women of a desire to take charge of their reproductive lives.

Clearly, the situation in Japan is unique, with the Japanese experience differing greatly from that of the United States. In Japan, the benefits of the low-dose pill need to be promoted aggressively, and the advantages of avoiding the need for abortion, and repeat abortions especially, need to be stressed. If the pill is eventually approved, educational campaigns will be needed to promote continued condom use to prevent the spread of STDs, including HIV.

Female gynecologists who are well informed about the safety of the pill should speak out in public and lobby to sit on the committees that decide the fate of the low-dose pill. Currently, most obstetrician-gynecologists who speak favorably about the pill are men, and this fact alone has caused suspicion among feminist groups. International family planning experts also need to address this issue publicly in Japan.

In 1998, more than US \$125 million from the government's supplementary budget was allocated to research on endocrine disrupters.<sup>7</sup> The Environment Agency will receive part of this funding to build a new laboratory at its National Institute for Environmental Studies. As of this writing, front-page media reports on the topic continue to flourish, ranging from the obviously misleading (e.g., "Eating instant noodles in plastic containers may cause infertility") to those that reflect Japan's current pronatalist bent ("Sperm counts have fallen over 12% in 30 years").

The uphill battle to legalize the low-dose pill in Japan continues. The family planning community in Japan hopes that our international colleagues will lend us the moral support we need to win this debate. Once the pill receives its long-sought approval, the next generation of Japanese women can benefit from as complete an array of contraceptive options as their counterparts in the rest of the world.

## References

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\*Concerns about estrogen contamination resulting from widespread pill use seem misplaced, given that the urine of a woman in her 40th week of pregnancy contains 10,000 times as much hormone as that of a woman taking the pill. (Source: Environmental groups support Japan's ban on oral contraceptive, *Population Headliners*, 1998, No. 265, p. 6.)